Scott **Mankowitz**
Editor

CLINICAL INFORMATICS
BOARD REVIEW AND SELF ASSESSMENT

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Clinical Informatics Board Review and Self Assessment

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Foreword

Congratulations on your decision to take the board examination in clinical informatics. You are entering one of the youngest and possibly broadest fields of medicine. If you are in the process of fellowship training in Clinical Informatics, you probably have a shelf full of great textbooks and years of exposure to the best minds in informatics. You should have no trouble with this test.

However, for the rest of us, who have been doing informatics on a vocational or avocational basis for the past few years and are just hoping to pass the test before the grandfathering period closes, this book is for you.

What to Expect

There are 200 questions on the board exam, and you have 4 h to complete the test. All questions have equal weight and there is no penalty for guessing incorrectly. **Do not leave any questions blank.**

Board questions are based on well-established core content. There are no trick questions and there are no questions on recent advances or new theories. Stick with the basics.[1]

The test will include many "candidate" questions, or questions that the board is working on to determine if they are clear enough to be used as actual questions. You will have no way of telling which questions are "real" and which are "candidate." So, if you see a really hard question, just make a guess and keep going.

Time and Place

You should register and pay for the test with the American Board of Preventive Medicine by mid-September. The test is administered at Pearson Vue testing centers in many cities over a 2-week period during October. Results are typically mailed in December.

What Are My Chances?

Your chances of passing are pretty good, although the test seems to be getting harder, according to the chart below

EXAM DATE	CANDIDATES	PASS	PASS RATE %
October 2013	468	432	92%
October 2014	340	304	89%
October 2015	400	320	80%

(Source: https://www.theabpm.org/subpass_rates.cfm, accessed 1/17/17)

In order to sit for the exam, there are a number of qualifications

1. You must have board certification by one of the ABMS member boards (e.g., American Board of Internal Medicine, American board of Emergency Medicine)
2. Current, unrestricted license to practice medicine
3. ONE of the following pathways

1 If you are reading JAMIA to prepare for the boards, just stop. Put it down. Pick up Shortliffe instead.

(a) Fellowship pathway: 24-month ACGME accredited fellowship in clinical informatics
(b) Practice pathway: 3 years of at least 25% of a full-time practice in informatics during the 5 years preceding the test. (NOTE: the practice pathway will be deprecated in 2022)

How Should I Prepare?
Read this book last. This is only a review book, and it will not be useful to people who are completely unfamiliar with informatics topics. Start by reading Shortliffe, Finnel, Reston, Wager, and others. When you're done with those, take the practice test in this book to identify areas of weakness and review the text where you need to brush up.

Anatomy of a Question
In order to do well on the test, you have to think like a question writer. Good questions are really hard to write. The American Board of Emergency Medicine (ABEM) estimates that it spends up to $1000 for each question on the board exam in terms of researching, testing, and validating. Really great questions require you to know information from several different content areas at the same time. One of the challenges is that questions have to have a collection of wrong answers that are close enough to seem plausible but still wrong enough so that the question has only one right answer. One thing that board examiners hate more than anything else is to withdraw a question because it was ambiguous and there were two right answers.

For this reason, numerical questions are especially easy to write. Expect to see plenty of questions where the correct answer is the result of a simple mathematical calculation. It's probably a good idea to review the Numerical Methods appendix at the end of this book.

In the control group, 4 of 5 patients had vomiting. In the study group, 3 of 4 patients had vomiting. What is the relative risk reduction?

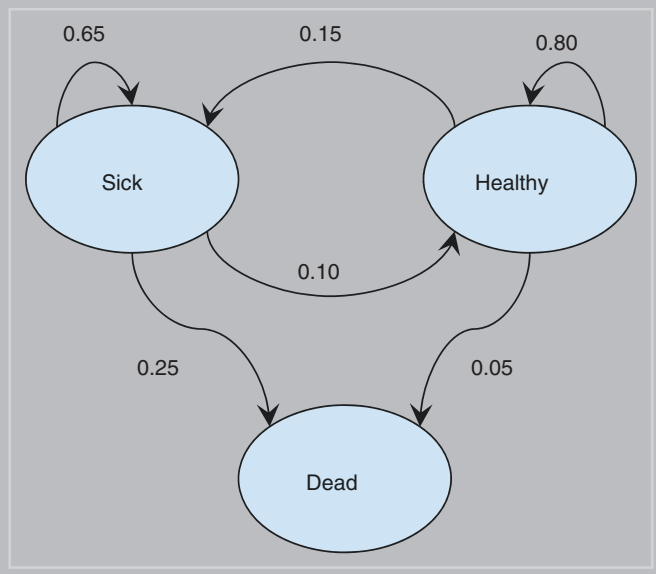
(a) 6.25%
(b) 12.5%
(c) 25%
(d) 50%

Relative risk reduction is the absolute risk reduction divided by the risk in the control group.

$$RRR = \frac{risk\ reduction}{control} = \frac{\frac{4}{5} - \frac{3}{4}}{\frac{4}{5}} = \frac{0.80 - 0.75}{0.80} = \frac{5}{80} = \frac{1}{16} = 0.0625$$

It would be very difficult to answer this question if you did not know the formula for relative risk reduction. However, if you do, the math is very simple, and it would be difficult to get it wrong.

Diagrams, especially those that are specific to informatics, also make for great questions. I would expect to see at least one Markov chain on the test.



In the diagram above, assume that the population is 95% healthy and 5% sick. What percentage will be dead in the next cycle?

(a) 2%
(b) 6%
(c) 25%
(d) 80%

To solve this question, recognize that 5% of the population is sick and, of those, 25% will be dead the following cycle. In addition, 95% of the population is healthy, and of those, 5% will be dead the following cycle.

$0.05 \times 0.25 + 0.95 \times 0.05 = 0.0125 + 0.0475 = 0.06$

This highlights another point. You should be good at estimating numbers. While it is quite satisfying to get an exact answer, the options will usually be far enough apart so that you could guestimate.

Information that comes in lists makes great fodder for test questions. For example, Safe Harbor is a de-identification standard which specifically lists 18 pieces of information that must be excluded in order for a medical record set to be considered de-identified. If I were writing a question on Safe Harbor, I'd expect the candidate to be able to identify at least some of the more common identifiers.

Which of the following pieces of information is most likely to violate the de-identification standard of the Health Insurance Portability and Accountability Act?

(a) Blood pressure
(b) Number of clinic visits per year
(c) Account number
(d) Year of birth

For this question, choices A and B are nearly impossible to use for re-identification and are not listed in Safe Harbor. Choices C and D are both listed in Safe Harbor, but year of birth is only relevant for patients older than 90 years old. Therefore, choice C, which uniquely identifies a patient, is the MOST LIKELY answer. This is not to say that choice D is a WRONG answer—it's just that C is a better answer.

If lists make for good questions, ordered lists make for even better questions.

Clinical practice guidelines are based on various sources of evidence and are subject to change as new evidence becomes available. Guidelines based on which of the following sources are LEAST likely to change?

(a) Editorial
(b) Expert consensus
(c) Randomized controlled trial
(d) Systematic review

This question is asking the candidate to know the ranking of sources of evidence. ALL of the question choices are on the list, but the order of the list is what is being tested. The best answer here is D (systematic review) because it is based on the largest number and variety of subjects and is therefore least likely to change.

How This Book Is Set Up

The format of this book is identical to the Core Content for the Subspecialty of Clinical Informatics.[2] *Core Content* is a hierarchical list of items that the board felt to be the body of knowledge expected of a clinical informaticist. Unfortunately, there is some significant overlap among sections, which makes writing a coherent, linear text a bit of a challenge. For example, data warehouses are mentioned in section 3.1.2.1 and again in 3.1.5.5. Ethics is mentioned in three separate sections.

I have tried to break up the material into sections that seem most relevant to the headings, but you may find yourself jumping from section to section for complicated topics. If you can't find what you are looking for, try the index. Then Google.

Low Yield Chapters

When looking at the core content, you will see that there are some areas that are really hard to test. For example, ethics is a really airy topic. There are no hard and fast rules, just ideas. Also, there are no definitive textbooks on informatics ethics. If you just remember that you shouldn't broadcast people's personal health information and sell it, you'll be fine. On the

2 Gardner RM, Overhage JM, Steen EB, Munger BS, Holmes JH, Williamson JJ, et al. Core Content for the Subspecialty of Clinical Informatics. Journal of the American Medical Informatics Association. 2009 Jan;16(2):153–7.

other hand, chapters like the Institute of Medicine's (IOM) quality components are a question writer's dream. The source material is well defined by the IOM. There are exactly six pillars they want you to know. They are easily differentiable.

Implementation Specific Information

Even if you are a guru with your hospital's EHR, it's not going to help you on this exam. Don't expect there to be any questions which target a single platform, format, or vendor (even if Epic does end up taking over the world). Similarly, if you are a coder and love writing in Haskell or python or (gasp!) Visual Basic, you're out of luck. I wouldn't count on any language-specific programming questions on the test. The only exception that comes to mind is Standardized Query Language (SQL) which seems to appear on the test routinely. On the other hand, it's probably a good idea to have a passing familiarity with commonly used standards like HL7 V2 and CDA.

Good luck on the exam,
Scott

Contents

Part I
Fundamentals

The basic knowledge that provides clinical informaticians with a common vocabulary and understanding of the environment in which they function.

Scott Mankowitz

1.1 Clinical Informatics

CHAPTER OUTLINE

1.1.1 THE DISCIPLINE OF INFORMATICS

Clinical informatics is the discipline that results from the intersection between computers and medicine. According to the American Medical Informatics Association (AMIA), those who practice this art "transform health care by analyzing, designing, implementing, and evaluating information and communication systems that enhance individual and population health outcomes, improve patient care, and strengthen the clinician-patient relationship".[1]

1.1.1.1 Definitions of Informatics

Data are measurements taken in the real world, such as a patient's height or weight. Alone, data have limited value. Informatics, as a field of study, aims to transform data into usable, actionable **information**. Informatics includes knowledge acquisition, dissemination and implementation and everything in between, starting from basic science research and extending to clinical decision support systems. One way to understand informatics is by examining the kinds of questions that informaticists ask, such as:

- In research studies, how are the data are gathered?
  - How reliable is the recording mechanism? Is it susceptible to mechanical failure or human bias?
  - How often is it collected? Is that timeframe relevant to the question being asked?
  - How accurate is the measurement? Does it have the precision to show subtle changes? Is it reliable? (i.e. If you measure the same thing several times, do you get the same result?)

1 Gardner R., et al. J Am Med Inform Assoc. 2009;16:153–157.

- How are the data analyzed?
  - How are the data organized? Are the data from a single source or multiple sources? Can data from one source reasonably compare to data from another source? Should some form of correction be applied?
  - How do we account for missing data? Can we interpolate from adjacent measurements? How relevant are the missing data to our study? Do the missing data reflect a random failure or a systematic bias?
  - In what way are the findings tabulated? What statistical methods can be used? Is the data qualitative or quantitative? Is there enough data to properly conduct an analysis?
- Are my conclusions meaningful?
  - Is there a statistically significant finding in the data shown? Is this likely to make a real clinical difference, or just a laboratory difference? Are the data disease-oriented endpoints (DOEs) or are they patient-oriented endpoints that matter (POEMs)?
  - How can I tell if my findings are reproducible? Does my correlation imply causation? What other factors need to be controlled?
- How do I present the data?
  - Can I use standard methods, such as a line graph or bar chart, or do I need something more advanced like a bubble plot or a heatmap? Does the interpretation of the data change when I change the method of visualization?
  - What is the best way to publicize the information? Is it robust enough to be published in a peer-reviewed journal? If not, should it be reported locally to my group or my organization?
- Does the data demand a change in practice?
  - Are the findings compelling or are they ambiguous? Do they indicate a "better way" of doing things? Does the "old way" have any benefit that is not measured by my data? Do these findings apply to all populations or only to a specific population? How can I define the population most likely to benefit from my research?
  - Are there other sources of information that contradict mine? Are those studies comparable to what I am doing? Are they using similar methods? Can data from similar studies be comingled to produce more meaningful results?
- How do I bring this information to the forefront when the subject and decision maker (e.g. doctor and patient) are both present?
  - How do I identify patients for the intervention? Is the identification based on some simple, readily visible characteristics? Are the inclusion criteria rigorously algorithmic, or do they involve a "gut feeling" by one of the managers?
  - Once I identify the correct subject, how do I give the provider everything they need to know in order make the best decision possible? How do I know if providers are making good decisions? Are there cases when a machine should resist or even override a human decision?

1.1.1.2 History of Informatics

Until 1900, medicine was very much a cottage industry. Although doctors were formally educated, practice patterns varied widely and were based on dubious science. Medical recordkeeping was rare, and when it was done, it was almost always in the form of retrospective case reports of interesting or unusual patients.

The Flexner Report, released in 1910 chastised American medical education for having lax admission and graduation criteria and for not adhering to established principles of science. The report had a tremendous impact on medical education. Over the next decade, many smaller medical schools closed or merged. Clinical teaching in hospitals was now

under the control of medical schools. Requirements for medical licensure became much stricter.

As medical science began to mature, medical care was held to more rigorous standards. Doctors (and nurses) were expected to write notes on patient care at the point of contact, encouraging communication amongst the various caregivers. More and more, the resulting document was being used to explain, analyze or even critique the care received.

In 1910, the epidemiological study of disease began to gain traction with the publication of the International Classification of Causes of Sickness and Death. This compendium of illness sought to classify and tabulate all the different types of illness and causes of death in the United States. This document would later be shortened to the International Classification of Disease, or ICD. At the time of this writing, most hospitals are using the tenth revision of the ICD.

By 1960, mainframe computers were available in large research institutions, and many were used for the financial systems in hospitals. By 1970, a specialized health care programming language, called **MUMPS** (Massachusetts General Hospital Utility Multi-Programming System, also called **M**) became the dominant platform for hospital-based application development. Since a hospital generally had only one mainframe computer (with many terminals available for time-shared access), the Hospital Information System (**HIS**) was a huge, bespoke application, heavily customized for the host institution.

In 1966, the American Medical Association (AMA) released its first version of Current Procedural Technology (CPT), a set of procedural codes used to describe medical services. The initial version contained mostly surgical procedures, while subsequent versions included diagnostic and medical services. The CPT is updated every year and is copyrighted by the AMA. Entities who use CPT codes must pay licensing fees to the AMA.

In order to ensure accuracy, insurers developed standard formats for submission, processing and payment of claims. In most cases, this included CPT codes for services and ICD codes for diagnoses. This also represented the first time that an insurance claim could be rejected entirely by computer. If a claim didn't have a diagnosis appropriate to justify a procedure, the insurer's computer could identify the mistake and return it to the physician for clarification.

Simultaneously, and probably as a result of better reimbursement, the variety and quantity of medical services increased dramatically, resulting in significantly more information being generated for each patient encounter. In a private office, this information resided in large paper filing cabinets. In hospitals, much of it was stored in the HIS.

In the 1980s, computational power became exponentially cheaper with the arrival of the personal computer (PC). As a result, complex computing tasks shifted away from the monolithic HIS into smaller departmental applications. Although this allowed the purchase of commodity software and hardware, weaving these applications together required an intricate mesh of interfaces and protocols. Commonly, these interfaces failed to yield the tight integration that was present in the original HIS.

In the 1990s, insurers began demanding more structure in medical records. The medical record was also formalized so that Evaluation and Management services were reimbursed based on the thoroughness of the record with specific details required in sections of the chart, such as History of Present Illness, Review of Systems, Physical Exam and so on. Records that did not possess this level of detail were denied payment.

The need for robust and reliable documentation coupled with the rapidly increasing volume of data led to what we now know as the Electronic Health Record (EHR), or Electronic Medical Record (EMR).

The first EHR's were little more than word processors with privacy protection. Some offered spelling correction, but that was the limit of their interactivity. Today's EHR's not only record medical data but also analyze it and provide relevant clinical information and even suggest treatment options. The question of whether or not EHR's actually improve medical care is hotly debated.

EHR's got an enormous boost in popularity in 2009 with the Health Information Technology for Economic and Clinical Health Act (HITECH). This act established criteria for "meaningful use" of electronic medical records and listed a total of 25 capabilities that modern EHR's were expected to have. Most importantly, it also provided a large cash award

to providers and institutions who implemented certified EHR technology. The cash awards were divided into three stages. The first stage ran from 2011 to 2012 and involved data capture and sharing. The second stage, from 2012 to 2016, was intended to improve clinical processes. The third (and final) stage will measure improved outcomes.

1.1.1.3 Domains, Subspecialties of Informatics

There are many sub-fields of informatics, primarily defined by the type of information that is studied.

- **Clinical Informatics** is the application of informatics to delivery of healthcare services. It is also known as **applied informatics** and **operational informatics**.
- **Clinical Research Informatics** includes management of information related to clinical trials and also involves informatics related to secondary research use of clinical data, such as mining medical records for interesting information.
- **Consumer Health Informatics** analyzes information from the perspective of the health care consumer. It stresses health literacy, patient education and access to personal health records. The focus is on empowering consumers to manage their own health and make their own healthcare decisions.
- **Public Health Informatics** is focused on the health of communities rather than individuals. It includes surveillance, prevention, preparedness, and health promotion by identifying geographical, social or other environmental risks.
- **Translational Bioinformatics** involves the translation of large amounts of data into smaller chunks which can be used for proactive or predictive health. This includes harnessing very large data sources as well as new or innovative methods of collecting biological measurements (such as wearable computers)

1.1.1.4 Careers in Informatics

What can you do with a degree in informatics? Actually, quite a bit.

The majority of graduates will work in hospitals or larger medical practices to support clinical activities. A **physician champion** is a respected member of the medical staff who encourages his colleagues to embrace new technology. One common example is when a hospital switches from paper orders to Computer Provider Order Entry (CPOE). Many members of the medical staff will resist the change because they find the process time-consuming. The physician champion's responsibility is to demonstrate how the new process actually makes order entry more accurate and safer than it was before.

A **departmental information manager** collects and analyzes data for a particular department. He is involved in the selection, budgeting, implementation, integration and management of new technology. He helps make sure that the department's IT interests are aligned with those of the organization. An example is the manager of the Picture Archiving and Communication System (PACS) in the radiology department.

The **chief medical informatics officer** is responsible for supporting medical applications across the organization. This role varies greatly in responsibility. In some organizations, the CMIO reports directly to the Chief Executive officer (CEO) or the board. In others, the CMIO reports to the Chief Information Officer (CIO) or the Chief Medical Officer (CMO). The CMIO works with departmental information managers and quality officers to ensure that the organization's technology is powerful, reliable and useful. In many cases the CMIO recruits and trains physician champions in various specialties. When a non-physician occupies this role, the title is often **chief health informatics officer**.

Not all health care institutions can support permanent informatics officers, and instead rely on **health informatics consultants**, who work collaboratively with the organization's staff on a project-by-project basis. Their roles and responsibilities are very similar to permanent staff, but they have the advantage of bringing a perspective from many other organizations.

When technology vendors create new products, they require medical input in the development, implementation and training process. Some of the larger EHR companies maintain a staff

of physicians to advise and guide their development. This panel usually consists of doctors from many different specialties so as to provide as broad a spectrum of activity as possible.

Public sector clinical informaticists may be involved in epidemiology, health literacy, education, syndromic surveillance, prescription monitoring programs, health information exchanges (HIE's) and many other public health issues.

One can safely say that any time a doctor interacts with a computer, a clinical informaticist has been involved.

1.1.1.5 Professional Organizations

There are many fantastic organizations which aim to advance medical informatics. Some of the larger ones are listed here. In most cases, the information is taken from the respective organization's web site.

Departments of Health Information Management (formerly known as Medical Records) include professionals who organize, maintain, index, encode, categorize and store medical information. Two of the largest professional organizations are **American Health Information Management Association** (AHIMA) and **Healthcare Information and Management System Society** (HIMSS).

With over 100,000 members, AHIMA's primary goal is to provide the knowledge, resources and tools to advance health information professional practice and standards for the delivery of quality healthcare. AHIMA also provides certification pathways for health information managers, coders, and others.

HIMSS, with 52,000 members is a global, cause-based, not-for-profit organization focused on better health through information technology (IT). HIMSS leads efforts to optimize health engagements and care outcomes using information technology.

While HIMSS and AHIMA are geared towards management of medical records and Health IT, the **American Medical Informatics Association** (AMIA) and **American Nursing Informatics Association** (ANIA) represent healthcare providers and nurses.

AMIA, with about 5000 members, is probably the best known informatics association in the United States. The AMIA mission statement is: to lead the way in transforming healthcare through trusted science, education, and the practice of informatics. ANIA, with 3000 members is dedicated to advance the field of nursing informatics through communication, education, research and professional activities.

AMIA was the driving force in creating the Accreditation Council for Graduate Medical Education (ACGME)—certified fellowships and board examinations in Clinical Informatics. In the coming years AMIA will develop certification for non-physicians called Advanced Health Informatics Certification. The core curriculum for AHIC will likely mirror that of the Clinical Informatics board exam.

Health Level Seven International (HL7) is a not-for-profit, American National Standards Institute (ANSI)-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 has more than 2300 members, including approximately 500 corporate members who represent more than 90% of the information systems vendors serving healthcare. HL7 is most famous for endorsing an interoperability messaging standard, which we will learn more about in Sect. 3.4.4.

1.1.1.6 Current and Future Challenges for Informatics

Today is, perhaps, the golden age of medical informatics. There are several emerging trends that aim to make informatics much more relevant and valuable to health care.

1. Without a doubt, the US government's 20-billion dollar investment in health information technology through the Health Information Technology for Economic and Clinical Health Act (HITECH) has been the single greatest enticement for large and small medical practices

to convert their paper systems into electronic medical records. The reimbursement for a single provider is in the range of $40,000–$70,000, and for a large institution can run into the tens of millions of dollars. During the next decade, as the various phases of Meaningful Use criteria evolve, clinical informaticists are going to be intimately involved in creating, implementing, maintaining and certifying electronic medical records systems.

2. At the same time that money is being poured into health information technology, the cost of any unit of that technology is dropping precipitously. Widespread broadband internet access has allowed previously unimaginable access to data. In the coming years, wearable and implantable technology will provide a nearly continuous stream of measurements which will be stored safely and securely in ever-growing data warehouses. One of the great challenges for informaticists is to devise useful ways to sift through that data and provide meaningful displays through **data visualization**.
3. Quality measures and pay-for-performance (P4P) initiatives require providers to collect metrics on their provision of care. Payors are inviting hospital systems to share the risk of caring for patients, and the more quality metrics that are met, the greater the overall reimbursement. Future work includes creating fair and reliable metrics, aggregating relevant and meaningful data, and determining proper incentives.
4. Telemedicine is allowing people in remote areas access to specialists all over the world. Clinical informaticists will be highly involved in creating networks, defining scopes of practice and enabling these kinds of practices.
5. **Disease management** is a system of rules and supports designed to manage specific medical conditions, empowering individual patients to manage their own illness. This process has been used successfully in diabetes, hypertension, heart failure and many other conditions. In most cases, this requires patients to periodically record their own measurements. From time to time, these measurements are reviewed and management decisions are made according to a predefined algorithm. In some cases, algorithmic management actually produces outcomes superior to those actively managed by physicians. Clinical informaticists will play a pivotal role in transitioning patients into disease management programs.
6. While health information exchanges offer the promise of sharing patient data between institutions, true interoperability is far away. Although many standards for information exchange exist, vendors are reluctant to allow their products to be too similar for fear of losing market share. As a result, patients who are seen in different institutions are faced with significant difficulty when they try to transfer their medical records from one system to another. When the records are actually transferred, the receiving institution is usually unable to incorporate the new data in a meaningful way. During the coming years, informaticists will develop protocols and specifications to improve the sharing of data between different software vendors.
7. From a physician standpoint, very few electronic health record systems can be considered easy to use, and none are easier than the paper and pen they were trained on. One of the great challenges of the coming decade is to create more intuitive user interfaces and more responsive decision support systems. For example, one of the meaningful use stage 2 criteria was that at least 60% of orders are entered by a provider (Computer Provider Order Entry, (CPOE)). As a result, many physicians complain that their clinical workload has increased dramatically as they have now taken on the additional responsibility of being data-entry clerks. Finding ways to mitigate this workload while maintaining patient safety is a difficult task indeed.

1.1.2 KEY INFORMATICS CONCEPTS, MODELS, AND THEORIES

Key concepts in clinical informatics can be found throughout this book. Those that do not get specific treatment elsewhere can be found here.

The **Data-Knowledge-Information-Wisdom** (DKIW) framework expresses the way that medical facts and measurements become increasingly useful as they are collected,

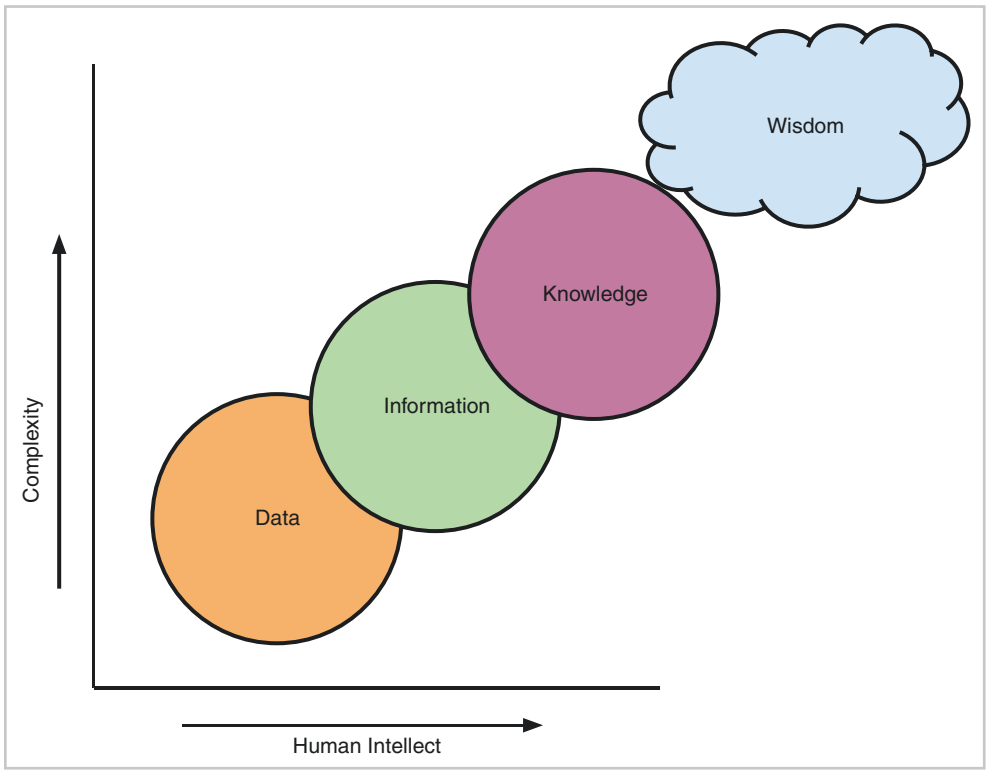


FIGURE 1-1

The Data-Information-Knowledge-Wisdom framework. Data are interpreted into information. Information is analyzed into Knowledge. Knowledge is applied and becomes wisdom

analyzed and displayed. **Data** are the smallest components of the DIKW framework. They are usually self explanatory and refer to a single measurement in time (such as blood pressure). When a series of data points are connected, making a meaningful picture, the result is **Information.** Information can be thought of as "data with context". For example, a series of blood pressure measurements showing a steady decline is much more meaningful than a single, isolated measurement. Information answers the questions of "who", "what", "when" and "where". **Knowledge** is information that has been analyzed so that relationships and meanings are visible. Knowledge answers the questions of "why" or "how". For example, a downward trending blood pressure may be associated with sepsis in a sick person or possibly with better control of an otherwise healthy hypertensive patient. **Wisdom** refers to the appropriate use of knowledge to manage and solve human problems. Wisdom also implies ethical considerations, such as examining the patient's needs and desires and consolidating them into sound clinical judgment. Wisdom is knowing when to initiate emergency treatment for septic shock and when to continue observation. (See Fig. 1-1).

Informatics Competencies

The Technology Informatics Guiding Education Reform (TIGER)[2] Summit listed three competencies in informatics:

Computer Competency is a set of skills that allow individuals to use computer technology to accomplish tasks, such as using a word processor or spreadsheet.

Information Literacy is a set of cognitive processes that allows an individual to recognize what, when and where information is needed and how to obtain it.

Informatics Management is a process consisting of (1) collecting data, (2) processing the data, and (3) presenting and communicating the processed data as information or knowledge.

2 http://www.thetigerinitiative.org/docs/tigerreport_informaticscompetencies.pdf

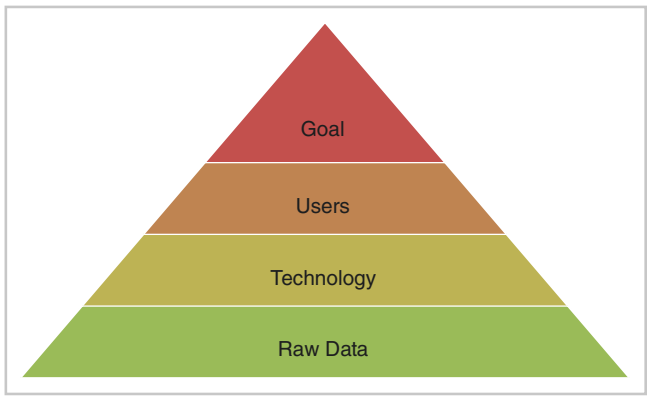


FIGURE 1- 2

The Nursing Informatics Pyramid, after Schwirian. Raw data forms the base, which is consumed by technology and presented to the user in order to achieve a goal

Nursing Informatics Pyramid

According to the Schwirian model, nursing informatics begins with **raw data**, such as patient observations, progresses through **technology**, which might be some form of data processor, then is presented to the **users** (in her case, nurses) and then finally reaches a predefined **goal**. (See Fig. 1-2).

For example, a patient in the intensive care unit (ICU) has low blood pressure. He is attached to a monitor which measures his central venous pressure (CVP). The physician consults the CVP readings and decides to increase or decrease the rate of IV hydration. In this case, the CVP measurements are the raw data. The monitor represents the technology. The physician is the user and the goal is appropriate fluid management for the patient.

1.1.3 CLINICAL INFORMATICS LITERATURE

1.1.3.1 Core Literature

Amazon.com sells about 5000 books on different kinds of informatics and there are over 100 peer-reviewed journals related to the study of information. With this much literature, what is the best way to identify the most relevant and trustworthy sources?

The following recommendations apply to all academic literature, not just clinical informatics:

1. Look at the author and his scholarly reputation. Some authors have a reputation for producing excellent science, while others do not. Alone, this may not have much relevance. Remember that even famous scientists like Galileo, Mendel, Kepler and others were rejected at their time.[3]
2. Look at the author's institution. Nearly all medical journals require the author to be a representative of an institution, such as a hospital or university. The larger the institution, the more zealously they protect their scholarly reputation. Most big institutions have academic integrity boards and will sanction or fire their members for academic violations. For example, if a professor at a prestigious university publishes bogus research, he will quickly be terminated in order to preserve the reputation of the institution. Therefore, both the institution as well as the author have great incentive to produce high-quality work.
3. Look at the publication and consider its scholarly reputation. Reliable journals are **peer-reviewed**, which means that every article is reviewed by other experts in the field of study to make sure that the research is reasonable and logical. In some cases, reviewers will ask to see raw data or original specimens before they are willing to render judgement. Articles that don't pass this test are never published.

3 Similarly, consider the science proffered by Dr. Mehmet Oz.

4. Check the publication date. A maxim in medicine is that you should never be the first person or the last person to adopt a new teaching. If an article is too new, it has not had a chance for the community to assess its value. If an article is too old, it may refer to ideas that have been supplanted by newer, better or safer practices.
5. Be careful with websites. Educational (.edu) and governmental (.gov) websites tend to have large institutions which govern their contents and make efforts to preserve accuracy. For example, the Centers for Disease control (www.cdc.gov) is an excellent source of up-to-date information on emerging infectious diseases. Emedicine (www.emedicine.com) hosts many scholarly monographs on a variety of medical subjects. On the other end of the spectrum, it takes only a few dollars to set up a commercial website and there is absolutely nothing preventing a person from widely disseminating false information.[4] Somewhere between these extremes lies sites like Wikipedia (www.wikipedia.org) which has hundreds of thousands of articles which are continuously reviewed by millions of people. While the site is anonymous and continuously edited (i.e. unstable), it is generally considered useful, but not reliable.

Suppose you limit yourself to the highest quality publications and only read current, peer-reviewed scholarly journals with good reputations. How can we separate the good journals from the great ones? One way is to look at absolute circulation. If a journal is valuable, people will spend money to buy it. For example, the *New England Journal of Medicine* is the world's most popular printed medical journal with over 200,000 subscribers. Does that make it the most reliable?

Another way to rank journals is to see how often other scientists cite the work they publish. The simplest method is known as the **impact factor**. Journal impact factors are calculated based on the number of articles published during the past 2 years and cited during this year. For example, to calculate the 2015 impact factor for a journal, we tabulate the total number articles published in 2013–2014. Next, we count the total number of citations for those articles in 2015. The ratio of citations to articles is the impact factor. An impact factor of 1.00 means that, on average, each article is cited once during the following year. In general, editorials and letters to the editor are excluded from the calculation. Table 1-1 shows the top 10 informatics journals as ranked by Journal Impact factor. However, since the methodology of journal ranking is well-known, there will always be attempts to game the system. See box 1–1 for some examples.

TABLE 1-1

JOURNAL IMPACT FACTORS FOR THE MOST POPULAR INFORMATICS PERIODICALS

RANK	JOURNAL	IMPACT FACTOR
1	Journal of Medical Internet Research	4.669
2	Journal of the American Medical Informatics Association	3.932
3	Implementation Science	3.47
4	International Journal of Medical Informatics	2.716
5	Journal of Biomedical Informatics	2.482
6	Journal of Telemedicine and Telecare	1.736
7	Telemedicine Journal and E-Health	1.544
8	Biomedical Signal Processing and Control	1.532
9	BMC Medical Informatics and Decision Making	1.496
10	Computers in Biology and Medicine	1.475

4 Although I don't have an example of a bad website handy, numerous examples exist. Try searching for "male enhancement" on your favorite search engine.

Box 1-1: Methods to Increase Impact Factor

As you can imagine, many things determine how often a journal is cited, some more obvious than others. For example, with the New England Journal of Medicine's vast circulation, it is no surprise that it is widely cited. However, with a little creativity, there are ways that smaller journals can enhance their impact factor.

1. *Make the journal free.* Most citations come from journals published and indexed in PubMed or one of its commercial derivatives. When the full text of the paper is available online for free, it is much more likely to be cited.[5] PubMed Central® (PMC) is a free full-text archive of biomedical and life sciences journal literature at the U.S. National Institutes of Health's National Library of Medicine (NIH/NLM). There are over 2000 fully participating journals and over four million free full-text articles.
2. *Articles should be appropriately titled.* Articles with short titles describing the results are cited more often.[6]
3. *Review papers* and *method papers.* Review papers are reviews of other papers and tend to be cited more frequently than original research. This effect becomes even more pronounced when an editor encourages authors to review only papers published in the same journal. Method papers (i.e. those that describe a method for a particular procedure) are cited often because anyone who wants to use that procedure in a study has to cite the original paper.
4. *Publish the best articles in January*. Since writing a paper usually takes a few months, articles written in December are much less likely to be cited in papers published during the following year, which is how the impact factor is calculated.

TABLE 1-2

SCIMAGO JOURNAL RANK FOR THE MOST POPULAR INFORMATICS PERIODICALS

RANK	TITLE	SJR
1	Journal of the American Medical Informatics Association : JAMIA	2.594
2	Implementation Science	1.988
3	Medical Image Analysis	1.977
4	Journal of Medical Internet Research	1.685
5	International Journal of Medical Informatics	1.507
6	BMC Medical Research Methodology	1.392
7	Journal of Biomedical Informatics	1.097
8	Journal of NeuroEngineering and Rehabilitation	1.053
9	Journal of Telemedicine and Telecare	0.955
10	Journal of Clinical Bioinformatics	0.802

Another common method to rank journals is using the SCImago Journal Rank, a system modelled after Google's PageRank algorithm. This algorithm also measures the relative frequency that a journal is referenced. It gives greater weight to prestigious journals and gives lesser weight to journals that cite themselves. (see http://www.scimagojr.com/journalrank.php?category=2718) (Table 1-2).

5 For example, BMJ, the British Medical Journal has an impact factor 17. BMJ makes every research article freely available as soon as it is published.

6 Paiva CE, Lima JP da SN, Paiva BSR. Articles with short titles describing the results are cited more often. Clinics. 2012;67(5):509–513.

1.1.3.2 Critical Analysis of Informatics Literature

Statistical analysis is an essential component of all medical research including informatics. Since much of informatics research revolves about describing new techniques and demonstrating their efficacy, the informaticist must be familiar with basic statistical methods, such as sensitivity, specificity, precision, recall, p-values, confidence intervals and others. (These will be reviewed in Sect. 2.1.2).

In addition to being statistically significant, the results must be clinically significant. For example, a study may show a particular therapy is associated with a statistically significant improvement from 33% cure rate to 33.1% cure rate. Although numerically advantageous, this therapy offers only trivial benefit to the patient and should be considered in the context of expense, side-effects, stewardship and other factors.

Similarly, a study may examine a very limited population and attempt to extrapolate to a more general population, or there may be other methodological flaws that weaken the author's conclusions. Bias may have tainted the results, or sponsorship by a pharmaceutical company may have cast a shadow of doubt upon the study authors. These will be reviewed in Sect. 2.1.1.

1.1.4 INTERNATIONAL CLINICAL INFORMATICS PRACTICES

Kyle Marshall

Until recently, countries such as the United Kingdom (UK) and Denmark led others, like the United States, in regards to informatics research, development, and adoption (Collen 1994). The term *informatics* originated in the 1960s. In 1962, Philippe Dreyfus of France coined the term "informatique" as the application of computers to the storage and processing of information (Fourman 2002). The Soviet engineer and scientist Alexander Mikhailov used the term "informatika" to refer to the field concerning the properties and structure of information (Kabene 2010). Around the same time, the German computer scientist Karl Steinbuch published a paper describing "informatik," or the automatic processing of information (Steinbuch 1957). Prior to this, and even now in some countries, informatics is incorrectly synonymous with computer science.

Early on, members of health professions with interests in informatics were thinly scattered across their respective countries. Learning what was being discussed or done in other locations was difficult. Professional organizations were created as a way for individuals to come together and share their work, research, and ideas.

In the UK, the British Computer Society (BCS), founded in 1957, was conceived to provide a national body representing all aspects and activities of the emerging computing profession (Hayes and Barnett 2008). Initially, there were five health specialist groups which served as a forum for discussing medical computing possibilities as a specialty. Over time, the number of groups has increased as has their focus on health informatics (Hayes and Barnett 2008). In 2005, the BCS Health Informatics Forum (BCS HIF) was formed to provide leadership in all aspects of health informatics.

In the late 1990s and early 2000s, the United Kingdom's single-payer, tax-supported health system called the National Health Service (NHS), along with other companies, began a large and ambitious project to create and deploy a single electronic health record system for the entire country. Unfortunately, the idealistic goals were too lofty. The project took longer than expected and costs quickly ballooned, wasting more than $24 billion (12 billion GBP) of taxpayer money (Stone 2014). Lessons learned from this informatics failure include the importance of a competitive model that encourages electronic health record (EHR) innovation and the value of continuous improvement. Also, EHRs need to be able to accommodate large populations with significant diversity (Stone 2014). Despite this failure, the UK is still seen as a leader in the field of health IT. More recently, their GP2GP program facilitates the electronic transfer of health records when a patient moves from one general practitioner to another.

In France, an annual International Medical Informatics Conference was started in 1969 by the Institut de Recherche en Informatique et en Automatique (IRIA). This organization, along with the BCS, and leaders in other countries such as Denmark, Belgium, Finland, and Italy, laid the foundation for the European Federation for Medical Informatics (EFMI) at a meeting held under the auspices of the World Health Organization (WHO) in 1976. Over the next few decades, initial work of the EFMI focused on decision support, image processing, multimedia patient records, cooperative working, telemedical applications, and signal handling (Hayes and Barnett 2008).

In Denmark, MedCom's Health Data Network has been cited as an excellent model of health informatics implementation. While not an EHR, the Health Data Network acts as a data integrator and supports interoperability by facilitating communication and health information exchange. All hospitals, pharmacies, and emergency medicine physicians use this system, as well as 90% of general practitioners. More than 80,000 messages are sent through this system daily (Kuhn et al. 2007).

In Singapore, key drivers for change, as it relates to health information technology, include a shift in national demographics and burden of disease, threats of emerging infectious disease, and the globalization of healthcare services (Lim 2006). By 2030, it is estimated that 1 in 5 Singaporeans will be over the age of 65. This, along with other factors, has motivated the country toward an integrated healthcare delivery system with better allocation of resources (Liew 2015). This movement was spearheaded by the Ministry of Health (MOH) and the associated holding company (MOHH) which owns all public hospitals. In 2008, a national health informatics strategy was formed, along with clinical advisory groups, task forces, and the Integrated Health Information Systems (IHiS) entity, which acts as the de-facto Chief Information Officer and centralized IT office for all public healthcare groups. This work has led to the development of a national electronic health record with the vision of "one patient, one record." Key to this implementation were stakeholder input, support of the government, rich technology foundations, and collaboration (Liew 2015). An example of Singapore's success is the Ng Teng Fong General Hospital (NTFGH), which achieved Healthcare Information and Management Systems Society's (HIMSS) prestigious Electronic Medical Record Adoption Model (ERAM) Stage 7 only 16 months after opening (JurongHealth 2016). ERAM is an eight stage model that measures the adoption and utilization of EHR functions. NTFGH is only the fifth hospital in all of Asia Pacific to reach Stage 7 (JurongHealth 2016).

In Australia, the Electronic Health Records Act of 2012 laid the foundation for a national EHR system. Integral to their approach was the importance of focusing on the public's interest as well as privacy and data protection. The act requires personal health data to be encrypted prior to transmission, judicial penalties for privacy breaches, allowing patients to opt-out from the national EHR at any time, and creating the Access Control Center which provides participants full control over their data (OECD 2013). The health informatics network in Australia is made up of a number of discipline, focus, or geographically based health informatics groups which are members of the Health Informatics Society of Australia (HISA). HISA is the country's official representative to international informatics associations (Hovenga 1996).

In developing countries, challenges to health informatics are numerous, including structural deficits in physical networks, high costs, geographic dispersion, and high percentage of patients living in rural areas (Luna et al. 2014). Mobile health or telemedicine is proving to be useful, when there is lack of infrastructure, but not without its own difficulties, such as fragmented information and issues with scalability. Software can also be a challenge and expense. Open-source solutions are a viable alternative in resource-limited countries. For example, PostgreSQL is a powerful open-source object-relational database system that has been shown to be reliable and scalable (Luna et al. 2014). Open Medical Record System (OpenMRS), built with an enterprise-quality data repository modeled on the Regenstrief Medical Record system, enables the customized design of EHRs with no programming experience (Mamlin et al. 2006). It has been successfully implemented in Africa, Asia, and Central America (Luna et al. 2014). Other challenges facing health informatics in developing countries include the lack of developed health IT agendas, cultural barriers, lack of interoperability standards, and a limited qualified workforce.

In order to support the field and profession, the International Medical Informatics Association (IMIA), began as a special interest group and technical committee in the late 1960s under the International Federation for Information Processing (IFIP) (Kabene 2010). The organization developed into a world body linking medical informatics across the globe and allowed leaders to meet other experts in every aspect of health informatics (Hayes and Barnett 2008). International conferences are held every 3 years and recent locations include Brisbane, San Francisco, London, and Seoul.

Even though the countries and organizations above have made tremendous strides in developing and improving the field of informatics, the full impact falls short of expectations. As is true in other fields, the future success of clinical informatics on an international stage requires the knowledge of past challenges and of those yet to be faced (Luna et al. 2014).

1.1.5 ETHICS AND PROFESSIONALISM

Texts on medical ethics usually begin with ***Primum non nocere,*** a Latin phrase that means "**first, do no harm**." The cardinal sin in clinical informatics is inappropriate disclosure of personal information. Since informaticists are often in control of large amounts of data, privacy tends to be the primary context of ethics discussions. Ethics concerns itself with finding balance between harms and benefits.

HARMS	BENEFITS
Disclosure of private information can harm a person by causing shame or embarrassment, or can affect insurability, employability and other social opportunities.	Physicians can review records to diagnose disease, avoid duplicative tests, design and share treatment plans. Researchers can secondarily analyze records to improve public health.

Privacy is the right of an individual to control disclosure of his personal information, while **confidentiality** refers to responsibility to protect information that has been received and to use it only in ways that benefit the patient. **Security** is the set of policies and procedures which safeguard the integrity of the information systems.

Broad categories of inappropriate disclosure include: (in decreasing order of occurrence)

1. **Insider accidental disclosure**. For example, two physicians discuss a patient while standing in an elevator; a nurse forgets to log out of a computer whose screen displays a patient's lab results.
2. **Insider Curiosity**. A medical professional is concerned about a co-workers adherence to medical recommendations and looks through her chart to see how she is doing.
3. **Insider Criminality**. A medical professional deliberately copies medical records with the intent to sell. For example, a celebrity comes to the hospital and an unreputable newspaper pays a filing clerk for inside information.
4. **Outsider Criminality**. Hackers use a combination of social engineering and technical vulnerabilities to break into a system to steal data. A complete medical record can fetch $10 on the black market (as compared to a stolen credit card which is worth $1 or less).[7] One increasingly common tactic is for the hackers to disable a network or encrypt data and demand money in exchange for return of normal functioning. (e.g. ransomware)

In addition to doing no harm (referred to as the principle of **non-malfeasance**), some other general medical ethical principles as applied to informatics include:

7 Humer C, Finkel J. Your medical record is worth more to hackers than your credit card. Reuters 2014. http://www.reuters.com/article/us-cybersecurity-hospitals-idUSKCN0HJ21I20140924 (accessed November 26, 2016).

1. **Autonomy**—the patient's right to make his own decisions. In the context of informatics, one of the most pressing questions relates to ownership of medical records. If records belong to a patient, should she be able to modify them at will, even if she may be misleading her doctors? If the records belong to the EMR vendor, may they sell the data to third parties? (Spoiler alert: they have.[8])
2. **Beneficence**—a provider should act only in the best interest of the patient; computer systems should be implemented for the benefit of the patient and society, not strictly for the insurer, provider or institution.
3. **Justice/equality**—fair distribution of limited resources. It is well known that poorer patients are less likely to have broadband internet access, which may limit their access to their medical records compared to patients with greater resources.
4. **Dignity**—patients have a right to be treated respectfully; while computers treat everyone with the same degree of dispassion, it could be considered embarrassing to have to check a computer for lab results.
5. **Honesty**—providers must be completely truthful with their patients at all times; again, this is a human foible. Computers are unable to lie, although improper programming can yield results that are deceptive or misleading.
6. **Integrity**—a person should fulfill their obligations to the best of their ability.[9] EMRs have the potential to boost integrity because of their advanced auditing functions and non-repudiation.

A Clinical Decision Support (CDS) system has its own set of ethical issues.

1. CDS should only be implemented after thorough evaluation of safety and efficacy, just like pharmaceuticals or medical devices.
2. All systems can provide misleading information if misused or misconfigured. All users of tools should be provided adequate training and availability of help should they need it.
3. The system should only provide *support* for decisions. Actual decisions must be made by professionals on the basis of their licensure, training and experience.

The Code of Ethics published by the International Medical Informatics Association[10] is summarized below.

1. **Information Privacy:** patients have a right to keep their information private.
2. **Openness**: when personal information is stored, the subject must be made aware of how the information is used.
3. **Security**: when data are collected, they must be protected from loss or corruption with all reasonable methods available
4. **Access**: the subject of an electronic record has a right to view, modify and correct his own information.
5. **Legitimate Infringement**: when the data must be used by other persons, it is done in a way that is most beneficial to society.
6. **Least Intrusive Alternative**: when personal data is used, only the minimum necessary should be accessed and it should be used in a way that is least intrusive to the subject.
7. **Accountability**: whenever personal data are used, it must be justified and explained to the affected person.

8 Sittig, DF, Singh H. Legal, Ethical, and Financial Dilemmas in Electronic Health Record Adoption and Use. Pediatrics. 2011 Apr; 127(4): e1042–e1047. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3065078/
9 Mercuri, JJ. The Ethics of Electronic Health Records. Clinical Correlations. January 15, 2010. http://www.clinicalcorrelations.org/?p=2211
10 See http://www.imia-medinfo.org/new2/pubdocs/Ethics_Eng.pdf

In addition, health information professionals (HIPs) have particular responsibilities to the patients, doctors, institutions, society at large, the informatics profession and to themselves.

Some examples include:

1. **Patient**: When a medical record is created, the HIP has the obligation to inform the patient that the record exists. In addition, the patient should know who created the record and for what purpose, where the information came from and who verifies it, who maintains it, who has access to it, and under what circumstances it may be communicated to other parties, and what rights the patient has regarding his record. In addition, the HIP should ensure the security, reliability and integrity of the record using reliable mechanisms. When these safeguards fail, the HIP has a duty to inform the patient about the data breach.
2. **Providers**: The HIP must assist providers by providing them with the best quality information possible and keep them informed when data may be unreliable.
3. **Institutions**: HIPs must exemplify loyalty and integrity to their employers by implementing the highest quality standards for data collection, storage, retrieval, processing, accessing, communication and utilization. They must notify their institutions of any possible impairments in quality or security of the data.
4. **Society**: When data are collected from a community, the HIP should ensure that only data relevant to providing healthcare are actually collected. When community data are acquired, they are de-identified as much as possible.
5. **Self**: HIP's should recognize the limits of their competence and be willing to ask for help. They should take responsibility for their actions and avoid conflict of interest.
6. **Profession**: In order to maintain the reputation of the profession, HIP's must act ethically in all circumstances. They should develop standards of professional competence and ensure that these standards are applied impartially and transparently.

1.1.6 LEGAL AND REGULATORY ISSUES

Federal Law

The Patient Protection and Affordable Care Act of 2010 (PPACA, also known as Obamacare) intended to decrease the number of Americans without health insurance by creating statewide insurance exchanges and by increasing eligibility for Medicaid, free health insurance for the poor. The act sought to level the costs of insurance by forcing insurers to grant policies to people regardless of pre-existing conditions and prohibited cancellation of policies when patients became too sick (a process known as rescission). The act also encouraged the formation of **Accountable Care Organizations** (ACO's) which would be reimbursed based on achieving certain benchmarks in patient care.

ARRA and Meaningful Use

The American Recovery and Reinvestment Act of 2009 (ARRA) provided a government bailout to many failing companies. A section of that act, the Health Information Technology for Economic and Clinical Health (HITECH) act set aside approximately $18 billion to fund the implementation of electronic health records. Eligible Providers (EPs) who were able to demonstrate **meaningful use** of healthcare technology were given awards of up to $70,000. Critical Access Hospitals (CAHs) received grants of $1 million or more.

The Meaningful Use program was managed by the Center for Medicare and Medicaid Services (CMS) and was divided into three stages. Stage 1, data capture and sharing, ran

11 https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Hosp_CAH_MU-TOC.pdf

from 2011 to 2012.[11] Requirements were divided into two categories: (1) core requirements which must be met completely; and (2) menu options, where individuals could select 5 of 9 options to satisfy the requirement. When the entity could attest to meeting the requirements, it was eligible to receive money from the government. Some of the Stage 1 requirements included Computerized Provider Order Entry (CPOE); medication lists; drug-drug, drug-allergy interaction checks; clinical decision support; and providing patients with electronic copies of their medical record and discharge instructions. Most of the requirements maintained certain threshold values for success. For example, the measure was considered a success when 10% of patients were offered electronic copies of their record or 30% of laboratory orders were entered through CPOE.

EHR Systems that were capable of these tasks had to be certified by the Office of the National Coordinator (ONC), or by one of its approved testing labs. As you can imagine, this was an incredible market opportunity for firms that created or certified EHRs. One of the drawbacks to this process was that the goals of the EHR were defined externally by CMS instead of by actual providers. Predictably, hospitals and providers purchased many systems that were difficult to use but met all the CMS criteria. This resulted in mistrust and frustration with EHRs.

Meaningful use stage 2, advance clinical processes, ran from 2012 to 2014 (although certain providers may attest with modified criteria as late as 2017). In addition to upgrading the threshold for success of various items in stage 1, it included provisions to track medications from order to administration using assistive technologies (such as bedside barcode scanning) and electronic transmission of the medical record in a structured format known as the **Consolidated Clinical Document Architecture** (CCDA). Some of the menu options included electronic prescribing (eRx) and recording progress notes in the EHR.

Meaningful use stage 3 started in 2016, however it will be replaced by the Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act, known as MACRA. There are eight requirements for stage 3.

1. PHI: Entities must conduct a risk analysis to find vulnerabilities which might lead to data breaches and disclosure of protected health information (PHI).
2. eRx: At least 80% of prescriptions must be electronic.
3. CDS: Clinical decision support must be used for at least five interventions; drug-drug and drug-allergy checking must be in place.
4. CPOE: Orders for laboratory, radiology and medication must be entered electronically by the provider.
5. Patient Portal: More than 80% of patients must be given personal access to the EHR, and 35% must have the option to receive educational information.
6. Patient Engagement: More than 25% of patients must access their EHR; 35% must receive a secure digital message from their provider; 15% must provide patient-generated health information (such as from a fitness tracker).
7. HIE: More than 50% of care transitions or referrals include transmission of electronic records; providers who are seeing a patient for the first time must acquire medical records from a secondary source at least 40% of the time; at least 80% of new patients must have their medication list reconciled with an online source.
8. Public Health: Providers must report data to three of the following: immunization registry; syndromic surveillance; public health registry; clinical data registry; case reports of reportable conditions.

After Meaningful Use Stage 3, what is the incentive for providers and hospitals to continue using EHRs? The Merit-Based Incentive Payment System (MIPS) is a new payment

mechanism that starts in 2019, based on performance in four categories: quality, resource use, clinical practice improvement and meaningful use. Providers will receive grades in each of these areas and a total composite score will be used to determine reimbursement. As with most of these program, it begins as an incentive for high achievement but becomes a penalty for low achievers after a few years.

Other Federal Laws

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides data privacy and security provisions for safeguarding medical information. See Sect. 3.1.4 for more information. The executive branch of the federal government is discussed more in Sect. 1.2.4.

State and Local Government

While the federal government enacts national laws, states are responsible for much of the day-to-day governing of healthcare. Licensing of physicians, nurses, other health professionals, hospitals and insurers is all controlled at the state level. Different states have different regulatory requirements and licenses are not transferrable from state to state.[12]

Most public health programs, such as sanitation, investigation of epidemics and food inspections, are the responsibility of state or municipal authorities. However, in each case, the federal Centers for Disease Control and Prevention provides national oversight.

Private Regulators

In the mid 1900s, the American Medical Association (AMA) helped create a number of organizations which provide regulatory support to healthcare. The Association of American Medical Colleges (AAMC) helps accredit medical schools and coordinate the application process. The Accreditation Council for Graduate Medical Education (ACGME) monitors and accredits residency programs. The American Board of Medical Specialties (ABMS) and its member boards (such as the American Board of Preventive Medicine) make pronouncements about standards of care and certify individuals as having expertise in their specialty.

In order to receive payment from the Centers for Medicare and Medicaid Services (CMS), hospitals must be **deemed** compliant. Deeming authority is granted to state health agencies as well as private companies, such as The Joint Commission, Det Norske Veritas Healthcare, Inc. (DNV) and Healthcare Facilities Accreditation Program (HFAP).

A Complex Partnership

It turns out that regulation is achieved by a meshwork of federal, state and private regulators. For example, in order to market a new drug, a manufacturer has to file with the United States Patent and Trademark Office (USPTO) and get permission to begin testing from the Food and Drug Administration (FDA). It must then try to get the drug included on formularies of various insurers and hospitals, which are private companies regulated by state authorities. Finally, it must persuade pharmacists to stock the drug and physicians to prescribe the drug. Pharmacists and physicians are state-licensed.

12 In the past, most states would grant licenses to doctors who had licenses in other states as part of a process called reciprocity. At this point, the only state that still has reciprocity is Michigan. Some states, such as New Mexico will grant short term Endorsements which allow physicians to practice in the state, but only under certain circumstances.

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Scott Mankowitz

1.2 The Health System

CHAPTER OUTLINE

1.2.1 DETERMINANTS OF INDIVIDUAL AND POPULATION HEALTH

There are several factors (or **determinants**) that contribute to the health of a person or a population. According to McGinnis, these factors are divided into five categories[1]: Biology, Behavior, Social, Environment and Medical care. Of these, biology and behavior have the largest contribution to the health of an individual, followed by social, medical care and environment. Figure 2-1 shows the relationship among these determinants.

1. **Biology**: the age and sex of the person; the genetic makeup including heritable diseases. At the current time, biological factors are the hardest to change, although many are hopeful that genetic engineering may change this at some point. For this reason, most public-sector investment in public health aims to affect the behavioral, social, environmental and medical access determinants.
2. **Behaviors**: alcohol, tobacco, substance abuse; risk-prone lifestyles, such as working as a miner or prostitute.
3. **Social**: discrimination, income disparities, socioeconomic status, education, occupation, class, social support. Poorer people often lack time and opportunity to exercise. Food for a healthier diet tends to be more expensive and takes longer to prepare. A strong and consistent finding of epidemiological research is that there are health differences among socioeconomic groups. Lower mortality, morbidity, and disability rates among socioeconomically advantaged people have been observed for hundreds of years.
4. **Environment** (or total ecology): where a person lives, sanitary and crowding conditions, air and water quality, lead exposure, and the design of neighborhoods. Some of the most dramatic improvements in population health during the twentieth century include: improved water, food, and milk sanitation, reduced physical crowding, improved

1 McGinnis JM, Foege WH. Actual causes of death in the United States. *JAMA* 1993; 270:2207–2212.

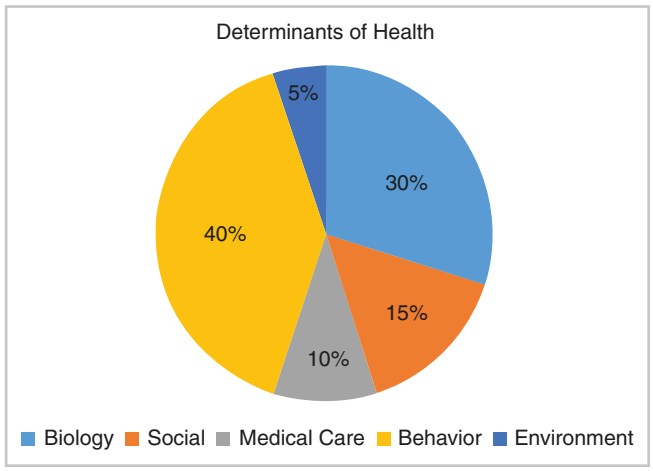


FIGURE 2-1

Determinants of health. Biology and Behavior are the most important determinants of health, followed by social, medical care and environment. Based on data from McGinnis JM, Foege WH. Actual causes of death in the United States. JAMA 1993; 270:2207–2212

nutrition, and central heating with cleaner fuels. Most Americans live in urban areas, which are often associated with harmful health behaviors, such as lack of exercise, poor diet, sexual behavior, alcohol and substance abuse.[2] Cities also have higher levels of air pollution, which may cause cardiovascular and respiratory disease. Crowded buildings may increase the risk of lead exposure as well as asthma. Those that live in rural areas have other risks, such as exposure to pesticides.

5. **Medical care**: access to quality health care; having insurance. For example, the availability of Medicaid (health insurance for the poor) was expanded greatly with the passage of the Affordable Care Act. This resulted in greater access to medical care for a previously underserved population. Similarly, the nationwide shift to high-deductible insurance plans has actually reduced accessibility to affordable healthcare for many.

None of these determinants functions in a vacuum. They are intertwined and often interdependent. Ameliorating issues in one of the determinants may exacerbate issues in another. For example, a Health Impact Assessment by the World Health Organization studied the effects of transportation on public health. As with any intervention, there are both risks and benefits.[3]

1. More vehicles on the road increases the risk of motor vehicle accidents (especially at extremes of age).
2. Air pollution results in climate change and increased incidence of respiratory disease.
3. Noise pollution may cause disrupted sleep cycles.
4. Building highways or train tracks may separate communities or decrease the amount of arable land.
5. Increased transportation allows for better access to employment and economic development, possibly resulting in better infrastructure and better access to medical care.
6. Cycling or walking may improve physical activity. Driving or taking a train may reduce physical activity.
7. Better transportation allows for wider dispersal of vector borne diseases (e.g. SARS, Ebola).

2 Some cities, especially New York City, are healthier than their rural neighbors. Prohibitively expensive private transportation coupled with a thriving culture encourage denizens of New York to get out and walk more. See New York Magazine article at http://nymag.com/news/features/35815. This is supported by research by Jawbone, showing that New Yorkers walk more than most Americans. See https://jawbone.com/blog/jawbone-up-data-by-city/

3 The determinants of health. WHO. http://www.who.int/hia/evidence/doh/en/index2.html (accessed February 6, 2017).

Place-Based Approaches

Some argue that the natural and built environment in which a person lives may be more predictive of future health than his genetic make up.[4] Therefore, solutions which target specific social or community problems are more likely to succeed. For example, the Colorado Health Foundation sought to fight obesity by building parks and playgrounds with walking trails. In Camden, NJ, public health officials noted an extraordinarily high rate of patients going to the Emergency Department (ED) for issues that could be handled by primary care doctors. In response, they set up a referral program which set up high-utilizing patients with clinics, thereby reducing unnecessary ED visits.

Most individual health efforts involve clinical interventions with high-risk groups (such as treating patients with hypertension). However, these measures do very little to prevent a population from getting sick in the first place. Recognizing the spectrum of risk and applying interventions more broadly may be more efficacious.[5]

1. All risk exists on a spectrum. Risk factors for certain diseases have traditionally been recorded as either present or not present (i.e. either the patient has a history of diabetes or he doesn't). However, a more accurate way of recording risk is through continuous instead of dichotomous variables. For example, there is no convenient level of zero risk for conditions such as blood pressure, cholesterol, alcohol consumption, tobacco consumption, physical activity, weight or lead exposure.
2. Only a small percentage of the population is at the extremes of risk. Exposure of a large number of people to a small risk results in more burden of illness than exposure of a small number of people to high risk. Therefore, the most effective interventions will be aimed at the moderate risk categories, even though they are not themselves sick.
3. An individual's risk can only be interpreted in the context of his population. For example, the risk of a person in the United States of dying from an acute myocardial infarction is higher than a person in Japan, possibly because the incidence of hyperlipidemia is higher in the US than Japan. People planning population based health interventions should first ask why the population in Japan has lower cholesterol and only then try to figure out ways to lower cholesterol in the US.

1.2.2 PRIMARY DOMAINS, ORGANIZATIONAL STRUCTURES, CULTURES, AND PROCESSES

There are many domains, structures, cultures and processes which define the health care system.

1.2.2.1 Health Care Delivery

The American health system is a complex web of healthcare providers, insurers, regulators, pharmaceutical and equipment manufacturers, and, of course, patients. These interact in myriad patterns, often productive, sometimes ethical, occasionally wonderful. One thing is constant: a huge amount of information is generated and recorded during these interactions. See Figure 2-2.

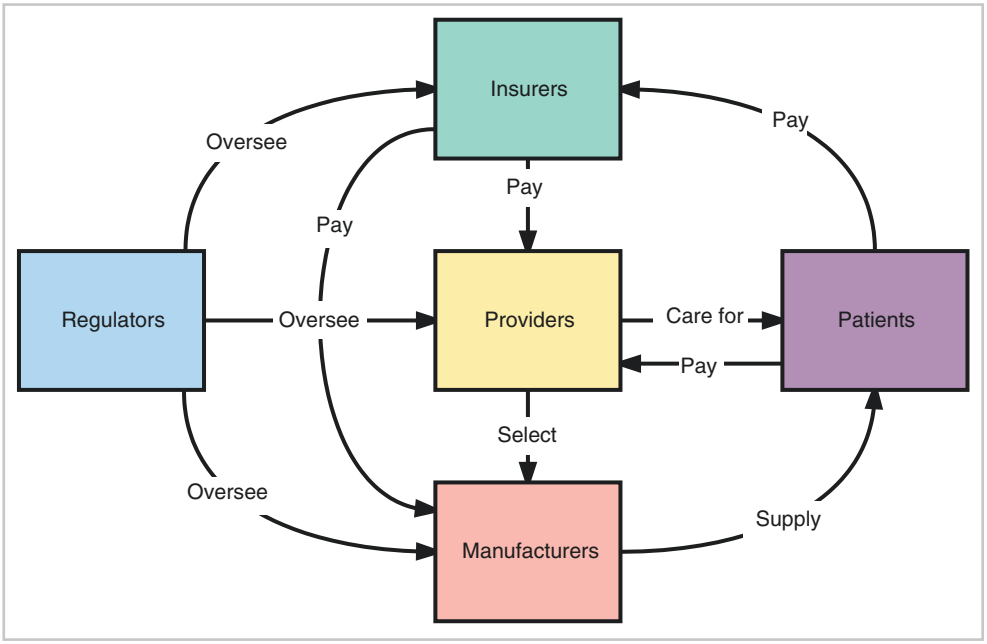
Healthcare **providers** include those persons and institutions who provide direct or indirect care for patients, such as doctors, hospitals, nurses, respiratory therapists, nutritionists, and many others. There are many ways that these individuals are paid—sometimes directly, but usually by means of a third-party payor, such as an **insurer**. The insurer may be a traditional health insurer, or may be a workmen's compensation insurer in the case of a workplace injury, or may be an auto insurer in the case of a motor vehicle accident.

4 It is sometimes said that a person's zip code is a better predictor of longevity than his genetic code.

5 Understanding Population Health and Its Determinants. Institute of Medicine. 2003. The Future of the Public's Health in the 21st Century. Washington, DC: The National Academies Press.

FIGURE 2-2

The relationships among regulators, insurers, providers, manufacturers and patients. It's complicated



In the course of care, the patient may require medication or durable medical equipment, such as a wheelchair. These items are made by **manufacturers** and are generally paid for by insurance, although there is significant variation in coverage, especially for medications. Manufacturers tend to spend a great deal of energy marketing their products to providers and directly to consumers as well.

In order to protect all stakeholders, **regulators** oversee the activities of manufacturers, providers and insurers. Oversight may be federal (such as the Food and Drug Administration) or on a state by state basis (such as state licensing boards).

For example, a patient complains of symptoms of gastroesophageal reflux disease. On television, he sees an ad for over-the-counter (OTC) omeprazole (manufactured by Procter and Gamble) as well as an ad for prescription-only pantoprazole (Pfizer). The FDA was responsible for approving both of these medications for sale in the US. The FDA also regulates ads for prescription medications, while the Federal Trade Commission regulates non-prescription ads. The patient is unsure which medication is better for him, so he makes an appointment with his provider. The provider (who holds a state license to practice medicine) reviews several published studies on proton pump inhibitors and suggests omeprazole as it is noninferior to and less expensive than pantoprazole. When the patient goes to the local pharmacy (which is licensed by the state as well as the federal Drug Enforcement Agency), he compares prices for the available drugs. His insurance plan does not cover OTC drugs, but it will cover part of the cost of prescription drugs with a co-payment. The state Department of Banking and Insurance has mandated that there must be more than one drug in each therapeutic class placed in the lowest tier of co-pays, which means that the co-pay for pantoprazole is actually lower than the retail cost of omeprazole.

1.2.2.2 Public Health

While most of medicine focuses on individual patients, the field of public health is dedicated to improve the health of populations by treating and preventing disease. This may include many activities, such as surveillance of different symptoms, tracking of infectious diseases and promotion of healthy behaviors.

Syndromic surveillance involves tracking the presentation of certain symptoms as a potential early warning sign of an epidemic. For example, an unexpected rise in Emergency Department visits for gastroenteritis in a small geographical area could signify

contamination of a water supply or spoiled produce, or even a terrorist attack. Early detection may prevent others from becoming sick.

Keeping track of infectious disease and controlling its spread is an important public health function. At the end of 2014, there was an outbreak of ebola virus in West Africa. Through a coordinated effort, public health officials were able to restrict travellers and prevent the disease from spreading within the US. In addition, they ensured that hospitals had adequate education and supplies to care for patients if they did arrive.

Promoting healthy behaviors includes funding public education on health risks such as smoking or obesity. It may involve prevention programs directed at certain high-risk groups, such as distributing condoms and needle exchange programs.

1.2.2.3 Clinical Research

Clinical research entails creating a study question, formulating an experiment to test that question, and ultimately publishing the results (be they positive or negative). Drug and device manufacturers spend approximately $70 Billion per year on research, with an additional $50 Billion from public sources, most notably the National Institutes of Health.

Industry funded research may be carried out within the company's own laboratories, but also may exist as a partnership with an academic institution. In order to preserve the autonomy of the academic researchers, institutions are given unrestricted grants (monies dedicated to furthering the goals of the institution, rather than a particular project). In practice, however, unrestricted grants are usually given to those institutions that further the goals of the industry. For this reason, studies funded by industry sources are generally less reliable than those funded by public sources.

Research findings are promulgated through publication in journals dedicated to the particular area of study. Peer-review is a process which enables other scientists to validate the methods and/or findings prior to publication. One unfortunate weakness of this process is that journals only tend to publish articles which have positive findings that impact readers. This leads to a relative difficulty in publishing negative studies known as publication bias. (See Sects. 2.2.1 and 2.2.2).

1.2.2.4 Education of Health Professionals

Nurses

Most hospitals require nurses to have 4-year Bachelor in Science of Nursing (BSN) degrees, although 2-year associates (ASN) degrees are still relatively common in doctors' offices, schools and home care. A Licensed Practical Nurse (LPN) is a 1-year degree and often assists other nurses, but the scope of practice is limited compared to other nurses.

Physicians

In the US, physicians and surgeons typically receive 4 years of medical school training after completing an undergraduate bachelor's degree. After medical school, they typically have 3–7 years of postgraduate education (internship/residency) in their particular field of study. Those pursuing subspecialization will do a fellowship for 1–3 additional years. National, standardized exams punctuate each of the transitions between phases of training.

Getting into medical school is competitive, and only 44% of US college seniors who apply will ultimately get in. Approximately 80% will matriculate in an allopathic medical school and earn a Medical Doctor (MD) degree, while 20% will obtain a Doctor of Osteopathy (DO) degree. Osteopathic schools are slightly less competitive than allopathic schools. Due to the high cost of premedical education, applicants from lower socioeconomic status tend to have a disadvantage compared to their wealthier rivals. Applicants whose parents are among the top 40% earners in the US make up about 75% of acceptances.

Medical education itself is quite expensive. The average medical student attending a private medical school will pay nearly $300,000 in tuition over the course of 4 years. Most of

this money will be borrowed against the hope of future earnings, and is repaid over the ensuing 10–20 years.

Traditionally, the first 2 years of medical school are dedicated to the study of basic sciences (anatomy, physiology, histology, genetics, biochemistry, microbiology, pharmacology, etc), while the third and fourth years are composed of clinical clerkships. Many modern medical schools have modified this curriculum to introduce students to clinical medicine earlier in their studies. Others have reduced the basic sciences requirement so as to emphasize other aspects of medicine or to offer students the opportunity to earn another degree, such as a Masters of Public Health, or a Masters of Business Administration. Yet others have required students to perform original research to produce a dissertation.

After medical school, students enter a competitive match for residency programs. Residencies in popular cities and in specialties that pay well tend to be more competitive. Most primary specialties and subspecialties have board exams which are taken during the first year or two after finishing residency. Clinical informatics is unusual in that candidates may take the board exam without having formal training, although they must demonstrate real-world experience. Starting in 2022, doctors who wish to take the Clinical Informatics board exam will have to complete a 2-year fellowship. Many board exams require recertification every 10 years, although this has become a contentious topic amongst practicing physicians.

After graduation from residency or fellowship, physicians are required to complete courses as part of Continuing Medical Education (CME) every year that they maintain their license. CME courses are generally accredited by universities or state medical societies and must meet certain criteria for content and relevance. In addition, certain states require specific CME content. New Jersey, for example, requires two credits on End-of-Life care per 2-year licensing cycle.

Dental schools and podiatry schools have similar educational programs, although there is less reliance on residency programs.

Associate Practitioners[6]

Not all providers are physicians.

Nurse Practitioners are nurses who have obtained an advanced degree, usually a Masters of Science in Nursing, sometimes a Doctor of Nursing Practice. Nurse Practitioners are allowed "full practice" in 21 states, which means that they are allowed to practice medicine without supervision of a doctor. They are allowed to perform simple invasive procedures, but are not allowed to perform complex operations alone. Some advanced practice nurses have very specific training, such as nurse midwives and nurse anesthetists.

Physician Assistants usually obtain a Masters of Science degree, but occasionally a Bachelors of Science. Physician Assistants are licensed to practice medicine under the supervision of a physician, but their scope of practice is limited to that of their supervisor. The degree of physician oversight varies from state to state, and from practice to practice. For example, California requires *one* of the following levels of supervision[7] (1) The physician sees the patients the same day that they are treated by the PA; (2) The physician reviews, signs and dates the medical record of every patient treated by the PA within 30 days of treatment; (3) The physician adopts written protocols which specifically guide the actions of the PA. The physician must review 5% of the medical records within 30 days. There is some debate as to whether PAs should complete a residency similar to physicians. Currently they do not.

Other Certifications

There are many other medical certifications with widely varying educational requirements. Certified Nurse Assistants have a 6- to 12-week training program after high school. Emergency Medical Technicians who staff ambulances have a 125-h training course. Paramedics, who are allowed to administer medications, have about 1000 h of education.

6 There is great debate about the appropriate terminology for nurse practitioners and physician assistants. The term *midlevel provider* has been cited as demeaning, while the term *non physician provider* has been cited as nonspecific.

7 Section 1399.545 of Title 16 of the California Code of Regulations.

Dieticians require a bachelor's degree in order to practice, while audiologists require a doctorate (Aud. D.). Physical therapists and Occupational therapists may hold a 2-year master's or 3-year doctoral degrees.

1.2.2.5 Personal Health

The World Health Organization defines health as a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. There are many dimensions to health and wellness which must interact to make a person feel "healthy".

1. Emotional wellness involves being in touch with one's feelings, developing love, trust and self-confidence.
2. Intellectual wellness refers to developing the mind to perform critical thinking, curiosity and creativity.
3. Social wellness helps people find their station in life and develop meaningful relationships with their peers
4. Spiritual wellness revolves around developing a personal belief system and adherence to that system, while finding meaning and validation in actions.
5. Physical wellness includes paying attention to medical problems and treating them appropriately. It also involves developing safe habits regarding activity, sleep, nutrition and exercise.

1.2.3 THE FLOW OF DATA, INFORMATION, AND KNOWLEDGE WITHIN THE HEALTH SYSTEM

In healthcare, data flows in many directions, often at the same time. As an example, medical research produces medical literature which informs clinical guidelines which are incorporated into an Electronic Health Record (EHR) which is used for patient care. Patient information and demographics are collected by registrars who also enter this information into the EHR. Physicians use a clinical decision support system to place orders for laboratory, radiology and pharmacy. Each of these departments performs tests or therapies. When the tests have been resulted, the information is returned to the EHR to further guide patient care. When care is complete, the data is sent to billing and collections. This often requires two-way communication with insurers and other payors to provide justification and explanation of services. The EHR is also used for chart reviews within the institution for quality assurance, performance improvement and utilization review. Patient data is also sent to the regional health information exchange, where it will be used to guide care if this patient is seen at another institution. In addition, the data may be used for secondary analysis for epidemiological studies by researchers who then contribute to the medical literature and so on (Figure 2-3).

Some dataflows are unidirectional while others involve two-way communication. When a department director conducts a performance improvement (PI) project, she reviews data from the EHR regarding care given to particular patients. Since the data only flows from the EHR to the PI activity, it is unidirectional. However, when a doctor orders a laboratory test, the laboratory receives the order from the EHR, completes the order and then sends results back to the EHR, resulting in bidirectional dataflow.

As we have mentioned before, there is a distinction between data, information and knowledge flow. Data are raw and without context, such as the result of a blood test. Information is data in a clinical context, such as a creatinine which is trending upwards. Knowledge is the application of information, such as using a clinical decision rule. Bidirectional communication is relatively straightforward with data, but becomes increasingly difficult with information and knowledge.

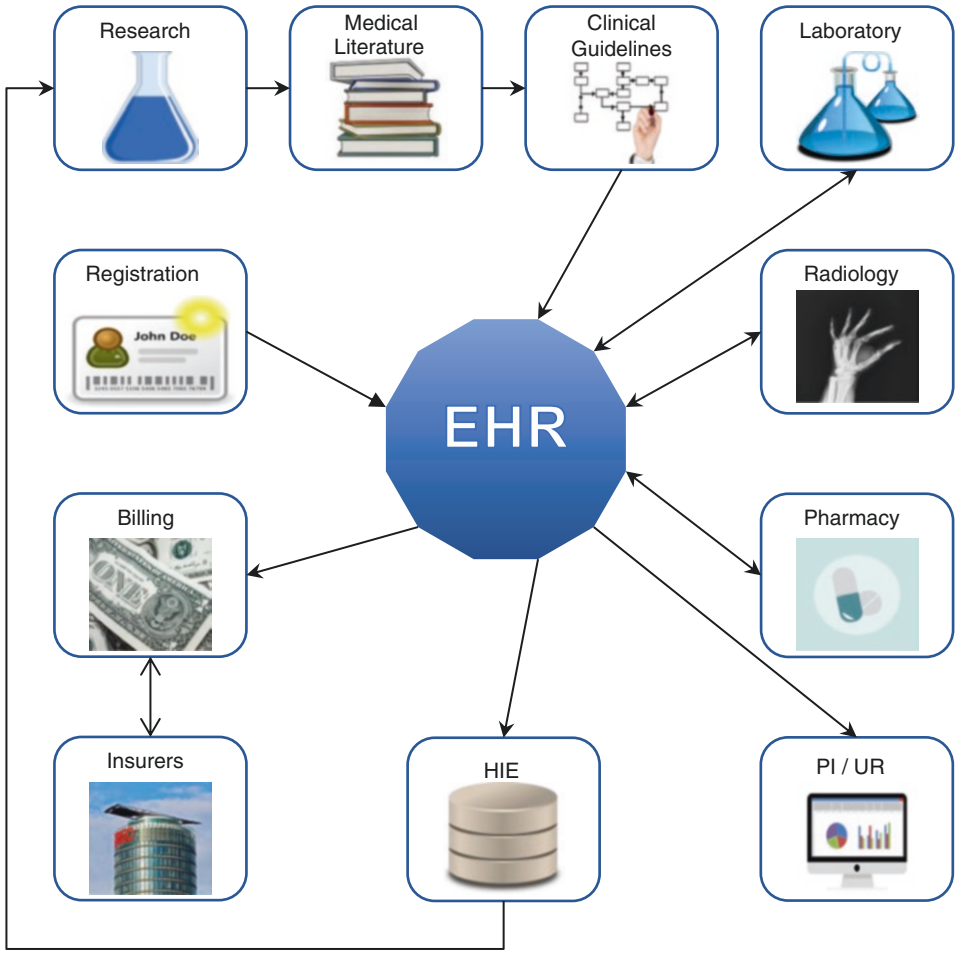


FIGURE 2-3

Information flows. *EHR* Electronic Health Record, *HIE* Health information exchange, *PI/UR* Process improvement/utilization review. *Arrows* indicate direction of flow

1.2.4 POLICY AND REGULATORY FRAMEWORK

The rules under which medicine is practiced in the United States originate from multiple intersecting and occasionally conflicting sources, including federal, state and local governments as well as quasi-governmental agencies such as the Joint Commission. Superimposed on this dense thicket of regulatory controls are institutional policies and procedures.

The broadest source of rulemaking is the federal government, which is composed of three branches: Legislative (writes laws), Executive (enforces laws) and Judicial (interprets laws).

The legislative branch (Congress) includes the Senate and the House of Representatives. Laws are created when a bill is presented, discussed and approved by both houses and then sent to the president for signature. Examples of federal laws impacting medicine include the Emergency Medical Treatment and Active Labor Act (EMTALA, 1985); Health Information Technology for Economic and Clinical Health Act (HITECH, 2009) and countless others.[8]

In the executive branch, the Department of Health and Human Services (HHS) is the agency responsible for monitoring and administrating healthcare in the US. HHS has many well-known divisions.[9]

1. **Agency for Healthcare Research and Quality (AHRQ)**. AHRQ supports research designed to improve the outcomes and quality of health care, reduce its costs, address patient safety and medical errors, and broaden access to effective services.

8 It seems that having an easy-to-pronounce law increases its perceived importance. The same may be true in medical research. See Stanbrook MB, Austin PC, Redelmeier DA. Acronym-Named Randomized Trials in Medicine—The ART in Medicine Study. N Engl J Med 2006; 355:101–102.

9 You can see the complete organizational chart for the department of health and human services at https://www.hhs.gov/about/agencies/orgchart/

2. **Agency for Toxic Substances and Disease Registry (ATSDR)**. ATSDR's mission is to prevent exposure and adverse effects from hazardous substances in the environment.
3. **Centers for Disease Control and Prevention (CDC)**. CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. The CDC is often at the forefront of detecting and controlling infectious disease outbreaks (such as Ebola)
4. **Food and Drug Administration (FDA)**. The FDA ensures the safety of foods, cosmetics, pharmaceuticals, biological products, and medical devices.
5. **Health Resources and Services Administration (HRSA)**. HRSA directs national health programs by assuring equitable access to comprehensive, quality health care for all.
6. **Centers for Medicare and Medicaid Services (CMS)**. CMS administers Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). CMS also provides administrative support for the Health Insurance Portability and Accountability Act (HIPAA).
7. **Indian Health Service (IHS)**. IHS is the principal Federal health care provider for American Indians and Alaska Natives.
8. **National Institutes of Health (NIH)**. NIH is the research arm of HHS. It provides grants and leadership to researchers. The National Library of Medicine supports MEDLINE/Pubmed, the most comprehensive database of research articles.
9. **Substance Abuse and Mental Health Services Administration (SAMHSA)** SAMHSA works to improve the quality and availability of prevention, treatment, and rehabilitative services to people with substance abuse and mental illnesses.
10. **Office of the Assistant Secretary for Preparedness and Response (ASPR)**. ASPR provides advisory staff on bioterrorism and other public health emergencies.
11. **Office of the Secretary (OS)**. Two divisions of the OS are noteworthy for informatics.

    (a) **Office of the National Coordinator for Health Information Technology (ONC)**. ONC is responsible for achieving the mission of the Health Information Technology for Economic and Clinical Health Act (HITECH), which is to establish a national Health IT infrastructure. ONC certifies technology to be eligible for Meaningful Use payments, in coordination with CMS.
    (b) **Office for Civil Rights (OCR)**. OCR administers HIPAA in coordination with CMS.

In addition to federal law, states and municipalities often create statutes that impact medical practice. These laws may differ from state to state or from region to region. See Sect. 1.1.6 for more information.

1.2.5 HEALTH ECONOMICS AND FINANCING

The United States has, by far, the most expensive healthcare system in the world. In 2016, the United States spent $3.3 trillion on healthcare, representing about 18% of the gross domestic product (GDP), and amounting to $10,345 per person. Most of that money (54%) went to doctors and hospitals, with the remainder spent on drugs, medical equipment, long term care and administration.[10] For a comparison with other countries, see Figure 2-4.

Healthcare hasn't always been so expensive. Historically, doctors were tradespeople who would provide services in exchange for professional fees. Since these fees were paid directly by the patient to the provider, doctors used trade secrets such as patent medicines or specialized

10 Keehan SP et al. National Health Expenditure Projections 2015–25: Economy, prices and aging expected to shape spending and enrollment. Health Affairs 2016 35(8): 1–10.

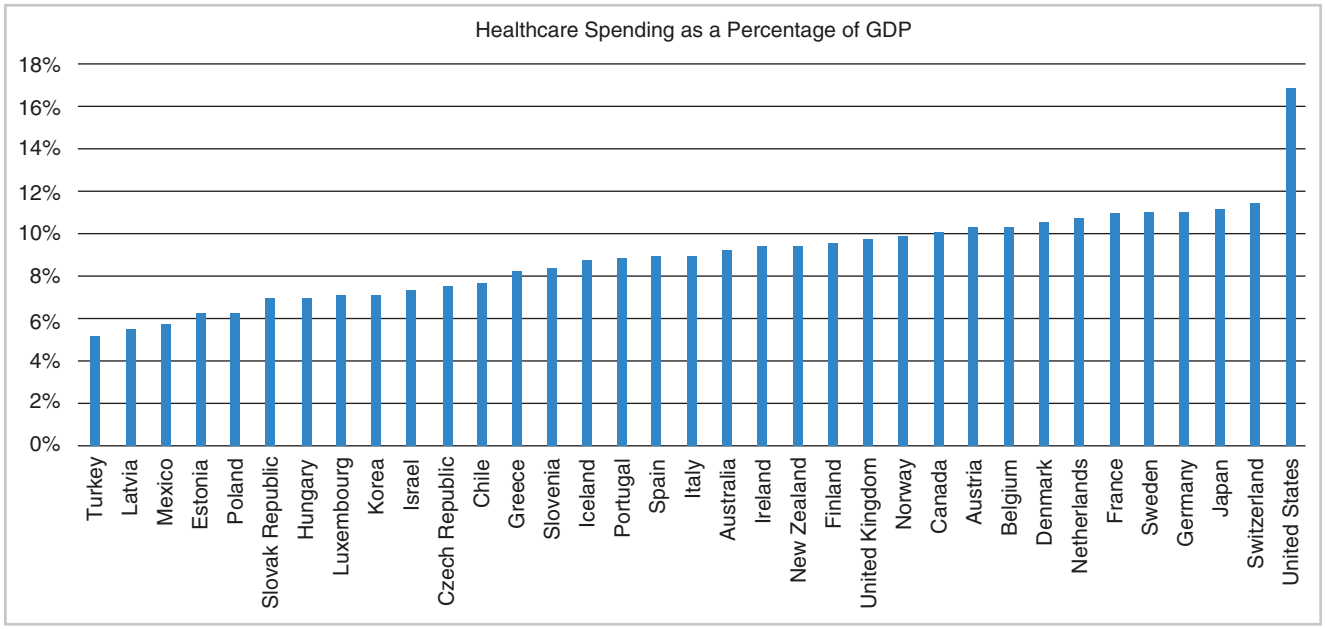


FIGURE 2-4

Healthcare spending as a percentage of GDP in 2015. Data courtesy Organization for Economic Co-operation and Development, accessed May 10, 2017

surgical implements to distinguish themselves from one another. Without a backing of science, it was charisma more than any other trait that helped patients choose their physician.

In the 21st century, the advent of formalized medical education and widely published research reduced some of the most egregious variations in practice and helped eliminate some of the quackery that had plagued the field. The commoditization of medication and surgical supplies helped define standards of care to which the majority of physicians would adhere. Charisma, reputation and cost still played a role in a patient's decision to choose a physician.

By the 1970s, health insurance, rather than individuals, paid for the majority of care. More than three-quarters of the population had health insurance through their employer. Public health insurance, in the form of Medicare (for persons aged 65 and older or those with disabilities) and Medicaid (for the poor) accounted for most of the remainder. A small minority purchased their own insurance, and some had no insurance at all.

Insurance companies function by collecting regular premiums from their customers (or taxpayers in the case of public insurance). Using actuarial tables, the insurer calculates how likely an insured person is to need medical services over the course of a year. In practice, a large number of people will require a small amount of service, and a small number of people will require a large amount of service, even though everyone's premiums are essentially the same. The process of distributing the cost of care over a large number of people is called **risk spreading**.

Since Medicare and Medicaid paid less than commercial insurance, they were less desirable to physicians. Patients with this type of coverage found themselves in a position where they had insurance but did not have **access** to health care because doctors wouldn't accept their insurance. Hospital-run clinics, which were staffed by physicians in training, were obligated to accept public insurance.

Among commercial insurers, however, **indemnity** policies were common. Patients chose their doctors at will and submitted their bills to the insurer for reimbursement. In most cases, the fees were completely paid, based on the services provided (**fee-for-service**). When the fees seemed outrageous, the insurer would pay what they felt was **usual, reasonable and customary.** This was calculated by determining the average cost for similar services in the

region where the service was provided. In many cases the reimbursement for particular services was negotiated beforehand. Depending on the supply and demand for services, either the insurer or provider has an upper hand in constructing the pay scale. When a person pays for healthcare directly, there is frequently much more room for negotiation.

This arrangement encouraged patients to seek care more frequently and encouraged physicians to increase the intensity and diversity of services provided. This was the heyday of the fee-for-service system. Doctors and hospitals continued to provide increasingly expensive treatments which were paid in full by insurers. Hospitals were paid a daily rate for inpatients, and therefore tended to keep their patients as long as possible.[11] As the cost of being sick skyrocketed, it became financially impossible for persons without insurance to pay for their care. As a result, profitable hospitals would routinely refuse to accept uninsured patients.

In an effort to decrease utilization, insurers began requiring **co-payments** at the time of service. Co-pays are typically a small fraction of the total cost of care and are paid directly from the patient to provider. When each visit requires a co-pay, patients may think twice before seeing their doctor. More recently, **co-insurance** has become a standard part of most policies. Co-insurance requires the patient to pay a fixed fraction (usually 10–40%) of the cost of care. Since hospital admissions can easily run into $100,000 or more, this becomes a significant financial burden for the majority of healthcare consumers. Needless to say, it functions as strong disincentive for seeking medical care. The mechanism of requiring patients to pay some fraction of the cost of care is called **cost sharing.**

Managed Care Organizations were created to control healthcare spending. In 1973, Congress passed the **Health Maintenance Organization** (HMO) Act which required employers to offer HMO insurance if they offered traditional insurance. The essence of managed care was that patients were limited to providers who had agreed to follow the HMO's guidelines and restrictions. One of the common managed care strategies involved shifting the financial risk from the insurer to the providers. One example is **capitation**, where a primary care doctor was given a certain amount of money per patient per year. If the patient required hospitalization or an expensive procedure, it came out of the doctor's share. Similarly, if the patient remained healthy, the doctor profited. In theory, doctors were now incentivized to provide preventive care to their patients, in order to avoid expensive hospitalizations.

HMO's also expanded the process of **pre-authorization,** which required the patient to obtain permission before acquiring certain costly services. Some drugs, radiology procedures (especially MRI) and even hospital admission required the approval of the insurer. Patients were warned that they would be fully responsible for the costs of care if they did not obtain the appropriate pre-authorizations. Practically speaking, the responsibility for obtaining pre-authorizations has fallen upon physicians.

In 1983, Medicare began the **inpatient prospective payment system** based on **diagnosis related groups** (DRGs). Instead of paying a daily rate for hospitalized patients, Medicare now paid the hospital a fixed rate based on the primary discharge diagnosis. Additional payments are made to hospitals which are training residents (indirect medical education) and to hospitals which treat a large number of indigent patients (disproportionate share hospital adjustment). Very quickly, hospitals began looking for ways to minimize the amount of time patients spent in the hospital (Length of Stay (LOS)). Unfortunately, this created a conflict between the hospitals and the physicians, who were not paid via IPPS but instead were paid on a fee for service basis.

In 1985, the Emergency Medical Treatment and Active Labor Act (EMTALA) mandated that hospitals provide a medical screening exam to anyone who comes to the hospital and on whose behalf a request for treatment is made. This had profound implications for care. Since hospitals were no longer able to discriminate on the basis of ability to pay, they had provide identical care to patients regardless of the reimbursement that they would ultimately receive. In order to pay for indigent care, the hospital had to use money collected from insured patients to pay for uninsured patients. This process is called **cost-shifting**.

11 In the mid-1960s, for example, it was not uncommon for a woman to remain in the hospital for 10 days after a vaginal delivery. Today, most patients are discharged in 48 h.

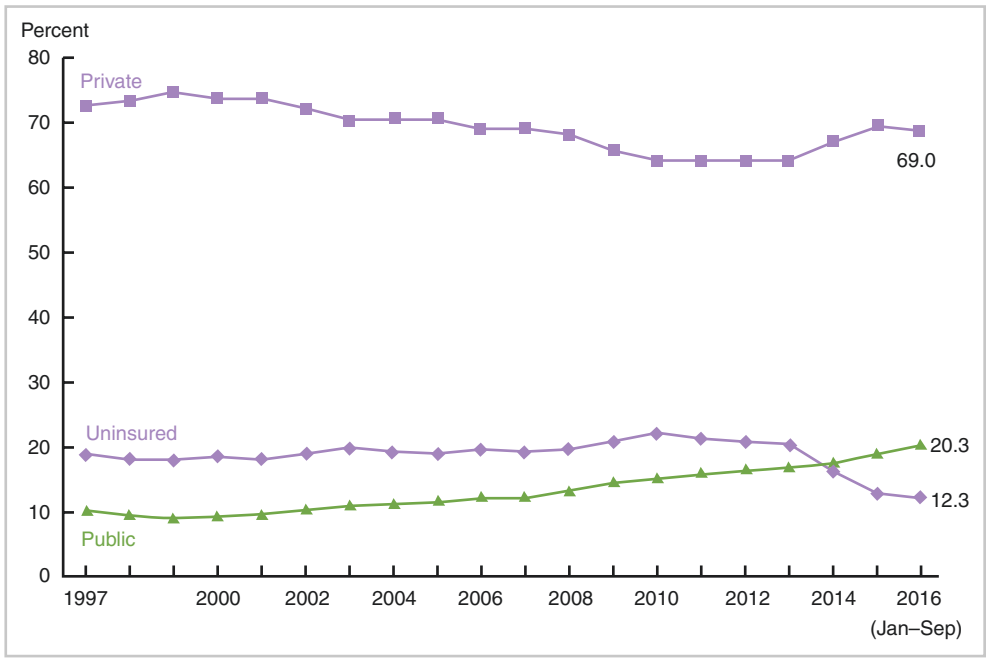


FIGURE 2-5

Percentage of Americans with private and public insurance, 1997–2016. The decrease in uninsured population is associated with the passage of the Affordable Care Act in 2010. Image public domain by U.S. Department of Health and Human Services • Centers for Disease Control and Prevention • National Center for Health Statistics • Released 2/2017

Several initiatives have been designed to link quality of care to reimbursement, usually under the rubric of **pay for performance (P4P)**. In general, a basket of quality measures is defined and incorporated into a scorecard. Doctors and hospitals can then earn a bonus based on their performance on the scorecard. For Medicare, the IPPS payment is modified on the basis of certain quality metrics (called value-based purchasing) and the number of times a patient is readmitted to a hospital within 30 days of their last discharge (via the hospital readmission reduction program).

The modern iteration of the HMO is an **Accountable Care Organization** (ACO), which is a group of providers who voluntarily band together to coordinate services. Although the initials have changed, the key motivating factor in the ACO remains capitation. The organization will be paid a certain fee for the number of lives covered. The fewer services provided to the patients, the more money is made by the ACO.

There are many instances where health care services are given without direct reimbursement. Communities often establish free clinics which are supported by grants and contributions. Many states have a payment tier between medicaid and traditional insurance. In New Jersey, for example, patients who earn too much to qualify for medicaid, may be eligible for a program known as Charity Care. Physicians frequently donate their time and expertise for charitable causes, although the regulatory burden and the medical liability climate in the United States makes it unattractive to do so. Charitable organizations (e.g. Doctors Without Borders) often provide free medical services to indigent populations.

Perhaps the most important change in financing in recent memory is the passage of the Affordable Care Act (ACA), designed to improve access to health insurance by providing state-run insurance exchanges, requiring people to sign up for health insurance or face a tax penalty and expanding public insurance (mostly medicaid). Figure 2-5 shows that the ACA decreased the number of uninsured Americans by encouraging enrollment in private insurance as well as dramatically increasing public insurance. At the same time, however, the cost of private insurance is still increasing at a rate that easily outstrips increases in family income, as seen in Figure 2-6.

As the cost of insurance increases and the percentage of costs that are borne by the patient increases and the cost of healthcare itself increases, there is a renewed public debate in the US about universal health care, similar to the single-payer model that exists in most other developed nations.

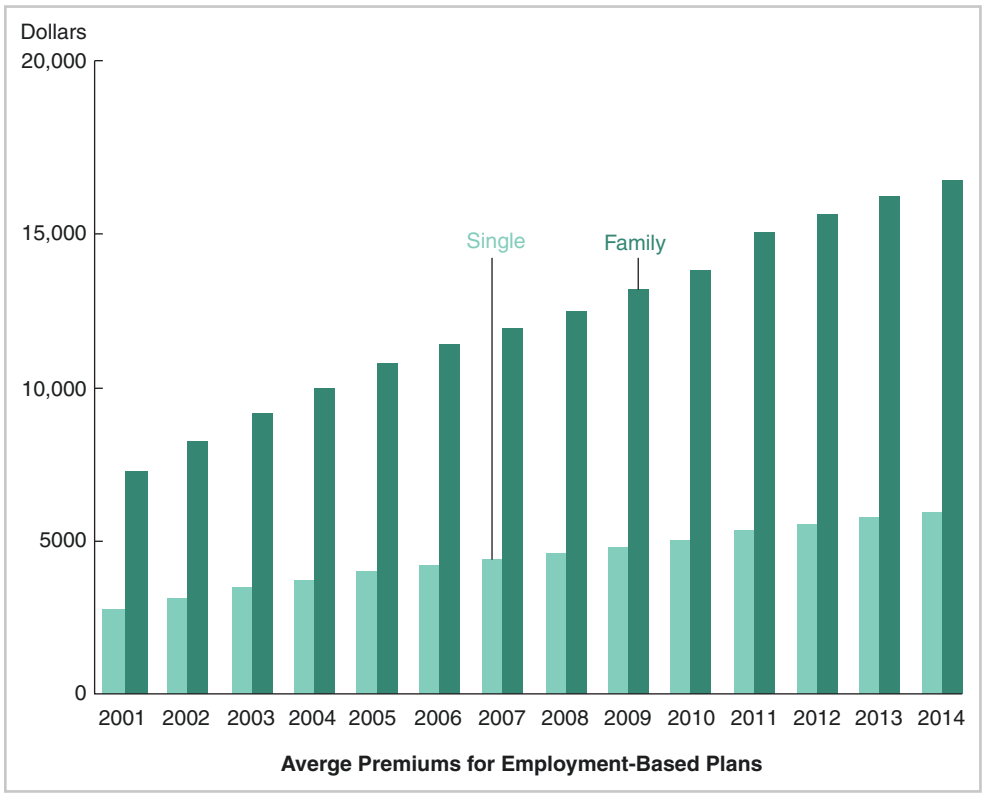


FIGURE 2-6

Average premiums for employer-based insurance plans, 2001–2014. Image public domain by Congressional Budget Office, Feb 2016

1.2.6 FORCES SHAPING HEALTHCARE DELIVERY

Reimbursement

Many forces shape healthcare delivery, the most important of which is reimbursement. See Sect. 1.2.5 for some examples about how reimbursement has changed during the past century and how it has impacted on the physician-patient relationship.

Defensive Medicine

Nearly every doctor will be sued for malpractice at some point in their careers, and some will be sued more than once. Even when unfortunate cases do not result in litigation, doctors often feel that they are under a microscope. State boards of medicine, hospital quality committees and patients themselves often question, probe and otherwise critique medical care.

In order to avoid lost time, embarrassment and financial losses, many physicians practice in such a way as to minimize the possibility of later inquiry. This may include ordering tests in situations of low clinical suspicion or prescribing drugs which are unlikely to alter disease progression and to recommend consultations with other physicians when very little clinical uncertainty exists.

For example, a patient presents to the Emergency Department with a nonproductive cough of two days duration. He has no travel or sick contacts. There is no fever, hypoxia, tachycardia or respiratory distress. Examination reveals clear breath sounds.

The physician has two choices: one option is to discharge the patient home with reassurance; the other option is to order a chest x-ray, consult with a pulmonologist and prescribe antibiotics. The physician is afraid that if the patient ultimately has a bad outcome, no matter how unlikely, he will be held liable for "not doing enough". Moreover, it costs the physician literally nothing to provide those interventions. In fact, there are several real benefits: providing his pulmonologist-colleague with business; increasing customer satisfaction; granting some measure of liability protection; providing the patient with a degree of validation that his

disease was real. Some may argue that ordering a needless chest x-ray increases the risk of malignancy and therefore violates the ethical principle of *primum non nocere*, or first do no harm. However, practically speaking, the harm caused by the increased radiation exposure is very remote, while an unhappy patient can create a problem right now.[12]

Efforts such as *Choosing Wisely*,[13] have attempted to remind physicians about their fiduciary responsibilities to populations, but have been only minimally effective in reducing the impact of defensive medicine.

Pharmaceutical Companies

Pharmacology remains the basis of therapeutics for the majority of disease conditions. However, the Food and Drug Administration requires significant evidence of safety and efficacy before it will allow a drug to be sold. Bringing a new drug from the research bench to the pharmacy shelves often takes hundreds of millions of dollars. To provide financial incentive to support research into new drugs, the US offers 20 years of patent protection for new drugs. Typically, a company applies for a patent on a new drug and then does about 10 years of research to demonstrate safety and efficacy on voluntary subjects. If successful, the drug goes to market, and the drug company enjoys a 10-year monopoly, charging whatever price the market may bear. When the patent expires, generic drug manufacturers are free to produce the drug at whatever cost they choose. For example, during the time that ondansetron (Zofran®) was under patent, the average retail cost was about $30 per 4 mg pill. When it became generic, the price dropped to $0.30 per pill.

Pharmaceutical companies have used aggressive sales techniques with providers for many years. Since convincing a single doctor to switch from one blood pressure medication to another may result in hundreds of thousands of dollars in annual profit, drug manufacturers are willing to spend lavishly to "educate" physicians.

Generic drug manufacturers are also responsible for some of the changing costs in retail pharmaceuticals. Often, the margin on a generic drug is so small that only one manufacturer will endeavor to make it. In those cases, even though the drug is generic, the manufacturer can quickly raise the price as high as the market will bear until a competitor is willing to undercut them.

Quality Organizations

Various quality organizations, most famously the Joint Commission, establish criteria for quality management of patients. In some cases, the recommendations are merely mirrors of common practice, such as administration of aspirin for stroke or acute myocardial infarction. In other cases, the recommendations have been well intended but not based on clinical evidence, such as the admonition to prescribe antibiotics for pneumonia within 4 h of hospital arrival. Under pay-for-performance systems, adherence to these guidelines directly influences reimbursement, which can have dramatic effects on physician behavior.

Specialization

Physicians who pursue specialization generally earn more than their primary care counterparts. As the number of specialists increases and primary care doctors become more familiar with their practice, the number of consultations increases. As time goes on, primary care providers become less familiar with problems that have been delegated to specialists, which causes a shift in standard of care. After a time, caring for patients with these kinds of problems falls outside the usual scope of practice for primary doctors.

12 Consider, for example, a child with a traumatic neck injury. Ordering a CT scan is more likely to cause thyroid cancer than it is to discover a fracture. However, the cancer will not likely be detected for another 20 years and will be very difficult to tie to this individual encounter. Therefore, the provider chooses to order the study. See Muchow RD. Theoretical increase of thyroid cancer induction from cervical spine multidetector computed tomography in pediatric trauma patients. J Trauma Acute Care Surg. 2012 Feb;72(2):403–9.

13 See http://www.choosingwisely.org/ for more information and recommendations.

1.2.7 INSTITUTE OF MEDICINE QUALITY COMPONENTS

In *Crossing the Quality Chasm: A New Health System for the 21st Century*, the Institute of Medicine claims "The American health care delivery system is in need of fundamental change."[14] In addition to the safety concerns raised in *To Err is Human*,[15] the authors cite systematic inefficiencies in the way medicine is practiced. Tests are often duplicated because various providers are unable to access each other's records; patients are harmed by adverse drug events which could have been prevented by a robust drug interaction checking system; despite rapidly advancing medical knowledge, bedside care lags far behind the state of the art. The committee gave four recommendations: (1) create an infrastructure to support evidence-based practice, (2) expand the use of information technology, (3) align payment incentives, and (4) prepare the workforce to better serve patients in a world of expanding knowledge and rapid change.

They further specified that care should be dictated by patient needs and desires: care should be always available with the patient in control. Patients should be provided with unfettered access to their medical information as well as resources needed to interpret their medical conditions and make rational care choices based on best-available evidence. Safety and transparency should be built into the system, which would anticipate patient needs instead of react to them. Continuous and easy cooperation among clinicians would result in a decrease in wasted time and costs.

The six pillars of quality are Safety, Effectiveness, Efficiency, Patient-centeredness, Timeliness and Equity.

1.2.7.1 Safety

Safety implies that patients will not be harmed by the care that they receive. As a corollary, the members of the healthcare team should not be harmed when providing care to patients. Medical errors which have the potential to cause patient harm are generally classified as either failure to complete a planned action or selecting an inappropriate action for a given problem.

The committee emphasizes that safety should be pervasive for all patients at all times. Institutions should not have a lower standard for safety on nights, weekends or during times of change. Further, patient information should be wholly available to all people involved in care in an easily accessible manner. When errors do occur, the patient should be notified and institutions should strive to investigate ways to prevent future occurrences.

1.2.7.2 Effectiveness

Effectiveness is the use of evidence to guide interventions that produce better outcomes than alternatives, including the alternative of doing nothing at all. Evidence must be robust, reliable, well-collected, properly tabulated and analyzed, and must take into account patient's personal needs and values. In order to be effective, evidence garnered from the medical literature must be combined with clinical acumen, skill and experience to produce effective interventions.

1.2.7.3 Efficiency

In an efficient system, limited resources are maximized to get the best bang for the buck. There are two ways to accomplish this goal: (1) modify inefficient and costly processes; and (2) reduce or eliminate administrative overhead.

14 Institute of Medicine. 2001. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: The National Academies Press.
15 Institute of Medicine. 2000. To Err Is Human: Building a Safer Health System. Washington, DC: The National Academies Press.

Most successful quality improvement projects reduce waste, either by decreasing the amount of unnecessary work, or by protecting against future injuries. Administrative overhead can often be addressed with improvements in technology. For example, replacing a paper-based filing system with an electronic one can improve accessibility of documents while simultaneously decreasing the human labor costs associated with such a system.

Another example: in most hospitals, the operating room schedule is far busier on Monday than Saturday because surgeons tend to schedule procedures earlier in the week to avoid weekend stays in the hospital. Smoothing out the operating schedule can make better use of resources and reduce waiting times.

1.2.7.4 Patient-Centeredness

The patient's experience of health and disease is a reflection on the care he receives. A system is considered patient-centered when it embodies compassion, empathy, responsiveness, and respect for individual values and preferences.

There has been some research demonstrating the extent to which patients are excluded from decision-making. In one study from 1984, it was shown that physicians interrupt patients an average of 18 s into giving a history.[16] Research has also shown that patients rarely understand when they give written informed consent.[17]

However, there are examples where patient-centeredness is improving. Today, it is commonplace for patients to independently review medical diagnoses online and bring their concerns to their physician.

Gerteis[18] listed six dimensions of patient-centeredness

1. Respect for values, needs and preferences. Historically, doctors have treated patients in a patrician way by making all decisions based on their own value system, which may not be concordant with the patient's value system. This privilege was predicated on the assumption that patients did not possess enough information or understanding to make their own medical decisions. In a patient-centered environment, the provider assumes the role of teacher and advisor, rather than decider.
2. Coordination of care. Patients who travel from one institution to another may find themselves subjected to repeated failed therapies simply because the current providers are unfamiliar with the workup which has been done before. In a patient-centered environment, a patient gives a history once and it follows the patient wherever he goes
3. Education and communication. Inherent in coordination of care is education of the patient and communication of all relevant information at all times.
4. Comfort. Providing relief of pain and suffering is one of the cornerstones of medical practice. Some providers feel that treating disease is more important than treating pain (which may obscure important symptoms). However, research has shown that patients who are comfortable are better empowered to make reasonable and rational decisions about their own care.
5. Emotional support. Alleviating emotional pain, such as fear and anxiety, can be as important to empowering patient decision making as is relief of physical pain. Providing a supportive environment with easily reachable providers and complete transparency can help a patient understand their disease and begin the coping process.
6. Involvement of friends and family. Recruitment of other caregivers into the patient's illness provides the Social and familial support that is required to overcome illness.

16 Beckman HB, Frankel RM. The effect of physician behavior on the collection of data. Ann Intern Med 1984;101(5):692–6.

17 Gerteis M, Edgman-Levitan S, Daley J. Through the Patient's Eyes. Understanding and Promoting Patient-centered Care. San Francisco, CA: Jossey-Bass, 1993.

18 Grady C. Enduring and Emerging Challenges of Informed Consent. N Engl J Med 2015;372:855–62.

1.2.7.5 Timeliness

Timeliness refers to respecting a patient's time and convenience as much as possible. Lack of timeliness indicates a systematic disregard for flow and a degree of disrespect that would not be tolerated in other consumer-centered environments.

Queueing theory and other flow-directed technologies exist in other industries and may be applied to healthcare. In some cases, a balance must be struck between timeliness and efficiency. Consider, for example, the example of the operating room schedule smoothing example (above, in Sect. 1.2.7.3).

Most healthcare encounters currently require face-to-face interaction in order to qualify for reimbursement from insurers. Replacing some of these visits with telephone or virtual interactions has the potential to dramatically improve timeliness. However, in order for this to happen, insurers must be willing to align the goals of cost containment with timeliness.

1.2.7.6 Equity

The aim of equity is to ensure that all people are equally able to avail themselves of health care services when needed. At the population level, equity requires that any systematic improvements in health care be provided in a way that reduces disparities among various subgroups. In essence, equity demands universal access to healthcare. Specifically, the quality and availability of care should not depend on characteristics as gender, race, age, ethnicity, income, education, disability, sexual orientation, or location of residence.

Part II

Clinical Decision Making and Care Process Improvement

The knowledge and skills that enable a clinical informatician to implement effective clinical decision making systems and participate in the development of clinical processes that support effective, efficient, safe, timely, equitable, and patient-centered care.

Scott Mankowitz

2.1 Clinical Decision Support

CHAPTER OUTLINE

2.1.1 THE NATURE AND COGNITIVE ASPECTS OF HUMAN DECISION MAKING

Samuel Alfano

Most of decision theory is concerned with identifying the best decision to make (in practice, there are situations in which "best" is not necessarily the optimum, and may also include values within a specific or approximate range), assuming an ideal decision maker who is fully informed, able to compute with perfect accuracy, and fully rational. The practical application of this prescriptive approach (how people ought to make decisions) is called **decision analysis,** and aimed at finding tools, methodologies and software to help people make better decisions. The most systematic and comprehensive software tools developed in this way are called decision support systems (CDS).

Decision analysis often includes the concept of expected value. That is, when faced with a number of options, each of which could give rise to more than one possible outcome, the rational procedure is to identify the likelihood and value (positive or negative) of all possible outcomes associated with each option. You can then multiply the likelihood and value to calculate an expected value. The action to be chosen should be the one that gives rise to the highest total expected value. See Sect. 2.1.2.1 for examples of expected value.

2.1.1.1 General

Cognitive biases are tendencies to think in certain ways that can lead to systematic deviations from a standard of rationality or good judgment. Making decisions based on opinion is subject to predictable patterns of bias. These are effects of information-processing rules (i.e., mental shortcuts), called **heuristics**, that the brain uses to produce decisions or judgments (Figure 3-1).

Some common Heuristics that lead to bias are listed below.

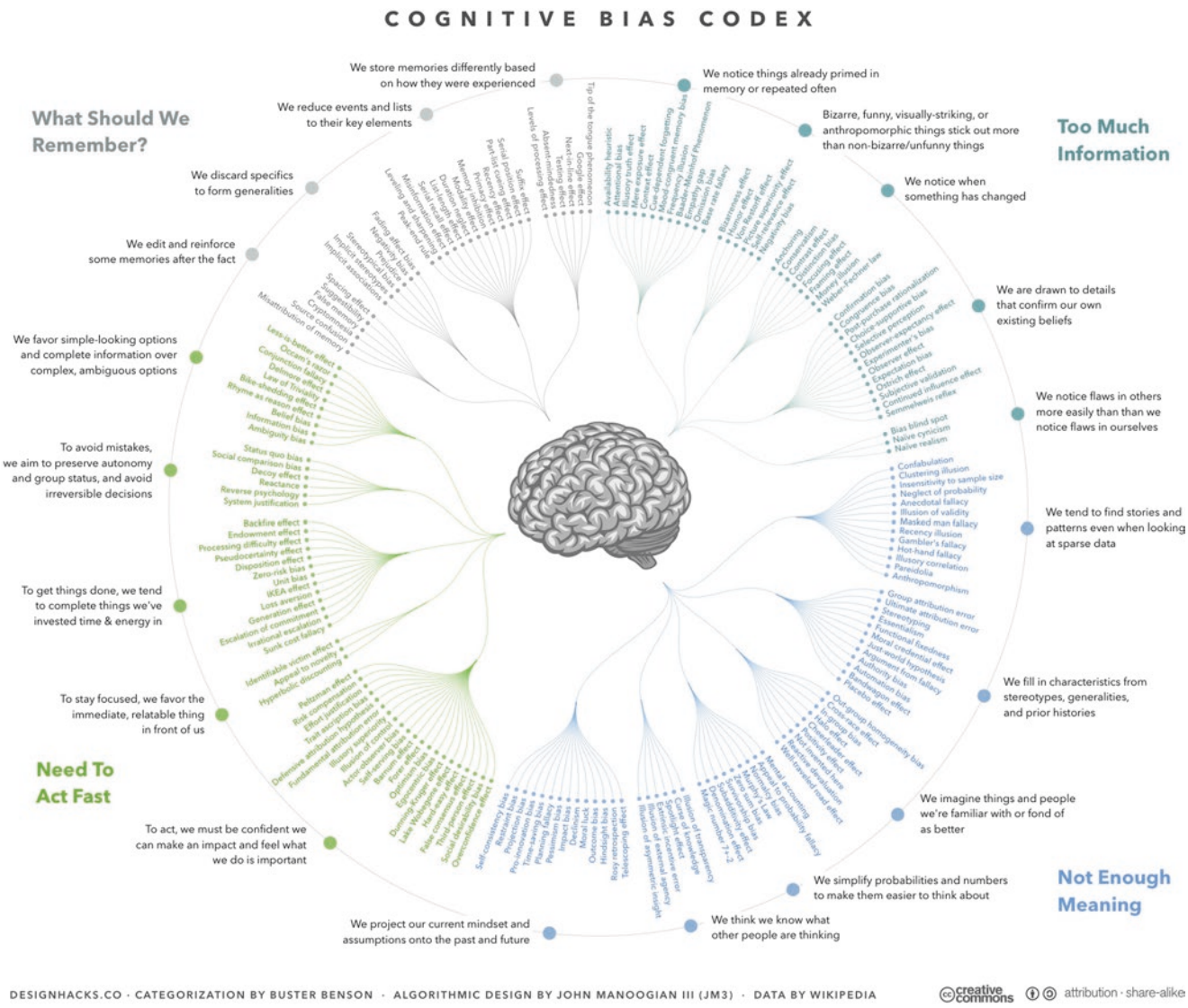


FIGURE 3-1

Cognitive biases, categorized. Illustration by John Manoogian III, CC-SA

Availability Bias
This is the tendency to overestimate the probability of unusual events because of recent or memorable experiences. These memories can be influenced by how recent the memories are or how unusual or emotionally charged they may be. "The last patient I saw with atypical chest pain died of a heart attack 3 days later. I better rule out cardiac disease in this patient" is an example of this type of bias.

Representativeness Bias
This is the tendency to overestimate unusual diseases or conditions due to matching pieces of the typical picture of that disease. This bias helps to quickly limit the possibilities and reduce the decision making time. "The patient has bilateral knee pain, we should check an ANA to make sure he does not have lupus" is an example of representativeness.

Anchoring Bias
The tendency to rely too heavily, or "anchor", on one trait or piece of information when making decisions (usually the first piece of information acquired on that subject). This usually leads to a failure to adjust the probability of a disease based on new information. "Even

though he had abnormalities on his ECG, he has a previous diagnosis of peptic ulcer disease, so I don't think he has cardiac disease" is an example of this type of bias.

Value Based Bias
The tendency to over or under estimate the probability of an outcome based on the perceived value associated with that outcome. We tend to add more weight to information which supports a more valuable outcome. "Even though this patient's headache is certainly a migraine, we should do a CT scan to rule out a brain tumor" is an example of this type of bias.

Confirmation Bias
The tendency to search for, interpret, focus on and remember information in a way that confirms one's preconceptions. We tend to believe and interpret data in a way that supports our beliefs and initial conclusions. "I think this patient has esophageal reflux disease, he responded well to treatment, so I don't think his ECG abnormalities are significant enough to warrant further investigation" is an example of this type of bias.

Automation Bias
The tendency to depend excessively on automated systems which can lead to erroneous information that can override or interfere with correct decisions. This can be seen frequently when electronic medical record systems are installed and has been referred to as "task blindness". "I thought it was unusual dose of medication to give to my patient, but the order was confirmed in the system and no medication alerts were triggered." is an example of this bias.

These biases affect belief formation, business and economic decisions, medical decision making, and human behavior in general. They arise as a replicable result to a specific condition.

2.1.1.2 Medical

Clinical reasoning is the cognitive process that clinicians use to discard or confirm a hypothesis. Several models of this process have been proposed.

Additive model: In this model, clinicians assign a positive weight to findings that tend to confirm a diagnosis and negative weights to findings that disconfirm the diagnosis. The clinician's decision to discard or accept a hypothesis is based on the sum of the diagnostic weights. Clinical prediction rules use this model. A clinical example would be the Caprini DVT risk[1] scoring where numerical values are added to the score depending on the patient's history. In many cases though, Physicians probably assign weights to probable conclusions based on the clinical findings. This may happen subjectively and subconsciously.

Bayesian model: Bayes' theorem is the method to calculate the probability of a condition based on the prevalence or pretest probability of the condition and other related events, such as diagnostic test results. Bayes' theorem informs the clinician how to adjust his degree of confidence in a hypothesis when new information becomes available. At some point, he may conclude that the probability is low enough to discard the hypothesis.

Algorithmic model: Algorithms are commonly used to represent the logic of diagnosis. Clinicians follow an internal flow sheet with branching logic as they test a hypothesis. A series of *no* branches eventually leads to discarding a hypothesis and a series of *yes* answers may lead to accepting a diagnosis.

Blois' Funnel illustrates the notion that when a doctor begins the diagnostic process for a given patient's condition, he initially brings the widest range of skills and experiences to bear (the area under the upper-left curve on the graph). The patient begins that encounter by describing and presenting a wide, but often vague, range of complaints and symptoms (the area above the lower-left curve on the graph). As the examination continues, a complex set of interactions occur between the two people as they communicate. Body language, targeted questions, readings, measurements, etc., are exchanged as the two arrive at a specific diagnosis (represented by the

1 Bahl V, Hu HM, Henke PK, Wakefield, TW, Campbell, DA, Caprini, JA. A Validation Study of a Retrospective Venous Thromboembolism Risk Scoring Method. Ann Surg 2010. 251(2):344–350.

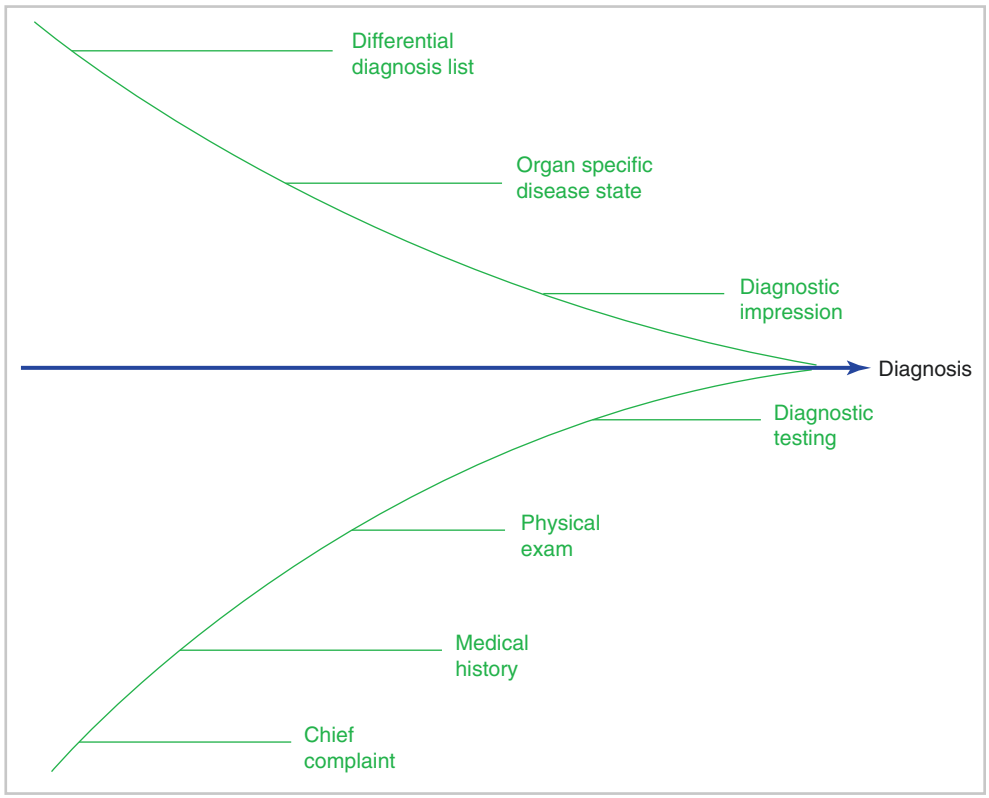


FIGURE 3-2

Blois' Funnel illustrates the process of finding a diagnosis. Initially, the physician maintains a broad differential diagnosis and the patient elaborates a chief complaint. By applying information from the medical history, physical exam and diagnostic testing, the physician is able to narrow his differential into a diagnostic impression

convergence of the two curves on the right side of the graph). Thus, the practitioner's knowledge, skills, and tools must connect with the patient's complaints, testimony, and anatomy to interoperate technically, semantically, and with orchestrated processes, possibly involving multiple teams, just to produce the working diagnosis (Figure 3-2).

2.1.2 DECISION SCIENCE

Samuel Alfano

2.1.2.1 Decision Analysis

Patients and Providers often make decisions based on the expected value or utility of the outcome of their decisions. **Expected value** is the summation of the independent probabilities of events. **Expected utility** includes expected value but also takes into account mitigating factors like risk aversion, personal preferences, or circumstances. Though the expected value of a high risk game may be zero or negative to play (given the low rate of return), someone might still choose to play if he gets pleasure out of taking risk, is desperate for money, or for other reasons. In order to calculate the expected value or utility, it is necessary to have a working knowledge of the principles of probabilities.

2.1.2.2 Probability Theory

1. **Probability Notation.** The probability that event A will happen is written as *P(A)*. The probability that event A will NOT happen can be written as *P(!A)* or *P(~A)* or *P(A′)* or simply *P(not A)*.
2. **Conditional Probabilities** The probability of event A happening given that B has happened is notated with a vertical pipe. If A is the probability of having HIV and B is the probability of using IV drugs, *P(A|B)* is the probability of having HIV given IV drug use.

3. **Addition Rule**: The probability of "A" plus the probability of "not A" must add up to one. $P(A) + P(A') = 1$.
   (a) Corollary: If another event, B is related to event A, the probability of B is equal to the probability of A and B plus the probability of not-A and B.
   $P(B) = P(A \text{ and } B) + P(A' \text{ and } B)$
4. **Multiplication Rule**: The probability of A and B occurring is equal to the probability of A times the probability of B, given A.
   P(A and B) = P(A) • P(B|A)
5. **Outcomes Rule**: All of the possible outcome probabilities in a specific instance with multiple outcomes add up to one.
   $P(A) + P(B) + P(C) \ldots = 1$

Sequential events can be described as a **decision tree** or graph which can be used to model a decision using the sum of conditional probabilities. Rules governing decision trees:

1. Decision nodes are designated by a square and represent branching points in the decision tree.
2. Chance nodes are designated by a circle and represent the probability of a specific outcome occurring.
3. Each branch is assigned a probability.
4. The probability of all branches of a node must add up to 1.
5. Outcome nodes are designated by a triangle.
6. Outcomes are assigned a value (cost, utility, Quality Adjusted Life Years, relative value, etc.)
7. If life or death are the outcomes of interest then life = 1 and death = 0

Clinical example: Your patient has prostate cancer. The disease is fatal in 15% of untreated patients. The remaining 85% have spontaneous improvement. When patients are given treatment Y, survival improves from 85 to 95%. Unfortunately, 5% of treated patients have a fatal reaction. The question is whether treatment produces better results than non-treatment (Figure 3-3).

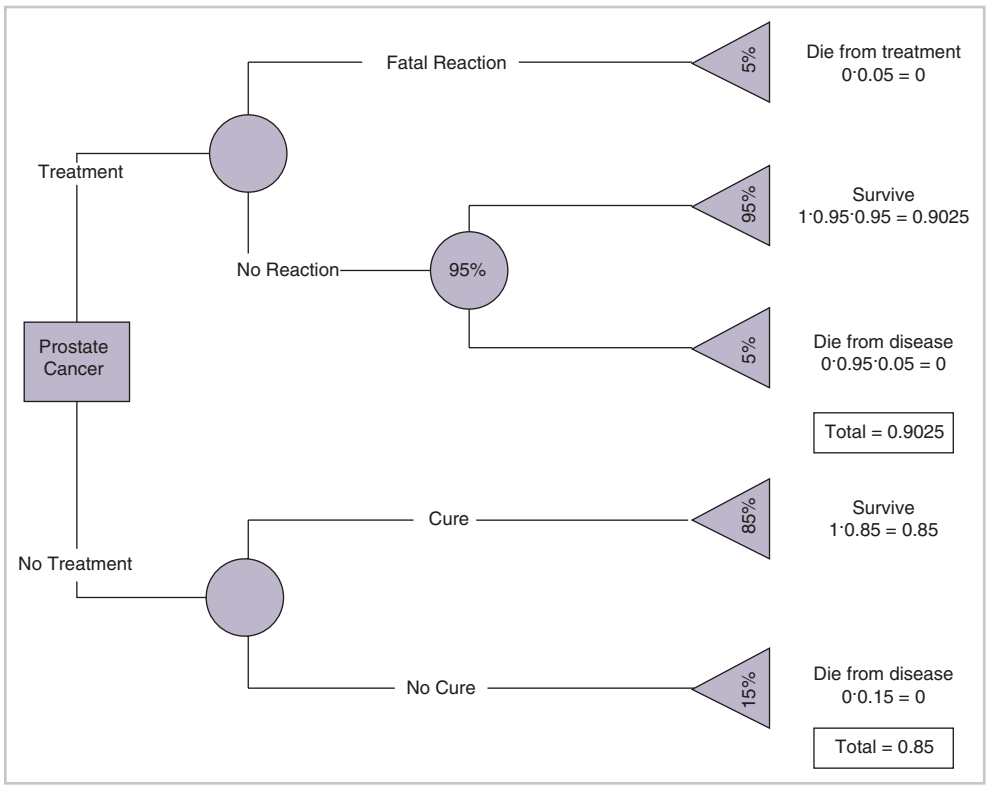


FIGURE 3-3

Decision tree

Example Calculations (see chart below)
Expected Value of treatment branch = 0.9025

Fatal Reaction = 0 • 0.05 = 0
No reaction = ((1 × 0.95) + (0 × 0.05)) • 0.95 = 0.9025
Sum of both = 0 + 0.9025 = 0.9025

Expected Value of no treatment branch = 0.85

Cure = 1 • 0.85 = 0.85
No cure = 0 • 0.15 = 0
Sum of probabilities of both = 0.85 + 0 = 0.85

This model very slightly favors giving treatment Y despite a 5% chance of fatal reaction. What if the probability of treatment complications or fatality due to treatment Y increases? At what threshold does the therapy become too risky and confer no additional benefit? Also defined as **sensitivity analysis**, what-if analysis is a technique used to determine how projected performance is affected by changes in the underlying assumptions.

2.1.2.3 Utility and Preference Assessment

Utility can be used in decision analysis to adjust the value of a choice based on a patient's perceived utility of a potential outcome. Methods include Standard Gamble, Time Trade Off, Visual Analog, and Quality Adjusted Life Years. The expected value of gambling is the sum of the expected probabilities. One can compare this to the expected utility of not gambling.

Expected Value vs Expected Utility:

A $10 bet gives you a 1 in 80 chance of winning $1000. If you gamble and win, you get $1000, however, if you gamble and lose, you get nothing. If you do not gamble, you keep your $10.

Expected value of doing nothing (not gambling) = 1 • $10 = $10
Expected value of gambling $1000 • (1/80) + 0 × (79/80) = $12.50

This example favors gambling. In the long run, gambling will produce a more favorable outcome than not gambling. However, expected utility is a function of value and also risk aversion, personal preferences and circumstances. If you desperately need $10, you might choose not to gamble. If you are a risk taker or have lots of money, you might choose the gamble.

Patient preferences require more input than straight probability. Two outcomes may not have same effectiveness or impact. (e.g. surgical debulking vs. chemotherapy). In addition, the numerically favorable therapy is not always the one the patient prefers. Some decisions require subjective input by the patient. Consider:

Therapy A: 50% chance of 10 year survival: expected value = 5 years
Therapy B: 90% chance of a 2 year survival: expected value = 1.8 years

Utility can be used in decision analysis to define the "value" of an outcome node. One can adjust the value of the outcome based on the perceived utility of that outcome for that patient. There are several common approaches:

Standard Gamble

In the Standard Gamble, the patient is assumed to have a chronic health condition and is offered a potentially disease-altering treatment, however the treatment is not without risk. The patient is given two alternatives: (1) continue life with the current medical condition; (2) choose the intervention, even though there is a defined risk of death. If the patient strongly

chooses either option, the risk of death is adjusted up or down and the question is posed again. At some point, the patient reaches a **point of indifference**, where he really can't choose between the two options. That resulting value is the utility.

As an example, suppose a patient has chronic renal failure on maintenance hemodialysis and we are trying to determine the utility of renal transplant. The patient is asked, "would you rather have renal failure or have a transplant? The risk of dying from a transplant is 90%". The patient recoils and says that he would much prefer dialysis to a 90% chance of death. What if the risk of death were only 0.05%? At this point, the patient gladly accepts the transplant. Next, we go back to the patient and say, "what if the risk of death were 25%". Again, the patient refuses transplant. We keep modifying the risk of death up and down until we arrive at 2%. At that point, the patient can't really decide which option is better. He has reached his point of indifference, and the utility of transplant is determined to be 2%.

Time Trade Off

In a Time Trade Off (TTO), sick patients estimate how many years of their life they would be willing to give up to live a certain number of years in full health. For example, you have a chronic disease and are told that you have 10 years left to live. In connection with this you are also told that you can choose to live these 10 years in your current (less than healthy) state or that you can choose to give up some life years for a shorter period in full health. How many years in full health do you think is of equal value to 10 years in your current health state?

The TTO utility (the indifference point) is the length of remaining life in perfect health divided by the length of remaining life with the evaluated health state. In the above example, one might choose to give up 5 years of life in their current state in order to live a more healthy life. The TTO utility would be 5 years/10 years or 0.5.

Visual Analog

When using this approach, patients are asked to rate different health states on a marked or unmarked scale where 0 = death and 100 = perfect health.

Quality Adjusted Life Year

The quality-adjusted life-year (QALY) is a measure of the value of health outcomes. Since health is a function of length and quality of life, the QALY was developed as an attempt to combine the value of these attributes into a single number. The QALY calculation is simple: the change in utility value induced by the treatment is multiplied by the duration of the treatment effect to provide the number of QALYs gained. QALYs can then be incorporated with medical costs to arrive at a ratio of cost/QALY. This parameter can be used to compare the cost-effectiveness of any treatment. Some believe that there are states of health that are worse than death so QALY can have a negative value.

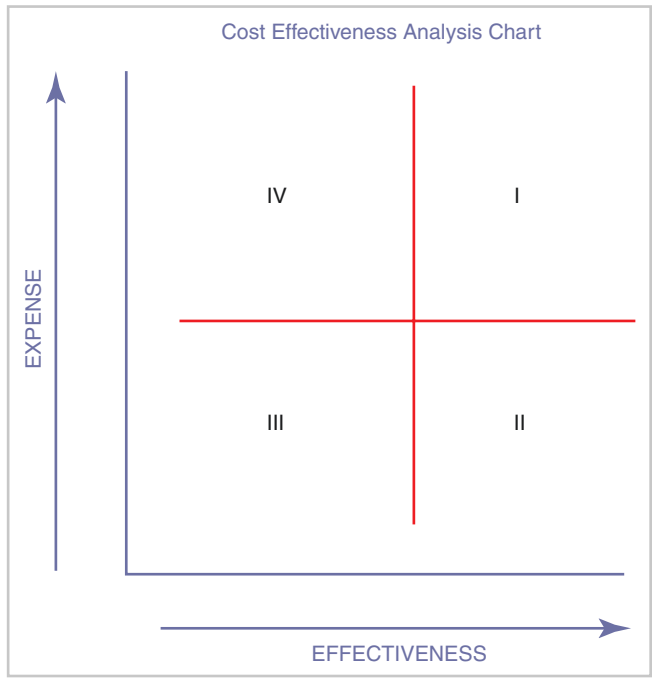
2.1.2.4 Cost-Effectiveness Analysis (CEA)

Cost-effectiveness analysis (**CEA**) is a form of economic analysis that compares the relative costs and outcomes (effects) of two or more courses of action. Cost-effectiveness analysis is distinct from cost-benefit analysis, which assigns a monetary value to the measure of effect. Cost-effectiveness analysis is often used in the field of health services, where it may be inappropriate to monetize health effect. Typically the CEA is expressed in terms of a ratio where the denominator is a gain in health from a measure (years of life, premature births averted, sight-years gained) and the numerator is the cost associated with the health gain. The most commonly used outcome measure is quality-adjusted life years (QALY). **Cost-utility analysis** is similar to cost-effectiveness analysis. Cost-effectiveness analyses are often visualized on a cost-effectiveness plane consisting of four quadrants (Figure 3-4). Knowing cost and utility/value of an outcome allows you to calculate the Incremental Cost/Effectiveness Ratio (ICER). Comparing the calculated ICER to the "willingness to pay" can help to determine if a therapy is cost effective. Assuming two options, A and B, ICER is defined as:

ICER = (Cost of A – Cost of B)/(Effect of A – Effect of B)

FIGURE 3-4

Cost effectiveness analysis



2.1.2.5 Test Characteristics

Besides understanding the probabilities of treatments and disease states, it is equally important to understand the diagnostic testing that is used to make decisions and its limitations.

Sensitivity is defined as the probability that a test result will be positive when the disease is present (true positive rate).The true positive rate is equal to the number of true positives divided by the total number of sick patients in the population. Recall that the number of sick patients is equal to the true positives as well as the false negatives. A negative result in a test with high sensitivity is useful for ruling out disease. A high sensitivity test is reliable when its result is negative, since it rarely misdiagnoses those who have the disease. A test with 100% sensitivity will recognize all patients with the disease. A negative test result would definitively *rule out* presence of the disease in a patient.

Since sensitivity does not account for false positives, a positive result in a test with high sensitivity is not useful for ruling in disease.

Sensitivity = True Positive/(True Positive + False Negative)

Specificity is defined as the probability that a test result will be negative when the disease is not present (true negative rate). The true negative rate is equal to the number of true negatives divided by the number of people in the population who do not have the disease. Recall that the number of healthy patients without disease is equal to the true negatives plus the false positives. A positive result in a test with high specificity is useful for ruling in disease. The test rarely gives positive results in healthy patients. A test with 100% specificity will read negative, and accurately exclude disease in all healthy patients. A positive result signifies a high probability of the presence of disease. A negative result in a test with high specificity is not useful for ruling out disease.

Specificity = True Negative/(False positive + True Negative)

	DISEASE	NO DISEASE
TEST +	8	10
TEST -	2	980

In this example, the prevalence of the disease is 1% (i.e. because 10 of 1000 people have it)

Sensitivity = 8/(8 + 2) = 80%
Specificity = 980/(980 + 10) = 99%

Screening tests tend to be highly sensitive and relatively inexpensive. False positives are common, and the person ordering the test must use this knowledge when interpreting the results. Confirmatory tests tend to be more expensive and are are designed to minimize false positives (i.e. have high specificity). The two by two table (above) is also called a **confusion matrix**.

Likelihood ratios are used for assessing the value of performing a diagnostic test. They use the sensitivity and specificity of the test to determine whether a test result usefully changes the probability that a disease exists.

The **Negative Likelihood Ratio**, sometimes written as LR(−), is defined as the ratio between the probability of a negative test result given the presence of the disease and the probability of a negative test result given the absence of the disease, i.e. (False negative rate/ True negative rate) = (1 − Sensitivity)/Specificity.

The **Positive Likelihood Ratio**, written as LR(+), is defined as the ratio between the probability of a positive test in the presence of disease and the probability of a positive test in the absence of disease, i.e. (True positive rate / False positive rate) = Sensitivity/(1 − Specificity).

A likelihood ratio of greater than 1 indicates the test result is associated with the disease. A likelihood ratio less than 1 indicates that the result is associated with absence of the disease.

Positive and Negative Predictive Values

While sensitivity and specificity are characteristics of the test being used to diagnose a disease, **positive predictive value** (PPV) and **negative predictive value** (NPV) are predictive characteristics of of the patient given certain test results.

The **PPV** is the probability that the disease is present when the test is positive and the **NPV** is the probability that the disease is not present when the test is negative.

PPV = TP/(TP + FP)
NPV = TN/(TN + FN)

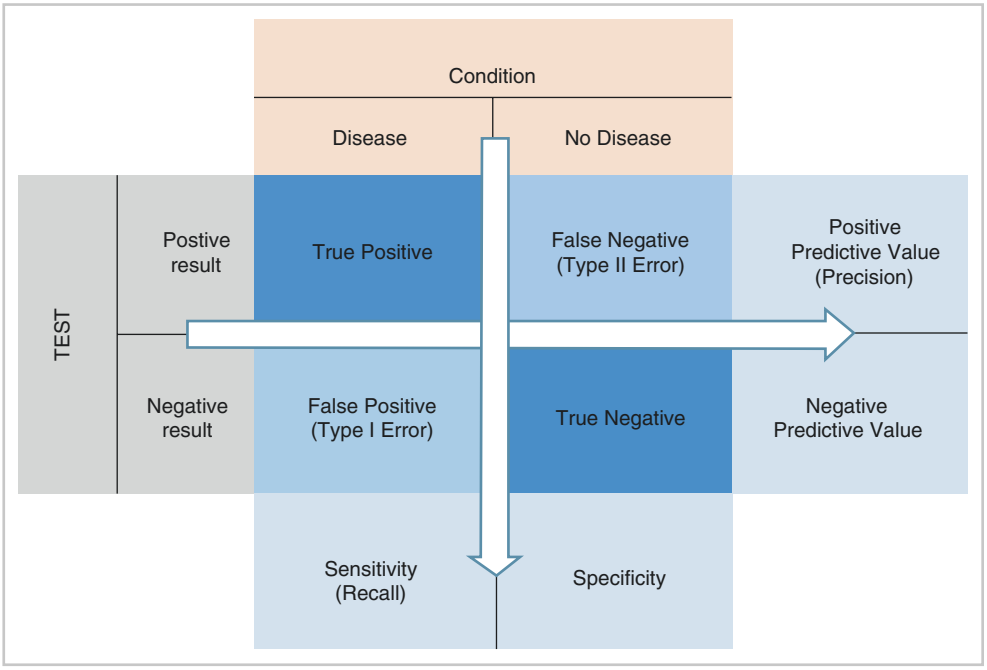
Sensitivity and specificity assume the disease state is known, and are used to determine if the test performs as intended. PPV and NPV are more useful in clinical practice, where the test result is known and the disease state is being sought.

Another way to state the relationship between these values:

Sensitivity: Given the patient has disease, what is the probability of a positive test?
Specificity: Given the patient does not have the disease, what is the probability of a negative test?
PPV: Given a positive test, what is the probability the patient has disease?

FIGURE 3-5

Relationship between test results and presence of condition



NPV: Given a negative test, what is the probability the patient does not have disease?

In statistics, a null hypothesis (H_0) is a statement that one seeks to disprove with evidence to the contrary. Most commonly it is a statement that the phenomenon being studied produces no effect or makes no difference. Usually, an experimenter frames a null hypothesis with the intent of rejecting it: that is, intending to run an experiment which produces data that shows that the phenomenon under study does make a difference. In most cases there is a specific alternative hypothesis (H_a) that is opposed to the null hypothesis, in other cases the alternative hypothesis is not explicitly stated, or is simply that the null hypothesis is false.

A type I error (or error of the first kind) is the incorrect rejection of a true null hypothesis (i.e. a false positive). This error usually leads one to conclude that a supposed effect or relationship exists when in fact it doesn't.

A type II error (or error of the second kind) is the failure to reject a false null hypothesis (i.e. a false negative). This error leads one to conclude that a relationship does not exist when it truly does (Figure 3-5).[2]

Increasing prevalence decreases negative predictive value of the test. Even though a test predicts the disease as absent, the more prevalent the disease, the less likely the test is right. This means that a negative test isn't very good with a common disease—and a positive test isn't very good for a rare disease.

For every possible cut-off point or criterion value you select to discriminate between the two populations (disease or no disease) there will be some cases where the disease is incorrectly classified. Suppose we have a diagnostic test which yields a result between 1 and 5. The healthy population is centered around 2.5 with a standard deviation of 0.5. Similarly, the sick population has a mean of 4 with a similar standard deviation. A plot of the two populations is shown in Figure 3-6. When designing our test, where should the cut-off value be? If we set it at 3, some of the healthy population (i.e. those with values from 3 to 3.5) will be falsely characterized as sick (i.e. false positives). Similarly, if we set the cut-off at 3.5, some of the sick patients will be categorized as healthy (i.e. false negatives).

2 A mnemonic to remember this is "Ladies First". A type I error, is a girlfriend's mistake. She assumes that a relationship exists when it truly doesn't. The type II error is the boyfriend's mistake. He assumes that there is no relationship when there really is. -Ed.

When you select a lower criterion value, then the true positive fraction and sensitivity will increase. On the other hand the false positive fraction will also increase, and therefore the true negative fraction and specificity will decrease. This can be depicted as a **receiver operating characteristic** (ROC) plot (Figure 3-7).

A ROC space is defined by FPR and TPR as *x* and *y* axes respectively, which depicts relative trade-offs between true positive (benefits) and false positive (costs). Since TPR is equivalent to sensitivity and FPR is equal to 1 − specificity, the ROC graph is sometimes called the sensitivity vs (1 − specificity) plot. Each prediction result or instance of a confusion matrix represents one point in the ROC space.

The best possible prediction method would yield a point in the upper left corner or coordinate (0,1) of the ROC space, representing 100% sensitivity (no false negatives) and 100%

FIGURE 3-6

Example distribution of healthy and sick patients in a population. Note the overlap in test results between 3-3.5

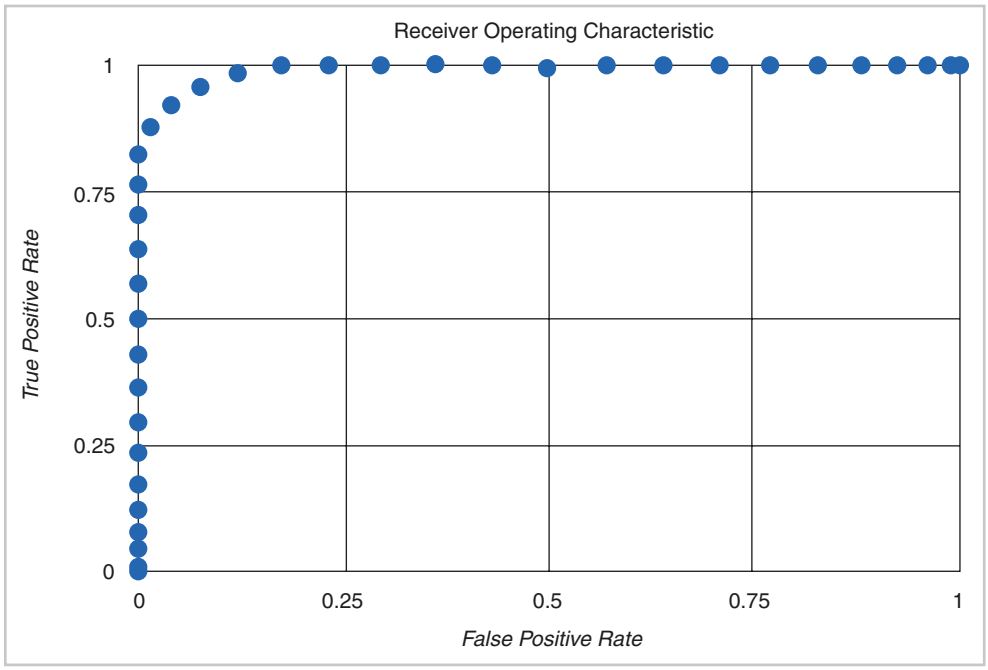


FIGURE 3-7

Construction of the receiver operating characteristic (ROC) curve based on true positive rate (TPR) and false positive rate (FPR). Each point on this curve represents a particular value for TPR and FPR

specificity (no false positives). The (0,1) point is also called a **perfect classification**. A completely random guess would give a point along a diagonal line (the so-called line of no-discrimination) from the left bottom to the top right corners (regardless of the positive and negative base rates). The diagonal divides the ROC space. Points above the diagonal represent good classification results (better than random), points below the line represent poor results (worse than random).

Bayes' Theorem

Bayes' theorem helps overcome many well-known cognitive errors in diagnosis, such as ignoring the base rate, probability adjustment errors (conservatism, anchoring and adjustment) and order effects. It is calculated as the probability of disease given a positive test. This is equal to the probability of a positive test given disease (sensitivity) multiplied by the probability of disease (prior probability) divided by the probability of a positive test.

Bayes's theorem is stated mathematically as the following form:

$$P(A|B) = \frac{P(B|A) \cdot P(A)}{P(B)}.$$

Suppose a drug test is 99% sensitive and 99% specific. That is, the test will produce 99% true positive results for drug users and 99% true negative results for non-drug users. Suppose that 0.5% of people are users of the drug. If a randomly selected individual tests positive, what is the probability he or she is a user? To solve this, we set A = probability that he is a drug user and B = probability that the test is positive. Therefore, P(A|B) is the probability that he is a user given that his test is positive.

To calculate the probability that the test will be positive (e.g. P(B)), we have to add up all the true positives (i.e. users who test positive) and the false positives (non-users who test positive), resulting in the following equations

$$\begin{aligned} P(User \mid Test+) &= \frac{P(Test+ \mid User) \cdot P(User)}{true\ positives + false\ positives} \\ &= \frac{P(Test+User) \cdot P(User)}{P(Test+User) \cdot P(User) + P(Test+ \mid Nonuser) \cdot P(Nonuser)} \\ &= \frac{0.99 \cdot 0.005}{0.99 \cdot 0.005 + 0.01 \cdot 0.995} \\ &\approx 33.2\% \end{aligned}$$

Despite the apparent accuracy (high sensitivity and specificity) of the test, if an individual tests positive, it is more likely that they do *not* use the drug than that they do.

This surprising result arises because the number of non-users is very large compared to the number of users; thus the number of false positives (0.995%) outweighs the number of true positives (0.495%). To use concrete numbers, if 1000 individuals are tested, there are expected to be 995 non-users and 5 users. From the 995 non-users, $0.01 \times 995 \cong 10$ false positives are expected. From the 5 users, $0.99 \times 5 \cong 5$ true positives are expected. Out of the 15 positive results, only 5, about 33%, are genuine. The importance of specificity can be illustrated by showing that even if sensitivity is 100% and specificity is at 99% the probability of the person being a drug user is ≈33% but if the specificity is changed to 99.5% and the sensitivity is dropped down to 99% the probability of the person being a drug user rises to 50%.

Odds and Likelihood Ratios

$$Odds\ of\ X = \frac{P(X)}{1 - P(X)}$$

For example, a coin toss has a 50% chance of heads, which means that the odds of heads are 1:1. Events with 1:3 odds have probability of 0.25. Odds, likelihood ratio, sensitivity and specificity are related as follows:

Post-test odds = (pretest odds) x (positive likelihood ratio).

Positive likelihood ratio (LR+) = sensitivity / (1-specificity) = TPR/FPR.

Negative Likelihood ratio (LR−) = (1-sensitivity) / specificity = FNR/TNR

$$LR = \frac{\text{Probability of result in diseased persons}}{\text{Probability of result in nondiseased persons}}$$

$$LR\,(+) = \frac{\text{Probability that test is positive in diseased persons}}{\text{Probability that test is positive in nondiseased persons}} = \frac{\text{Sensitivity}}{1-\text{Specificity}}$$

$$LR\,(-) = \frac{\text{Probability that test is negative in diseased persons}}{\text{Probability that test is negative in nondiseased persons}} = \frac{1-\text{Sensitivity}}{\text{Specificity}}$$

Example:

	Disease	No Disease
Test +	**19**	**7**
Test −	**2**	**439**

Sensitivity = 19/(19 + 2) = .904

Specificity = 439/(7 + 439) = 0.984

LR (+) = Sensitivity / (1 − specificity) = 57.6

Pre-test odds of having disease are (19 + 2)/(7 + 439) = 0.047 and if the test is positive, post test odds are 0.047 × 57.6 = 2.71. Since odds = P(x) / (1-P(x)) you can determine that P(x) = 73%. That is, a positive test means the patient has a 73% chance of having the disease and a 27% chance of not having the disease sensitivity / (1-specificity)

Fagan Nomogram

The Fagan nomogram (Figure 3-8) is a tool for estimating how much the result on a diagnostic test changes the probability that a patient has a disease (1-sensitivity) / specificity. To use this tool LR(+) = sensitivity / (1-specificity) = 57.6.

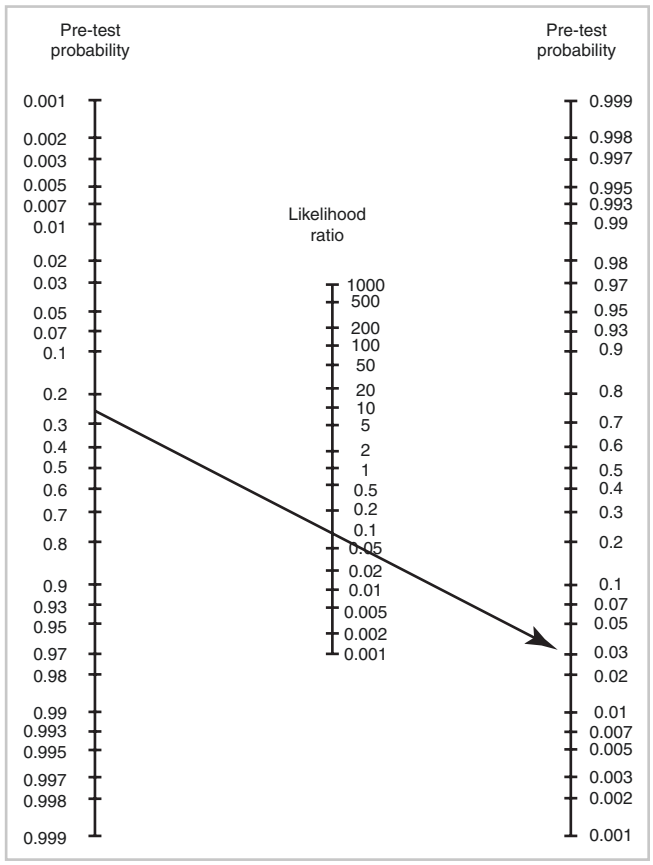
Draw a line connecting the pre-test probability and the likelihood ratio. Extend this line until it intersects with the post-test probability. The point of intersection is the new estimate of the probability that your patient has this disease (Figure 3-8).

Precision and **Recall**

In pattern recognition and information retrieval, precision (also called positive predictive value) is the fraction of retrieved instances that are relevant, while recall (also known as sensitivity) is the fraction of relevant instances that are retrieved. Precision can be seen as a measure of exactness or quality, whereas recall is a measure of completeness or quantity. In simple terms, high precision means that an algorithm returned substantially more relevant results than irrelevant, while high recall means that an algorithm returned most of the relevant results.

FIGURE 3-8

The Fagan nomogram for calculating the post-test probability from the pre-test probability and the likelihood ratio. After Fagan TJ. Nomogram for Bayes theorem. N Engl J Med 1975; 293 (5):257–61



2.1.3 APPLICATION OF CLINICAL DECISION SUPPORT

Lisa Masson

2.1.3.1 Types of Decision Support

Clinical Decision Support (CDS) is any electronic tool that provides structured guidance. By this broad definition, CDS is any means to reduce the cognitive burden of patient care.

Often, team members seeking to solve an organizational problem suggest building an alert. Technology is not always the answer to the problem; when it is, the technology that is the answer is not always an alert.

CDS includes general references, specific guidelines, and a broad assortment of interventions.[3] Order sets and data visualization techniques also fall under the umbrella of CDS. Broad groups of CDS include: (1) information management; (2) focused attention (alerts); and (3) patient-specific recommendations.[4]

Benefits of CDS include preventing errors, optimizing decision making and improving care processes. An example of preventing errors is automatic dosage calculations in the ordering of medications. A cardiovascular risk calculator embedded in an Electronic Health Record (EHR) can be used to optimize decision making. An example of improving care

3 Berner ES. Clinical decision support systems: State of the Art. AHRQ Publication No. 09-0069-EF. Rockville, Maryland: Agency for Healthcare Research and Quality. June 2009.

4 Buntin MB, Burke MF, Hoaglin MC, Blumenthal D. The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results. Health Affairs 30, No. 3 (2011): 464–471.

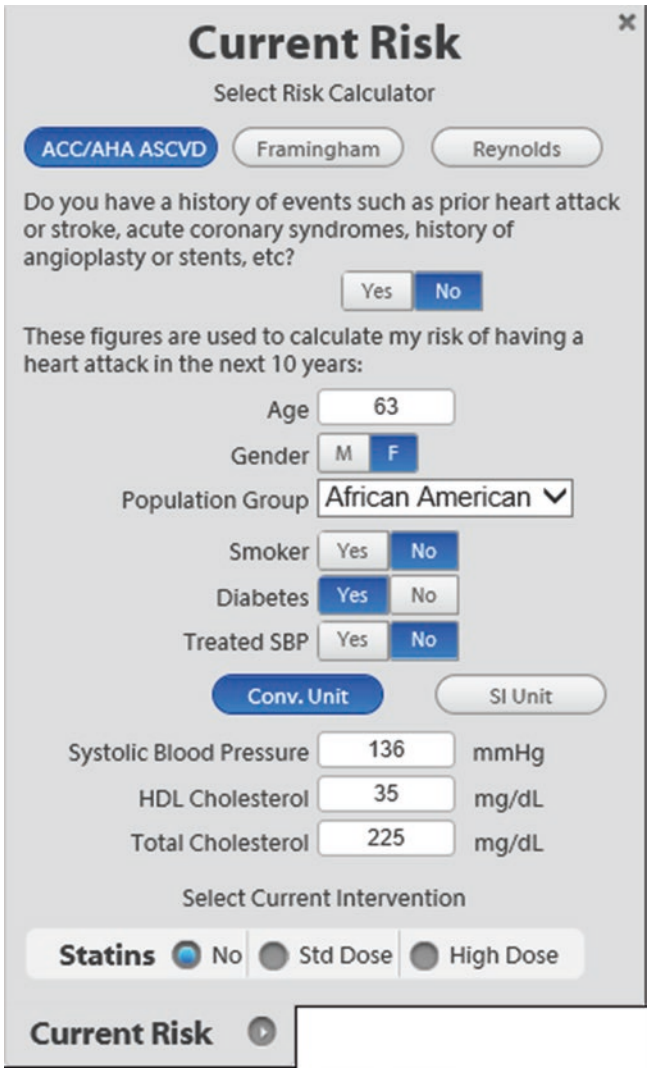


FIGURE 3-9

Example of an embedded calculator, invoked when the physician types a certain phrase asking for the information

processes is automatically providing flow sheets for appropriate home support during the discharge process (Figure 3-9).

A **knowledge-based clinical decision support** system includes several elements. First, the knowledge base is comprised of clinical information such as drug interactions and guidelines. Second, the system will consider each individual patient's information including problem lists, medications, allergies, age, weight, and lab results. Finally, the CDS has a communication mechanism to convey relevant information to the physician. This information could include: lists of possible diagnoses, warnings of potential drug interactions, clinical guidelines suggesting workup and treatment options, and preventative care reminders.

CDS interventions have shown benefits in every area of healthcare. In preventative care, there are provisions for immunizations and appropriate screening examinations. In patients with established diseases, disease management guidelines embedded in the EHR may support medical care. CDS may aid in the process of establishing a diagnosis by making suggestions which match signs and symptoms. Treatment guidelines and drug dosage recommendations, as well as drug-drug interactions, once painstakingly memorized, are now so commonplace as to be expected benefits of an EHR. CDS is leveraged for provider efficiency by offering care plans to standardize care and minimize length of stay. These pathways help prevent common hospital complications such as deep venous thrombosis and decubitus ulcers by automating the process of writing admission orders via pre-populated order sets. Duplicate testing alerts and drug formulary guidelines help reduce costs.

FIGURE 3-10

An example of Arden Syntax for encoding of a Medical Logic Module (MLM) which gives a warning if hematocrit has dropped by 5 or is more than 30

```
maintenance:
  title: Alert on low hematocrit;;
library:
  purpose: Warn provider of new or worsening anemia.;;
knowledge:
  type: data-driven;;
  data:
    blood_count_storage := event {'complete blood count'};
    hematocrit := read last {'hematocrit'};
    previous_hct := read last { {'hematocrit'} where it occurred before
                the time of hematocrit};;
  evoke: blood_count_storage;;
  logic:
    if hematocrit is not number then conclude false; endif;
    if hematocrit <= previous_hct-5 or hematocrit < 30 then conclude true;
    endif;;
action:
  write "The patient's hematocrit ("|| hematocrit ||") is low or
       falling rapidly.";;
end:
```

Clinical practice guidelines (CPGs, see Sect. 2.2.3) aim to improve quality of care, reduce unjustified practice variations and reduce healthcare costs.[5] Effective guidelines can be seamlessly incorporated into the clinical workflow. CPGs have been enacted as **computer-interpretable guidelines (CIGs).** To be effective, the CIGs must be recognized as relevant to the physician in their daily practice. A goal of a CIG is to match the patient data, and provide evidence-based guideline support in an appropriate fashion during a care provider's work.

CIGs face barriers in translating from English to a computer language due to different types of ambiguity. S**yntactic ambiguity** exists if the sentence is constructed such that it could have more than one meaning: I'm glad I'm a man, and so is Lola (Ray Davies) or I shot an elephant in my pajamas (Groucho Marx). **Semantic ambiguity** refers to one word having different meanings; a mole can be a lesion on one's skin or a small burrowing mammal. **Pragmatic ambiguity** arises from inconsistent or conflicting recommendations. Additional vagueness arises from **under-specification** (using the word *children* rather than specifying ages 0–18 years), **strength qualifiers** (should be effective) and **passive voice** (should be performed). To address these issues, a set of building blocks such as tasks, rules, nodes or frames is used to create a model. Formal language must be used to clarify the actual guidelines within the constraints of the model and this language must be machine-interpretable.

Many active CIG approaches are currently in place with unique features. No standard CIG language or model exists. Most approaches model guidelines via a **Task-Network Model** (TNM), which contains a flowchart of specific tasks.

Arden Syntax, a language for encoding medical knowledge, is most useful for simple guidelines. Unlike most of the other approaches, Arden Syntax does not use TNM. In contrast, the guidelines in Arden Syntax are a collection of Medical Logic Modules (MLMs). Each MLM represents a single decision. These independent modular rules render Arden Syntax less than ideal for complex multi-step guidelines. Arden Syntax is most appropriate for representing simple alerts in reminder systems (Figure 3-10).

5 Mor Peleg. Computer Interpretable Clinical Guidelines: A methodological review. Journal of Biomedical Informatics. Volume 46, Issue 4. August 2013: 744–763.

2.1.3.2 Users of Decision Support (Including Clinicians and Patients)

To realize the benefits of CDS, the interventions must tackle the **five rights of clinical decision support**. They are the right **(1) information (2) person (3) format (4) channel and (5) time.** The **right information** should be patient specific, and accurate. The **right person** refers to displaying the information to the appropriate team member who can act, whether it be the physician, the nurse, the pharmacist, or the hospitality suite. The **right format** may be less obvious. Would this data be easier to digest as a dashboard or as a pop up box? Can a guideline be protocolized (such as ordering annual flu shots for appropriate populations) and simply enacted by staff, or should it be an order set for a clinician to choose? Multiple channels exist beyond the graphic user interface of the EHR. For example, the **right channel** for decision support may be provided via the patient portal or e-mail. The **right timing** of the information is critical for acceptance. The information should be actionable. Don't tell a physician about a drug-drug interaction after the medication has been administered; warn her before the order is placed. Don't suggest a clinical pathway during the history taking portion of the exam, as this might be forgotten in the complexities of patient care, but rather in the orders section during the active cognitive process pertinent to this knowledge (Figure 3-11).

If an alert is chosen as the method of CDS, the alert can be **interruptive or non-interruptive**. The modeless alert appears in the background or on the toolbar. It stays on the screen available for use but allows other activities, and is retrievable when the clinician is ready. An example is an unread lab result indicator on the toolbar. A **modal** is a pop-up alert, such as a reminder, which requires acknowledgment before continuing (See figs. 3-12, 3-13 and 3-14).

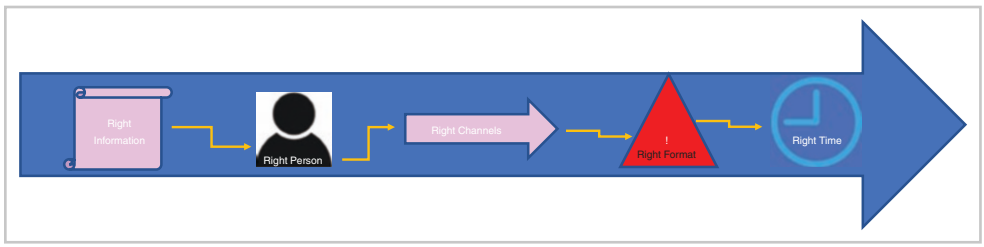


FIGURE 3-11

The five rights of clinical decision support: Right information, person, format, channel and time

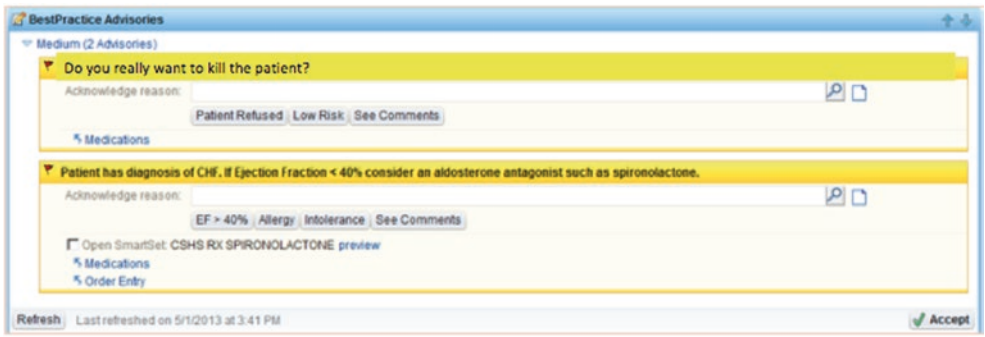


FIGURE 3-12

An example of a pop-up alert

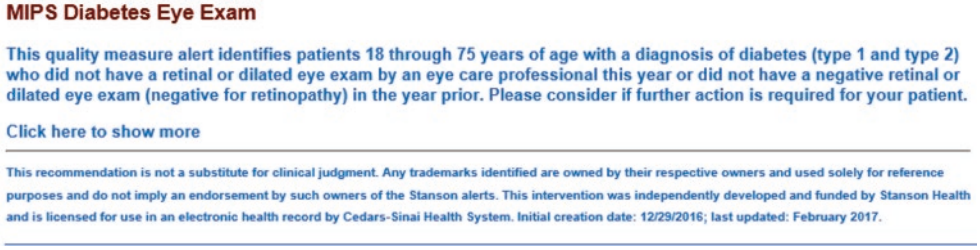


FIGURE 3-13

An example of a passive or modeless alert. The clinician is not asked to interact with the alert and can simply continue her workflow

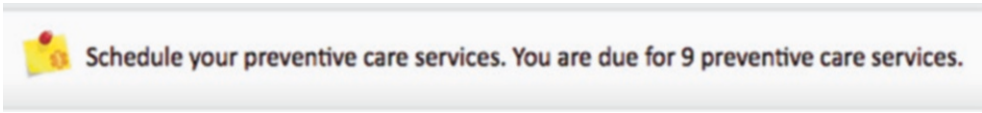


FIGURE 3-14

Passive alert in a personal health record

The decision support may simply supply information, issue reminders, correct errors or suggest changes in care plans. The urgency and impact of the support are considerations in assessing the five rights. The best accepted support matches the clinician's intentions while relieving cognitive burden or memory. This is exemplified in a reminder to order a mammogram while the patient is being seen in an unrelated visit for flu-like symptoms. Neither the rushed clinician nor the ill patient would think to obtain the mammography order. Well-orchestrated CDS would have the order suggested or pended so it automagically occurs for the patient on completing the visit. Ease of use is critical for acceptance.

2.1.3.3 Implementing, Evaluating and Maintaining Decision Support Tools

Review of recent literature indicates predominantly positive results from technology in health care delivery.[6] In a systematic review of literature from July 2007 to February 2010, 92% of the articles had positive conclusions. Smaller practices, for whom the overhead was higher, are slowly beginning to enjoy benefits of health information technology as well.

Examples of positive findings in clinical decision support abound. CDS for erythropoietin dosing in a dialysis clinic reduced the staff time spent on anemia management by half while clinical outcomes remained unchanged.[7] In an inpatient setting, an alert to reduce unnecessary RBC transfusions efficiently showed a reduction in transfusion costs without an increase in patient length of stay or mortality.[8] Evidence has shown that CDS can alter our decisions and actions thus reducing medication errors, increasing ordering of screening measures, and adhering to evidence based practice.

Despite all the evidence that CDS is beneficial, studies on CDS remain limited. Publication bias limits reporting of CDS that were harmful or offered no benefit. Most research still concentrates on the process of care and decision making. There are few controlled studies focused on patient outcomes, and more are needed.

Moreover, in any and every institution, vocal physicians tout their dissatisfaction with their EHR. Commonly avowed hindrances include poor usability, excessive uncompensated time spent interfacing with a keyboard, alert fatigue, and patient dissatisfaction caused by the physician spending time looking at a screen.

There are several factors affecting a clinician's acceptance of CDS suggestions, and ways to overcome limitations. To be effective, CDS must be carefully planned. When crafting a framework for CDS, it is helpful to consider the five rights (see above). Successful CDS includes the matching the user intention. For example, reminders to do things physicians intended to do are usually more accepted than an alert to reconsider. In terms of user control, disruptiveness and risk, too many alerts truly can cause a "wall of yellow" or "alert fatigue". Robert Wachter describes popular software in place at University of California, San Francisco, with advanced CDS. Alert fatigue allowed a common antibiotic to be delivered to a patient at a 39-fold overdose.[9] Alerts had been shown to a resident physician, nursing and pharmacy staff. All missed the alert buried among other warnings. Just like the wailing of multiple car alarms in an urban setting, the deafening noise ceases to have meaning.

6 Buntin MB, Burke MF, Hoaglin MC, Blumenthal. The benefits of health information technology: a review of the recent literature shows predominantly positive results. Health Aff (Millwood). 2011;30(3):464–71.
7 Miskulin DC, et al. Computerized Decision Support for EPO Dosing in Hemodialysis Patients. Am J Kidney Dis. 2009 Dec;54(6):1081–8.
8 Goodnough LT, et al. Improved blood utilization using real-time clinical decision support. Transfusion. 2014 May;54(5):1358–65.
9 Wachter R. The Digital Doctor: Hope, Hype and Harm at the Dawn of Medicine's Computer Age. New York, NY: McGraw-Hill; 2015.

One way to overcome fatigue is the use of tiered alerts, which have been shown to improve acceptances of alerts. Tiered alerts vary in the degree of alert disruptiveness. User options are modified on the basis of the seriousness of the situation prompting the alert. For example, an alert with low-risk is shown passively while a life-threatening drug-drug interaction is displayed automatically and cannot be overcome. An alert in the middle may show up automatically but have an override option.[10]

Implementation

Design and implementation play a large role in the success of CDS. The culture and leadership of the arena must also be considered. As CDS is used more, the potential for harm from CDS rises proportionally. Analysis has shown problems stem from system implementation issues as opposed to incorrect recommendations or intrinsic flaws. The Joint Commission emphasizes proper implementation, which involves users to resolve workflow and process problems before the CDS is live. Users need to be trained as well as have their performance monitored.

It cannot be overemphasized that a key issue with the use of CDS is workflow integration. Workflow assessment should occur early in the process. Clinicians should be consulted throughout the entire process of CDS design and implementation. Process improvement should drive workflow changes; implementation teams need to be aware of multiple workflow patterns. Departments, clinics and in many cases, individual physicians exhibit distinct requirements. A successful CDS is modified, as possible, to meet a physician's needs.

CDS interface issues are present in both data entry and output. A CDS integrated into an EHR is far more likely to be used than a stand-alone system requiring duplicate data entry. A clinician immersed in the processes required in the EHR is unlikely to seek advice by logging into a separate system, and typing in redundant data, but may be quite likely to accept the advice when conveniently presented to him during his usual documentation and order entry. Exceptions to this rule exist, as many users prefer other resources, or believe information outside the EHR is more accurate or comprehensive, such as when physicians use their smartphones to access UpToDate or Epocrates rather than use the EHR's embedded database. Some CDS is found by going to the internet for well known calculators that may not be integrated in the EHR. Examples include cardiac risk, fracture risk, and suicide risk calculations.

CDS requires local customization. Standards and transferability are ubiquitous issues. No national standards exist for which evidence-based guidelines should be built into CDS. As mentioned above, the goal is to embed guidelines, and the methods and scope remains to be defined and standardized. Similarly, there are no national standards for clinical data definitions. For example, there are different definitions of "tachycardia". How fast is too fast? Or what is anemia? How do you order a chest radiograph? Is it a CXR or a chest x-ray? Even when guidelines are accepted, local implementation varies by system. CDS cannot be used "out of the box." Much of the cost of CDS implementation is clinician time to select and design content, recognizing local definitions, language, needs and workflows.

Maintenance

CDS remains an ongoing quality project. The practice of medicine changes, with new pharmaceuticals, new guidelines, and new technology. CDS must remain fluid and highly accurate. Should CDS become misleading, users will mistrust the entire system.

A fundamental source of error is incorrect data in the patient record. This is unfortunately common. As many people access one chart, the data upon which CDS is based must be verifiable and accurate. Any one person who is sloppy can lead to erroneous CDS in the future. (See Figure 3-15)

The Leapfrog group was created in November 2000 in response to the 1999 Institute of Medicine report "To Err is Human." This well publicized report underscored the cost and frequency of adverse drug events. The Leapfrog Group chose to address Computer Physician Order Entry (CPOE) as their first task due to the potential to lower patient harm from

10 Slabodkin G. Cedars-Sinai reduces unnecessary care using EHR alerts. Health Data Management. May 22 2017.

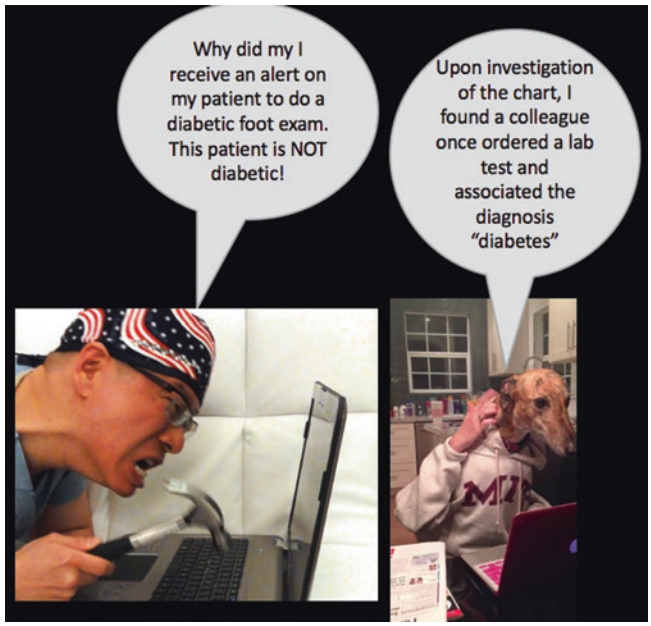


FIGURE 3-15

Inappropriate alerts can induce provider dissatisfaction

medications. This decision was based on the fact that adverse drug events (ADEs) are one of the leading causes of iatrogenic patient injury. They noted examples such as prescribing a beta blocker to an asthma patient, or a medication metabolized by the kidney to a patient with compromised renal function.

Compounding the problem is the capricious nature of knowledge. On the first day of medical school, we are told that half of what we learn will be proven to be false. Unfortunately, we don't know which half. CDS specific problems occur as guidelines change, and require maintenance and monitoring. Maintaining CDS is as critical as the initial implementation. AHRQ has funded a CDS Consortium providing an online database of guidelines which may be adapted for local use.[11]

The end result is that CDS requires physician cooperation. Time pressures, arguably, are the greatest influence in the use or disuse of the CDS. Traditionally, physicians value their autonomy; however, this culture is changing, as the norm is to not only accept information from outside sources, but to insist on verification of our memories. CDS is not foolproof. The clinician must have a good sense of what should be right, and recognize that the CDS is only a tool. Clinical acumen and experience still override CDS, yet clinicians feel angst in the face of potential liability when overriding CDS.

When evaluating a CDS, look to the clinics and hospital, not the usability lab. It should be evaluated for its use in practice, not a controlled environment. Osheroff,[12] in his book, created the mnemonic METRIC or "Measure Everything That Really Impacts Customers." Customers are defined as all stakeholders including clinicians, patients and the care delivery organization. Outside of academic medical systems, there are few evaluations of CDS. Only a few randomized trials have been performed due to expense and level of difficulty. These are invariably sponsored by industry.

CMS incentivized electronic prescribing as part of Meaningful Use. E-prescribing has been shown to decrease errors and adverse drug events even without medication decision support. This has been attributed to elimination of hand writing illegibility and reduction of incomplete prescriptions by mandating a structured entry form. There is little evidence that patient safety has improved with this type of decision support. The best evidence for benefit is shown for drug-disease interaction checking and drug dosing.

11 See https://healthit.ahrq.gov/ahrq-funded-projects/clinical-decision-support-cds

12 Osheroff JA., Teich JA, et al. Improving Outcomes with Clinical Decision Support: An Implementer's Guide. 2nd Edition. Chicago, IL: HIMSS, 2012: p. 15.

Technological developments in the United States continue to facilitate the use of CDS. There has been an increased purchase and use of EHR systems. Funding and policy initiatives to improve systems, standardization and interoperability have also been created. Currently, the Commission for Certification of Healthcare Information Technology (CCHIT) is developing standards for CDS. In addition, healthcare workers now have the use of Internet resources and the promise of broad dissemination of CDS interventions.

In summary, over the last several years it has been recognized that a well-designed and implemented CDS can improve health care quality, increase efficiency and reduce healthcare costs. CDS should not be looked as a substitute for a clinician. Instead, it is an intervention which requires close examination of its goals, delivery and user audience. Clinicians need to understand its benefits and limits in order for a CDS to be optimized. This includes understanding the difficulties in designing and implementing CDS. CDS implementation requires integration into workflow. This requires compliance of the user. CDS alerts and recommendations will fail if this is not addressed. Researchers need to examine the informatics, structural, cognitive and workflow issues that have lead to suboptimal CDS design or implementation which have led to limited use and effectiveness. Vendors must focus on the knowledge learned from research and development efforts that have focused on clinician efficiency. It is important to carefully look at the evaluations of commercial CDS systems in community settings to improve optimization of design, implementation and impact.

2.1.4 TRANSFORMATION OF KNOWLEDGE INTO CLINICAL DECISION SUPPORT TOOLS

Lisa Masson

2.1.4.1 Knowledge generation

The challenge presented in translating **knowledge** into computer systems is an obstacle to the application of clinical decision support in healthcare.

What is knowledge?

Knowledge may be explained as a subjective assimilation of information, merged with experience, situational awareness, and intellect. Wisdom assumes there is added awareness, morality and insight.

In medicine, the main source of knowledge is original research. Generating knowledge requires a cyclic process of publication, review, acceptance, and more publications.[13] Ultimately, knowledge is acquired from the intersection of evidence and preferences.

2.1.4.2 Knowledge acquisition

From the beginning of time with pen and paper, through the information age, the amount of literature published has increased at a terrifying rate. In 1913, Penzoldt of Erlangen, a wise German teacher, offered advice relating to the enormous growth of medical literature.[14] No mortal can keep up. The information age has moved us from sequestered information systems to a seemingly unrestrained exchange of information. Between 1665 and 2009, more than 50 million scientific papers were published, and approximately 2.5 million are added each year (Figure 3-16).[15]

13 William Hersh. Information Retrieval: A Health and Biomedical Perspective. Springer. 2009.

14 December 25, 2013**The Growth of Medical Literature** JAMA. 2013;310(24):2680. doi:https://doi.org/10.1001/jama.2013.5484.

15 Jinha, Arif E. **Article 50 million: An estimate of the number of scholarly articles in existence** Learned Publishing 23(3):258–263 July 2010.

FIGURE 3-16

Estimated annual global research article output at 3% annual growth (from Jinha)

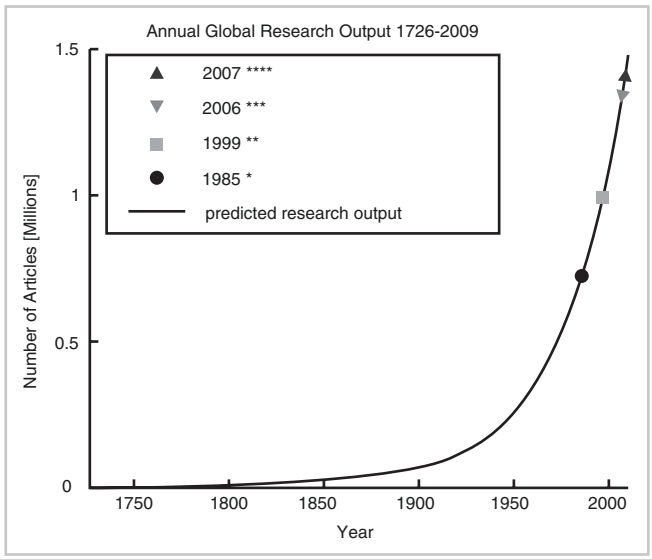
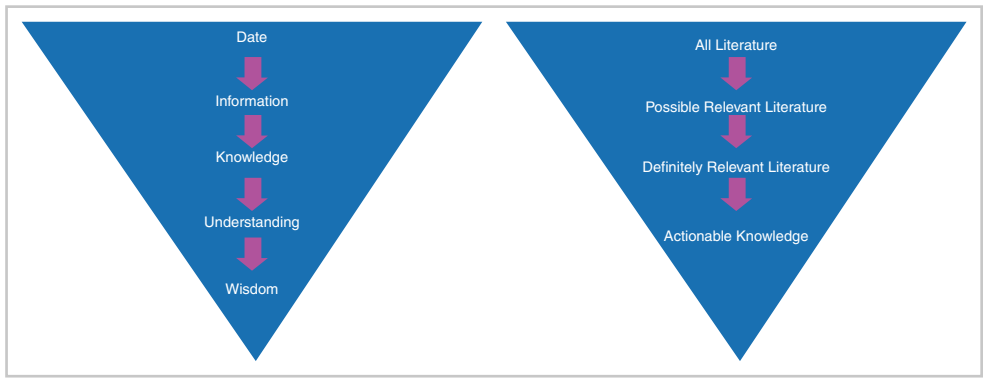


FIGURE 3-17

The pyramid of knowledge and the funnel of knowledge acquisition



The estimates suggest that our 1.8 zettabyte (which is 1.8 trillion gigabytes) of data will continue to grow with the number of servers managing our world's data increasing an order of magnitude in the next decade.[16]

How is this lavish abundance of information turned into knowledge?

The Data-Information-Knowledge-Wisdom pyramid (funnel) emphasizes that as data becomes more refined, it also becomes more actionable. (Initially made prominent by Russell Ackoff in 1989, but the pyramid is recorded as far back as 1934 was referenced in a song by Frank Zappa "Packard Goose".)[17] The emphasis in this pyramid (or funnel) is on the knowledge being actionable. Remember there is far more to knowledge than data (Figure 3-17).[18]

16 Mearian, Lucas. World's data will grow by 50× in the next decade, IDC study predicts. Computerworld from IDG. June 28, 2011.

17 From Frank Zappa: Packard Goose Lyics:
"Information is
Not knowledge
Knowledge is
Not wisdom
Wisdom is not truth
Truth is not beauty
Beauty is not love
Love is not music
Music is the best...
Wisdom is the domain
Of the wis
(which is extinct)."
Read more: Frank Zappa—Packard Goose Lyrics | MetroLyrics.

18 Weinberger, David. The Problem with the Data-Information-Knowledge-Wisdom Hierarchy. Harvard Business Review. February 02, 2010.

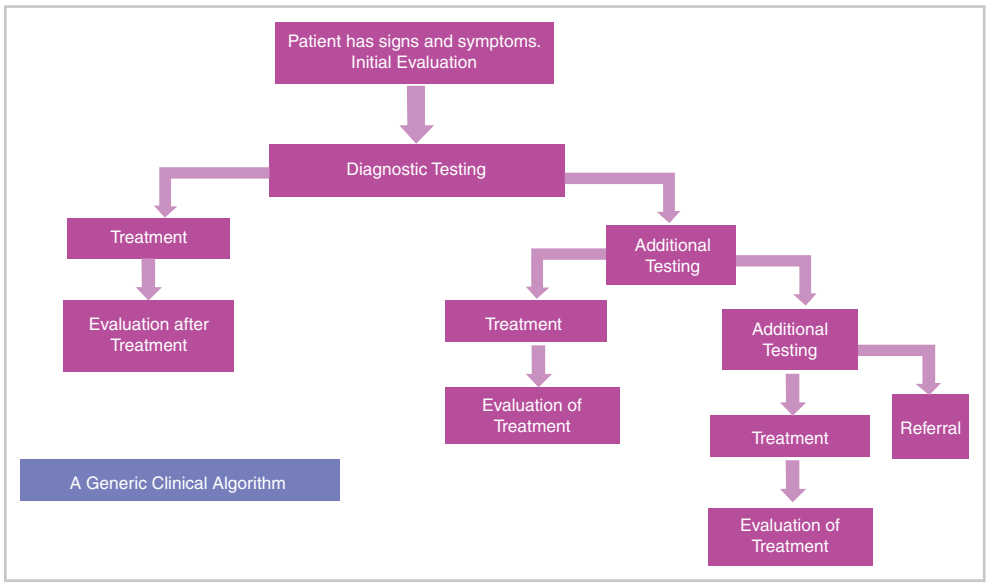


FIGURE 3-18

Example clinical algorithm

In most cases, no single factor is sufficient to make a decision. Scientific evidence is complicated and often contradictory. Neither the patient nor the physician is without emotion (yet). Cultural, personal and temporal biases are always at play, consciously or unconsciously. Education and experience color the decision process. Other constraints include regulatory and financial concerns. Knowledge, and decision making, is muddled at best.

2.1.4.3 Knowledge modeling

Knowledge Modeling is a process of creating computer interpretable model of knowledge or standard specifications about a kind of process. This knowledge model can only be computer interpretable when it is expressed in some knowledge representation language or data structure that the software can interpret and that can be stored in a database or a file system.

The four general approaches to creating a knowledge model are: **(1) Clinical algorithms (2) Baysian statistics (3) Production Rules** and **(4) Scoring and heuristics**. The current approaches avail themselves of the advances in electronic health record technology.

A clinical algorithm is defined as a systematic process through an ordered sequence of steps, with each step dependent on the outcome of the previous step. A clinical algorithm follows a path through a flow chart. A flow chart is composed of different types of nodes. Data is gathered at the information nodes; decision is made at decision nodes. Benefits of clinical algorithms include the ease of encoding the knowledge. In a flowchart, the knowledge is clearly expressed. Conspicuous limitations in the algorithmic approach is the inability to pursue new treatments or etiologies and the lack of accounting for prior results. Clinical algorithms are the precursors to clinical guidelines (Figure 3-18).

A modelling tool should realistically represent uncertainty and should be adaptive. Bayes' theorem calculates the likelihood of an event based on prior probability and new information, thus permitting inference from known quantities to make predictions and to learn from the new data. Bayes' theorem relies on two assumptions: (1) **conditional independence** (i.e. there is no relationship between different findings for a given disease); and (2) **mutual exclusivity** of conditions.

Bayes' theorem, as you learned in Sect. 2.1.2, tells us that the probability of a disease given one or more findings can be calculated from the prior probability of the disease and the probability of findings occurring in the disease. Unfortunately, Bayesian analysis is limited because findings in a disease are not conditionally independent and the diseases themselves are not mutually exclusive. If there are many diagnostic findings important to a diagnosis, the computational complexity increases rapidly.

Production Rules encode the knowledge as "if-then" rules. The system brings together the evidence from different rules to arrive at a conclusion. A rule-based system can use backward chaining or forward chaining. Backward chaining starts with a goal (or presumed diagnosis), and asks questions to determine if there is data to support that answer. In forward chaining the computer follows a defined path, similar to an algorithmic approach, to reach a conclusion.

MYCIN, developed as Edward Shortliffe's PhD dissertation in the 1970s, was an innovative system in its use of production rules. MYCIN used backward-chaining deduction system to help physicians diagnose infections. The system assembled the observations entered by the clinician to arrive at a recommendation. As more rules were added, the recommendations improved. Shortliffe noted that a major lesson from the work on expert systems is that large knowledge bases must be built by successive additions of inductive and deductive steps.[19]

A production rules based system allows for maintenance with additions, deletions and modifications to rules. However, rule bases are large and difficult to maintain. MYCIN had 400 rules to cover two types of bacterial infection. The approach is best suited to a constrained domain. Also note the system was developed in an era prior to modern computers and graphical user interfaces. A session with MYCIN could take over 30 min to enter information. Personal computers had not yet been developed to allow for clinical interfaces.

In the quest to design a more comprehensive decision support system, a more scalable approach was necessary. Using a method of **scoring and heuristics**, knowledge is represented as profiles of findings found in diseases. These are then measured for importance and frequency for each disease.

INTERNIST-1 is a good example of using scoring and heuristics. This system was originally intended to mimic the expertise of an expert diagnostician. The novel approach in this knowledge model was in the way it responds to the user with follow up questions to narrow the field of possible diagnoses. In addition, the system scored findings from the history, exam and laboratory. The scoring included the likelihood of a disease given the finding (with zero being non-specific and five being pathognomonic) and the frequency of the finding given the disease (with one being rare and five being always). Properties included taboos, such as a male not being pregnant and not having ovarian cancer. This expert system performed equally as well as the experts in the New England Journal of Medicine Cases.[20]

The principles of INTERNIST-1 are used in DxPlain, still in existence and available for use today.[21]

Limitations to INTERNIST-1 included the long learning curve and time consuming data entry. The knowledge base was incomplete. Importantly, diagnostic dilemmas did not fit the information needs of most clinicians. INTERNIST-I was unable to construct a differential diagnosis spanning multiple problem areas and unable to explain its "thinking".[22]

2.1.4.4 Knowledge representation

As systems evolved through the 1980s and 1990s, it became apparent that the information provided did not meet the wants of the medical practices. Diagnostic support systems are less effective than therapeutic decision support systems.[23] Generally speaking, artificial intelligence and expert systems promised in the 1980s have yet to live up to the promise. As technology advances at a rapid rate, striving to help clinicians, diagnostic errors continue in medical practice. Thus the evolution through the 1990s to Clinical Decision Support (CDS) with recognized value in the electronic health records. **Clinical algorithms, Baysian**

19 Buchanan B, Shortliffe E. Rule-Based Expert Systems: The MYCIN Experiments of the Stanford Heuristic Programming Project. Addison Wesley, Reading, MA 1984.

20 Miller RA, Pople HE, Myers JD. Internist-1, an experimental computer-based diagnostic consultant for general internal medicine. N Engl J Med. 1982;307(8):468–76.

21 Barnett GO, Cimino JJ, Hupp JA, Hoffer EP. DXplain. An evolving diagnostic decision- support system. JAMA. 1987;258(1):67–74.

22 Miller, RA, Pople HE, Myers, JD. N Engl J Med 1982; 307:468–476.

23 Garg AX, Adhikari NKJ, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene J, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. JAMA. 2005;293(10).

statistics, Production Rules and **Scoring and heuristics** remain in use. These concepts are being implemented in large scales electronic health records.[24]

2.1.4.5 Knowledge management and maintenance

Maintaining knowledge bases for the foundation for CDS is not simple. Which knowledge base will be used? The abundance of published literature can not be consumed by a single human or committee. Information retrieval requires an understanding of databases, precision and recall. Translating information into decision support is a rapidly advancing science. Once in place, clinical decision support requires maintenance. Maintenance requires ongoing measurements and metrics examining the tools in place. These metrics may examine change in behavior, times the knowledge was acknowledged, or a change in outcomes. Maintenance requires that the decision support adapts to new clinical guidelines. Decisions around CDS require local governance, communication, training and support. Health systems must adapt appropriately to manage the complexity of CDS. Increasingly, this tsunami of information is managed by third party vendors. Examples of vendors of CDS and knowledge base solutions include Zynx, Lexicomp and Stanson Health.

Clinical decision support remains distinct from clinical decision automation. However, advances in natural language processing will aid knowledge acquisition by translating medical literature into a machine-usable format.

2.1.5 LEGAL, ETHICAL, AND REGULATORY ISSUES

Clinical decision support (CDS) systems are in widespread use in many institutions, bringing with them a host of legal, ethical and regulatory issues.

Software developers clearly have responsibility to reduce the risk of using a CDS to a level that is as low as reasonably practicable (ALARP). Despite an absence of case law, it seems reasonable that a supplier of medical systems would have some responsibility to patients who may suffer an adverse outcome as well as to providers who use the system in good faith.

Many systems contain End-User Licensing Agreements (EULAs) which claim that the software is provided "AS IS" without any claim or warranty of quality, fitness for purpose, completeness, accuracy or freedom from errors. These systems require users to acknowledge the EULA before using it. It is unclear to what extent these EULAs would protect a developer in the case where a CDS harmed a patient.

Information Overload

In large, well-established institutions (such as the Veterans Administration), Electronic Health Records (EHRs) have been in use for many years, which means that the amount of data available for any given patient is voluminous. With the advent of regional health information exchanges (HIEs), even a non-institutional clinician now has access to vast amounts of patient data. From a practical standpoint, it would be nearly impossible for a clinician to review all this data in a timeframe reasonable to provide care. However, since all this data is readily available, a clinician who overlooks a critical detail could be held liable. A wily attorney could demonstrate the relative ease of searching the HIE portal to find the relevant information.

This risk becomes even more acute when a physician is a part of a care team. Suppose an internist orders a test which shows an abnormally low hemoglobin. The patient is referred to a specialist who orders more tests. Since the internist is still involved with the patient's care, he daily reviews all new laboratory results, even those tests which he did not order. If the results of the specialist's tests are not addressed, who is at fault? In the past, the internist would simply claim that he was unaware of the abnormal results of the test that he did not

24 Osheroff J, Teich J, Levick D, Saldana L, Velasco F, Sittig D, Rogers K, Jenders R. (2012). *Improving Outcomes with Clinical Decision Support: An Implementer's Guide* (2nd Ed.). Chicago, IL: Healthcare Information and Management Systems Society (HIMSS).

order. However, since modern EHRs provide excellent auditing procedures, it would be trivial to demonstrate that the internist had viewed the results at a certain time and date. As the number of providers increases, the liability could conceivably extend to each of them.

Copy and Paste
Most EHR progress notes are composed largely of boilerplate. This may arise as the result of a common note template or because of the use of "macros" which are short phrases which automatically expand into a larger string. In some cases, notes contain text that is wholesale copied from other provider notes, which may be outdated, inaccurate or irrelevant. However, since the EHR provides the only written record of the patient encounter and is digitally signed, it would be very difficult for a clinician to disavow responsibility. Moreover, this creates billing and reimbursement problems. If notes are not significantly different from 1 day to the next, a payor may argue that the provider did not provide any service and could deny payment for that day.

Order Sets
Just as notes can be copied and pasted without thinking, orders can be placed according to miswritten or incomplete protocols. For example, suppose an EHR vendor creates an order set for patients who are short of breath. Included in the orders is a D-Dimer test, which has an unfortunately high false-positive rate. If this test is ordered indiscriminately over a large number of patients, providers will feel obligated to order follow-up tests (such as CT scans of the chest) in order to explain the abnormal D-Dimer results, causing unwarranted exposure to radiation and needlessly increasing the cost of care.

Alert Fatigue
Clinical Decision Support systems have grown in scope and complexity over the years. Institutions and EHR vendors are motivated to keep the number of alerts as high as possible, relying on clinicians to differentiate the important alarms from background noise. It is unclear to what extent a provider will increase his liability when a bad outcome can be linked to an alert that was ignored. Similarly, there are many instances when a CDS failed to fire because of a programming error. The liability for missing a clinical opportunity rests on the provider, even though it is his custom to rely on the CDS to protect him.

Privacy Breaches
The Health Insurance Portability and Accountability Act (HIPAA, see Sect. 3.1.4.1) codifies many privacy rules. Clinicians (or non-clinicians) who inappropriately or inadvertently access patient records can be fired or face legal retribution.

2.1.6 QUALITY AND SAFETY ISSUES

There is now ample evidence that clinical decision support (CDS) systems can make meaningful contributions to patient care. Every informaticist hopes that that contribution is positive, or at least mostly positive. For this reason, great effort must be spent ensuring the quality and safety of CDSs. (See Sect. 2.1.5, for legal and ethical issues surrounding CDS)

Fox[25] describes four primary approaches to safety and quality in CDS

1. Use rigorous software engineering to ensure reliability
2. Systematic quality control for the medical component of the CDS
3. Hazard management during system operation
4. Comprehensive auditing to allow quality reviews

Quality Engineering

25 Fox J, Thomson R. Clinical decision support systems: A discussion of quality, safety and legal liability issues. Proc AMIA Symp. 2002. 265–9.

Software is created within a "development lifecycle" (see Sect. 3.5.6) under certain quality standards, such as ISO 9000. Unfortunately, no software is perfect and errors will always exist. There will always be a trade-off between costs of development, ease of use and maximizing safety.

Fox suggests the use of Hazards and Operability Analysis (HAZOP) to analyze risk and to stratify into categories.

1. **Risk level 1**. There are significant and avoidable hazards that could be caused by the CDS. For example, the CDS may recommend a dangerous medication or intervention.
2. **Risk level 2**. There is no direct hazard associated with the CDS, but it may lead to a situation where a beneficial intervention is overlooked. For example, the CDS normally advises the clinician to check lead levels in healthy children, but fails to do so.
3. **Risk level 3**. There is no direct or indirect hazard with the CDS, but it fails to anticipate future conditions. For example, it fails to recognize that prolonged use of antibiotics may lead to *C. difficile* colitis.
4. **Risk level 4**. There are no identified risks.

It is important to remember that there are two components of quality engineering for a CDS. On one hand is the technology aspect, such as user interface, data access, storage, presentation methods, etc. On the other hand is the medical knowledge repository upon which recommendations are given. The problem with medical knowledge is that it is relatively dynamic and the software is only able to encapsulate the consensus of experts at a given time. As time goes on and new discoveries are made, recommended therapies may change. The developer of CDS has to ensure that its advice remains as complete and up-to-date as possible.

In addition, it seems prudent to have a medical professional (or committee) review the CDS recommendations periodically. This review should include evaluation of the CDS rules in plain text as well as applying the CDS to known test cases to check for a desired outcome. An auditing trail should be available for forensic analysis if the system does not behave as expected.

Safety Concerns

A CDS that is well-designed and properly implemented with high-grade medical information can still give bad advice, especially in atypical situations or patients with unusual combinations of diseases. For example, consider a patient with acutely decompensated heart failure (HF) as well as diabetic ketoacidosis (DKA). The CDS rule for DKA may recommend an intravenous fluid bolus, while the CDS rule for HF would list IV fluid as a contraindication. Unlike a human, the CDS does not know which rule it should favor, or to what extent. Its output could be unpredictable. Therefore, it is vital to test the system with as many cases as possible so as to minimize the unexpected failures.

Errors may also arise from the method in which a CDS is used.[26] Commercial CDS will not be tailored to the host institution, and may recommend therapies or drugs that are not locally available. Moreover, the in-house health information technology (HIT) staff may not have sufficient training or permissions to modify the CDS.

Errors may also arise from the method in which the CDS is used. For example, with a paper system, the physician may examine the patient at the bedside and immediately write medication orders. If the patient objects to the medication because of allergy or some other reason, he can quickly change to another option. However, a complicated electronic prescribing system removes the physician from the bedside and prevents direct interaction with the patient. Without that two-way communication, the problem may not be detected until much later, if at all.

Order entry (OE) systems require input of structured data, and may trigger an error when information is incomplete. Unfortunately, the very structuring of data may prevent nuances

26 Coiera E, Westbrook JI, Wyatt JC. The safety and quality of decision support systems. IMIA Yearb Med Inform 2006:20–25.

of orders to be placed. For example, most OE systems require a flow rate for IV fluids (e.g. 1000 mL/h). In the setting of trauma, the first liter is often given "wide open" (i.e. as fast as gravity allows). Many OE systems will only accept a numerical flow rate, and not "wide open" as a rate of infusion, which essentially prohibits placing the order as desired.[27]

In institutions where the CDS has been present for longer times, users become completely reliant on the automation it provides. Many users will trust the CDS to do accurate drug-drug interaction checking and will be less vigilant because they assume that the computer is able to check orders more thoroughly than they could themselves. Similarly, when the CDS recommends a certain care path, users will accept the advice, even if it runs contrary to their own training because they assume that either the computer is correct, or there is some institutional motivation to proceed a certain way. The opposite problem is alert fatigue, where the CDS gives so many false-positive alerts, that the user begins to ignore all alerts.

■ Safety Recommendations

1. Usage of the CDS should be limited to persons who are properly trained to understand its capacities and its limitations
2. The CDS should provide robust auditing functionality so that if it does not function as expected, debugging will be much easier
3. End users should be in direct contact with the CDS maintainers to resolve problems before they affect other patients.
4. The medical knowledge of the CDS must be periodically reviewed for accuracy, efficacy and currency. Numerous test cases should be applied to see how the system responds to rare or unusual combinations of conditions.
5. Usability testing must be done on each of the warnings to ensure that the advice is reasonable for the setting in which it is used. If it appears that certain warnings are being ignored, it may be necessary to review the appropriateness of that warning to that setting.
6. When users become too familiar with CDS, they give up autonomous thought and trust the CDS too much. Alternatively, if the CDS gives inappropriate warnings too frequently, they will ignore it.

2.1.7 SUPPORTING DECISIONS FOR POPULATIONS OF PATIENTS

Public and widespread reporting of infectious disease enables early detection and control of epidemics. For example, when a cluster of cases is detected and reported to a public health agency, it can educate and warn local providers about diagnostic and therapeutic options.

The majority of Clinical Decision Support (CDS) systems are aimed at improving the health of individual patients. While Electronic Health Records (EHRs) are commonly used to aggregate data, they are only now gaining purchase for helping to inform decisions on population health. In stage 2 of the EHR incentive program (i.e. Meaningful Use), one of the menu options included transmission of structured data to a public health agency. Standards and protocols for this type of data transfer are still evolving. The hope is that automated public health data collection systems can be used to detect outbreaks more rapidly than traditional systems which rely on human analysis of disease trends.

There are seven elements of public health informatics.[28]

27 In response to problems like this, users will enter the largest number they can before triggering the high rate alarm. At my institution, this is 4000 mL/h. But this still does not address the issue. What should the nurse do gravity only results in a flow rate of 3000 mL/h? Must she use a pump? The OE system would imply she should.

28 Savel TG, Foldy S. The Role of Public Health Informatics in Enhancing Public Health Surveillance. MMWR 2012. 61:20–24.

1. Planning and system design—identifying readily available information sources that best inform a particular surveillance goal.
2. Data collection—combining data from various sources and differing formats, including both structured and unstructured data
3. Data management—identifying and correcting data anomalies and inconsistencies;
4. Analysis—Using statistics and data visualization techniques to understand the data; creating alarms and thresholds for initiating public warnings.
5. Interpretation—determining the actual utility of the surveillance data by reviewing it in the context of other available data
6. Dissemination—optimizing the broadcast of this information to the intended audiences
7. Application to public health programs—linking health care providers and public health workers to this new information and assessing its value in clinical decision making.

In the past, public health agencies were primarily concerned with confirmed diagnoses, such as the number of cases of culture-proven methicillin resistant *Staphylococcus aureus*. However detection can be enhanced by simply searching for clusters of symptoms. According to the World Health Organization, **syndromic surveillance** is "the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice"[29]

For example, a Health Information Exchange (HIE) collects Emergency Department triage data from several hospitals and aggregates the information into a single repository. Automated review of the free-text patient complaints reveals a higher-than-expected rate of gastrointestinal illness. This triggers the release of a public health advisory. Meanwhile, epidemiologists determine that the cluster of cases are likely related to a particular eatery. Inspection of the restaurant reveals rotavirus and it is temporarily closed in order to protect the public health.

Surveillance data does not always originate in medical encounters. In 2008, Google famously claimed that it could predict influenza trends by analyzing search data.[30] Unfortunately, their prediction model was not so successful during subsequent years.[31] This highlights the utility of using surrogate markers (such as search engine flu queries) to predict actual disease.

29 WHO | Public health surveillance [Internet]. Who.int. 2017 [cited 4 March 2017]. Available from: http://www.who.int/topics/public_health_surveillance/en/

30 Ginsberg J, Mohebbi MH, Patel RS, et al. Detecting influenza epidemics using search engine query data. Nature 2009. 457:1012–1014.

31 Butler D. When Google got flu wrong US outbreak foxes a leading web-based method for tracking seasonal flu. Nature 2013. 494:155–156.

Scott Mankowitz

2.2 Evidence-Based Patient Care

CHAPTER OUTLINE

2.2.1 EVIDENCE SOURCES

Many sources of evidence exist between the anecdotal experience of expert clinicians and quality studies that are done at individual institutions. This chapter deals primarily with published sources of evidence, such as journal articles and books. When faced with a journal article or textbook chapter, the informaticist must be able to critically analyze the presented information to assess its value.[1]

Journals typically publish articles according to certain criteria. While every journal has its own submission rules, these are the most common types of articles. For more information, see the "instructions for authors" section of your favorite journal.

1. **Original Research**—In this type of article, the author has generated a hypothesis and tested it using standard statistical methods. There are different types of research studies, which will be reviewed below.
2. **Application** (or **method**) **papers**—The author describes a particular application that he has developed or a procedure for accomplishing some task. Often, the author will attempt to prove that the new method is faster, cheaper, safer, more efficient or generally better than the current methods.
3. **Review papers**—The author collects original research papers from other authors and journals and summarizes them, highlighting the important trends and differences.
4. **Case series**—These are very small studies, usually less than ten patients, and the findings do not have enough statistical weight to be considered original research.
5. **Case report**—The author describes a novel or unusual patient presentation. Since case reports are anecdotal, they have primarily educational value and carry no statistical weight.
6. **Perspectives**—The author (usually an industry leader) gives an opinion on current trends.

1 Unlike most other chapters, you will note that this one and the next one, Sect. 2.2.2 Evidence Grading, are full of references. Most are available for free on PubMed Central.

7. **Editorials**—One of the journal's editors gives an opinion on current events, trends or other published papers. While journals routinely solicit submissions for other categories, only editors can write editorials.

There are three questions to ask about published material:

1. The first question to ask is: *is the study meaningful?* Does this study address a real clinical question that is relevant for my patients? Does this study present any new information, or does it simply review other available information? Does it agree or disagree with other published studies on the same question?
2. The next question involves how the study was carried out. *Was the study methodology appropriate for the question at hand?* How well did the study minimize or eliminate sources of bias? For that matter, was the study actually done according to the published protocol, or did the authors change the protocol halfway through because they weren't getting the results they wanted?
3. The final question involves the conclusions. *Were the data analyzed correctly?* Do the data justify the conclusions? Statistics are useful to determine if an observation is due to a real phenomenon or could be found by chance alone. Were statistical tests used? If so, were they applied correctly?

One of the problems with this type of repeated questioning is the eventual realization that no study is perfect and that every study has a flaw if you look hard enough.[2]

Lest we become too jaded, let's talk about how to design good studies.

1. Is the study meaningful?

The meaningfulness of a study can only be interpreted in the context of where it will be used. Suppose a researcher discovers that the average centipede has 15 pairs of legs.[3] While an evolutionary biologist may find this data fascinating, a practicing physician would not. *Conclusion: the study is not meaningful for my patients.*

Another example: A computer scientist is working on user-interface research and determines that when a computer becomes unresponsive for more than 2 s, the user begins to lose focus.[4] Again, to the practicing physician, this information has little use… until he realizes that most of the nurses are ignoring the clinical decision support warnings on his EHR because the screens take too long to load. *Conclusion: the study is probably meaningful and relates indirectly to our patient care.*

Another example: When amiodarone was first introduced in 1999, it was used as an antiarrhythmic for patients in ventricular fibrillation and pulseless ventricular tachycardia. Clinical trials showed that patients who were given amiodarone in the ambulance were much more likely to survive to hospital admission.[5] Intuitively, this sounds like a resounding success. In practice, however, most of those patients ultimately died in the intensive care unit (ICU) or subsequently in a nursing home. Critics of the study asked what could be so good about a drug if all it does is change the location of death from the Emergency Department (ED) to the ICU. *Conclusion: the study is meaningful, but may not dictate a change in practice.*

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2 Some people refer to this as *journal club nihilism* which is the belief that nothing could ever be learned from published scientific research.

3 Chipman AD, Ferrier DEK, Brena C, Qu J, Hughes DST, Schröder R, et al. (2014) The First Myriapod Genome Sequence Reveals Conservative Arthropod Gene Content and Genome Organisation in the Centipede *Strigamia maritima*. PLoS Biol 12(11): e1002005.

4 Nah, F, "A Study on Tolerable Waiting Time: How Long Are Web Users Willing to Wait?" (2003). AMCIS 2003 Proceedings. Paper 285.

5 Kudenchuk PJ, Cobb LA, Copass MK, Cummins RO, Doherty AM, Fahrenbruch CE, Hallstrom AP, Murray WA, Olsufka M, Walsh T. Amiodarone for resuscitation after out-of-hospital cardiac arrest due to ventricular fibrillation. N Engl J Med. 1999 Sep 16;341(12):871–8.

What can be done when you have two or more clinical trials that are both well designed and yet flatly contradict each other? For example, etomidate is a potent sedative used for intubation in critically ill patients. In one study, it was shown to cause adrenal suppression, resulting in increased mortality.[6] In another study, there was no significant change in mortality.[7] In addition to these two studies, there are at least a dozen additional studies showing intermediate results. How are we to interpret this conflicting information?

A **systematic review** is a thorough and comprehensive search of the medical literature. It involves several steps: (1) formulate a reasonable question; (2) develop an explicit search strategy, with inclusion and exclusion criteria; (3) Using a large database, select titles, abstracts and manuscripts based on the search strategy; (4) record the findings in a structured format.

A **meta-analysis** is a statistical approach where the data gathered from the systematic review are pooled into a single data table. Care must be taken to ensure that the populations from the various studies are **homogeneous** (i.e. similar enough to be comparable). The hope is that if you combine the data from all the smaller studies, you will come up with a more definitive answer. Sometimes, it works[8] and sometimes it just generates more controversy.[9] Searching for the best available evidence by systematic review and meta-analysis is the cornerstone of **evidence-based medicine.** The Cochrane Collaboration Controlled Trials Register is an important source of studies for meta-analysis.

When comparing data from different studies in a meta-analysis, the **mean difference** (MD) or **weighted mean difference** (WMD) can be used to combine continuous numeric measurements. In cases where the units of measurement are identical between studies (such as millimeters of mercury—mmHg—when studying blood pressure), values in one study can be directly compared with each other. The mean difference is simply the difference between the study group and the control. A mean difference of zero indicates that there is no difference between the groups.

In cases where the units of measurement are different, such as when comparing a 10-point pain scale with a 100-mm visual analog scale, the differences are normalized with respect to the pooled standard deviation of the two groups, known as the **standard mean difference** (SMD). When SMD = 0, there is no difference between the groups. Somewhat arbitrarily, SMD = 0.2 is considered weak effect; SMD = 0.5 is moderate effect; and SMD = 0.8 is strong effect.

The results of a meta-analysis are usually displayed as a forest plot (see Sect. 2.2.3—Clinical Guidelines).

2. *Was the study methodology appropriate?*

There are many different ways to study nature. The prospective, double-blind, randomized controlled trial (RCT) is considered the most reliable methodology. In this kind of trial, when patients volunteer for the study, they are **randomized** into either the study arm or the placebo arm. Neither the investigator nor the subject know which arm has been selected (i.e. **double-blind**). After all the data is gathered, the randomization is revealed in order to perform statistical analysis. For example, an investigator wants to know if a certain drug cures a disease. A hundred people with the disease sign up for the study. Half of the patients are given an injection of the drug, and the other half are given an injection of an inert ingredient such as normal saline (the **placebo**). The syringes have been prepared earlier by the

6 Komatsu R, You J, Mascha EJ, Sessler DI, Kasuya Y, Turan A. Anesthetic induction with etomidate, rather than propofol, is associated with increased 30-day mortality and cardiovascular morbidity after noncardiac surgery. Anesth Analg. 2013 Dec;117(6):1329–37.

7 Tekwani KL, Watts HF, Sweis RT, Rzechula KH, Kulstad EB. A comparison of the effects of etomidate and midazolam on hospital length of stay in patients with suspected sepsis: a prospective, randomized study. Ann Emerg Med. 2010;56:481–489.

8 Gu WJ, Wang F, Tang L, Liu JC. Single-dose etomidate does not increase mortality in patients with sepsis: a systematic review and meta-analysis of randomized controlled trials and observational studies. Chest. 2015 Feb;147(2):335–46.

9 Chan CM1, Mitchell AL, Shorr AF. Etomidate is associated with mortality and adrenal insufficiency in sepsis: a meta-analysis. Crit Care Med. 2012 Nov;40(11):2945–53.

pharmacy and are labeled with only a serial number. It is impossible to tell which syringe has drug and which has saline. The subjects are then observed to see if the disease improves. Since the data are gathered after the intervention takes place, it is called **prospective** (forward looking).

An RCT can be quite expensive. When an RCT is not possible, another option is the **cohort study**, which is an observational study in which a group (cohort) of people with a particular characteristic is compared to a group of people without that characteristic. Cohort studies can be prospective or retrospective. For example, an investigator wants to know if smokers are more likely to develop degenerative disc disease, so he enrolls 150 people. Using a survey, he finds that 35% of them are smokers. He divides the volunteers into the smoking group and the non-smoking group. He continues to survey them for 10 years until he finds that patients in the smoking cohort have a four-fold higher risk of disc disease.

Very similar to the cohort study is the **case-control study.** In this variation, the outcome (disease) is known, and the attributes (risk factors) are unknown. For example, a researcher identifies 100 people with disc disease (the cases) and 100 people without disc disease (the controls). He surveys those patients to find out which of them have a history of smoking. Since this kind of study is backward-looking, it is called **retrospective.**

A **cross-sectional study** examines a population at a single point in time. Either the entire population or a representative sample is surveyed. There are two main advantages to the cross-sectional study. Firstly, the study is relatively inexpensive and can be completed quickly. Secondly, since the whole population is studied, the prevalence of a disease can be computed, which is useful for population health. The disadvantages include the fact that the study is just a quick snapshot in time, if the study were repeated during a different timeframe, the results could be different. Also, since some diseases result in rapid death, they can be difficult to detect using this method.

Case Reports (or case series) are thorough descriptions of case presentations, management decisions and outcomes. They are very frequently combined with a review of the available literature. Since case reports represent the experience and biases of a single observer, they are termed **anecdotal evidence**.[10]

Case series are not without value. They are used when the disease or outcome is so rare that a larger study would be impossible. Case series can also be valuable when the measured effect is very large and not easily subject to bias. For example, a researcher determines that applying direct pressure to an arterial laceration reduces the amount of blood loss. Since the effect is so dramatic, further study would be considered unethical. Studies with dichotomous endpoints, often involving life and death are called **all or none studies.** If a case series is an all or none study, it is appropriate to rely on previously established disease patterns or to compare results with similar patients who did not receive treatment and were not involved in the study (**historical controls**). The term all-or-none does not imply a particular methodology. For example, an all-or-none RCT carries more weight than an all-or-none case series.

Ecological studies are studies that analyze geographical data to compare populations in terms of incidence or prevalence of disease. At least one variable is measured at the group (e.g. incidence) level instead of the individual level. For example, a researcher collected data from 71 different countries and plotted risk of prostate cancer against annual sugar consumption, and found a direct correlation.[11]

Outcomes research seeks to understand the end results of particular health care practices and interventions in terms of outcomes that matter to patients. Although outcomes research may include traditional clinical trials, it also includes studies where the intervention being evaluated is not a new drug or method, but the opening of a new clinic or enforcement of certain policies by regulatory bodies. For example, traditional researchers may measure visual acuity (VA) before and after a surgical procedure to determine if the procedure is effective. An outcomes researcher would study the effect of adding a new ophthalmology clinic on the health of seniors living in its service area. Further, instead of measuring VA,

10 Verweij KE, van Buuren H. Oriental cholangiohepatitis (recurrent pyogenic cholangitis): a case series from the Netherlands and brief review of the literature. Neth J Med. 2016 Nov;74(9):401–405.

11 Colli JL, Colli A. International comparisons of prostate cancer mortality rates with dietary practices and sunlight levels. Urologic Oncology 2006:24;184–194.

they might use a VF-14, a standardized series of subjective measures that are important to the patient (e.g. able to identify a curb, able to drive at night, etc).[12]

Once the study design is decided, the author must work diligently to avoid or minimize sources of bias:

TYPE OF BIAS	WHAT CAN BE DONE ABOUT IT?
Selection bias—certain patients are preferentially enrolled into the study and may not represent the population at large. For example, a study on STD recruits patients at a monastery	Select patients according to rigorous criteria that closely match the intended study population
Channeling bias—patients are steered into study arms by organizers based on preconceived notions. For example an investigator pushes healthier patients into the study arm and sicker patients into the placebo arm, so as to make the study seem more effective than it really is	Use strict, blinded randomization to assign patients to various study arms
Interviewer bias—the investigator asks different questions of the patients, knowing which study arm they are in. Similarly, a subject may behave differently because he knows he is being observed. This is sometimes called the **Hawthorne effect**	Use a double-blind design so the interviewer can not tell which arm the patient is in
Chronology bias—study patients are compared to historical controls, at a time when standard of care may have been different	Use a prospective design
Recall bias—subjects may not remember they symptoms or exposures correctly, especially when they believe that they have a disease. Similarly, reporting bias is when subjects selectively hide information about themselves (e.g. sexual history)	Use only objective data sources
Transfer bias—certain types of patients are more likely to be lost to follow up. For example, the research office is on the fourth floor and there is no elevator. Healthier subjects are more likely to follow up. Also known as attrition bias	Carefully plan ways to contact patients who would otherwise be lost to follow up
Performance bias—in cases where the intervention involves a procedure, it is possible that different operators will perform the procedure differently	Clearly define the method of the procedure, using as much detail as possible. Another possibility is to separately analyze procedures done by each operator
Publication bias—journals tend to report positive findings more readily than negative findings	Before collecting any data, register the study with the NIH registry of clinical trials at ClinicalTrials.gov

For a checklist on how to make a really great RCT, check out the Consolidated Standards of Reporting Trials web site at http://www.consort-statement.org/.

3. *Were the data analyzed correctly?*

Statistical methods are the hallmark of clinical evidence.

The **relative risk (RR)** describes the increased risk associated with an intervention. For example, suppose 21 people are randomized into a control and study group. The study group are given a drug and the control group are given a placebo. In the study group, 3 of 10 patients get sick, and in the control group 5 of 11 patients get sick. The relative risk expresses the risk in the study group compared to the control group. Mathematically,

$$RR = \frac{risk\ in\ study\ group}{risk\ in\ control\ group} = \frac{3/10}{5/11} = \frac{0.3}{0.45} \approx 0.66$$

12 Boisjoly H, Gresset J, Fontaine N, et al. The VF-14 index of functional visual impairment in candidates for a corneal graft. Am J Ophthalmol. 1999 Jul;128(1):38–44.

If the RR is near 1, the risk in both groups is the same, and the intervention has no measurable effect. When the RR > 1, the study group has *greater* risk.

Instead of RR, some publications refer to **risk reduction**. Using the same example, how much less risk is found in the study group? The **absolute risk reduction (ARR)** is found by subtracting the study group's risk from the that of the control group. It is usually expressed as a percentage.

$$ARR = risk\ in\ control\ group - risk\ in\ study\ group = 0.45 - 0.3 \approx 15\%$$

In order to make the risk reduction appear more dramatic, it is often expressed as the **relative risk reduction (RRR)** which is the ARR divided by the control risk.

$$RRR = \frac{risk\ in\ control\ group - risk\ in\ study\ group}{risk\ in\ control\ group} = \frac{0.45 - 0.3}{0.45} \approx 34\%$$

This tactic is most frequently used by drug manufacturers whose drugs provide modest improvement in a rare condition. For example, suppose 12 of 113 patients got sick in the study group while 15 of 106 got sick in the control group. Let's compare the RR, ARR and RRR.

$$RR = \frac{12/113}{15/106} = \frac{0.106}{0.142} \approx 0.75$$

$$ARR = 0.142 - 0.106 \approx 3.5\%$$

$$RRR = \frac{0.142 - 0.106}{0.142} \approx 25\%$$

When a clinician chooses a treatment plan, a relative risk reduction of 25% sounds much more impressive than 3.5% absolute risk reduction. It is no surprise that pharmaceutical marketing tends to report RRR over ARR.[13]

Another useful measure of effectiveness is the **number needed to treat (NNT)** which is the reciprocal of the ARR. Continuing our example above,

$$NNT = \frac{1}{0.142 - .106} \approx 28$$

Which means that you would have to treat 28 people with the study intervention to prevent one person from getting sick. In general, an NNT less than 10 is considered very useful. When the outcome is harmful, the math is the same, but the NNT is called **number needed to harm (NNH)**.

The **p-value** indicates the probability that the results that were found in this study could be a result of pure chance. The lower the p-value, the more likely the results are reliable. For most medical publications, $p < 0.05$ is considered significant. For example, suppose a study reveals that a drug is effective with $p = 0.03$. That means that if this study were repeated with a placebo, there is a 3% chance that the same or better results would have been obtained by pure chance. Said differently, there is a 97% chance that the study drug is responsible for the measured success. In our example above, $p = 0.43$, which is NOT statistically significant.

A **confidence interval** (CI) indicates the likely range for a particular measure. It is usually reported as the 95% CI, or the range in which 95% of measured values will fall. Continuing our example, the RR is 0.75, and the 95% CI ranges from 0.37 to 1.53.[14] Since the interval includes values which show harm as well as values which show benefit (i.e. it includes

13 Othman N, Vitry A, Roughead EE. Quality of Pharmaceutical Advertisements in Medical Journals: A Systematic Review. PLoS One. 2009; 4(7): e6350.

14 Calculation of p-values and confidence intervals is beyond the scope of the exam, but you should know what they mean and how to use them.

numbers greater and less than one), we can conclude that the result is NOT statistically significant at the p = 0.05 level.

Odds Versus Probability
Probability is the chance of having a certain outcome. Odds is the chance of having the desired outcome compared to the other outcomes. Numerically,

Probability = (chance of desired outcome)/(total number of possible outcomes)
Odds = (chance of desired outcome)/(chance of all other outcomes)

In case-control studies, a group of patients who have the risk factor are matched with control patients who do not. Since the prevalence of the risk factor is unknown, the relative risk can't be calculated. Instead, we use the **odds ratio** which compares the odds of having the finding in patients with the risk factor compared to patients without the risk factor. In general, OR > 1 means that the event is more likely to occur in the exposed group; OR < 1 means that it is less likely; and OR = 1 means that there is no difference between the two groups.

Let's try an example using the same numbers as before. A novel gene is found in 10 people (study group). These are matched with 11 people who do not have the gene (control group). In the study group, 3 people get sick and 7 do not. In the control group, 7 get sick and 4 do not.

$$OR = \frac{odds\ of\ getting\ sick\ in\ study\ group}{odds\ of\ getting\ sick\ in\ control\ group} = \frac{3/7}{7/4} = .24$$

Since the OR is less than 1, it means that getting sick is less likely in the group that has the novel gene.

For a nice primer on statistics, see Medical Statistics Made Easy by Harris and Taylor.[15] For descriptions of Odds Ratio, Relative risk, Likelihood ratios, Sensitivity, Specificity, Receiver Operating Characteristic curves, see Sect. 2.1.2.5.

2.2.2 EVIDENCE GRADING

Clinical evidence comes from many sources, with varying degree of quality. Ideally, evidence of higher quality should have a greater effect on our clinical practice. For an explanation of the different types of studies, see Sect. 2.2.1 Evidence Sources.

The highest grade of evidence is given to conclusions are unlikely to change with the introduction of new data. For example, things that are well studied by many investigators in many institutions and have all found very similar results with little variation. The lowest grade is given to recommendations or hypotheses proffered with little to no experimental evidence at all, such as the proceedings from an expert panel or basic science studies which have been extrapolated into clinical practice. Some fields of medicine are more likely to publish lower quality evidence than others.[16]

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group suggests four domains to assess the quality of studies[17]

1. **Study Design**. In general, RCTs are considered more definitive than observational studies. For example, several observational studies in the 1990's showed that hormone replacement therapy was beneficial in preventing coronary artery disease. In the early

15 http://sumed.sun.ac.za/Portals/0/Repository/Medical-Statistics-Made-Easy.3f8ceb88-f35b-4f29-8d70-17e78ce071d8.pdf
16 Loiselle F1, Mahabir RC, Harrop AR. Levels of evidence in plastic surgery research over 20 years. Plast Reconstr Surg. 2008 Apr;121(4):207e–11e.
17 Grading quality of evidence and strength of recommendations. GRADE Working Group. BMJ. 2004 Jun 19; 328(7454): 1490.

2000's, there were RCTs that suggested otherwise. In this case, the RCTs were considered a higher grade of evidence than the observational studies. There are some cases where RCTs are not feasible or may not translate well to a population being studied, such as when studying rare complications of a procedure.

2. **Study Quality.** Studies are weakened by systematic flaws that introduce bias. For example, inadequate blinding, inappropriate allocation of study arms, and insufficient follow up all decrease the validity of studies
3. **Consistency.** When studies are repeated across populations, the data should essentially agree. If there is broad discrepancy between studies of the same entity, the overall confidence in the studies decreases. In some cases, however, a subgroup analysis may explain differences and bolster consistency. (**Subgroup analysis** refers to examining subsections of the study population to search for additional correlations. For example, Sacks[18] studied the effects of pravastatin on patients with previous myocardial infarction and found that pravastatin lowered the risk of recurrent coronary events by 24%. However, when he separated the population based on sex, he found that women had a 46% risk reduction, while men had only 20%)
4. **Directness.** When a study is planned, there must be a direct relationship between the population being studied and the population being treated. This may take several forms.

    (a) **Population differences.** For example, pharmaceuticals are usually tested on healthy volunteers. It is uncertain how findings of these studies may relate to patients who are older and sicker.
    (b) **Use of surrogate markers.** Studies that measure disease-oriented outcomes have less directness than those that measure patient-oriented outcomes. For example, it is known that patients with acute myocardial infarction (AMI) are at greater risk for arrhythmia. It is also known that patients with arrhythmia are at greater risk for sudden death. It seems logical, therefore that arrhythmia suppression should save lives. In other words, the arrhythmia is a **surrogate marker** for death. Using surrogate markers can lead to unexpected results. In the case of AMI, it turns out that preventing arrhythmia with anti-arrhythmics is associated with greater mortality.[19]
    (c) **No direct comparison.** When two interventions are compared to a third, but never with each other, it can lead to indirectness. For example, suppose there are studies comparing aspirin to placebo and plavix to placebo, but no trials that compared aspirin with plavix.

5. **Strength of association.** In studies where the finding of interest is very dramatic, such as all or none studies.
6. **Evidence of a dose response gradient.** Studies which show a direct correlation between increasing intensity of intervention and patient response are generally considered stronger.
7. When reasonable confounding would have pushed the effect in one direction, but the findings are the opposite, it lends credence to the results. For example, one would assume that overall care would be better in for-profit hospitals because of the greater availability of resources and intensity of services. Moreover, there would exist a selection bias which would steer wealthier, healthier patients to for-profit hospitals and sicker, poorer patients to non-profit hospitals. However, in a meta-analysis, it was found that mortality was actually higher in for-profit hospitals.[20] Since one would expect that bias would reduce the effect, the data is all the more convincing.

18 The Effect of Pravastatin on Coronary Events after Myocardial Infarction in Patients with Average Cholesterol Levels. Sacks FM, Pfeffer MA, Moye LA, et al. N Engl J Med 1996; 335:1001–1009.
19 Echt DS, Liebson PR, Mitchell LB, et al. Mortality and morbidity in patients receiving encainide, flecainide, or placebo. The cardiac arrhythmia suppression trial. N Engl J Med 1991;324: 781–8
20 Tanne, JH. Mortality higher at for-profit hospitals. BMJ. 2002 Jun 8; 324(7350): 1351.

Based on these guidelines, evidence is given a grade, as shown:

CODE	QUALITY OF EVIDENCE	DEFINITION	SOURCE
A	High	Further research is very unlikely to change our confidence in the estimate of effect	Several high-quality studies with consistent results (in special cases: one large, high-quality multi-center trial)
B	Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate	One high-quality study, or several studies with some limitations
C	Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate	One or more studies with severe limitations
D	Very low	Any estimate of effect is very uncertain	Expert opinion with no direct research evidence, or one or more studies with very severe limitations

The agency for healthcare quality and research (AHRQ) supports the EPC (Evidence-based Practice Center) approach which is similar to GRADE. Like GRADE, it requires assessment of four domains: risk of bias, consistency, directness, and precision. Additional domains to be used when appropriate include dose-response association, presence of confounders that would diminish an observed effect, strength of association, and publication bias.

Precision refers to the lack of random errors in measurement, usually caused by inaccuracies in the measuring instrument. For example, a person gets on the bathroom scale and it reads 195.4. He steps off the scale and then gets back on and this time it reads 195.2. While precision is a lack of random error, **validity** refers to a lack of systematic error. **Internal validity** relates to the ability of the study's interventions to explain the findings. Poor internal validity would be caused by systematic error in the study. **External validity** refers to the ability of the study to generalize to other populations.

Another taxonomy which is commonly used is the Strength-of-Recommendation Taxonomy (SORT).

CODE	DEFINITION
A	Consistent, good-quality patient-oriented evidence
B	Inconsistent or limited-quality patient-oriented evidence
C	Consensus, disease-oriented evidence, usual practice, expert opinion, or case series for studies of diagnosis, treatment, prevention, or screening

The following list can be useful to rank the strength of evidence (in decreasing order). Assume that all systematic reviews are homogeneous.

1. Systematic review of Randomized Controlled Trials (RCT)
2. Individual RCT with narrow confidence interval
3. All or none RCT
4. Systematic review of cohort studies
5. Individual cohort study
6. RCT with quality issues (e.g. poor follow up)

7. Outcomes Research
8. Ecological studies
9. Systematic review of case-control studies
10. Individual case-control study
11. Case series
12. Lower quality cohort and case-control studies
13. Expert clinical opinion
14. Basic science studies

Specialty societies often give recommendations on how to address certain common problems. While some recommendations are strong, others are weaker. In order to define the strength of these recommendations, classification systems have been developed. (See Box 4-1).

Box 4-1: Evidence Grading and Recommendation Classification

Evidence grading should not be confused with classification of recommendation. In some cases, the evidence for a particular theory may be compelling, but it does not result in advisories for clinical practice. For example, the American Heart Association gives many recommendations according to the following scale

Classification of Recommendations

- **Class I:** Conditions for which there is evidence, general agreement, or both that a given procedure or treatment is useful and effective.
- **Class II:** Conditions for which there is conflicting evidence, a divergence of opinion, or both about the usefulness/efficacy of a procedure or treatment.
- **Class IIa:** Weight of evidence/opinion is in favor of usefulness/efficacy.
- **Class IIb:** Usefulness/efficacy is less well established by evidence/opinion.
- **Class III:** Conditions for which there is evidence, general agreement, or both that the procedure/treatment is not useful/effective and in some cases may be harmful.

The AHA employs a three-tier level of evidence scale similar to GRADE. The level of evidence is recorded separately from the classification recommendation.

Level of Evidence

- **Level of Evidence A:** Data derived from multiple randomized clinical trials
- **Level of Evidence B:** Data derived from a single randomized trial or nonrandomized studies
- **Level of Evidence C:** Consensus opinion of experts

2.2.3 CLINICAL GUIDELINES

Samuel Alfano

Clinical practice guidelines (CPGs) are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.[21]

Typically, guidelines have two parts. The foundation is a systematic review of the research evidence bearing on a clinical question, focused on the strength of the evidence. The second

21 Consensus report, Institute of Medicine. Clinical practice guidelines we can trust. March 23, 2011. http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx (Accessed on January 13, 2012).

part, built on this foundation, is a set of recommendations, involving both the evidence as well as the evaluator's value judgments regarding the risks and benefits of various care options, addressing how patients with that condition should be managed. Guidelines are suggestions for care, not rules. There will always be individual patients who should be managed differently. Legitimate reasons for departing from the guideline may include: biologic differences in drug metabolism; immune response; genetic endowment; the presence of comorbid conditions; availability of resources as determined by the social and economic environment; and patient preferences.

The National Guideline Clearinghouse (NGC) is a public resource maintained by the Agency for Healthcare Research and Quality (AHRQ). The NGC provides structured, standardized summaries of guidelines from most major medical organizations and clinical specialty societies. To be included in the NGC compendium, guidelines are required to meet specific criteria based on the Institute of Medicine (IOM) definition of a clinical practice guideline, such as incorporating a systematic review and an assessment of benefits and harms.

Clinical practice guidelines provide a series of steps, often in algorithm form, for providing clinical care. They may consist of any combination of text, tables, and flowcharts. The typical steps in a CPG algorithm include the following:

Action—perform a specific action.
Conditional—carry out an action (or actions) based on defined criteria.
Branch—direct flow to one or more additional steps.
Synchronization—converge paths back from branches to a common outcome/end point.

An example of a generic algorithm is shown in Fig. 4-1.

Research has shown that CPGs have the potential to reduce inappropriate practice variation, enhance translation of research into practice, and improve healthcare quality and safety. CPGs have also had an important influence on development of physician and hospital performance measures. While CPGs are useful to guide therapy, certain factors may undermine their quality and trustworthiness. These include variable quality of individual scientific studies; limitations in the systematic reviews upon which CPGs are based; lack of transparency of the development groups' methodologies (particularly with respect to evidence quality and strength of recommendation appraisals); failure to convene multi-stakeholder, multidisciplinary guideline development groups, and corresponding non-reconciliation of conflicting guidelines; unmanaged conflicts of interest (COI); and overall failure to use rigorous methodologies in CPG development.

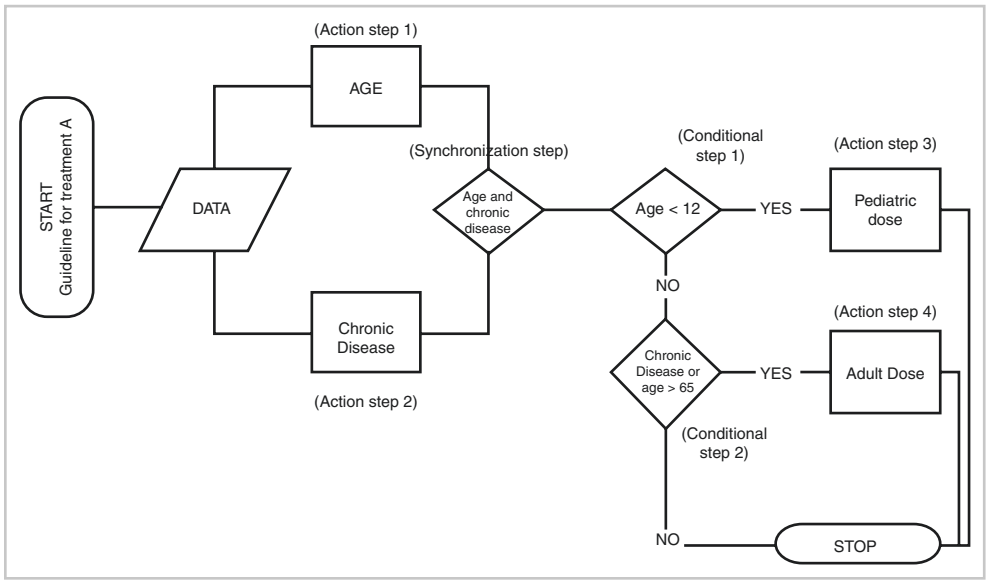


FIGURE 4-1

Example algorithm of a clinical practice guideline

When appraising a CPG, there are several components to consider. Did the developers carry out a comprehensive, reproducible literature search within the past 12 months? Are each of the recommendations rated as to the level of evidence (LOE) on which it is based? Is it linked to one or more specific citations? Is the CPG applicable only to very narrow, specific clinical settings or is it more broadly applicable (generalizable) and economically feasible?

Guidelines may have limitations in their use in clinical practice. They may not apply in complex patients with multiple comorbidities. They may be incomplete or inaccurate. They may be difficult to implement in an EHR setting and, they may have been developed by those with conflicts of interest, such as specialty societies.

The Institute of Medicine established a set of standards for guidelines to ensure validity, accuracy and reliability. They include the following metrics[22]:

- Has an explicit description of development and funding processes that is publicly accessible
- Follows a transparent process that minimizes bias, distortion, and conflicts of interest
- Is developed by a multidisciplinary panel comprising clinicians, methodological experts and representatives, including a patient or consumer, of populations expected to be affected by the guideline
- Uses rigorous systematic evidence review and considers quality, quantity, and consistency of the aggregate of available evidence
- Summarizes evidence (and evidentiary gaps) about potential benefits and harms relevant to each recommendation
- Explains the part that values, opinion, theory, and clinical experience play in deriving recommendations
- Provides a rating of the level of confidence in the evidence underpinning each recommendation and a rating of the strength of each recommendation
- Undergoes extensive external review that includes an open period for public comment
- Has a mechanism for revision when new evidence becomes available

Evidence in guidelines is often rated as to its usefulness and validity. Practice guidelines levels of evidence and grades of recommendations used by the National Guideline Clearinghouse are shown below.

Levels of Evidence:

IA	Evidence from meta-analysis of randomized controlled trials
IB	Evidence from at least one randomized controlled trial
IIA	Evidence from at least one controlled study without randomization
IIB	Evidence from at least one other type of quasi-experimental study
III	Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, and case-control studies
IV	Evidence from expert committee reports or opinions or clinical experience of respected authorities, or both

Grades of Recommendations:

A	Directly based on Level I evidence
B	Directly based on Level II evidence or extrapolated recommendations from Level I evidence
C	Directly based on Level III evidence or extrapolated recommendations from Level I or II evidence
D	Directly based on Level IV evidence or extrapolated recommendations from Level I, II, or III evidence

The results of a meta-analysis are often reported using forest plot (see Fig. 4-2). This is a graphical comparison of the results from a number of studies. Although forest plots can take several forms, they are commonly presented with two columns. The left-hand column lists

22 Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, Eds. Clinical practice guidelines we can trust. Institute of Medicine. 2011. National Academies Press, Washington, DC.

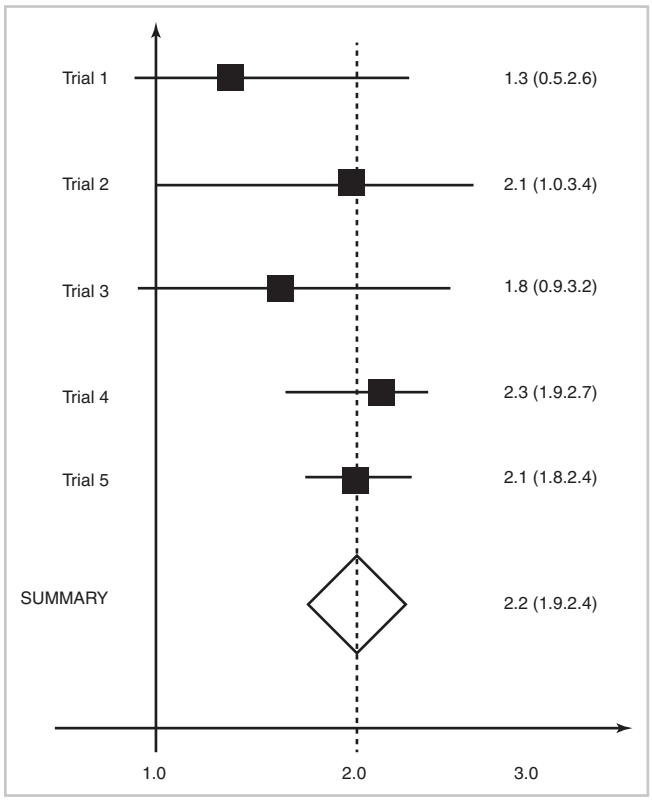


FIGURE 4-2

Forest Plot of 5 randomized studies. The x-axis shows odds ratio (OR) Trials 1,2,and 3 touch the "no effect" line (OR = 1) and thus by themselves are not statistically significant. When taken as a whole and combined with trials 4 and 5, the summary becomes significant

the names of the studies while the right-hand column is a plot of the measure of effect (*e.g.* an odds ratio) often represented by a square with confidence intervals represented by horizontal lines. The graph may be plotted on a logarithmic scale when using odds ratios or other ratio-based effect measures, so that the confidence intervals are symmetrical about the means from each study and to ensure undue emphasis is not given to odds ratios greater than 1 when compared to those less than 1. The area of each square is proportional to the study's weight in the meta-analysis. The overall measure of effect is commonly plotted as a diamond, the lateral points of which indicate confidence intervals for this estimate, with a dashed vertical line to show its position relative to other studies. A vertical line representing no effect is also plotted (e.g. at OR = 1). If the confidence intervals broach this line, it indicates a lack of statistical significance.

Comparative Effectiveness Research (CER)

According to the Institute of Medicine, "Comparative effectiveness research is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care."[23]

The key elements of CER are (*a*) direct comparisons of active treatments; (*b*) study patients, clinicians, and interventions that are representative of usual practice; and (*c*) a focus on helping patients, clinicians, and policy makers to make informed choices.

These elements have several implications for the principal methods of CER, which are randomized trials, observational research, and decision analysis. Because differences in treatment effects will be smaller in head-to-head comparisons of active treatments than in placebo-controlled trials, studies will require larger study populations, longer follow-up, or both. These requirements are more easily met with observational studies that use large data sets collected over the course of usual practice. The results of CER will often sacrifice internal validity (such as precision and reliability of measurements) for external validity (how well the study may be extrapolated to other populations). The best way to assure external

23 Sox HC. Defining comparative effectiveness research: the importance of getting it right. Med Care. 2010 Jun;48(6 Suppl):S7–8.

validity is to study interventions, clinicians, and patients that are typical of community practice, which will often mean using data that were not gathered for research purposes and are therefore plagued with missing data and subject to confounding.

While there are many challenges to successful CER, especially when using community data that is not designed specifically for research purposes, statistical tools can help deal with confounding and missing data.

Appropriate use criteria (AUC, sometimes referred to as "appropriateness criteria") are a variation on clinical practice guidelines, but differ in several ways.

- Appropriateness is tailored as much as possible to the specific characteristics of individual patients.
- AUC cover a broader array of specific conditions, sometimes hundreds for a given test or treatment decision, to encompass the majority of practice situations. Appropriateness may relate to individual patient demographic characteristics, clinical history, risk scores, and/or symptoms and signs.
- AUC are based upon scientific evidence where possible but, in part as a result of the breadth of specific clinical conditions addressed, rely more on expert opinion than do rigorous clinical practice guidelines.
- Panels that formulate AUC are typically comprised of representatives from the specialties that manage patients with the clinical question under consideration.
- A common approach is to rate specific clinical scenarios (or potential indications for an intervention) on a 1–9 scale by each panelist before and after a group face-to-face discussion, and the median of the panel ratings is then used to designate each clinical scenario as appropriate, uncertain, or inappropriate.
- AUC are intended not only to help clinicians make sound clinical decisions, but also to educate patients and improve the effectiveness, efficiency, and equity of care.

An example of AUC are the Appropriate Use Criteria published by the American College of Radiology to help in ordering advanced diagnostic studies for specific conditions, such as MRI in back pain patients.

Guidance Statements

The American College of Physicians (ACP) has issued several "guidance statements" that are based on reviews of other guidelines and not a de novo systematic review of evidence. These address conditions such as breast cancer screening in women aged 40–49, prostate cancer screening, or colorectal cancer screening for which there is general agreement on all or most of the eligible trials, but difference in how the evidence from those trials is interpreted. The ACP reviews existing guidelines on the topic and appraises them using the Appraisal of Guidelines, Research, and Evaluation (AGREE II)[24] criteria. The ACP then formulates its own guidance, based on a review of the literature, recommendations in existing high-quality guidelines, and considering the needs and values of its general internist membership and their patients.

2.2.4 IMPLEMENTATION OF GUIDELINES AS CLINICAL ALGORITHMS

Samuel Alfano

Clinical practice guidelines are developed and implemented to achieve the following objectives:

- To deliver effective care based on current evidence.
- To resolve common problems in the clinical setting (e.g. poor blood pressure control).

24 Brouwers MC, Kho ME, Browman GP, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. CMAJ 2010; 182:E839.

- To achieve excellence in care delivery by meeting or exceeding regulatory requirements.
- To introduce an innovative method of diagnosis or treatment.
- To eliminate use of interventions not recognized as best practice.

Clinical practice guidelines development is a rapidly expanding area, particularly since the introduction of electronic medical records and the use of decision support tools. Despite this, there continues to be variations in health-care practice that do not reflect best practice evidence. Moreover, there are ongoing challenges in promoting full utilization of guidelines by healthcare practitioners, particularly if they are not effectively introduced, implemented and supported. Multiple studies exist in the literature about what techniques help to influence adoption of clinical practice guidelines.

As early as 1999, Moulding[25] et al. described a multistep process for adoption of clinical changes. **Adoption** occurs through a series of communication channels over a period of time among the members of a similar group and is predictable and can be managed. It includes the following five steps.

1. **Knowledge** is the first stage of adoption. During this first stage, individuals are first exposed to an innovation, but have not yet been inspired to find out more information about it. Introduction to why the guideline was developed, what the expected outcome may be, and how the guideline will be used is presented.
2. **Persuasion** comes after introduction. The individual is interested in the innovation and actively seeks more information. It is here that a detailed understanding of how the guideline works and will be implemented is shared. Important in this stage is to encourage clinicians to become invested in the guideline and be allowed to offer critiques and suggestions for improvement.
3. **Decision** is the stage where the clinicians will take the concept of the change and weigh the advantages/disadvantages of adopting the innovation. They can then decide whether to adopt or reject the innovation. Identifying early adopters (see below) and opinion leaders among the clinical staff is important at this stage.
4. **Implementation** is where the tool is made available to clinicians and where they make a final determination to use the guideline. During this stage, the clinician decides whether or not the tool is easy to use, disrupts his workflow, and adds value to his treatment of patients.
5. **Confirmation** is where the clinician finalizes his decision to continue using the innovation. This leads to future use of the guideline as well as the clinician making it part of his routine work flow.

Further, five stages of assessment are usually needed to ensure full adoption and implementation. These have been described by Macdonald.[26]

Step 1: Assessment of Practitioners' Stage of Readiness to Change

Assessment of a practitioner's stage of readiness to change will help to ensure an appropriate mix of dissemination and implementation strategies. Different types of change strategies should be matched with each stage of readiness to change. There are commercially available evaluative tools, such as online surveys, that could be given to practitioners to provide feedback on readiness to adopt different sets of guidelines. Often, small focus groups or department meetings can be a source of discussion used to judge readiness for guideline adoption.

25 Moulding NT, Silagy CA, Weller DP. A framework for effective management of change in clinical practice: dissemination and implementation of clinical practice guidelines, *Qual Health Care.* 1999 Sep; 8(3): 177–183.

26 Macdonald G. Communication theory and health promotion. In: Bunton R, Macdonald G, editors. Health promotion: disciplines and diversity. London: Routledge, 1992.

Step 2: Assessment of Specific Barriers to Guideline Use
Assessment of the specific nature of competency based, social, and organizational barriers to guideline use will further ensure that appropriate strategies are selected. Assessment might be undertaken through various means, such as surveys of clinicians using questionnaires, interviews, or group consultations. The use of qualitative methods will provide a more detailed and comprehensive picture of practitioners' needs. Other relevant groups such as patients, other health professionals, and opinion leaders might also be consulted.

Step 3: Determination of Appropriate Level of Intervention
It is important to make an assessment of which level of intervention—individual/group or population—best addresses identified barriers and clinicians' stage of readiness to change before designing dissemination and implementation programs. For example, it may be unnecessary to use national opinion leaders when most practitioners are already positively disposed towards a particular guideline. It may be important, however, to work at the local level with specific groups of practitioners where there is less support.

Step 4: Design of Dissemination and Implementation Strategies
Strategies are selected and designed based on step three. Although the above framework can distinguish in some detail which strategies are likely to have the greatest impact in each stage of change, this depends on the organization's readiness and culture. The interventions most likely to induce change are those that require the clinician's participation in the change process.[27] No single implementation strategy is effective in all circumstances for all people. It is generally understood that the simple dissemination of guidelines is likely to have no impact at all on implementation.[28]

Change will occur only if specific interventions designed to encourage it are used. All of the following can be used to support implementation and adoption of clinical guidelines:

- media marketing
- the use of opinion leaders and 'champions'
- endorsement by clinical groups
- practice visits from known experts
- education of patients
- educational materials
- seminars and conferences
- reminder systems built into a clinician's' daily work i.e. clinical decision support
- continuing quality assurance and data feedback
- local adaptation and incorporation
- local involvement in evaluation
- financial incentives

Step 5: Evaluation
Evaluating the effectiveness of the implementation strategies in changing physician behavior is a vital component of the process. Evaluation can also be used to assess how the strategies could be used in a hospital setting to implement change. The type of evaluation tool used will be dependent on the setting and type of implementation strategies used. Measuring compliance with guidelines and providing feedback to Physicians, can help improve adoption after implementation.

Organization characteristics such as size, complexity, availability of resources, culture, communication channels and decision making processes are significantly associated with guideline utilization and explain considerably more of the variance in research and guideline utilization than other factors. The environment surrounding the practice exerts a powerful influence on practitioners. This environment can encourage or discourage the process of knowledge transfer and

27 Wise CG, Billi JE. A model for practice guideline adaptation and implementation: empowerment of the physician. Jt Comm J Qual Improv. 1995 Sep;21(9):465–76.
28 Oxman AD, Thomson MA, Davis DA, Haynes RB. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. CMAJ. 1995 Nov 15;153(10):1423–31.

use. Structural, social and patient related factors are also important determinants of a successful implementation. Structural factors include such characteristics as decision-making structure, workload, and available resources. Social factors include such variables as the politics and personalities involved and the culture and belief systems in place. Patient related factors include patient willingness or ability to comply with evidence-based recommendations. Although some studies have found combined strategies to be more effective than single ones, the evidence in inconclusive. In addition, there seems to be no significant relationship between the number of components of multifaceted strategies and the effects measured.

Complexity is an important predictor of guideline implementation. Several systematic reviews have shown that when a guideline can be relatively easily understood and tried out, the chance is greater that the guideline will be used.[29]

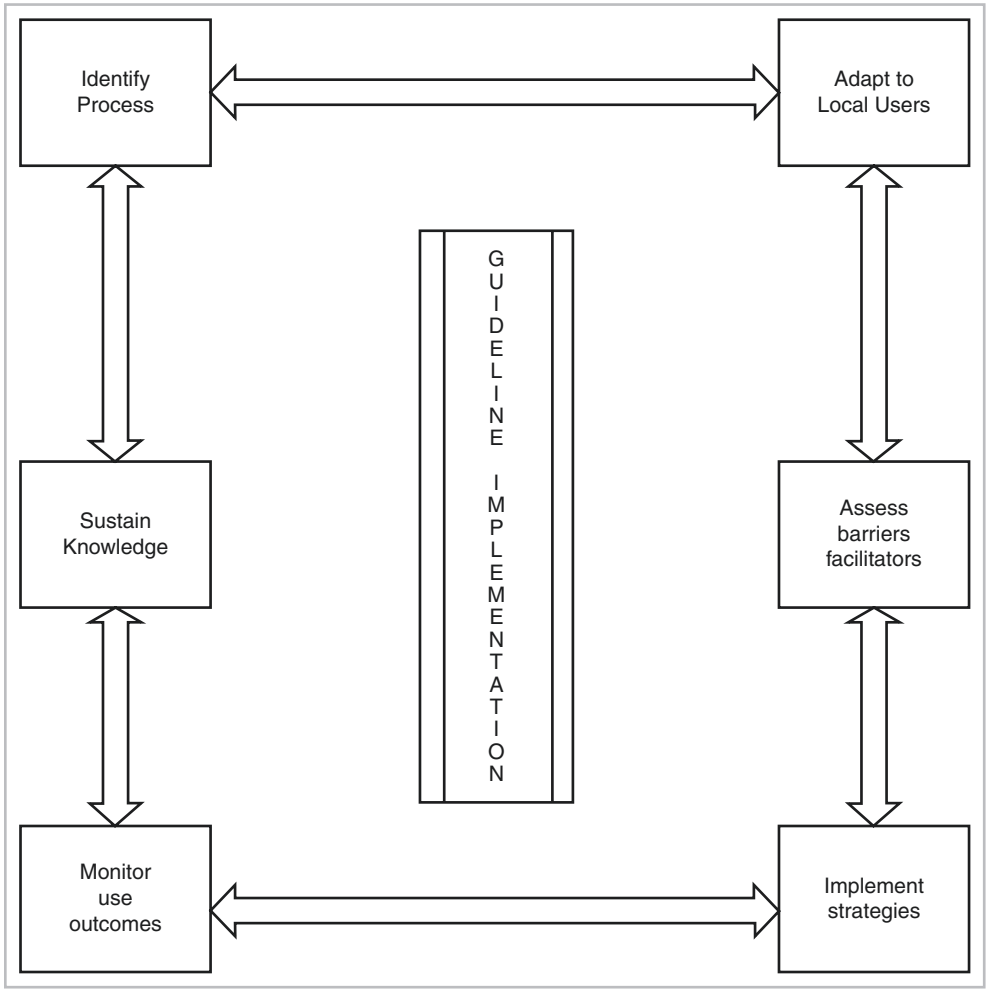
It is important therefore for guideline developers to take into account the complexity of the guidelines. Particularly for developers of multi-disciplinary guidelines directed at several target groups with varying educational levels and backgrounds (e.g. physicians, nurses, patients), it is a challenge to describe recommendations that are understandable and usable for all target groups.

Involving the professionals in the development phase enhances the chance of successful implementation. Groups that develop guidelines should be broadly composed and include all relevant health professionals. In addition, involvement of the target group may imply that the guideline is first being tested in practice before large-scale implementation takes place. Implementation may be hampered by the simple fact that professionals are often unaware that the guidelines exist, or are not familiar with their content. Clearly, it is not sufficient to merely disseminate a guideline. Targeted implementation interventions—in which professionals themselves are preferably directly and actively involved—should take place to create awareness. Characteristics of patients, too, appear to exert influence: for instance, comorbidity in a patient appears to reduce the chance that guidelines are followed. Professionals assume that guidelines are based on a general clinical picture and are insufficiently tailored to the often complex care needs of patients with comorbidity. In addition, environmental characteristics influence the implementation of guidelines. For example, support by peers in following the guidelines, and sufficient staff and clinical time appear to be important for guideline implementation.

A widely used Toolkit was conceptualized using the **Knowledge-to-Action Framework** as adapted for implementation of **Best Practice Guidelines**. The model depicts the following six essential components necessary for successful implementation.

1. **Identify** the problem: Identify, review, and select key knowledge. Identify gaps in knowledge and practice patterns using quality improvement tools and data from the institution where guidelines are to be used.
2. **Adapt** knowledge, tools, and resources to local context: Identify key stakeholders and their vested interests. Adapt the implementation process to the stakeholders identified and to the type of organization where they care for patients.
3. **Assess** barriers and facilitators to knowledge use: Identify barriers and develop strategies to overcome these. At the same time we often forget to identify and make maximal use of opinion leaders, early adopters, and other facilitators who can enhance adoption rates and implementation.
4. **Select**, tailor and implement interventions: Based on the above factors, lay out a detailed plan to support implementation and adoption. Project planning tools and dedicated project managers are valuable resources in this planning and execution.
5. **Monitor** knowledge use: Identify KPIs (Key Performance Indicators) early. Design methods to collect data on guideline use and patient outcomes. Positive early data can help win over late majority and Laggards in many cases.
6. **Sustain** knowledge use: Provide regular communication on the implementation and use of guidelines. As new information becomes available, update the guidelines and disseminate the changes. This ensures an iterative process that ensures continuous quality improvement.

29 Factors influencing the implementation of clinical guidelines for health care professionals: A systematic meta-review. Anneke L Francke, Marieke C Smit, Anke JE de Veer, Patriek Mistiaen, *BMC Medical Informatics and Decision Making* 2008 8:38.



2.2.5 INFORMATION RETRIEVAL AND ANALYSIS

Information retrieval (IR) is the process of finding material of an unstructured nature that satisfies an information need from within large collections. In medicine, the US National Library of Medicine MEDLINE/PubMed is the most commonly used search engine.[30]

Suppose I want to find documents about pheochromocytoma that are stored in a larger collection of documents (called a **corpus**). If the number of available documents is small, a simple linear search can be used. A search program simply reads through each document in the corpus, and if it finds the search text, the document is a hit. If not, it continues to the next document.

As you can imagine, this solution does not scale very well. As the number of documents in the corpus becomes large, performing a linear search becomes more and more time consuming. The solution is to construct an **index** (sometimes called an **inverted index**) of all the words in the document. Since the number of words in the index is much smaller than the number of words in the corpus, search time is much less. Moreover, since the index is already sorted, it decreases search time logarithmically. To give a rough idea how much more efficient this is, consider that in 2015, MEDLINE contained approximately 14 million English language articles with abstracts.[31] Since most abstracts at that time were truncated at 250 words, a linear search would require searching approximately a billion words. Using an

30 With approximately 40,000 searches per second, Google is the most famous IR company in the world.
31 See https://www.nlm.nih.gov/bsd/medline_lang_distr.html

index is much more efficient. Out of those billion words, there are only about 128,000 unique words.[32] Searching a sorted index only requires search of $\log_2(128{,}000)$ words, or about 17.

When constructing an index, it is important to omit certain extremely common words which do not differentiate one document from another (such as "and", "the", "if", etc). Words that are deliberately excluded from an index are called **stopwords**. Similarly, some words are quite ambiguous on their own, but have specific meaning when paired with other words. For example, "colic" is relatively nonspecific, but "renal colic" or "biliary colic" refer to particular entities. Incorporating multi-word expressions into an index makes it much more powerful. The process of breaking up a document into individually searchable items is called **tokenization.** It is important to make sure that the tokenizer used to parse a query is the same as the one used to parse the documents.

Another benefit to constructing an index is the inclusion of word count and word location. For example, a document that contains the word pheochromocytoma many times is likely more relevant than a document that contains the term only once. Storing word location allows users to perform queries on words that are close to each other in the text. (e.g. searching for "gates" within six words of "Microsoft").

Searchers often employ **Boolean logic** to further expand or limit a query. By using conjunctions such as AND, OR and NOT, queries can be made more specific. For example, "renal disease AND NOT hypertension" or "vomiting OR diarrhea".

Optimizing boolean queries can be quite challenging. Consider the following index from a corpus of 150,000 documents:

TERM	NUMBER OF DOCUMENTS
Renal disease	2343
Hypertension	55,232
Vomiting	17,322
Diarrhea	7442
Asthma	15,229

If someone searches for "renal disease", the search is straightforward. The database simply lists all 2343 documents which contain renal disease. This is called an index-only search because no further calculations are required.

However, if someone searches for "diarrhea OR vomiting", the database must compare the 17,322 documents with vomiting and the 7442 documents with diarrhea and remove the duplicates, which adds significant complexity to the search. Even worse, if the search is for "renal disease AND NOT hypertension", the database has to find all 94,768 documents that are not in the hypertension index and only then merge that set with the results of the renal disease portion of the query.[33]

Until this point, we have described **Boolean searches**, which means that either a document meets criteria or it does not. In practice, however, we usually get a list of results which are **ranked** from most likely relevant to least likely. There are several methods of doing this. In the case of a complex query (e.g. "asthma AND renal AND failure AND creatinine"), there may be very few documents which satisfy all the Boolean requirements. Instead, documents may be ranked by the number of matches they have with the query. Even when all the terms match, the optimizer may assign higher rank to documents which include the word multiple times, or include it in the first few words of the document. Words that are relatively rare may be given more weight in ranking because they are more specific.

32 Suomela BP, Andrade MA. Ranking the whole MEDLINE database according to a large training set using text indexing. BMC Bioinformatics. 2005; 6: 75.

33 It is also possible to start with the 2343 documents which contain renal disease and then weed out those that do not carry the hypertension tag, however, this can also create additional complexity which is beyond the scope of this book. For much more information, see https://docs.oracle.com/database/121/TGSQL/tgsql_optcncpt.htm

In summary, users start with **information needs**, from which they compose **queries**. They search a body of knowledge known as a **corpus** for individual **documents**. These documents are **tokenized** and stored into an **index** for rapid **retrieval**.

The goal of an IR system is to find the right documents without additional clutter. There are several measures of IR success: **Precision** (positive predictive value) measures the percentage of returned documents that are relevant to the query; **recall** (sensitivity) measures the percentage of all relevant documents in the corpus that were found. **Fall-out** (false positive rate) is the proportion of irrelevant documents that are retrieved. The F_1 score (also called the F-measure or F-score) is the harmonic mean of precision and recall. An ideal F_1 score is 1.0.

For example, suppose you have a corpus of 100 documents, and 24 of them are relevant to your search. Now, suppose you run a query that returns 20 of the relevant documents as well as 6 additional (irrelevant) documents. Calculate the precision, recall, fallout and F-score.

First we create a 2 × 2 matrix

	RELEVANT	NOT RELEVANT
Retrieved	20	6
Not retrieved	4	70

Precision = 20/(20 + 6) = 77%
Recall = 20/(20 + 4) = 83%
Fall out = 6/(6 + 70) = 8%

$$F_1 = 2 \bullet \frac{precision \bullet recall}{precision + recall} = 2 \bullet \frac{0.64}{1.6} = 0.8$$

2.2.5.1 Search Skills

Although IR generally refers to the search of unstructured data, most searches rely on **metadata** (i.e. data about the data) which can be used to further improve search results. Often, this will include file creation time or author or ownership. In the case of MEDLINE, metadata includes author, journal, publication date, article type and many other data points which can be individually searched in order to get more specific results. In addition, authors supply a list of keywords to assist other researchers in finding their articles. At the same time, independent indexers from the National Library of Medicine will assign headings from the **Medical Subject Heading (MeSH)** dictionary to each article. MeSH headings are hierarchical, so that related entities can be found by traversing the tree. A thesaurus of synonyms for MeSH headings is continually updated, so that a search for "asthmatic bronchitis" or "asthma" or "reactive airways" will all map to the same MeSH heading.

Assigning standardized MeSH headings also obviates the need to re-index articles when new terminology becomes available. For example, suppose a researcher describes a case of Reiter's Syndrome. Years later, the term becomes deprecated in favor of Reactive Arthritis. As long as the MeSH mappings are kept up to date, a modern researcher will still be able to find the older article.

2.2.5.2 Critical Analysis of Biomedical Literature

The skills required to critically analyze biomedical literature are the same as those for informatics literature. See Sect. 1.1.3.2 for more information.

Scott Mankowitz

2.3 Clinical Workflow Analysis, Process Redesign, and Quality Improvement

CHAPTER OUTLINE

2.3.1 METHODS OF WORKFLOW ANALYSIS

A **workflow** is a collection of processes designed to accomplish a specific goal. **Processes** are made up of **tasks** which are performed by different people. Different departments within an organization will have different workflows. For example, the patient accounts department will have its own processes for registration, billing, coding and preauthorizations. Meanwhile, the department of surgery will have a process for recruiting, orienting, credentialing and paying surgeons.
Types of workflows[1]

1. Inter-organizational. Work that spans more than one organization, such as when a hospital notifies the local public health agency about a communicable disease.
2. Organizational. Work that exists only within the organization or department, such as patient registration.
3. Individual. The flow of thoughts that an individual has while completing his portion of a workflow.

The implementation of an electronic health record (EHR) is a complex and disruptive process. Prior to going live, many organizations will analyze their current workflows so that they can be better poised to adapt to new technology.

There are four basic steps to workflow analysis [2]

1. Determine the organization's goals and objectives from senior management. This is a good first step to figure out

1 Kushinka SA. Workflow Analysis: EHR Deployment Techniques. California Healthcare Foundation 2011
2 Sheehan B, Bakken S. Approaches to workflow analysis in healthcare settings. Nurs Inform 2012:371

which processes are important to the business' success and which are not. These goals may not be immediately obvious to every worker.[3]

2. Delineate the roles of each employee and what sort of tasks he/she does for the business. Since many processes begin in one department and end in another, a multidisciplinary team is required to lead this endeavor. One approach is to trace a patient's entire interaction with the facility from the first interaction with the facility to the last, such as scheduling an appointment, check-in, registration, treatment, discharge and billing. In facilities transitioning from a paper-based system to an electronic system for the first time, it can be beneficial to collect all the paper forms that the department uses as a template to assess workflows.
3. Calculate the time, energy, resources and cost for each task. This process will help identify which processes are successful and which are obsolete and could be improved or replaced. Commonly, employees will identify processes which are difficult for them. These are the processes best suited for analysis.
4. Make recommendations for improvement. Recommendations should be vetted by workers as well as management to ensure that they are both doable and aligned with the organization's strategic goals.

Process maps are flowcharts which document the way a process works. They answer important questions such as: How efficient is the current processes? What are its challenges? Where are the choke points? What are the common variations of this process? When does this process fail? Which tasks are most error-prone or failure-prone?

When the process is depicted visually, it can be easy to identify when the exact sequence of tasks is important and when tasks can be run in parallel; it can identify bottlenecks and simple repeated tasks that are candidates for automation (Figures 5-1 and 5-2).

Over time, staff members develop shortcuts and workarounds and actual practice evolves away from the process maps that have been established. As a result, there may be different practices for the same process between different departments or even different units of the same organization. These variations may be important indicators of how a process may be optimized. Suppose, for example, that during a workflow analysis, it is discovered that the nurses on 3-Main rarely enter orders for routine tests. Meanwhile, on 3-North, they always

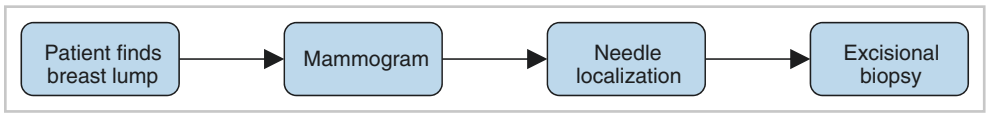


FIGURE 5-1

Example of process map. This process is linear and must occur in this sequence (e.g. biopsy must be done after needle localization)

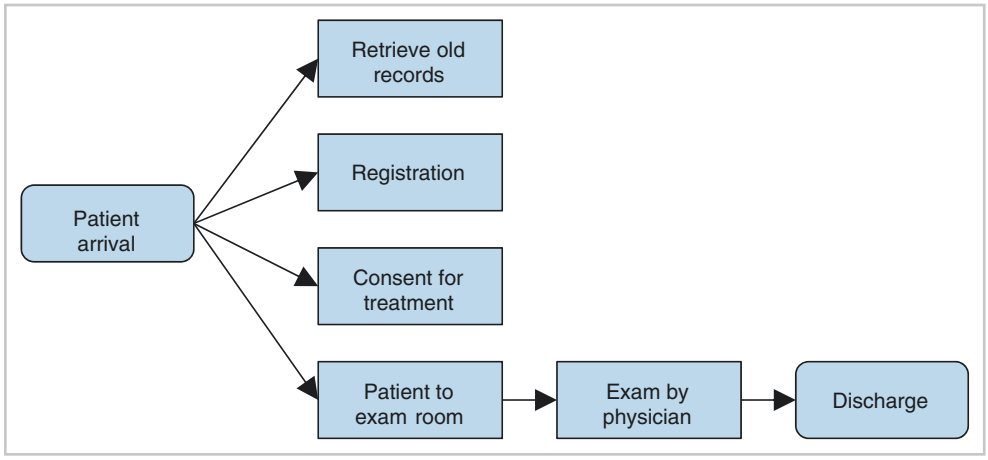


FIGURE 5-2

Example of a more complex process map. This process has several tasks which depend on patient arrival, but the order of the tasks is not important. For example, a patient could have registration before consent for treatment. The exam by physician represents a bottleneck because it relies on a limited resource (the physician) and is required for discharge

3 For example, the leadership of an outpatient radiology center may decide that its strategic goal is to achieve meaningful use. For this reason, it may select an EHR which sacrifices ease-of-use for thoroughness.

do. After some investigation, it turns out that the unit clerks on 3-Main have trained themselves to enter orders, while those on 3-North have not. Since order entry falls within the unit clerk's scope of practice and they are a less costly resource than nursing, the new workflow will include order entry by unit clerks across the institution.

The transition from current workflows to future workflows (which include the use of a new technology) must be carefully planned. In the case of an EHR, it is important for the team designing the new workflows to be intimately familiar with the EHR functionality, in order to utilize it to the fullest. When planning new workflows, all sorts of details must be considered, such as where documentation will be completed. Some inefficiencies may only become evident after implementation. For example, during a post-implementation analysis, it is found that physician assistants in the Emergency Department (ED) are still carrying around sheets of paper with patient labels on them to keep track of their patients. This indicates that the tracking system was not meeting their needs, and was not adding value to their work.

The creation of new process maps can be beneficial beyond the incorporation of new technology. For example, it can be used in new employee orientation, providing a visual description of each person's role and responsibility; since the workflow analysis process invites members from various departments, it can be used as a team building tool. Participants in this process will have greater understanding of their own roles as well as respect for the roles of others. Since the map explains the performance expectations, it can inform Human Resources on appropriate job descriptions and evaluation rubrics.

Process mining is a specific method of workflow analysis which involves reviewing the event log of an information system to see how various tasks are carried out. By studying the order in which tasks are undertaken, and which users are doing them, one can better understand the business processes. It is especially useful to examine which tools are bypassed and which tools are used in unexpected ways, as it provides insight into ways to improve the process itself.

2.3.2 PRINCIPLES OF WORKFLOW RE-ENGINEERING

Workflow re-engineering, also known as **Business Process Reengineering** (BPR) encourages businesses to fundamentally rethink how they do their work, in order to achieve greater efficiency, decrease costs, improve customer service and augment quality. In most cases, this involves the introduction of new technology.

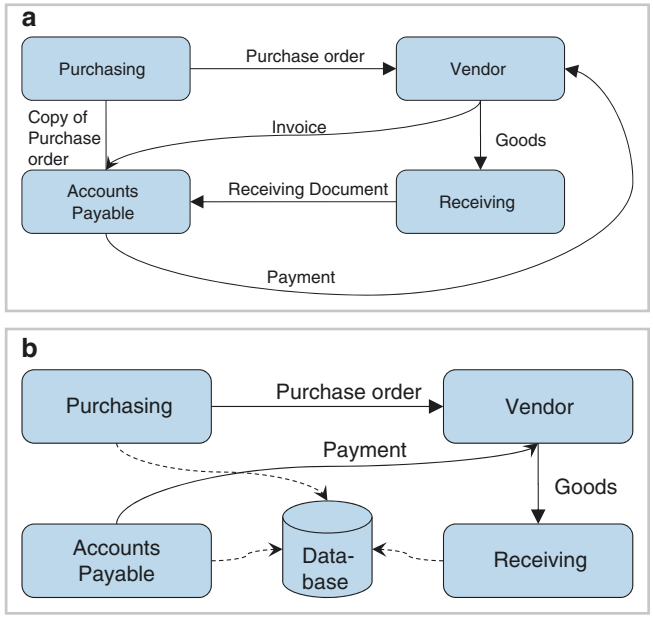
Technology alone is not enough. Many companies invest in computer systems only to see disappointing results, mostly because they use the new technology to automate the old ways of doing business. They leave the rules in place but use computers to speed things up. Only by analyzing workflows and reorganizing them from the ground up can useful gains be had. Reengineering can not be accomplished piecemeal. It has to be done all at once in order to be successful.

When reviewing workflows, there are some common threads.

1. Many current workflows are based on assumptions that are no longer valid. These may be based on outdated information or just peculiarities of personal preference.
2. There are many control systems, some with minimal value. In healthcare, there are elaborate systems for imposing control on individual workers, largely owing to the enormously varying levels of education and responsibility in the system. Many healthcare workers fear that they are less likely to be chastised for insubordination than they are for exceeding their scope of practice, even if they make the correct decision.
3. Handoffs are problematic. When work is handed off from person to person or from department to department, there are inevitable delays, loss of information, misunderstandings and other errors.

FIGURE 5-3

(**a**) Old process for purchasing goods at Ford Motor Company. (**b**) Modified process for purchasing goods at Ford Motor Company



4. There is an unfortunate habit of patching problems instead of fixing them. For example, a clinic discovers that its customer satisfaction scores are dropping. In response, it hires a concierge to oversee patient happiness. In essence, it creates a new role which is overlaid on top of the existing framework. As a result, there is more bureaucracy and greater costs. A better solution is to reevaluate the processes which led to poor satisfaction in the first place to see how they can be improved or streamlined.

Consider the following example[4]:

The Ford Motor Company wanted to redesign its purchasing operation. The current workflow is as follows. Purchasing creates a purchase order and sends one copy to the vendor and one copy to accounts payable. The vendor ships the goods to receiving and sends an invoice to accounts payable. When receiving acknowledges the goods, they send a receiving document to accounts payable. When all three documents are together (purchase order, receiving document and invoice), payment is sent out. If any of the documents were incomplete or missing, payment was held. Although the process worked overall, it required a large staff in accounts payable to collate and coordinate all the documents (see Figure 5-3 (a)).

In the redesign, the paper system was abolished and replaced with a database. Purchasing sends an order to the vendor, who ships the goods. Since the purchase order contains all the relevant information about the purchase, the vendor's invoice is no longer produced. When the goods arrive, the receiving clerk acknowledges the receipt in the database which automatically authorizes payment. The receiving document is no longer created. This process modification allowed Ford to trim its accounts payable staff by 80% (see Figure 5-3 (b)).

Not all reengineering is so neatly architected. Some arises organically. Consider the newspaper industry before and after the advent of the internet. In the traditional (newspaper) model, the content creators (e.g. columnists, photographers, reporters, etc) would submit their work to the editors. The editors would evaluate the submissions. Some would be rejected, some would be sent back for modification and some would be sent forward to the printer. Printed articles would be sent to distributors and then, ultimately to the readers. (See Figure 5-4a). Since newspapers are published (at most) once per day, a breaking story may take up to 24 hours to reach the reader. Readers who had comments would write a letter to the editor, who may publish it or simply forward it to the author. Most academic journals are published monthly and follow this direction.

In the modern information model, the content providers may submit their work to editors if they choose, but often post directly to the internet (in a blog, for instance). Their work is immediately visible to readers who may, in turn, publish comments immediately (Figure 5-4b).

4 Hammer M. Reengineering Work: Don't Automate, Obliterate. Harvard Business Review 1990. 68(1/2):

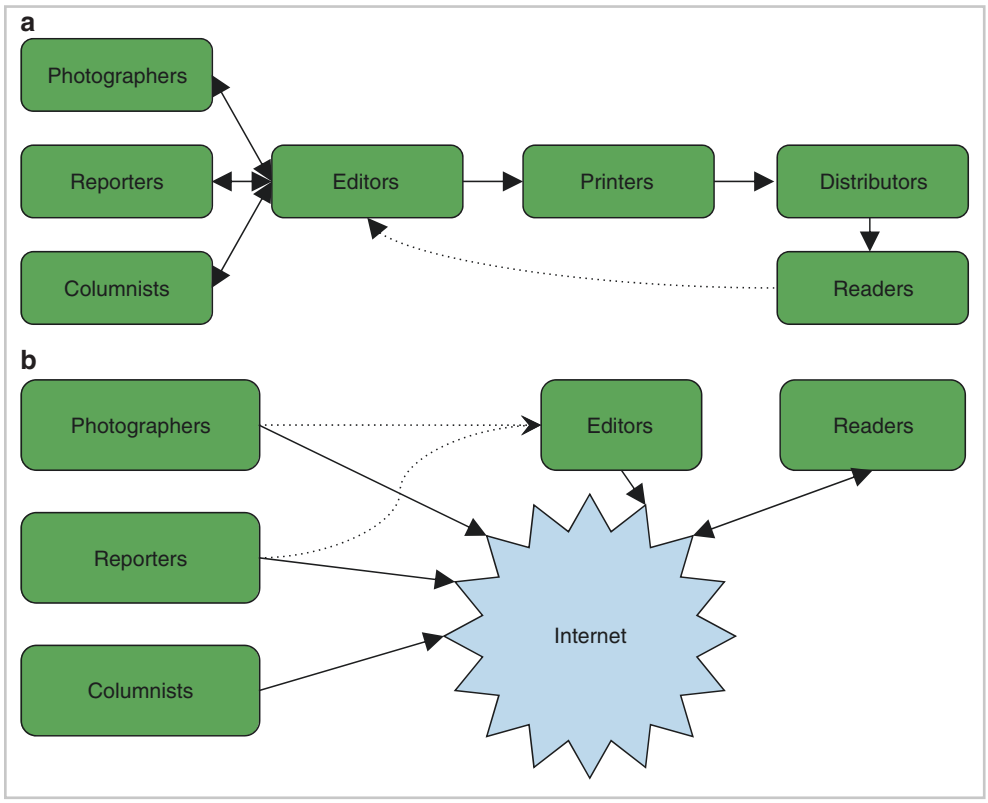


FIGURE 5-4

Traditional (**a**) workflow for newspapers compared to a more modern, internet-based (**b**) workflow

According to Hammer, several principles of reengineering have evolved.

Organize around outcomes, not tasks. Instead of looking at the six or seven things that must be done in order to complete a task, look at the final outcome to figure out how to get there. For example, a 25-year old patient is recovering from an appendectomy the day before. A hospital policy states that discharged patients are escorted to the hospital entrance by wheelchair to ensure that they have safe transportation home. In order to leave, the following things must happen: the doctor orders the discharge, the nurse alerts patient transportation, the transporter locates a wheelchair, the family notifies the nurse that they are present, the transporter brings the patient to the door, and the family accompanies the patient to their vehicle. One way to revise this process is for the nurse to recognize that the desired outcome is a safe discharge. In this particular case, the patient is low risk for falls or other bad outcome and may be safely discharged from his room, thereby obviating the additional steps.

Have those who use the output of the process perform the process. Healthcare benefits from extreme specialization, but is also hindered by it. Consider the case of a young woman who presents to the Emergency Department with first-trimester bleeding. The emergency physician wants to know if the bleeding is a result of an ectopic pregnancy (a life-threatening condition) or a miscarriage (generally not life-threatening). Traditionally, he orders an ultrasound, which requires the skills of an ultrasonographer as well as a radiologist. In many EDs today however, it is the emergency physician himself who is performing the ultrasound as well as interpreting its results and making decisions based on his findings.

Subsume information-processing work into the real work that produces the information. Most hospitals strive to maximize their adherence to core measures.[5] However, the person responsible for tallying the numerator and denominator is rarely the same person as the one

5 Core measures, as delineated by the Joint Commission and the Centers for Medicare and Medicaid services are simple arithmetic scores which reward accomplishment of important clinical services. For example, the AMI-4 measure computes the percentage of smokers with an acute myocardial infarction (AMI) who were given smoking cessation advice. Greater scores are associated with better care and better reimbursement.

performing the intervention. A potential process improvement would combine the nursing work and statistical tasks into one.

Treat geographically dispersed resources as though they were centralized. For example, a health system has seven clinics spread around the city. Although each clinic has its own laboratory, the laboratories have varying capabilities, and each clinic offers a limited set of clinical tests. By coordinating results into a database and adding a courier service to transport specimens, each clinic can offer every test. The fact that one clinic lacks certain testing becomes invisible and irrelevant to the ordering provider.

Link parallel activities instead of integrating their results. Patients with elusive medical complaints often travel from doctor to doctor while searching for a diagnosis. Depending on time constraints, individual doctors may or may not know what tests or hypotheses have been advanced by other professionals, often resulting in uncoordinated efforts and duplicate testing. By implementing a health information exchange, these parallel visits can be linked so that each provider will know what others have done.

Put the decision point where the work is performed, and build control into the process. Computed tomography (CT) scans often employ iodinated contrast medium, which can be harmful to patients with renal insufficiency. When a doctor requests a CT scan, he may not know the patient's kidney function, and thus must order serum chemistry first. After the chemistry test is resulted, he must place the order for the CT scan, with or without contrast as indicated, thereby incurring a delay of hours or days. One way to improve this process is to apply an expert system which enables the CT technologist to review the chemistry result himself and perform the CT scan as required.

Capture information once and at the source. Although laboratory results are normally transferred to an information repository automatically, vital signs tend to be recorded by hand, written on slips of paper and later transcribed into the EHR. Directly transmitting information to the EHR would save time and reduce error.

2.3.3 QUALITY IMPROVEMENT PRINCIPLES AND PRACTICES

The US Agency for Healthcare Research and Quality defines quality health care as "doing the right thing, at the right time, in the right way, for the right person—and having the best possible results."[6] This statement highlights both process and outcome. **Process** is the way that an activity is done, while **outcome** is the result. For example, following Advanced Cardiac Life Support (ACLS) guidelines is a process, while survival to hospital discharge is an outcome. The hope is that improving processes will improve outcomes.

All quality improvement paradigms are an iterative process designed to modify a system so that it no longer fails. There is much crossover between paradigms and it can be difficult to tell them apart. Practical approaches tend to borrow aspects from different quality improvement methodologies.

Total Quality Management

Total Quality Management (TQM) is one of the earliest quality-oriented philosophies to have transitioned from the business and manufacturing world into healthcare. It has three focal points: Continuous Quality Improvement (CQI); Customer Service; and Teamwork.

Proponents of CQI believe that opportunity for improvement exists in every process in every implementation. CQI recognizes healthcare as a process and aims to improve systematic problems with less focus on the individual. For example, a hospital is concerned about wrong-patient, wrong-site surgery. Instead of blaming individual doctors or nurses, it implements a time-out procedure which is systematically followed before any surgery.

Creating a patient-focused environment can improve quality because it encourages healthcare providers to listen to the patients' needs and desires. In this way, patients can be enlisted to help ensure their own quality.

6 For more information on AHRQ's impression of quality, see https://archive.ahrq.gov/consumer/qnt/qntqlook.htm

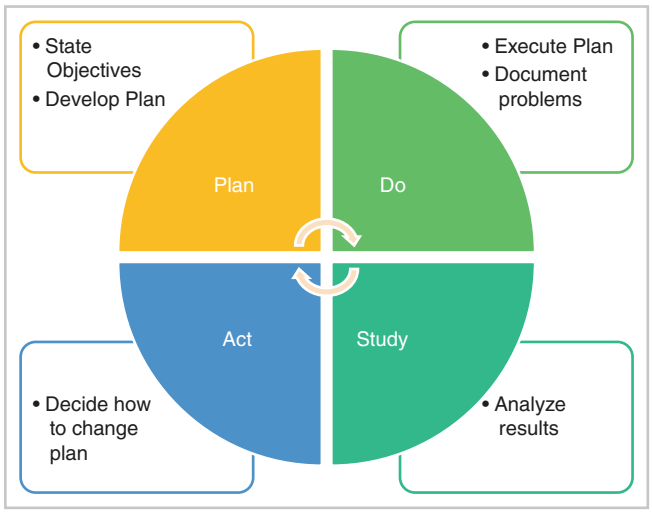


FIGURE 5-5

Plan Do Study Act (PDSA) is the most common quality improvement methodology in healthcare

Teamwork means that all employees are involved in quality improvement. By incorporating more voices and more opinions into the quality process, the systematic issues can be addressed and corrected.

Plan, Do, Study, Act

The most common QI paradigm in healthcare is PDSA[7]: Plan, Do, Study, Act. The process begins with the planning phase, deciding what kinds of interventions are most likely to be effective. They are implemented in the Do phase. Variations from the initial plan are called defects. After implementation, the interventions are analyzed during the Study phase to see if they had the expected outcome. During the act phase, the group determines what was successful, what was not successful and how the intervention should be modified. This leads back to the planning phase, and the cycle repeats. Commonly, each cycle takes weeks to months, based on the availability of the members of the quality team. However, cycles as short as 1 day have been reported (Figure 5-5).

Six-Sigma

Six-Sigma was developed by Motorola to decrease process variation and prevent defects. It is so named because the goal is to have defects occur at a rate that is six standard deviations (sigma) from the mean, or approximately 3.4 defects per million opportunities. The six-sigma steps are abbreviated DMAIC: define, measure, analyze, improve and control. The definition step involves defining the problem, creating a project charter, selecting the team members, picking the success criteria and agreeing on a deadline. Measurement involves choosing a method of data collection and creation of upper and lower acceptable bounds. These measures are incorporated into a control chart (see Sect. 4.4.5.3). In the analyze step, the data are reviewed and defects are identified. During the next step, improve, corrective actions are debated and selected. The final step, control, involves creating policies and procedures to crystalize the new methods into routine habits. Significantly, it also involves putting controls in place to prevent reversion to the old methods (Figure 5-6).

LEAN Methodology

Lean, developed by Toyota in the 1950s is a process improvement technique that seeks primarily to remove non-value-added activities or *muda* (Japanese for "waste"). There are seven categories of waste. Although these were originally used in manufacturing, some of these categories apply to healthcare: (1) Overproduction, such as ordering unnecessary tests, procedures or medications, or overstaffing a department; (2) Waiting, such as when patients sit idle in waiting rooms or exam rooms, or when staff members wait for patients to arrive; (3) Transporting, such as when supplies are stored in a location other than where they are

7 Varkey P, Reller K. Basics of Quality Improvement. Mayo Clin Proc 2007; 82(6):735–739.

FIGURE 5-6

The Six Sigma methodology contains five steps: Define, Measure, Analyze, Improve, Control

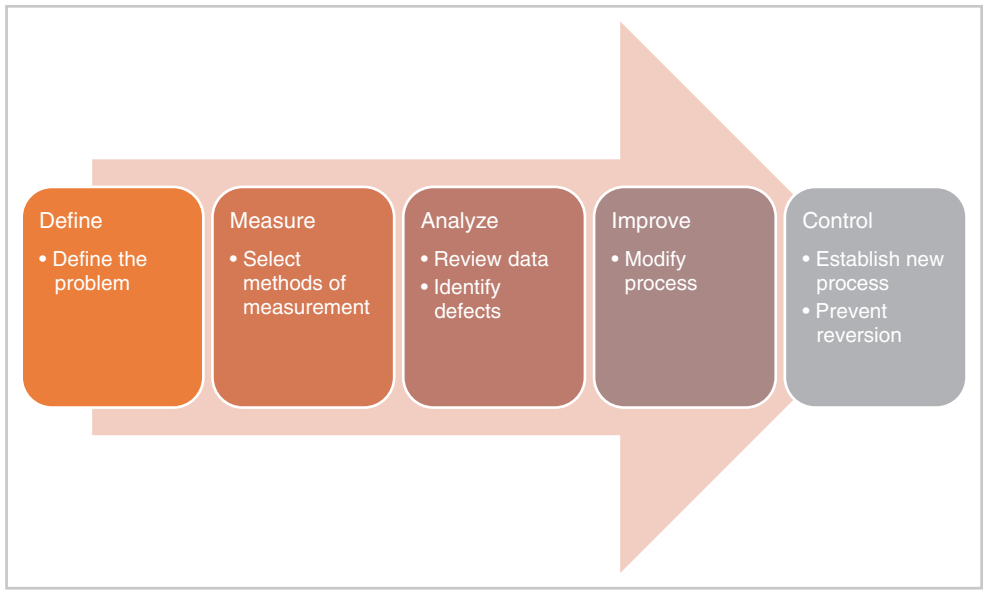


TABLE 1-1

VALUE STREAM MAP (TABULAR FORM) FOR EMERGENCY DEPARTMENT INTAKE

STEP	INPUT	OUTPUT/THROUGHPUT	RESOURCES	TIME
1—Arrival	Patient	Greeted, put in waiting room	Waiting room furniture	5 min
2—Call to triage	Patient	Brief history, triage assessment, vital signs	Nurse, triage room	8 min
3—Return to WR	Patient	Returns to waiting room	Waiting room furniture	3 min
4—Call to registration	Patient	Demographics and billing information obtained	Registrar, registration room.	10 min
5—Return to WR	Patient	Returns to waiting room	Waiting room furniture	3 min
6—Call to see MD	Patient	Examined by physician	Physician, ED exam room	10 min

used, or when patients are moved to different parts of the healthcare facility to get studies; (4) Inappropriate processing, such as ordering complex tests when a simpler test would have sufficed, or adding administrative work (like completing forms) which are not needed clinically; (5) Unnecessary inventory, such as storing medications that will likely expire before they are used, or using pre-printed forms when on-demand or electronic forms are available; (6) Excess motion, such as when the facility's physical plant requires excess movement from one place to another in order to achieve common, simple tasks; and (7) Defects, such as misdiagnosis, malpractice or other preventable misadventure.

The key to identifying waste is to create a **value stream map** (also called an **end-to-end system map**) which shows all the inputs, throughputs and outputs of a process. The value stream map includes all departments and organizational units that impact on the process along with the time and resources required. By closely analyzing such a map, waste can be eliminated.

For example, the diagram below shows a typical Emergency Department flow. The patient arrives, goes to the waiting room, sees the triage nurse, returns to the waiting room, sees the registrar, returns to the waiting room and finally is called into an exam room to be seen by the doctor. After analyzing this value stream map, some *muda* may be identified (Table 5-1 and Figure 5-7).

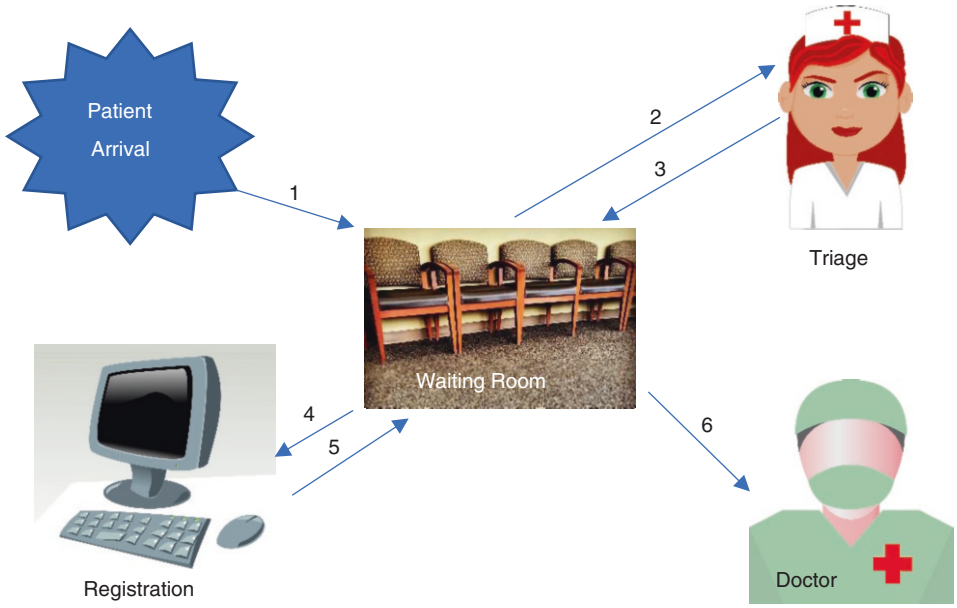


FIGURE 5-7

Value stream map of patients in the Emergency Department Intake including six steps: (1) Patient arrives; (2) Patient called from waiting room to triage; (3) Patient returns from triage to waiting room; (4) Patient called to registration; (5) Patient returns from registration to waiting room; (6) Patient called to see doctor

Part III
Health Information Systems

The knowledge and skills that enable a clinical informatician to participate in the development or selection of an information system for clinicians; prepare clinicians prior to implementation and support them during implementation and ongoing operation of a clinical information system; and evaluate the effectiveness of a system in meeting clinical needs.

Scott Mankowitz

3.1 Information Technology Systems

CHAPTER OUTLINE

3.1.1 COMPUTER SYSTEMS

The study of informatics must begin at the most elemental level. Only by understanding computer systems can we progress to understanding how they work and what they can do.

3.1.1.1 Programming

Programming is the technique by which we tell computers what we expect of them. From a physical (electronic) standpoint, all information in the computer must be represented by a series circuits which are either "on" or "off". For convenience, we usually refer to these values as 1's and 0's (binary). By convention, the computer reads a series of binary numbers (usually a multiple of 8) which correlates to a specific instruction. Each of these instructions tells the computer to perform some simple task. Most of these instructions involve fetching data from memory, storing data into memory or performing some kind of mathematical operation. By combining thousands or millions of very simple operations, we can instruct the computer to perform useful and interesting tasks.

For example, the following is a very short program written in Intel x86 **machine code** which adds the numbers 23 and 44.

MACHINE CODE	WHAT IT MEANS
01100110101110000001011100000000	Load the number 23 into a register called ax
01100110101110110010110000000000	Load the number 44 into another register called bx
01100110000000000111011000	Add the two numbers in ax and bx

When written on paper, binary notation can be quite verbose. For convenience, the above program can be expressed in

Box 6-1: Hexadecimal Notation

When humans talk about numbers, we use base 10 (decimal). Computers store data in base 2 (binary). Each **B**inary digi**IT** is called a **bit**. Eight bits compose one **byte**. Programmers often use base 16 (**hexadecimal**) to express numbers because it is more compact than binary. Since 16 is a power of 2, an 8-digit binary number can be represented as a 2-digit hex number. Longer strings of bytes are measured in multiples of 1024 (2^{10}). For example, a string of 1024 bytes is called a **kilobyte**; 1024 kilobytes is a **megabyte**, and so on.

DECIMAL	BINARY	HEX
1	0000 0001	01
2	0000 0010	02
3	0000 0011	03
4	0000 0100	04
5	0000 0101	05
6	0000 0110	06
7	0000 0111	07
8	0000 1000	08
9	0000 1001	09
10	0000 1010	0A
11	0000 1011	0B
12	0000 1100	0C
13	0000 1101	0D
14	0000 1110	0E
15	0000 1111	0F
16	0001 0000	10

hexadecimal notation (base 16). Note that the information is exactly the same, only the presentation is different. See Box 6-1—Hexadecimal Notation.

```
66B8170066BB2C006601D8
```

Although the computer understands this code natively, it is very difficult for us humans to parse. In order to make programming easier, computer scientists created **assembly language** which uses words and abbreviations in place of the long strings of numbers. The programmer writes the program in assembly language while another program (called an **assembler**) translates it into machine code.

In the code snippet below, the left column represents the machine code while the right column is assembly language. To the far right are human-readable comments which make the code easier to understand (The assembler ignores the comments when it produces machine code.)

```
0:     66 b8 17 00     mov ax,0x17     ;move the number 23 (17 hex)into
                                       register ax
4:     66 bb 2c 00     mov bx,0x2c     ;move 44 (2c hex) in register bx
8:     66 01 d8        add ax,bx       ;add the two registers ax and bx
```

As the complexity of programs grew, it became impractical to write programs in assembly language, and higher-order languages were created. By the late 1950s, IBM had developed a language called **FORTRAN** (FORmula TRANslator). Compared to assembly language, FORTRAN was easier to read, easier to write, and much easier to debug. Instead

of mapping the computer's machine code into short words and mnemonics, FORTRAN was a completely new language with its own syntax and grammar. Below is an example of an FORTRAN program in the f90 dialect which prints the result of an arithmetic problem.

```
program addnumbers
print *, 23*55+33*155
end program
```

That's much easier to read, even for non-programmers. Computers, however, don't natively understand Fortran. Instead, yet another program, called a **compiler**, is needed to convert the FORTRAN program (known as **source code**) into machine code. In compiled languages, the entire program has to be complete before the compiler can begin. Only after compilation is finished can the program be run.

It is important to note that while assembly language is simply a human-readable form of machine code, FORTRAN is its own language. There is no direct 1:1 mapping between FORTRAN and machine code as there is with assembly language. In fact, if two different FORTRAN compilers are given identical source code, they can produce entirely different machine code. In some cases, a good compiler can make up for a sloppy programmer by applying optimizations so that the code runs more quickly.

Sometimes, programmers would like to examine and change a program *while* it is running. This desire lead to the creation of the **interpreted language**, where each line of the program is passed through an **interpreter** for execution, and only the part of the program that is immediately needed will be translated. The program can be stopped and started whenever necessary. The cost of this flexibility is speed. Compiled languages tend to run much faster. Probably the most famous interpreted language is BASIC (Beginner's All-purpose Symbolic Instruction Code) which appeared on most home computers in the 1980s. Interestingly, Visual Basic, created by Microsoft, is a compiled language.

Today, there are more than 8000 established computer languages with widely varying purposes. There has been great progress in the development of both interpreters and compilers, especially with the advent of Just-In-Time (JIT) compilers, so that both speed of execution and real-time mutability can be had with either compiled or interpreted languages.

3.1.1.2 Data and Control Structures

Control Structures are the linguistic mechanisms that programmers use to tell a computer what to do in a given circumstance. The most simple control structure is the **if/then/else** block. Suppose you want the computer to address a female user using an age-appropriate greeting using the following rule: a person under age 10 is a girl, a person over age 40 is a lady and everyone else is a woman. In Visual Basic, this logic can be expressed as the following program. (Note: The command **Console.Write** prints text to the screen)

```
If age < 10 Then
    Console.Write("Girl")
ElseIf age > 40 Then
    Console.Write("Lady")
Else
    Console.Write("Woman")
End If
```

Another common construct is the **loop**, which executes code over and over. In the following Visual Basic program, the computer is instructed to print the word "cat" 100 times. In Basic, this kind of loop is called a **for/next** loop because it begins with the

word **For** and ends with the word **Next**. All of the instructions between the words **For** and **Next** are repeated.

```
For counter = 1 To 100
    Console.Write("cat")
Next
```

This program starts by setting a counter to 1 and then increasing that counter until it gets to 100. Each time the loop is run is called an **iteration.** The counter, which changes its value during the operation of the program, is called a **variable**. When using a placeholder for a value that does not change, it is called a **constant** or sometimes an **invariant.** Constants are commonly used in programs for numbers or strings that are unlikely to change. Some constants are even built into the language. For example, in Javascript there is a constant called Math.PI which equals 3.141592653589793.

In some cases, the programmer does not know exactly how many times to run a piece of code. The **while loop** instructs the computer to repeat a process until some condition is met. In this case, all the instructions between **While** and **End While** are repeated. The for/next loop above could be rewritten as

```
counter = 1
While counter < 100
    Console.Write("cat")
    counter = counter + 1
End While
```

Note that the instruction **counter = counter + 1** tells the computer to increase the value of counter by one, just like the for/next loop. The loop runs over and over (i.e. iterates) until the value of **counter** reaches 100.

Control structures can be incredibly powerful. Consider the following code that might be used to control an insulin pump[1]:

```
If (glucose < 60) Then
    ' Danger: Hypoglycemia
    Activate_Alarm_Bell()
    Page_Covering_Physician()
ElseIf (glucose > 60 And glucose < 180) Then
    ' No action required
ElseIf (glucose > 180 And glucose < 400) Then
    ' Use a formula to determine insulin dosage
    ' Insulin dose = 3.2 units for each 100 mg/dl glucose over 140
    Inject_Insulin(3.2 * (glucose - 140)/100)
ElseIf (glucose > 400) Then
    ' Danger: Hyperglycemia
    Inject_Insulin(10)
    Activate_Alarm_Bell()
    Page_Covering_Physician()
End If
```

Functions (or methods) are used to encapsulate pieces of code that are used multiple times. In the example above, `Inject_Insulin` and `Activate_Alarm_Bell` are examples of functions. In general, functions can take a certain number of arguments which provide the function with more information on what to do. In the above program, `Inject_Insulin`

1 There are bugs in this "program." Can you find them? Hint: what would happen if the blood glucose were exactly 60?

takes the number of units of insulin as an argument, so that `Inject_Insulin(10)` would tell the program to inject 10 units of insulin. Functions can also provide a return value. Consider the following Visual Basic function:

```
Function Words_In_Book(pages As Integer, words_per_page As Integer) As Integer
    Return pages * words_per_page
End Function
```

This function may be useful to figure out how many words there are in a book, given the number of pages and the number of words per page. The keyword **return** means that the function gives that number back to the calling program. For example, suppose our book had 200 pages with 450 words per page. We could use our newly defined function like this:

```
Console.Write("The book has")
Console.Write(Words_In_Book(200, 450))
Console.Write("words")
```

Every language has its own version of control structures and syntax tailored to make certain tasks easier. While some languages are designated all-purpose (such as C, Java, Basic and others), others are dedicated to a particular purpose. For example, Pascal is a language designed specifically to teach programming; SQL is designed to interact with databases; and R is designed for statistics. In some cases, languages can be designed for one purpose and evolve as needs arise. Both Java and Javascript (ECMAscript) were developed to provide interactivity to web pages. Today, they play significant roles in server-side programming and embedded systems.

An introductory programming course is beyond the scope of this book. A truly great and free reference to learn programming (and many other things) is Khan Academy, www.khanacademy.org.

3.1.1.3 Software Development Methods

Small programs are often written by individual developers, but as application requirements become more complex, the coordination of software teams becomes vital. One of the earliest software development methods is called **waterfall**. This is a sequential method, where each phase has to be complete before proceeding to the next level.

The key components of the waterfall method are arranged in the shape of a waterfall. (See Fig. 6-1).

The waterfall method has its origins in manufacturing, where applying structural revisions later on in production could be difficult or impossible. Usually, up to 50% of the project resources are consumed in the Requirement and Design phases. Once those are thoroughly hashed out, the remainder are spent on implementation (i.e. writing code), verification (i.e. debugging) and maintenance. In fact, this is the central tenet of the waterfall model: a few hours spent thoroughly evaluating requirements and design can save many hundreds of

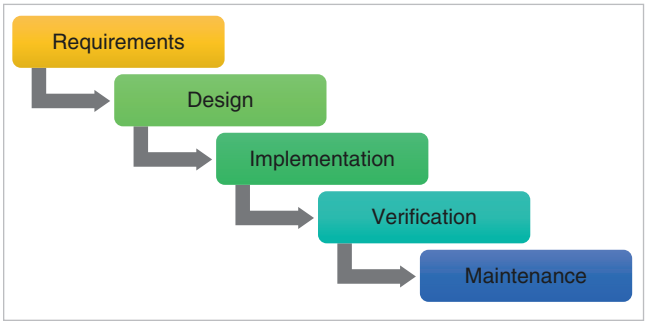


FIGURE 6-1

The waterfall development method

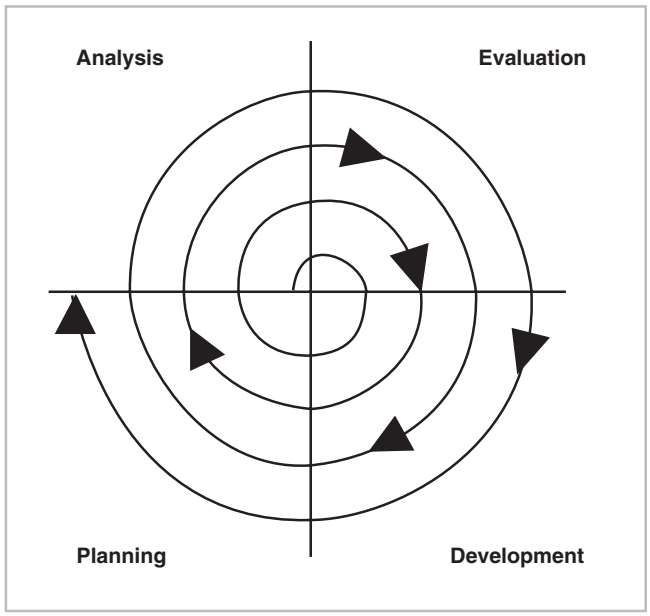


FIGURE 6-2

The spiral model of development emphasizes cyclical iterative risk assessment. Public domain image wikibooks.com. https://commons.wikimedia.org/wiki/File:Software_Development_Spiral.svg

hours later on. An additional benefit is that it provides recognizable and predictable milestones to ensure that a project is running on-time and within budget. Waterfall is often referred to as a **top-down** method because it starts at the design phase and works down towards implementation and maintenance.

Critics of the waterfall method point out that in the real world, project requirements rarely remain stationary.[2] For example, clients may not know what they really want until they have a working prototype in their hands.

This common occurrence lead to another method called **rapid prototyping** where the programmers create representative but incomplete parts of their program so that the client can see what it will look like in advance. Since the user is involved early on, future changes are less likely. Starting with the user interface and working backwards is often referred to as **bottom-up**.

In an effort to combine waterfall and rapid prototyping, Barry Boehm created the **spiral** model which emphasized cyclical iterative risk assessment. Each **cycle** or **iteration** represents only a part of the whole project. It begins with identification of the key stakeholders and their "win conditions" and ends with review and commitment. The cycles consist of four parts: (1) **Analysis** of objectives, alternatives and constraints; (2) **Evaluation** of alternatives and identification of risks; (3) **Development** and verification; (4) **Planning** for the next cycle (Fig. 6-2).

A similar method is **rapid application development (RAD)**. Like spiral, it attempts to reduce project risk by breaking the project into smaller chunks and adhering to strict timelines or **timeboxes**. If the project is not progressing as expected, the requirements are reduced to fit the timebox, instead of postponing the deadline. Emphasis is on keeping users involved in the development process and fulfilling business needs over technical excellence. In distinction to rapid prototyping, RAD involves building completely functional models as opposed to prototypes. RAD also favors computerized development tools such as code generators and object-oriented techniques.

Agile software development is another iterative method that advocates for a more lightweight and people-centric approach. It favors face-to-face, daily interactions between customers and programmers. It welcomes change, even late changes, as long as it doesn't disrupt the planned delivery date. Agile seeks to avoid being trapped by comprehensive documentation and strict planning, and instead stresses short cycles of continuously improving software. **Scrum** and **Extreme Programming (XP)** are variations of the agile theme.

2 Hence the old joke: Walking on water, like writing to a specification, is easy—as long as it's frozen.

In **Test-driven Development (TDD),** before any feature is added to a project, the programmer writes an automated test. After the feature is added and the test passes, it is added to the application's library of internal tests. As the application develops, the code is continuously re-tested to ensure that none of the previous tests fail with the addition of new features. Critics of this process point out that by the time the application is released, it is not uncommon for the testing code to be much larger than the application code.

3.1.1.4 System Integration

In an ideal world, there would be one computer system to manage information for an entire organization. In practice, however, most organizations employ a variety of different systems to accomplish different tasks. In a hospital, for example, the clinical laboratory may be running a Laboratory Information System (LIS), the radiology department may have a Radiology Information System (RIS) as well as a Picture Archiving and Communication System (PACS). Specialized units, such as the Emergency Department or Labor and Delivery may also have their own information systems tailored to their own particular workflow. The decision of what kind of system to use in each department is often both budgetary and political.

One of the greatest challenges in hospital information technology is to enable these disparate systems to communicate. In general, this process is called **System Integration.** In some cases, the integration is very weak and one system is barely aware of another. In tightly integrated systems, there is reliable and verifiable two-way communication. The software used to bind two systems is called an **interface.** In order to create an interface, the vendors from the two systems must agree on the volume and type of data to be transferred.

Vertical Integration is the process of integrating systems based on similar functionality. For example, a RIS may keep track of radiology orders and results, while a PACS may maintain the images. In a vertical integration example, these systems would be tightly integrated with each other, while other systems, such as dietary or patient billing would be more loosely integrated. The tightly integrated units are often called **silos** because they hold information in one place, but don't necessarily share it with other silos (Fig. 6-3).

In some cases, it is desirable for every single system to be able to communicate with every other system. With a small number of systems, this may be a reasonable option,

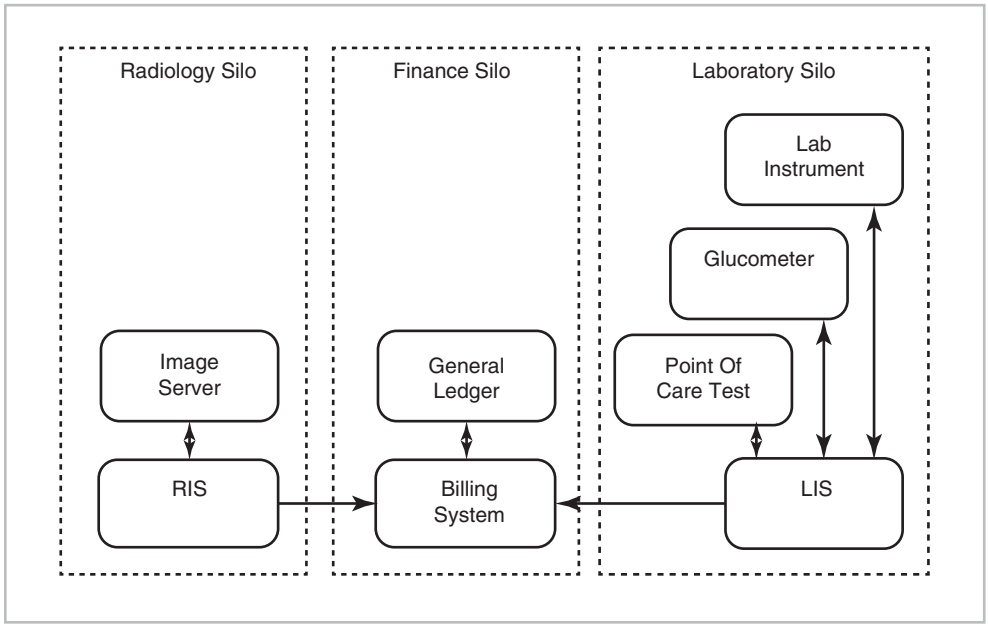


FIGURE 6-3

Vertical integration. Similar systems are located in silos (7 interfaces)

but as the number of systems increases, the number of interfaces increases exponentially. This topology is sometimes referred to as **star integration** because the resulting map looks like an N-pointed star where N is the number of systems. Colloquially, it is called **spaghetti integration** because the links look more like a spilled plate of spaghetti. Although expensive, this method provides the best inter-system communication (Fig. 6-4).

A compromise between the high cost of star integration and the weak communication offered by vertical integration is **horizontal integration**. In this method, an entirely new system is created which is dedicated to providing communication between the other systems. Once this system is created, the maintenance and expansion costs are minimal because each new system only requires a single new interface. Moreover, adding new systems is completely transparent to the existing systems, since systems only consume data that they require. Of course, the cost of the system to coordinate this information (often called a **bus** or **enterprise service bus**) can be quite high (Fig. 6-5).

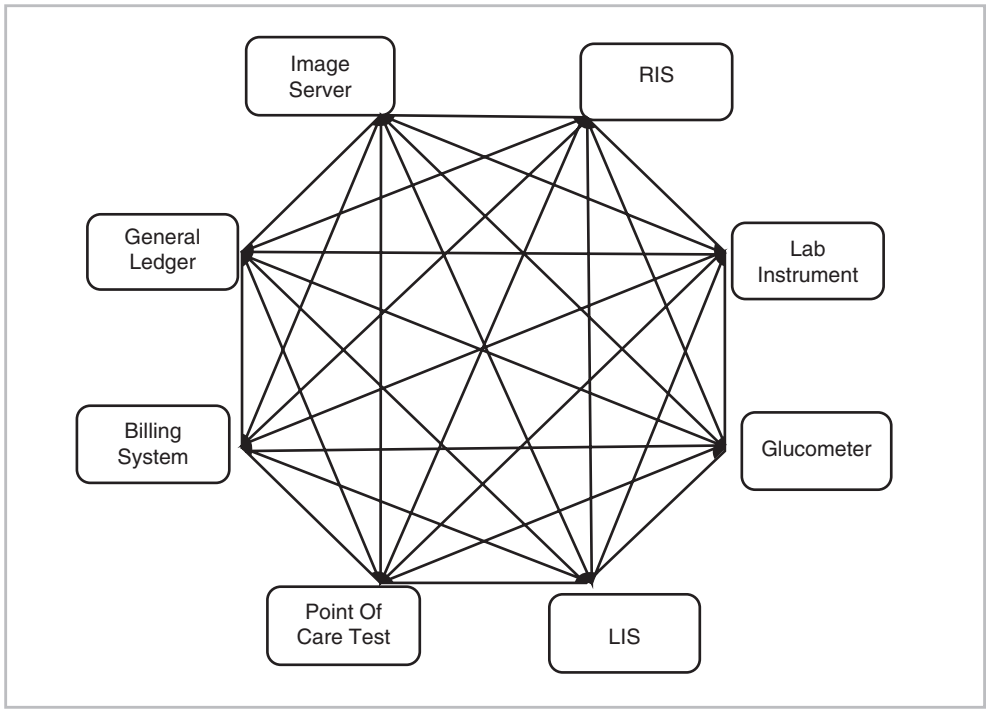


FIGURE 6-4

Star integration. Each system is connected to every other system (28 interfaces)

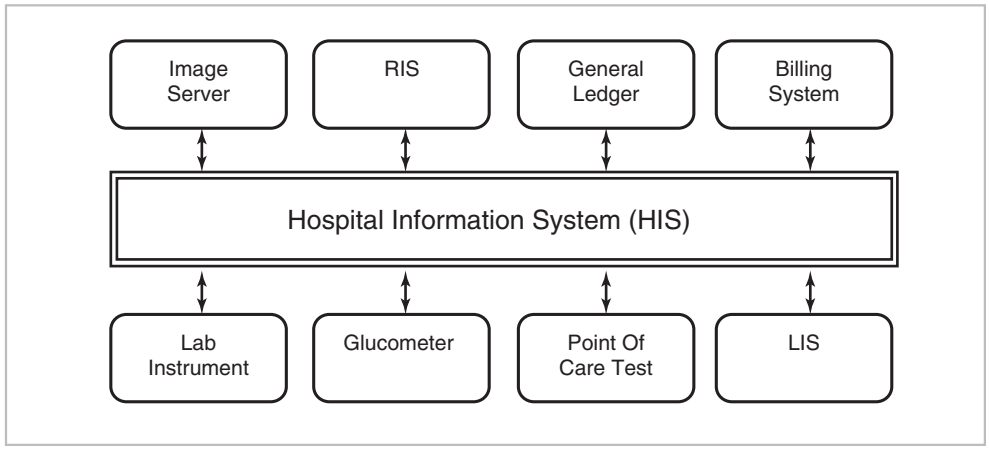


FIGURE 6-5

Horizontal integration. Each system is connected to a bus (8 interfaces +1 new system)

3.1.1.5 Quality

Quality in computer systems (as in medicine) is often difficult to define because of the many factors that need to be taken into account. Some define quality in terms of the usability or reliability of the final product. Others measure structural aspects of the code base. One attempt to describe quality is specified in the International Organization for Standards document 25010 (ISO-25010), which lists the following eight categories.

1. **Functional Suitability**—How well does the system meet the needs of the client? Does it provide correct and complete solutions to the user needs? Can it accomplish all the tasks it is supposed to do? For example, when a hospital or medical practice wishes to attest to meaningful use of a computer system, does it meet all the required specifications?
2. **Performance efficiency**—How well does this system function with a given amount of resources? Is the data store large enough to contain all the patient information required? Will it scale in capacity as the population grows? Does the system access that information quickly enough to be useful on a day-to-day basis?
3. **Compatibility**—Can this system communicate with other systems? (see Sect 3.1.1.4 **System Integration**, above) How expensive is it to build interfaces with other common computer architectures? Can this system coexist with other systems in the same environment?
4. **Usability**—Can an end-user figure this system out? Can he learn it easily? What is the cost of training users to operate this system? To what degree does it prevent errors, or at least prevent user errors from harming patients or other users? Once learned, how many steps are needed to accomplish common, simple tasks?
5. **Reliability**—How often must the system be taken down for maintenance? How often is this system expected to fail? When it does fail, how hard is it to recover?
6. **Security**—With the advent of the Health Insurance Portability and Accountability Act (HIPAA), security is a very important topic in assessing the value of a computer system. Does the system have a sufficient array of access levels so that users can be given exactly the permissions that they need and no others? Does the system prevent unauthorized access to data or computer programs? Is there a reliable authentication process to correctly identify users and prevent one user from masquerading as another? Are there detailed security policies?
7. **Maintainability**—This section is much more apparent to the software developer and may not be easily measured by potential customers. In many relationships, this measure can be boiled down to the question of how well the vendor supports its product. However, in order to make a supportable product, these questions are useful: Is the system composed of discrete components so that changing one aspect does not require modification of the whole system? Can aspects of the system be reused in other systems that require similar functionality? How difficult is it to test the system to make sure it is running correctly? To what extent does the system report internal errors? How are those errors tracked? How hard is it for a service engineer to analyze the errors to make improvements?
8. **Portability**—Can the system be moved ("**ported**") to another architecture or environment? When better hardware becomes available, will it be able to take advantage of the new technology? How difficult is the initial install? Does it use standard installation tools, or does it require special expertise? How well can it replace another product or be replaced by another product when needs change?

3.1.1.6 Information Systems Design and Analysis

When designing a data store, it is very important to make sure that your data architecture matches the data you intend to gather. Let's explore a simple example where a researcher is collecting information on patients for a study. She needs to know the patient's name, phone number, address and pulse rate at various times. We can organize the data in a table as follows (Table 6-1):

TABLE 6-1

PATIENT PULSE DATA

PATIENT ID	PATIENT NAME	PATIENT PHONE	ADDRESS	DATE/TIME	PULSE RATE
0002	Jon Harvey	(201) 555-1212	24 Front St.	11/12/16 11:39	78
0002	Jon Harvey	(201) 555-1212	24 Front St.	11/12/16 11:50	85
0001	Marc Jones	(201) 555-2342	90 Field Ave.	11/12/16 11:40	77
0001	Marc Jones	(201) 555-2342	90 Field Ave.	11/12/16 11:51	88
0003	Shara Bevs	(201) 555-6565	16 Broad St.	11/12/16 11:10	66
0002	Jon Harvey	(201) 555-1212	24 Front St.	11/12/16 10:35	90

Each **record**, or row, of the table contains information about a measurement. That data is stored in several columns, or **fields** of different types.

Whenever the researcher records another pulse rate, she adds another line in the table. For small amounts of data, this could be an Excel™ **spreadsheet**.

The problem with a spreadsheet is that it is not **scalable.** As the amount of data grows, a table might have a million or more rows, which can exceed the capacity of most spreadsheets. As the number of researchers grows, there may be many different people trying to access the data at the same time. Most spreadsheets can not accommodate multiple simultaneous users. Finally, spreadsheets are only able to provide a single representation of the data at a time. For example, suppose that one researcher wanted to sort the data by the patient's name in order to identify a trend. At the same time, another researcher is trying to enroll a new patient into the study. Spreadsheets lack the capacity to accomplish both tasks simultaneously. Despite these limitations, spreadsheets are used for a startling amount of scientific recordkeeping.

A more robust method of collecting and maintaining data is the **database.** A database is able to handle many simultaneous users and vast amounts of data. It usually contains a permission system so that specific users only have access to certain types of data.

The database is also able to enforce certain rules about what sort of data it will accept. These rules are often called a **schema**. For example, in our table, each column has a particular data type. The pulse rate column and the patient id column are always numbers; the Date/Time column always contains a date and time. The remainder of the columns are strings of different lengths. These rules, or **constraints,** ensure greater data integrity. Although constraints wouldn't prevent a user from entering a pulse rate that is inaccurate, they would prevent someone from inadvertently entering an address in the patient ID column. The database could also prevent someone from leaving one of the fields blank.

Standardized Query Language (SQL) is a language used to create and query databases. The code below can be used to create Table 6-1. Note that INT means an integer type, DATETIME stores a date and time, and VARCHAR stores a variable length character string with an optional limit. VARCHAR(25) is a string limited to 25 characters.

```
CREATE TABLE patient_pulse_data (
     patient_id      INT,
     patient_name    VARCHAR(25),
     patient_phone   VARCHAR(15),
     patient_address VARCHAR(45),
     pulse_date_time DATETIME,
     pulse_rate      INT
  );
```

SQL can be surprisingly easy to read for simple queries. The following **query** will select the patient name, patient address and pulse readings for a patient with ID of 0003 from the table called patient_pulse_data.

```
SELECT patient_name,
       patient_address,
       pulse_rate
FROM   patient_pulse_data
WHERE  patient_id = 0003
```

Normalization is the process of organizing the columns and tables in a database to reduce data redundancy and improve data integrity. How might we improve our Patient Pulse Data table, above? One way to do this is to remove repeating elements. For example, patient name, phone number and address is repeated multiple times. If we can assume that a patient will maintain the same demographic information throughout the length of the study, we could separate the table into two smaller tables, one which describes the patient and another which describes our measurements.

The corresponding SQL is

```
CREATE TABLE pulses (
     patient_id      INT,
     pulse_date_time DATETIME,
     pulse_rate      INT
  );
CREATE TABLE patients (
     patient_id      INT,
     patient_name    VARCHAR(25),
     patient_phone   VARCHAR(15),
     patient_address VARCHAR(45)
  );
```

In this representation, each row of the pulse table (Table 6-2) refers to a single pulse measurement. Each row in the patient information table (Table 6-3) refers to a single patient. Since a single patient can not be divided into smaller parts, these rows are said to be **atomic.**

The two-table format (i.e. Tables 6-2 and 6-3) is said to be **normalized** because each row of each table refers to one single indivisible idea (i.e. a pulse measurement or a patient, but not both). When a table is intentionally designed to keep redundant data for performance purposes, it is called **denormalized**.

There are two key benefits to normalized data. Firstly, since there is no duplicate information, it takes up less storage space and is generally easier to modify. The trade-off is that that if information is needed from both tables at the same time, the denormalized table is generally faster because the computer does not have to spend extra time matching up the patient ID values.

TABLE 6-2

PULSE INFORMATION (PULSES)

DATE/TIME	PATIENT ID	PULSE RATE
11/12/16 11:39	0002	78
11/12/16 11:50	0002	85
11/12/16 11:40	0001	77
11/12/16 11:51	0001	88
11/12/16 11:10	0003	66
11/13/16 06:00	0002	90

TABLE 6-3

PATIENT INFORMATION (PATIENTS)

PATIENT ID	PATIENT NAME	PATIENT PHONE	ADDRESS
0001	Marc Jones	(201) 555-2342	90 Field Ave.
0002	Jon Harvey	(201) 555-1212	24 Front St.
0003	Shara Bevs	(201) 555-6565	16 Broad St.

The second benefit of normalization is the prevention of **data anomalies**. If one needs to edit the address for Marc Jones in the normalized table (Table 6-3), it only needs to be edited in one place. In the denormalized table (Table 6-1), it has to be edited in three different places. If, for some reason, the address is only updated in one of those locations, the data becomes inconsistent. This is called an **update anomaly** because an incomplete update causes anomalous data.

Suppose a new patient was enrolled into the study, but did not have any pulse data acquired yet. In the one-table model, there would be no way to add the person to the table. (The pulse column can not be left blank because it would violate the constraint.) This problem is called an **insertion anomaly,** which is the inability to add new data to a table because of absence of other data.

The final anomaly is the **deletion anomaly,** where deletion of one piece of data causes unintentional loss of other data. In our example above, suppose the researcher made a mistake and had to delete Shara Brev's pulse reading for 11/12/14. Since the entire row would be deleted, all reference to this patient would disappear.

The two tables are linked (or **related**) by their common data element, namely the patient ID. If a user wants to know the pulse values for patient 0001, he would select those values from the pulse table. If he wants to get demographic information, he would look in the patient information table.

What if he needs data from both tables? Since the two tables are related by the patient ID, the computer will match up rows from the two tables to produce the necessary output. This process is called a **join**. The fact that tables can be related this way is the defining characteristic of the Relational DataBase Management System (**RDBMS**).

The following SQL command will select the patient name from the patients table and the pulse rate from the pulses table. The two tables will be joined using the common data point called patient_id.

```
SELECT patients.patient_name, pulses.pulse_rate
FROM   patients JOIN pulses ON (patients.patient_id = pulses.patient_id)
```

PATIENT_NAME	PULSE_RATE
Marc Jones	77
Marc Jones	88
Jon Harvey	78
Jon Harvey	78
Jon Harvey	85
Jon Harvey	90
Shara Bevs	66

3.1.2 ARCHITECTURE

The architecture of a health information system is every bit as important to its function as the physical architecture of a house. Understanding the different methods in which data is stored and retrieved is crucial to building a durable and usable system.

3.1.2.1 Systems (e.g., Distributed, Centralized, Relational, Object Oriented, Warehouses/ Data Marts)

Until this point, we have considered data that is rigidly assigned to tables, rows and columns. An alternative to the RDBMS is the **NoSQL** database, or the **object-oriented** (OO) database. In this format, there is no schema to define what data is required or what format it

should be in. The primary feature of the OO database is that persistent objects in the database should be as transferrable and manipulatable as in-memory objects that are used in an object-oriented programming language.

In one common manifestation of the OO database called a *document store*, each section of the database (often called a **collection**) contains numerous arbitrary objects called **documents**. In the example above, each patient could be stored in a document which would include all the demographic information as well as the pulse readings.[3]

OO data is often represented in eXtensible Markup Language (XML) or JavaScript Object Notation (JSON). The following is an example of what a document for patient 0002, Jon Harvey might look like. Note that all the pulse data pertaining to this patient is stored together with the demographic information which makes it easy to fetch all the patient information at once.

```
{
   "patient_id":2,
   "patient_name":"Jon Harvey",
   "patient_phone":"(201) 555-1212",
   "patient_address":"24 Front St.",
   "pulses":[
      {
         "pulse_date_time":"11/12/14 11:39",
         "pulse_rate":78
      },
      {
         "pulse_date_time":"11/12/14 11:50",
         "pulse_rate":85
      },
      {
         "pulse_date_time":"11/12/14 10:35",
         "pulse_rate":90
      }
   ]
}
```

Since there is no predefined format of these documents, they can be modified quite easily. If the need arose, adding data about blood pressure or temperature for a single patient would pose minimal challenge. To do the same thing in an RDBMS would require the creation of additional columns or even tables.

Another benefit of the OO family of databases is that they are designed to easily scale horizontally. In other words, the data is often distributed among many commodity computers which leads to nearly limitless storage and very high availability. RDBMS tend to scale vertically, which means that there is a single data store and scaling requires a larger hardware investment. The trade off is that RDBMS usually offer greater data consistency.

There are four characteristics used to describe the reliability of a database: (**1**) **Atomicity** is used to describe database transactions that must be done completely or fail completely. For example, suppose you had a table keeping track of money in different bank accounts, and you wanted to transfer money from one account to another. You would have to do two separate database edits: one to debit the money from the first account and one to credit the money to the second account. It would be completely unacceptable if one of the edits went through and the other one didn't. Since the two edits comprise a transaction that is indivisible, it is said to be atomic. (2) **Consistency** means that any transaction will bring the database from one valid state to another. Data written to the database must satisfy all existing constraints, and if an edit would have resulted in an inconsistent state, the edit should be

3 It is important to remember that each of these documents could contain any number of other objects, including other documents. If this sounds complicated, it is. Too complicated for the boards, anyway.

rejected. For example, suppose a database column is constrained to hold only a date, such as date of birth for a patient. A user accidentally enters an invalid date, such as 2017-02-30. There should be no time where the database contains this inappropriate data. (3) **Isolation** provides that if the database allows transactions to run concurrently, the database must ensure that the same state would be achieved if they had run sequentially. In other words, transactions must have adequate isolation from one another. (4) **Durability** means that once a transaction is complete, the change has to be permanent, even if there is a power loss or the computer crashes.

These properties are usually abbreviated as **ACID**, and most RDBMS provide ACID guarantees. OO databases are usually distributed over several computers and can not provide ACID guarantees (however some do). Instead, there are complex algorithms which are used to determine the most recent or most accurate data to be provided to the user. Some systems provide **eventual consistency,** which means that although the query result may not be accurate at this instant, it will get there eventually, usually within a few seconds. For legal and regulatory reasons, databases that can not provide ACID guarantees are not routinely used to store patient information.

In summary, **relational** databases usually maintain a single, **centralized** data store and usually provide ACID guarantees. NoSQL (object oriented) databases are usually **distributed** over many commodity machines in order to provide high availability while sacrificing consistency. *But not always.*

A **data warehouse** is an intentional abstraction of a database designed for analytics. For example, an Electronic Health Record (EHR) is an example of a database. It is designed for efficiently adding and querying information about a particular patient at a particular point in time. It is very rare that a clinician using an EHR would need to review multiple patients at once.

On the other hand, a hospital administrator is much more interested in the care provided to many patients over longer timeframes (e.g. how many CT scans are being performed on a month-by-month basis?). He would be interested in **aggregate** data instead of **individual** data (Table 6-4).

TABLE 6-4

DIFFERENCES BETWEEN A DATA WAREHOUSE AND A DATABASE

	DATABASE	DATA WAREHOUSE
Definition	An electronic information store, usually organized by data type	A subset of a database, organized for ease of aggregate queries
Optimization	Optimized for online transaction processing (OLTP). Tables tend to be highly normalized and the system is optimized for fast and reliable read-write of individual data points. This usually results in many tables linked in complex ways. However, good process modelling ensures that the data is only written once, resulting in fast response times	Optimized for online analytical processing (OLAP). Tables are usually read-only and are intentionally denormalized to make queries faster and easier. The data are organized into multidimensional arrays (also called cubes or hypercubes). Data are summarized in **pivot tables** and used to garner **business intelligence**
Uptime	Mission critical. Systems are expected to have very little unscheduled downtime. Data errors can be literally life-threatening	Usually, warehouse data is a replica of the original data, running on a separate system so as not to affect performance of the database. Many systems create an overnight "snapshot" of data for this purpose. Since the data are re-created periodically, reliability of OLAP servers is less of a concern

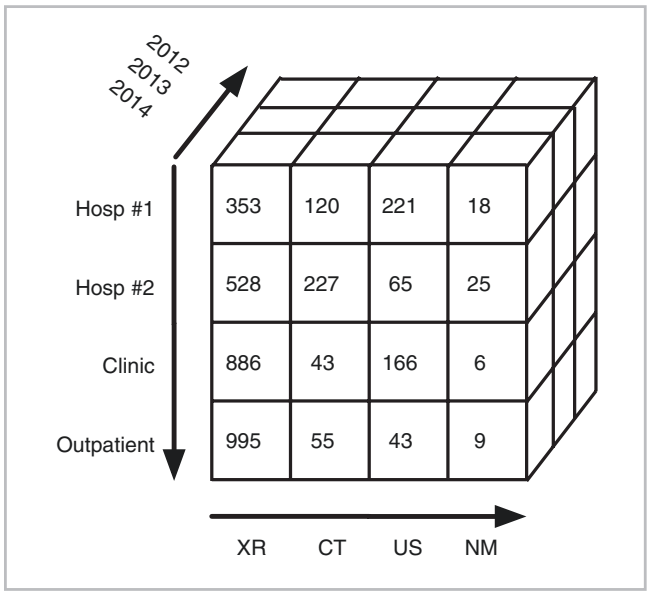


FIGURE 6-6

An example of an online analytic processing (OLAP) cube. This cube shows three dimensions. Along the X-axis is the study type. XR, X-ray; CT, computed tomography; US, ultrasound; NM, nuclear medicine. The Y-axis shows the location of the study. The Z-axis shows the year of the study.

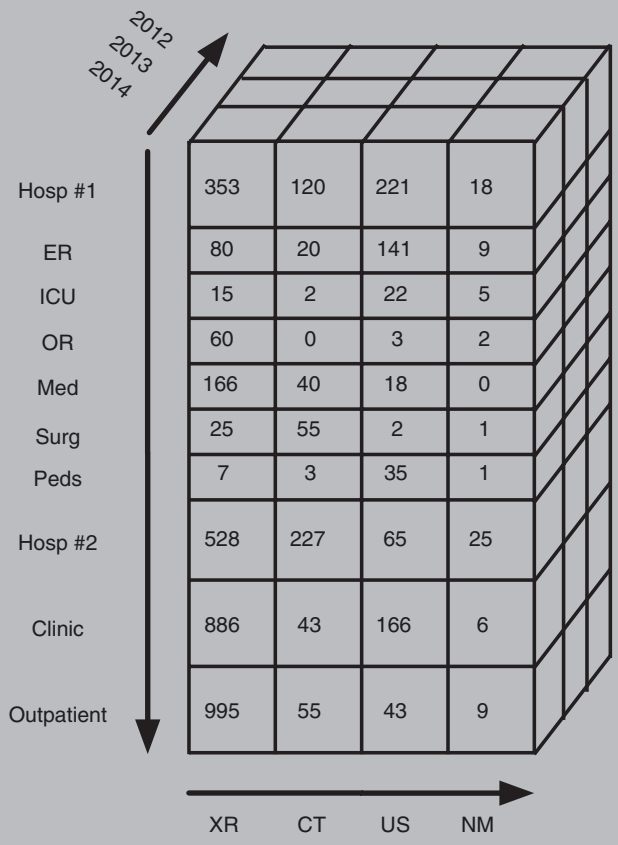
A **data mart** is a smaller slice of the original data, usually restricted to a particular line of business. For example, the radiology department may be given access to a data mart of radiology data, while housekeeping would use a different set of data pertaining to its needs.

Figure 6-6 is a representation of a **OLAP cube**, a multidimensional array used for gathering business intelligence. In this example, the data show the number of different kinds of radiology studies (X-Ray, Computed Tomography, Ultrasound and Nuclear Medicine) done in various clinical environments (Hospital #1, Hospital #2, Clinic and Outpatient) in the timeframe from 2012 to 2014. This type of analysis can help an administrator determine how to provision new equipment or advertise for existing services. In this representation, each axis is called a **dimension.** There is no limit to the number of dimensions in an OLAP cube, although it can be difficult to visualize more than three. Each box in the cube contains a number. For example, in diagram above, the bottommost left cube indicates that there were 995 X-Rays done in the outpatient department in 2014. The data in these cells are referred to as **facts** or **measures.**

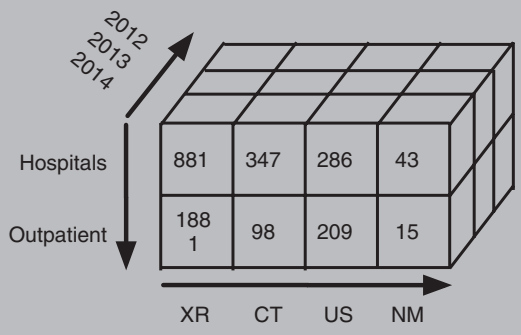
There are several OLAP operations which are used to investigate data. **Drill-down** is the process of breaking categories into smaller segments. For example, if the user wants to look at monthly data instead of yearly data, we could break 2014 down into 12 months. The reverse of drill-down is **roll-up** where several categories are combined. For example, the user could combine data from the two hospitals in order to compare it to the outpatient settings. **Slicing** is looking at a subsection of the data when one of the dimensions is held constant. For example, if the user wanted to look at only X-Rays. **Dicing** is looking at a subset of the data based on constraints in more than one dimension. For example, if the user wants to look at only XR and CT studies which were done in the clinic and outpatient departments. A **Pivot** is when the axes of the cube are changed in order to provide a different view. (see Box 6-2)

Box 6-2: Types of OLAP operations

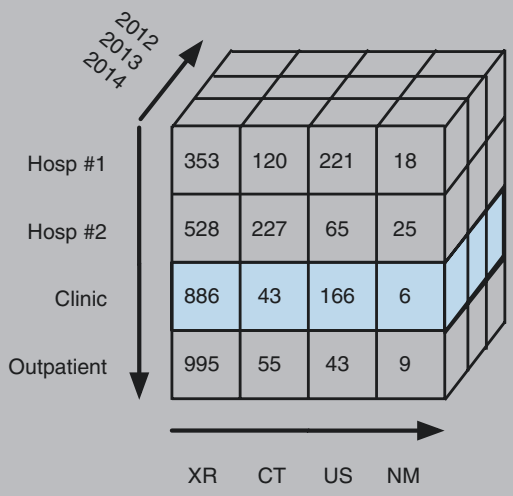
Drill Down—Breaking one category into smaller chunks. Here we see that Hospital #1 has an Emergency Room, Intensive Care Unit, Operating Room, Medical service, Surgical service and Pediatrics service.



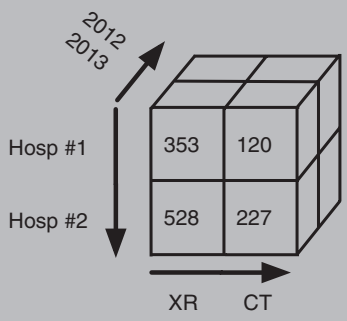
Roll-up—combining categories into larger chunks.



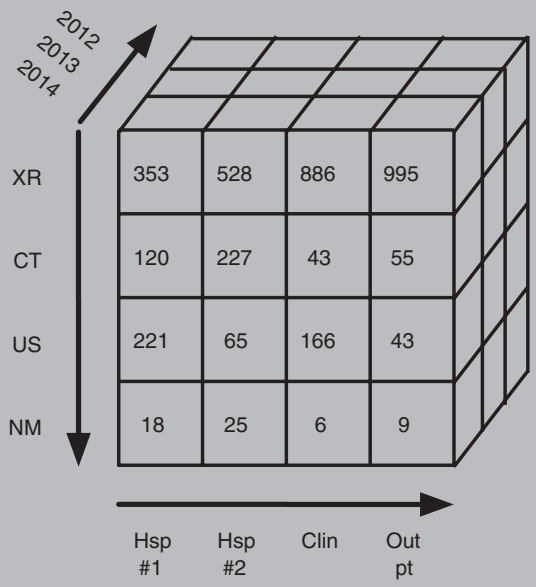
Slice—holding one dimension constant.



Dice—limiting data based on more than one dimension.



Pivot—rotating the data by changing axes.



3.1.2.2 Networks

Networking computers together efficiently is key for establishing interoperability. For further discussion, see Sect. 3.1.3.

3.1.2.3 Data/Database

As we have mentioned earlier, databases are computer programs which allow multiple users to have simultaneous controlled access to different types of data. These have been discussed in other sections.

3.1.3 NETWORKS

Computer networks are a set of protocols and transmission media which allow two or more computers to interact with one another. Networks can be as simple as two computers sharing files over a USB cable or can be as vast as the internet. Any device that can send or receive data is called a **node**. The path along which the data travels is called a **link**.

Some nodes are user nodes, such as computers or display terminals. Other nodes can be devices specifically designed for networking. A **hub** is a node that allows many other nodes to connect to it. Whenever it receives a signal from one node, it rebroadcasts it to all other attached nodes. A **switch** is similar to a hub, however it is more selective. When it receives a signal intended for a particular node, it rebroadcasts the signal only to that node. A **router** is a network device that functions similar to a switch, but it normally sits at the junction of two networks and decides which signals should be allowed to pass through. Some routers provide **Network Address Translation (NAT)** which allows computers to hide their actual identity in order to share a single public-facing address. This is very common in home and corporate networks.

The different aspects of the network are often referred to as **layers**, where the lowest levels deal with physical aspects of the network and the higher levels relate to interactions between programs. There are several models used to describe networks. The two most common are the *Open System Interconnect (OSI)* model and the *Transmission Control Protocol/Internet Protocol* (TCP/IP) model. (See Fig. 6-7).

In the OSI model, the lowest level is the transmission media, or the **physical layer**. Common physical layers include radio frequency, copper wire and fiber optic. The **data link layer** rests just above this and accounts for correcting errors in the physical layer and

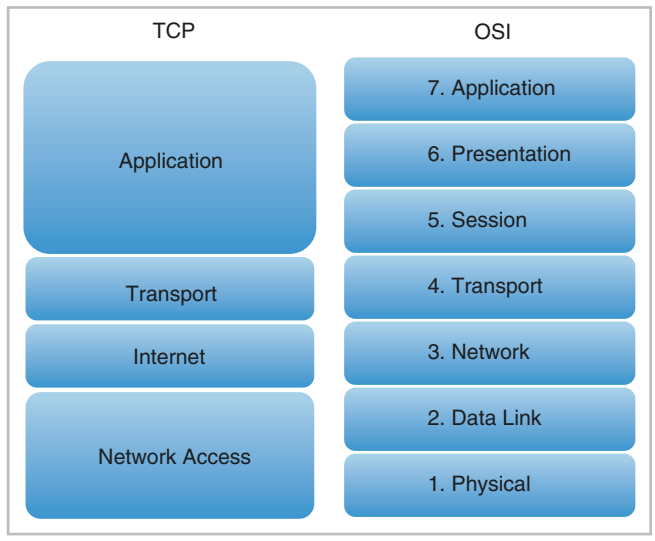


FIGURE 6-7

The Open System Interconnect (OSI) and Transmission control Protocol/Internet Protocol (TCP/IP) network models. OSI, right, contains seven layers. TCP/IP contains four

TABLE 6-5

COMPARISON OF DIFFERENT PHYSICAL NETWORK LAYERS

MEDIA	TYPICAL BANDWIDTH	PROS	CONS
Radio frequency	Cellular phones with 4G LTE can get 5–12 Mb/s; WiFi networks using the latest 802.11 ac are rated to 1.5 Gb/s. In practice, 70–100 Mb/s is common.	Nodes are easily moved and adding another node to the network is as simple as bringing it within range of the transmitter	Radio Frequency is highly subject to electromagnetic interference, and often can not penetrate into basements or through thick walls. As distance from the transmitter increases, bandwidth drops precipitously
Copper wire	Gigabit Ethernet can reliably provide 1Gb/s when using category 6 (CAT-6) cables	In commercial networking, Ethernet is ubiquitous and hardware is sold at commodity prices	Installing a new node requires running physical cables and/or purchasing hardware
Fiber optic	100 Gb/s on OTU-4 lines. Researchers have shown speeds of 1 Tb/s or more	Exceedingly fast and durable. Able to send long distances (>500 km) without repeaters.	Because of high cost, fiber is primarily used in network backbones and WANs

providing synchronization of data transport. Together, these two layers are called the **network access layer** in the TCP/IP model (Table 6-5).

The next layer up is the **network layer** which provides routing and switching capabilities. In the TCP/IP model, this is called the **internet layer.**

The next layer is the **transport layer** (it has the same name in both models). This layer employs error-checking algorithms to ensure that data is transported completely and correctly.

The **session layer** is responsible for opening and closing communications between software applications. The **presentation layer** transforms data into usable formats. For example, converting a binary data stream into a picture. In addition, encryption usually occurs at this layer. The top layer is the **application layer**, where all the higher-order interaction is done, such as authentication, user interaction and quality of service. Everything at this layer is application-specific. Web browsers, File Transfer Protocol (FTP), E-mail and all other applications function at this level.[4] In the TCP/IP model, these top three layers are all referred to as the application layer.

3.1.3.1 Topologies

A **network topology** refers to the map of connections between different nodes. The **physical topology** represents the physical location of nodes and the interconnects that run between them. In contrast, the **logical topology** refers to the way that signals pass from one node to another, regardless of the physical layout. For example, suppose that the finance department and the dietary department share office space. The network engineer connects all the computers with Ethernet cables, but installs specific network devices and protocols to ensure that the two departments' data remains separate.

There are several different network topologies.

Point-to-point is the simplest network topology, and involves two nodes and one link between them. An example is two computers connected with a USB cable. In telephony, a circuit-switching system establishes logical point-to-point network whenever a phone call is made. When the call is completed, the resources are returned to the network (Fig. 6-8).

4 Health Level 7 (HL7), a group responsible for many messaging standards in healthcare got its name from the top layer of the OSI model.

FIGURE 6-8

A simple point-to-point network

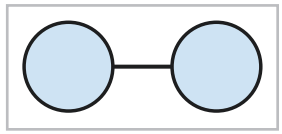


FIGURE 6-9

Network with Bus topology

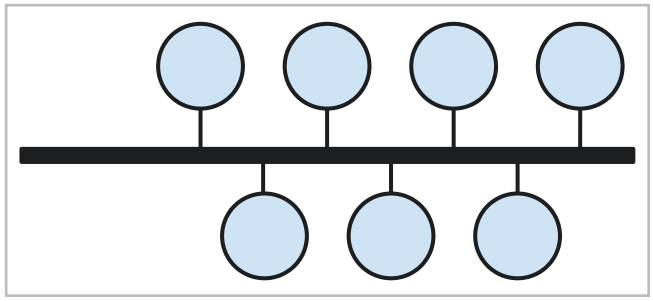
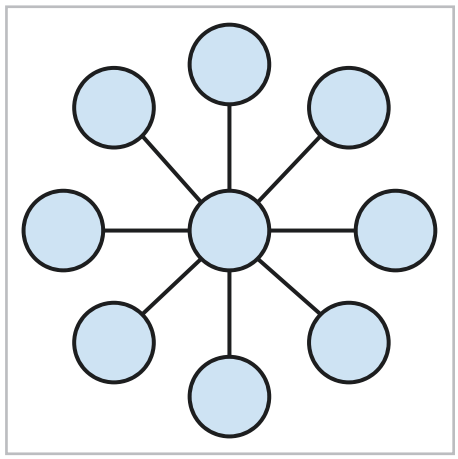


FIGURE 6-10

Star topology



In bus topology, all nodes are connected to a single wire, called the bus, or backbone. As the signal passes from one end to the other, each node examines the data to determine the appropriate recipient. The benefits to this topology are that it is relatively inexpensive, and adding nodes is relatively easy. The downside is that if the wire is cut, all nodes distal to the break are lost (Fig. 6-9).

In **star topology**, every node is connected to a single central node, called a hub. As with bus topology, nodes can be easily added or removed. However, in star topology, if the hub fails, the entire network fails (Fig. 6-10).

In **ring topology**, every node functions as a repeater to keep the signal moving between nodes. When the message reaches the node that originally sent the message, it is terminated. In unidirectional rings, messages travel in only one direction (e.g. clockwise or counter-clockwise). In bidirectional rings, messages are transmitted simultaneously in both directions. Although unidirectional rings use less bandwidth, they are prone to failure. If a single node fails, the whole network is affected. In a bidirectional ring, when one node fails, only that node is affected. When a ring is left open, it is sometimes called a **daisy-chain** (Fig. 6-11).

In a **mesh network**, each node is connected to multiple other nodes. Although this kind of network is very efficient and very secure, it becomes prohibitively expensive as the number of nodes increases. In a fully connected mesh (shown below) every node is connected to every other node. In a partially connected mesh, each node is connected to two or more other nodes, but not to every other node. The main benefit of a mesh network is that if any single node fails, the network remains intact. The internet is an example of an enormous mesh network (Fig. 6-12).

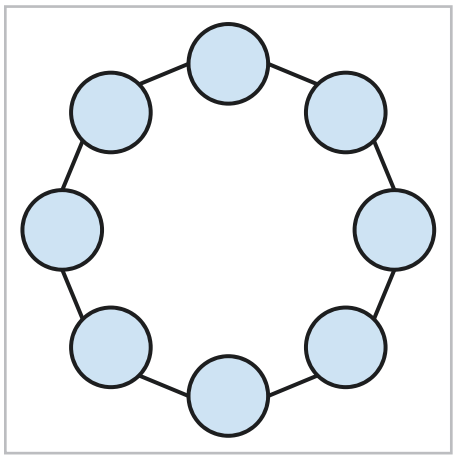


FIGURE 6-11

Network with ring topology

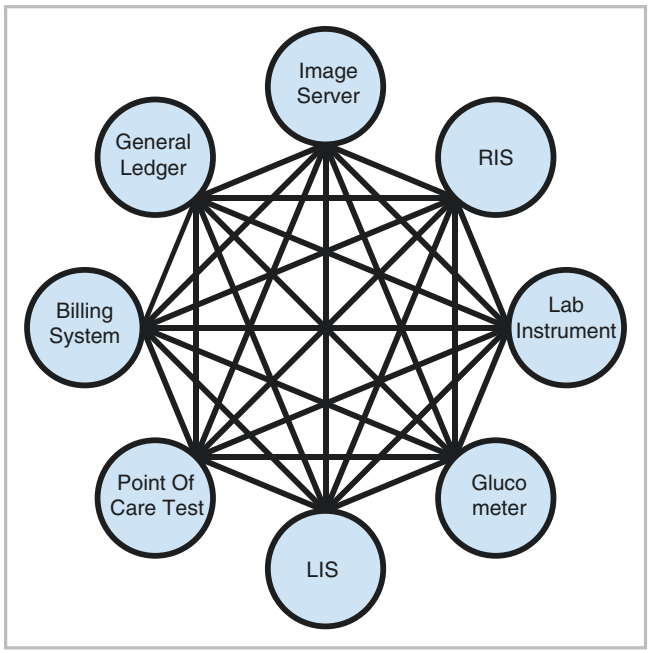


FIGURE 6-12

Network with mesh topology

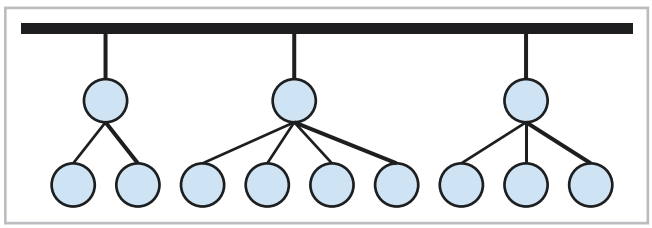


FIGURE 6-13

Hybrid network with tree topology (star networks linked with a bus/ backbone)

A **hybrid network** is a combination of two or more network topologies. For example, A **tree network** is a combination of star networks linked by a bus. This is a very common arrangement in large organizations, where each department has its own hub and all departmental computers connect to it. If the backbone fails, the departments become isolated from one another, but departmental nodes can still communicate with other nodes in the same department (Fig. 6-13).

Other common hybrid networks include the star-ring network, which is a series of star networks, connected by a ring, and the star-star network which is a star of stars (sometimes called a snowflake) (Fig. 6-14).

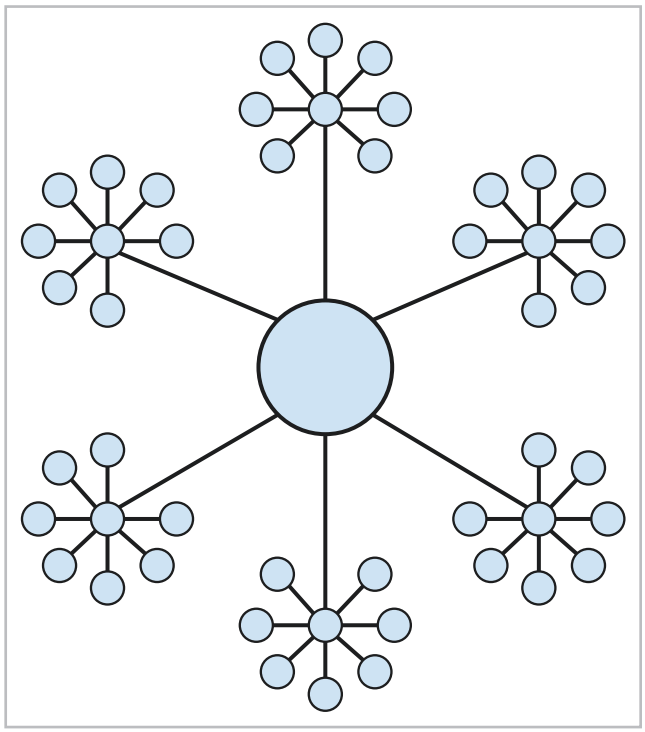


FIGURE 6-14

A star-star network, sometimes called a snowflake

3.1.3.2 Telecommunications

Telecommunication networks enable people and machines to communicate over long distances. In general, these are very large networks shared by many people. The **Public Switched Telephone Network (PSTN)** is the global network of telephones and switching systems. It provides an easy and generally inexpensive method for real-time voice communication. It is sometimes referred to as **Plain Old Telephone Service (POTS)**.

In the early days of telecommunication, when a person wanted to place a call, he would call an operator who would physically plug a jack into a receptacle to create a circuit. If the call required multiple connections, multiple operators were needed. If all the outgoing wires were in use, the call could not go through and the caller would be informed that all circuits are busy. More modern systems function very similarly, although the manual switching process has been replaced with digital switches. This process of sharing a finite number of circuits is called **circuit switching.** Since the circuit is used for only one conversation at a time, there is generally little lag between transmitting and receiving. The downside is that the entire circuit is reserved for one conversation, even if the line is completely silent.

Cellular phones and Voice-over-IP (VOIP) networks do not rely on physical circuits, but instead use **packet switching.** In this technology, each bit of the conversation is encapsulated into a packet of data, which is sent from station to station until it gets to the recipient. The recipient then reassembles the packets and converts them back into voice. Since the packets may arrive in any order, and can sometimes get lost, there is a variable delay between sending and receiving. In high quality local networks, VOIP can be indistinguishable from POTS. However, at the time of this writing, cellular phone communication has significantly more degradation that traditional land-lines.

3.1.4 SECURITY

Protecting patient information while still making it available to decisionmakers is a difficult, if not impossible task. Nearly every few weeks, there are reports of a large company being hacked and personal information being released. Healthcare organizations are required to safeguard patient information and prevent identity theft.

3.1.4.1 The HIPAA Security Rule and Other Government Regulations

In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA). Among the many provisions of the act, the **Privacy Rule** defined characteristics of Protected Health Information (PHI). PHI includes any *individually identifiable information* about the patient, including demographic information (e.g. name, birth date, social security number, address).

Another title in the act, the **Security Rule**, required that the department of Health and Human Services (HHS) develop policies to secure PHI. The Office for Civil Rights (OCR) was given responsibility to enforce the Security Rule and the Privacy Rule.

The Security Rule applies to organizations that transmit health information in electronic form, such as health plans, healthcare clearinghouses, and health care providers. Collectively, these groups are called **covered entities**.

The Security Rule specifically protects electronic protected health information (e-PHI) which includes all health information that a covered entity creates, receives, maintains or transmits in electronic form. Interestingly, the Security Rule does not apply to PHI transmitted verbally or in writing. Faxes are something of a gray area.

In the course of business, Covered Entities often need to enter into agreements with other organizations or **Business Associates** (BA). For example, a physician group (a covered entity) may hire an outside billing company to process claims. In these cases, the covered entity is only allowed to share the **minimum necessary** PHI for business purposes. In most cases, the BA is required to sign a contract called a **Business Associates Agreement** (BAA) with the covered entity to ensure that PHI will remain protected.[5] At a minimum, the BAA should

1. Establish the permitted uses of PHI
2. Prohibit the BA from disclosing PHI inappropriately
3. Establish safeguards to protect PHI
4. Report any breaches of security
5. Allow individuals access to their own PHI
6. Ensure that the BA be held to the same privacy standard as the covered entity itself
7. Allow HHS to review the BA's privacy practices
8. Ensure that the BA will destroy all data when the relationship with the covered entity ends
9. Require any of the BA's subcontractors to follow the same rules as the BA itself
10. Allow the covered entity to terminate the contract if violations occur

The Security Rule divides safeguards into three categories: Administrative, Physical and Technical. Some of the safeguards are mandatory while others are considered addressable, which means that the entity is allowed to make a cost/benefit decision as to whether they want to implement the safeguard or employ some reasonable alternative. In either case, the risk analysis must be thoroughly documented. For example, according to § 164.312(a)(2)(iii), computer systems must have an automatic logoff after a period of inactivity. If the EMR does not directly support automatic logoff, it could be very expensive to add that functionality. Instead, the covered entity decides to use the operating system's own password-based screen saver program. Although the user isn't logged off *per se*, the PHI remains protected, so the safeguard is addressed.

Administrative Safeguards establish policies and procedures within an organization to protect PHI. This process begins with regular risk assessment to identify and analyze vulnerabilities in the information systems. Staff training and compliance monitoring are key to enforcing privacy policies. Information access rules have to be defined so that each person only has access to the minimum necessary to do their job. Finally, there must be an emergency plan to respond to data leaks or lost data.

5 An example Business Associate Agreement (BAA) can be found at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html

Physical Safeguards refer to efforts put in place to limit physical access to data or workstations. Some examples include: security personnel to patrol data centers; locks and alarms on workstations; or computer monitor privacy filters which prevent onlookers from reading sensitive data. The covered entity also must have a plan regarding the transfer, removal, disposal, and re-use of electronic media, to ensure appropriate protection of electronic protected health information.

Technical Safeguards include hardware, software, and other technology that limits access to PHI. These controls fall into four basic categories: (1) **Audit Controls** keep track of which users are accessing what kinds of PHI. In the event that PHI becomes public, it is important to review the access logs to see who had access to the leaked information. (2) **Access Controls** restrict access to various systems to users who are authorized. (3) **Integrity Controls** prevent improper alteration or deletion of PHI. (4) **Transmission Security Controls** protect PHI when it is transferred over an electronic network. Specifically, this requirement demands that data is protected in motion and at rest.

Box 6-3: Is texting prohibited under HIPAA?

It is fairly common for physicians to communicate with their patients and with one another by sending messages through their smartphones or other devices. However, since HIPAA requires that PHI be protected in motion and at rest, this could potentially represent a violation. To address this, let's examine how texting works.

A text message passes through five phases during its lifecycle:

1. on the sender's device
2. enroute to the cell tower
3. transiently stored on the carrier's server while waiting for receipt confirmation
4. enroute to the recipient
5. on the recipient's device

Protecting the message while stored on the user's device (stage 1 and 5, above) is problematic. Most devices store copies of sent and received messages for an indefinite period of time. Both sender and receiver have to be careful to remove messages that are no longer needed. Many devices have lock screens which protect unauthorized users from reading their contents. In some cases, such as Apple's iOS 10, messages are automatically encrypted on the device so that even if the device were lost or stolen, it would be impossible for a hacker to read the messages. Android 5.0 uses full disk encryption (FDE) by default.

Protecting data in motion (stages 2 and 4) is easier. Short Message Service (SMS) messages which are sent over GSM networks are encrypted between the device and the cell tower, so that even if a hacker were situated right next to the sender or recipient with a radio receiver, he would only be able to intercept the encrypted message. Apple's iMessage protocol, a competitor to SMS, uses encrypted internet connections in place of cellular radio.

Messages stored by the carrier (stage 3) may not represent a violation, even if unencrypted: these messages are temporary; they are not routinely screened by the carrier; and they are not available on public networks.

So, is physician texting OK? Maybe.

The weakest points in this system are usually the physicians themselves. Forcing doctors to lock their phones has proven difficult, especially for the technically uninclined. Many organizations have opted for a third-party application that ensures end-to-end encryption at the cost of easy usability.

3.1.4.2 Firewalls

In construction, a firewall is a structural entity meant to keep a fire from spreading from one part of a building to another. In computing, a firewall is a device that sits at the junction between two networks and decides what kinds of information is allowed to pass through, thus protecting one network from another (Fig. 6-15).

When information is sent from one computer to another over a network, it is broken down into smaller packets. These packets are reassembled on the target computer to create the original message. (see packet switching, Sect. 3.1.3.2).

The simplest type of firewall is the **packet filter.** The firewall inspects each packet to ensure that it is coming from an acceptable source and is travelling to a permitted endpoint. This is a fairly swift operation because the list of acceptable computers is well known in advance. The weakness of this method is that the contents of the packet are never examined.

The next generation of firewalls were able to overcome this limitation by **stateful inspection** of packets. The packets are temporarily reassembled on the firewall itself and examined for prohibited information. In healthcare organizations, this kind of firewall can be used to prevent users from visiting unauthorized web sites, downloading viruses and playing online games. Since the firewall operates in both directions, it can also be used to prevent users from inadvertently disseminating protected health information. Most modern firewalls employ a combination of stateful inspection and simple packet filtering.

Network Address Translation (NAT) is a process by which computers in a private network are able to share a public-facing address without divulging their local address. Although this function is normally performed by a **router**, many firewalls incorporate this functionality as well. In this scenario, the firewall has a public IP address. Whenever any of the computers on the private network want to connect to a public site, they send packets to the router, which replaces the actual origin address with its own. When the public site returns information, it is replies to the router, which then transmits the packet back to the local machine. In a standard configuration, uninvited packets are simply rejected by the router and can not get into the private network.

3.1.4.3 Virtual Private Networks

Many healthcare networks are closed networks, which means that they can not be easily accessed from outside the walls of the institution. A **virtual private network** (VPN) allows a remote computer to access an otherwise closed network by making it appear as though the

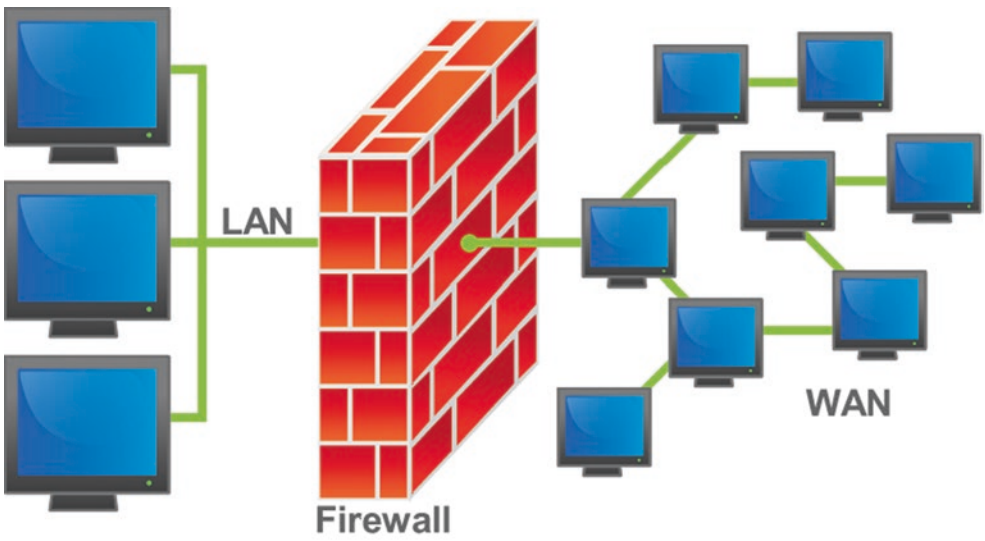


FIGURE 6-15

A firewall separates the LAN from the WAN. Image: "Firewall" by Bruno Pedrozo—Feito por mim. Licensed under CC BY-SA 3.0 via Wikimedia Commons—http://commons.wikimedia.org/wiki/File:Firewall.png#/media/File:Firewall.png

remote computer has an address in the local network. The communication between the remote computer and the network is encrypted and can travel in the public internet without fear of interception.

3.1.4.4 Encryption

When private networks are unavailable, health information must be transmitted over public networks such as the internet. In order to prevent interception of sensitive information, data are encrypted by the sending computer and decrypted by the receiving machine. In all cases of cryptography, the original message (**plaintext**) is only known to the sender and recipient, while the encoded message (**ciphertext**) is widely available. In addition, there may be one or more secret keys which are known only to sender or recipient (Fig. 6-16).

One of the simplest forms of cryptography is simple substitution. Each letter of the alphabet is substituted for another letter using a predetermined plan.[6] According to legend, Julius Caesar used this method, and a Caesar rotate is named for him.

For example, a coded message may read as follows.

```
Lqirpdwlfv
```

Before the message was sent, the recipient was given the secret key of 3, which tells him to shift the letters ahead by three and create the following dictionary.[7]

```
Cipher: DEFGHIJKLMNOPQRSTUVWXYZABC
Plain:  ABCDEFGHIJKLMNOPQRSTUVWXYZ
```

As you can imagine, this method is fairly easy to break, as there are only 25 different encrypted possibilities. If a hacker tried each one, it would take a short time to have the original message. A slightly more difficult method involves substituting letters in random order (instead

FIGURE 6-16

Decoder ring. Photo courtesy Retro Works, shopretroworks.com

6 Think of the secret decoder ring found in cereal boxes.
7 The plaintext is: Informatics.

of alphabetical order). In this case, the secret key would be much longer than just a number. This complexity results in 4×10^{26} different possibilities, which sounds much harder to break.

Unfortunately, it isn't. Analysis of common texts show that certain letters appear much more frequently than others. Using this well known distribution, a series of educated guesses will allow a hacker to decode a longer message fairly easily.[8]

Modern cryptography employs a combination of substitution, transposition and mixing of plaintext in order to create the ciphertext. In order to make it more difficult to crack, the newly created ciphertext is then passed through the encryption algorithm several times to make it harder to break. After multiple rounds of encryption, the message can be nearly impossible to break.

Advanced Encryption Standard (AES) is a common encryption mechanism. It requires that the sender and recipient possess the same 256-bit key. One way to break this kind of security is to try every possible password (called the **brute force method**). There are approximately 10^{77} possible 256-bit keys. AES was designed so that encryption process is fairly quick, the decryption process takes a significant fraction of a second to complete. As a result, it would take 3×10^{69} years to crack an AES encrypted message.

Another useful type of encryption is called **public key cryptography** or **asymmetric key cryptography.** In this method, the key is composed of two parts. One is the public key, which is well known and the other is the private key, which is known only to the sender. While the two keys are mathematically linked, it is impossible to derive one from another. The public key is used for encryption, while the private key is used for decryption. For example a person could give out his public key and anyone who wants to send him a message could do so securely.

Asymmetric keys can also be used to verify a **digital signature.** For example, a person could use his private key to encrypt a document. If the public key is able to decrypt the document, that proves the authenticity of the original signer.

3.1.5 DATA

3.1.5.1 Integrity

Data integrity reflects the degree to which we can trust our data. There are two aspects to data integrity. **Physical integrity** refers to the way information is stored on various media. When media is subject to physical insults, the data can become corrupted. One way to protect the data is to employ redundant data stores, such as a Redundant Array of Inexpensive Disks (RAID). **Logical integrity** means that the data makes sense and is appropriate to our needs. For example, if a thermocouple is malfunctioning, an oral thermometer may register a temperature of 300°. Even if the database records the information faithfully, it is logically impossible.

Database integrity includes three special integrity requirements in order to guarantee consistency. **Entity integrity** requires that every table in the database has a unique primary key. This is not always enforced. **Referential integrity** requires that whenever a database column refers to a row in another table, that row exists. **Domain integrity** specifies a specific list of values that are acceptable for a particular column. For example, we can preserve the logical integrity of our temperature field by restricting input values to the range of 20–40 °C.

Consider the following example, shown in figure 6-17. A database contains two tables. The *purchases* table lists the customers and the items that they purchased. The *items* table shows a description of the items. The two tables are related by the common column item_code. The problem with this database is that the GHI company has purchased an item with code A9, but there is no corresponding item in the items table. This database lacks referential integrity because an item in the purchases table refers to a row in the items table which does not exist.

8 For a great demonstration of a computer program to solve cryptoquotes, see http://quipqiup.com/. Note that this works for longer messages, but shorter messages are much harder to solve. For example, all the following are possible plaintexts to the ciphertext Lqirpdwlfv: Objections; Speciously; Spaciously; Operations; Exchangers.

FIGURE 6-17

The purchases table has an item with code A9, but this item doesn't exist in the items table, a violation of referential integrity

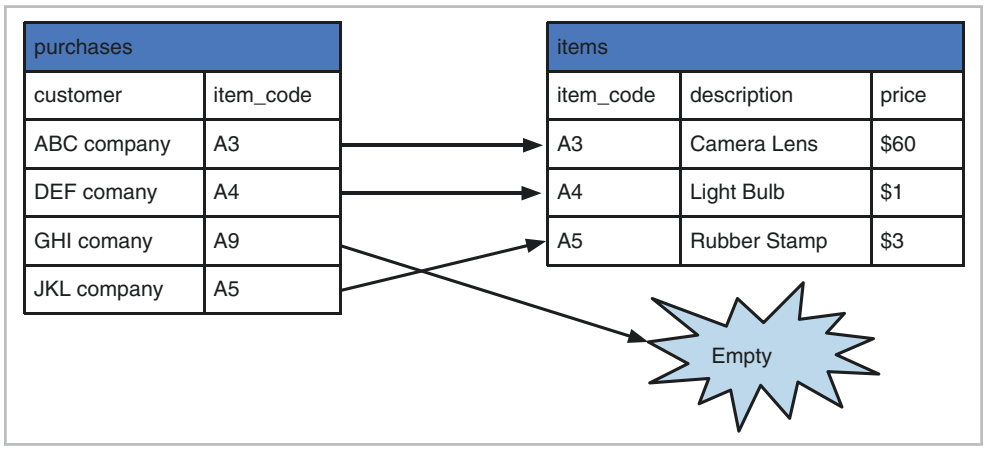


FIGURE 6-18

Direct mapping between source and target tables

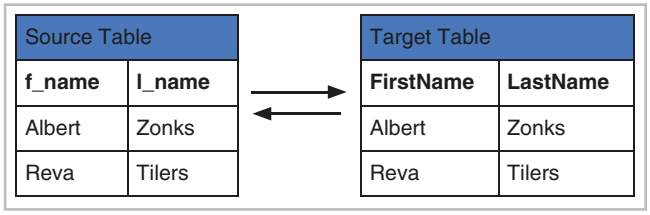
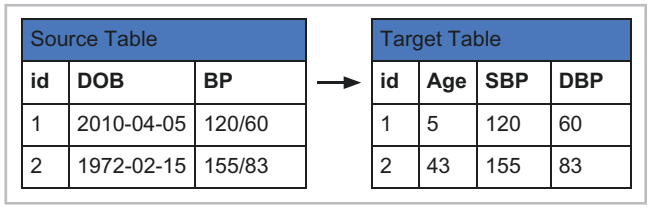


FIGURE 6-19

Mapping from date of birth to age is possible, but the reverse is not



3.1.5.2 Mapping

Data Mapping is the process by which data is compared or transferred between two different data models. In some cases, the mapping is fairly straightforward, such as when similar elements exist in both models and simply require changing the field name. When this is possible, bidirectional mapping is possible (Fig. 6-18).

In other cases, mapping can be more complicated and require calculation. In the example below, the age (in the target table) can be calculated from the current date and the date of birth (in the source table). The Blood pressure can be separated into systolic and diastolic measures. It can be tricky to provide bidirectional support for this mapping because it depends on knowing the date on which the conversion took place in order to calculate the age. In this case, the age is recorded as an integer, so the exact DOB would be impossible to determine (Fig. 6-19).

Sometimes, the data themselves prohibit bidirectional mapping. Systematized Nomenclature of Medicine-Clinical Terms (SNOMED) is a vast terminology which describes many different clinical entities. The International Classification of Diseases, ninth edition (ICD9) describes diagnoses, but has much fewer terms than SNOMED, so that a single ICD9 term may map to many SNOMED terms and sometimes vice-versa. In these cases, an approximate mapping can be done, but there is no guarantee that the reverse mapping will be relevant.

3.1.5.3 Manipulation (e.g., Querying, SQL, Reporting)

The standardized query language (SQL) is a relatively simple computer language for interacting with databases. There are four basic functions for manipulating data, Create, Read, Update and Delete. These are commonly abbreviated as CRUD. For some more examples of SQL, see Sect. 3.1.1.6

OPERATION	SQL EXAMPLE	EXPLANATION
Create	`INSERT source (id, dob, bp) VALUES (3, '1937-04-11', '166/75');`	Insert a new row into the table named "source" with id=3, blood pressure and DOB as shown.
Read	`SELECT id, dob FROM source;`	Show the id and DOB for all patients in the table named "source"
Update	`UPDATE source SET dob = '1955-08-14' WHERE id = 2;`	Update the row of the person who has id=2 and set the birthday to 8/14/1955
Delete	`DELETE FROM source WHERE id = 3;`	Remove the row from the table named "source" for the person who has id=3

Database reporting is one of the most important professional tasks the informaticist will perform. Being able to locate the right piece of data, ensuring that it is logically correct and reflective of the real world is vitally important to making decisions and measuring outcomes. Once the query has been written, it can be re-run periodically to determine if a clinical or operational change has a desired result.

3.1.5.4 Representation and Types

Data exists in many different formats within a computer. The simplest form of data is a whole number (**integer**). In order to store a number, we have to allocate a certain amount of memory for it. If we know in advance that a number falls into a certain range, we can specify how many bytes of data are required to store it. For example, suppose we want to record the number of children a person has and store it in a database. A negative number is impossible; a fraction is impossible, and a number greater than 30 is probably a data error. So what container should we use? In Standard Query Language (SQL), a **tinyint** is defined as a whole number between −127 and +128. Since there are 256 distinct possibilities (2^8), this number can be stored in 8 bits, or one byte[9], and this would be the best answer to our needs.

Now, suppose we also want to record the population of various countries. Again, we can not accept numbers less than zero and we can not accept fractions. The maximum value is going to be very high, as both China and India have over 1 billion residents. Fortunately, there exist larger integer type, such as an **unsigned int** which allows whole numbers between 0 and 4,294,967,295. This represents 2^{32} different possibilities, and thus requires 4 bytes. Different languages and different systems have many options of varying sizes for storing integers[10]. In general, the programmer should choose the data

9 Truthfully, we could express this number using only 5 bits, since $2^5 = 32$, but there is usually little benefit of using only part of an 8-bit byte for storage. It does not improve calculation time or storage requirements.
10 Gangam Style by PSY is the most-watched video on Youtube. When the creators of Youtube initially created their video database they used an int to store the number of times a video is watched. In October, 2014, Gangam surpassed 2.1 billion views and exceeded the available storage capacity, resulting in data

type which requires the smallest amount of space but whose range includes all reasonable values.

What if I wanted to record the mass of different elements or mean temperatures? Real numbers (or **floating point numbers**) are usually represented as a number times a base raised to an exponent. For example, the number 350.15 could be expressed as 3.5015×10^2. In this example, 3.5015 is the **mantissa** or **significand**; 10 is the **base** and 2 is the **exponent**. If we assume a convention where the decimal point is always to the right of the first digit and the base is always 10, this number could be represented as two integers: 35,015 and 2. By varying the number of significant digits available for the significand and the exponent, we can express a wide range of numbers. It is important to remember that this format does not always represent numbers exactly. For example, if you only allow 4 significant digits to the significand, you will find that the number 250,000 is stored the same as 250,001. In practice, a **single precision floating point** number occupies 32 bits and provides 7 significant digits and an exponent up to 127.

Letters and words are also commonly stored as data. The American Standard Code for Information Interchange (**ASCII**, see Table 6-6) encodes the 100 or so most commonly used letters, numbers and punctuation to particular numbers. In this method, one byte corresponds to one letter. **Unicode** is a much more encompassing system and includes 1,114,112 characters, with the more common characters requiring one byte and the more esoteric characters using up to four bytes. While ASCII is limited to Latin-based languages, Unicode is able to represent most known languages, including pictorial languages such as Chinese. For example, consider the string of English letters in the word Informatics. This can be expressed in ASCII as the following series of numbers: 73, 110, 102, 111, 114, 109, 97, 116, 105, 99, 115.

Screen colors are commonly expressed as the value of their Red, Green and Blue (RGB) components, where each component is completely off (0) or completely on (255) or somewhere in between. For example, bright red would be (255,0,0); black, the absence of color is (0,0,0) and white is the combination of all colors (255,255,255).

Using this methodology, it is possible to describe a photograph by dividing the picture into a sufficient number of small boxes (picture elements, or **pixels**). Similarly, a movie can be encoded as a series of still images. Sound can be encoded by digitally sampling the audio in discrete timeframes.

Nearly any kind of information can be expressed as a combination of the above elemental data types. Documents, drawings and even computer programs can be encapsulated and stored this way.

3.1.5.5 Warehousing

A data warehouse is an intentional abstraction of a database which is organized for easy reporting. The data warehouse is often designed with particular queries in mind and organized for maximum efficiency. In addition, it is often created so that the user can interact with the data without needing specific database programming skills. See Sect. 3.1.2.1 for more information on data warehouses and datamarts.

3.1.5.6 Data Mining and Knowledge Discovery

Data mining is a process meant to explore large volumes of data (sometimes called **big data**) looking for patterns or relationships among different variables. In contrast to most biomedical research, there is no hypothesis to be tested by data mining. Instead, the goal is to look for correlations and then work backward to see if causation exists.

errors. Google (the owner of youtube) was forced to rework their database and change the storage capacity from int which is 4 bytes to bigint which is 8 bytes, effectively raising the limit to 1.8×10^{19} (one quintillion).

TABLE 6-6

ASCII TABLE

ASCII	HEX	CHAR	ASCII	HEX	CHAR	ASCII	HEX	CHAR	ASCII	HEX	CHAR
0	0	NUL	32	20	(spc)	64	40	@	96	60	`
1	1	SOH	33	21	!	65	41	A	97	61	a
2	2	STX	34	22	"	66	42	B	98	62	b
3	3	ETX	35	23	#	67	43	C	99	63	c
4	4	EOT	36	24	$	68	44	D	100	64	d
5	5	ENQ	37	25	%	69	45	E	101	65	e
6	6	ACK	38	26	&	70	46	F	102	66	f
7	7	BEL	39	27	'	71	47	G	103	67	g
8	8	BS	40	28	(	72	48	H	104	68	h
9	9	TAB	41	29	)	73	49	I	105	69	i
10	A	LF	42	2A	*	74	4A	J	106	6A	j
11	B	VT	43	2B	+	75	4B	K	107	6B	k
12	C	FF	44	2C	,	76	4C	L	108	6C	l
13	D	CR	45	2D	-	77	4D	M	109	6D	m
14	E	SO	46	2E	.	78	4E	N	110	6E	n
15	F	SI	47	2F	/	79	4F	O	111	6F	o
16	10	DLE	48	30	0	80	50	P	112	70	p
17	11	DC1	49	31	1	81	51	Q	113	71	q
18	12	DC2	50	32	2	82	52	R	114	72	r
19	13	DC3	51	33	3	83	53	S	115	73	s
20	14	DC4	52	34	4	84	54	T	116	74	t
21	15	NAK	53	35	5	85	55	U	117	75	u
22	16	SYN	54	36	6	86	56	V	118	76	v
23	17	ETB	55	37	7	87	57	W	119	77	w
24	18	CAN	56	38	8	88	58	X	120	78	x
25	19	EM	57	39	9	89	59	Y	121	79	y
26	1A	SUB	58	3A	:	90	5A	Z	122	7A	z
27	1B	ESC	59	3B	;	91	5B	[	123	7B	{
28	1C	FS	60	3C	<	92	5C	\	124	7C	|
29	1D	GS	61	3D	=	93	5D	]	125	7D	}
30	1E	RS	62	3E	>	94	5E	^	126	7E	~
31	1F	US	63	3F	?	95	5F	_	127	7F	DEL

Data mining includes three stages: exploration, model building and deployment.

The **exploration** phase involves taking a good look at a sample of the data to identify important variables and to make sure that the data is accurate enough for analysis. Since the source of the data is often vast, the informaticist must make special attention to narrow the scope of data before embarking on further analysis. The process of **model building** includes the competitive evaluation of models which compares various data models on the basis of their predictive ability. When the best model is chosen, it must be validated to ensure that it is able to produce stable results across many different samples. **Deployment** involves using the model selected above and applying it to new data to make predictions.

3.1.6 TECHNICAL APPROACHES THAT ENABLE SHARING DATA

Isolated data is practically useless. When that data is shared among patients, providers, administrators, consultants and public health agencies, it becomes useful and valuable for making important decisions.

3.1.6.1 Integration Versus Interfacing

There are two methods for sharing data between software applications. **Integration** means that the two applications share the same data store. **Interfacing** means that they are able to communicate with one another via some messaging system and can synchronize their data when needed. The communication system is sometimes called a **bridge.**

	INTERFACE	INTEGRATION
What is it?	A messaging system that exists between two software applications enabling them to share data. Interfaces typically use a standard file format, such as XML or HL7	Two applications that share the same data store
Benefits	Consumers can choose "best-of-breed" software tailored to their needs, and synchronization occurs when needed	Both software applications have access to real-time data, so that reports from one system should be equivalent to reports from the other
Pitfalls	Data may be out of sync. The mapping between systems may not be robust enough and the interface may not include all data points needed	Unifying a database is often very costly, and may destroy backwards-compatibility with the original applications

Deciding between an integrated system versus an interfaced system can be difficult. Here are some questions to help decide:

1. Is there particular functionality in the "best-of-breed" system that can not be replicated in the integrated system? If so, interface may be better.
2. Is there a requirement for real-time data? For example, suppose you are choosing a Human Resources and Payroll systems. Since checks are written only once every 2 weeks, the payroll synchronization process is run infrequently, and an interface would be adequate. However, in an EMR system, vital signs should be updated every few minutes, an integrated system may be better.
3. Is isolation required? Are there certain parts of the database that should not be shared because of HIPAA or some other requirement? If so, a selective interface may be better.

3.1.6.2 Dealing with Multiple Identifiers

Whenever patient data is inserted into a database, there are certain fields that are used as unique patient identifiers. For example, a social security number[11] or a medical record number usually identifies a particular person for their lifetime. When comparisons are made within a single health system, these identifiers are usually adequate to uniquely identify a person. These identifiers are stored in a **Master Patient Index (MPI)** or an **Enterprise Master Patient Index (EMPI).** However, when patient data are shared with other systems

11 Social Security Numbers (SSN) are commonly used to identify patients, but they have some drawbacks. Firstly, they are not always unique. Until the 1970s SSNs were not issued to non-workers, and the spouse of a worker would usually use the same number as the worker. In addition, SSN are commonly used in financial transactions such as applying for a credit card, and a data breach could lead to identity theft. For these reasons, many healthcare organizations (such as Kaiser Permanente) do not use SSN to identify patients.

(for example, with a regional health information exchange), the problem of matching and identifying patients can be more tricky.

One solution to this problem is to create a national patient health identifier, such as exists in Denmark. This has failed to gain traction in the US because of privacy and security concerns. In 2014, the Office of the National Coordinator commissioned a report[12] to address methods of patient matching. The two key recommendations included placing emphasis on accurate initial data collection and industry standardization of data identity elements.

There are several ways to make sure data are entered correctly

1. Rigorous training and or certification for registrars
2. Using data entry forms which require the operator to select from a set of validated options instead of allowing free text.
3. Allowing the patient to review the data before it is committed to the database
4. Maintaining a list of abbreviations and diminutive forms to assist in duplicate detection (e.g. William would match Will, Willy, Bill, Billy, etc)

For the second objective, there is no "official" identity data set, but some of the common items are shown below. Note that primary data relates to things that most people have, are unlikely to change, or are unlikely to forget. Secondary items are those that are more variable or less reliable.

PRIMARY	SECONDARY
Legal Name	Date of Death
Date of Birth	Birthplace
Sex	Birth order
Race	Marital status
Ethnicity	Other Phone numbers
Primary Phone Number	Social Security Number
Previous Names	Driver License Number
Mother's Maiden Name	Passport Number
Street Address	E-mail address
	Biometric information

A probabilistic matching algorithm would try to match as much as data as possible, placing more weight on primary than secondary data elements, in order to identify potential duplicates. In some cases, these algorithms can be very complex.

3.1.6.3 Anonymization of Data

In order to permit the secondary use of PHI, data must be de-identified. Section 164.514 of the HIPAA Privacy Rule states that "health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information."

There are two methods to meet the HIPAA Privacy rule. The first is the **expert determination** method. An expert is defined as a person with appropriate knowledge and experience in statistics and scientific methods for de-identifying data. If this expert deems that the risk of identifying an individual is very small, the standard is met. It is notable that the term "very small" is not clearly defined.

When using the expert determination rule, emphasis will be placed on characteristics of the population as a whole as well as the population being studied. For example, a patient identified with a first name of Muhammad may be unique in Montana[13] but fairly common in Saudi Arabia.

Another point to take into account is the availability of public databases. Since vital records (birth, death, marriage) are widely available in most states, it may be easy to

12 http://www.healthit.gov/sites/default/files/patient_identification_matching_final_report.pdf
13 Although hardly a canonical reference, see http://names.whitepages.com/first/Muhammad

re-identify a patient whose birthdate and zip code are known. Health plan numbers and patient account numbers that exist within proprietary databases and are harder to collect, however data breaches have been known to exist and re-identification is not impossible. Similarly, at one point, it was assumed that there could never exist a database of IP address or hardware MAC address. That is, until Google was caught collecting this data through its network of Street View vehicles.[14]

The second, and more common, solution to de-identifying data is the **Safe Harbor** method, in which the data is considered de-identified when all of the following identifiers are removed.

1. Names
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:

   (a) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
   (b) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000

3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) addresses
16. Biometric identifiers, including finger and voice prints
17. Full-face photographs and any comparable images
18. Any other unique identifying number, characteristic, or code

De-identified health information created following these methods is no longer protected by the Privacy Rule because it does not fall within the definition of PHI.

14 Kravets D. An Intentional Mistake: The Anatomy of Google's Wi-Fi Sniffing Debacle. WIRED 2012. https://www.wired.com/2012/05/google-wifi-fcc-investigation/

Scott Mankowitz

3.2 Human Factors Engineering

CHAPTER OUTLINE

3.2.1 MODELS, THEORIES, AND PRACTICES OF HCI

John Manning

Human factors engineering (HFE) and human computer interaction (HCI) are multidisciplinary sciences that seek to optimize the interactions between humans and a given system (Holden et al. 2016). HCI began in the early 1980s as a blend of HFE with software engineering, with the intent of applying scientific principles to address real problems in the software development space (Carroll 2003). HCI assimilates cognitive, social, and behavioral sciences into its frameworks, and members of the HCI community reach far into a myriad of domains including computer science, cognitive psychology, anthropology, mathematics, and communication studies.

3.2.1.1 Models

Many conceptual models exist within HCI, which are utilized both in the design and in the evaluation of a given system. Figure 1-1 provides a visual representation of the common evaluation methods used in HCI. Techniques shown in the analytic approaches (left) are often synergistic with usability testing methods (right), and some degree of overlap does exist among the various categories of methods. For further information on HCI evaluation methods and usability testing, see Sect. 3.2.2.

Task Analyses

Task analyses are simple methods used to evaluate an existing system based on the actions that are performed and the motivations/decisions underlying them (Kannampallil and Abraham 2015). Two of the more common variations of task analyses used in biomedical informatics include hierarchical task analysis and cognitive task analysis. **Hierarchical task analysis** separates large goals into various tasks, sub-tasks, sub-sub-tasks, etc. as desired to achieve an appropriate level of detail (Kannampallil and Abraham 2015; Stanton 2006; Annett 2003). It has been used in the evaluation of medical devices (Chung et al. 2003), clinical workflows (Unertl et al.

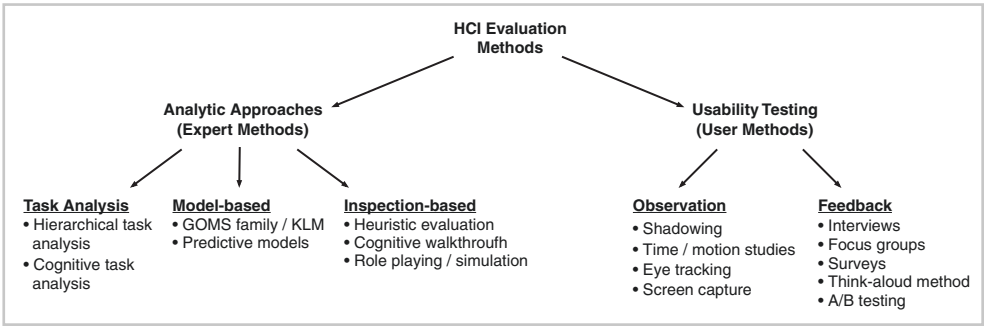


FIGURE 7-1

Classification of Human Computer Interaction (HCI) evaluation methods. Definitions: Goals, Operators, Methods, and Selectors (GOMS); Keystroke-Level Modeling (KLM); Task, User, Representation, and Function (TURF). Adapted from Kannampallil and Abraham (2015)

2009), and medication errors (Lane et al. 2006). While no theoretical limit exists as to the number of subprocesses included, doing so may limit the overall algorithm's utility and should be used with caution (Stanton 2006). By contrast, **cognitive task analysis** focuses more heavily on the internal perceptions and cognition that ultimately result in an observable action (Kannampallil and Abraham 2015; Schraagen et al. 2000). Cognitive task analyses have been utilized in healthcare to assess how primary care providers manage alert notifications (Hysong et al. 2010), and methods for cognitive task analyses frequently employ some of the inspection-based, observational, and feedback techniques also listed in the above figure (Cooke 1994).

Conceptual Models

While technically a task analysis as well as a conceptual model (Kannampallil and Abraham 2015), the **Goals, Operators, Methods, and Selectors (GOMS) model** is an important foundational model within HCI. The GOMS model separates tasks into smaller components to approximate how much time and effort may be required. At its most basic level, GOMS follows a user through their intended task (*Goals/Subgoals*); the actions performed to accomplish said goals (*Operators*); the order in which each action is taken (*Methods*); and the choice of one method over another similar one (*Selectors*). Many variations exist within the GOMS family, including the more simplified **Keystroke-Level Modeling (KLM)** tool, where operators focus more heavily around keyboard/mouse clicks and mouse movements (Card et al. 1980). Like many other HCI models, KLM also tracks the amount of cognitive time required to perform an action and the time required for the system to respond to the user.

The KLM model also takes into account the predictive model **Fitts Law**, which defines the shortest time interval required to acquire a target (Card et al. 1980; Fitts 1954). When clicking an object on a computer screen, Fitts Law can be applied based on the distance from the mouse to the target and the target's size (Carol et al. 1978). Another predictive model utilized in HCI is the **Hick-Hyman Law**, which states that each new choice logarithmically adds time to human processing and selection (Hyman 1953; Hick 1951). This model can be employed to determine the number of objects that a menu should contain, or to guide the display of choices with colors/highlighting to help augment human information processing time (Holden et al. 2016; Kannampallil and Abraham 2015).

3.2.1.2 Theories

As with HCI's models, cognitive theories played an integral role in shaping HCI techniques (Kaufman et al. 2015). These models typically fall within one of the three basic categories listed in Fig. 7-2.

Human Information Processing

Human Information Processing theories describe in various detail how we as humans absorb, process, and respond to our external environment. Inputs from our senses are distinguished from cognitive methods of processing and from internal storage in short- and long-term memory. One of the foundational theories within Human Information Processing is **Norman's Theory of Action**, which separates each mental activity cycle into seven

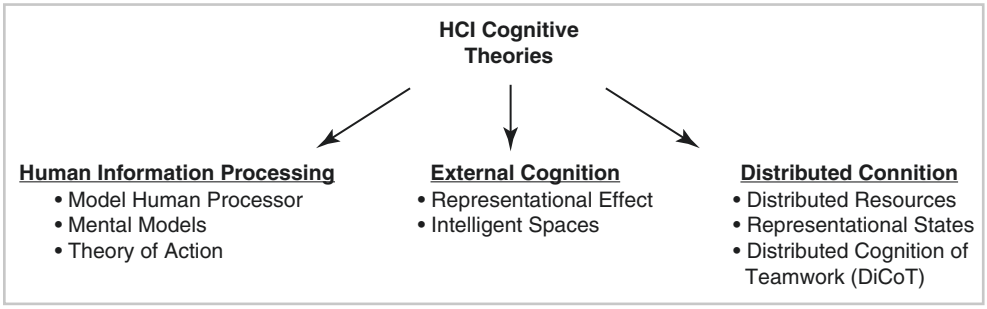


FIGURE 7-2

Classification of Human Computer Interaction (HCI) cognitive theories. Adapted from Kaufman et al. (2015)

inter-related stages (Norman 1986). Beginning with a *Goal* (e.g. to order a medication), the three stages within the "*Gulf of Execution*" (Intent to order a medication, Action sequence of steps, and Execution) are performed internally first, and then the action is actually performed in the real world. Once performed, the steps within the *"Gulf of Evaluation"* (Perceive the state of the world, Interpret this perception, Evaluate the interpretations) are employed to determine if the goal has successfully been achieved or not.

External Cognition

Just as we interact with the world, so too can the world affect our cognitive states. **External cognition** is the way in which we employ parts of our external environment to help guide and augment our cognitive behavior (Zhang 1997). These parts—also known as **external representations**—may exist in the form of memory aids, diagrams, symbols, pictures, or some other abstraction. The largest requirement for something to be labeled as an external representation is that its use must change the cognitive task at hand in some way (Zhang 1997). Some basic examples of external representations are the use of pen and paper to assist with complex math problems; the use of hand-drawn sketches to assist with brainstorming (Visser 2006); and the graphical visualization of a patient's lab results to understand what trends have occurred over time (Kaufman et al. 2015).

Distributed Cognition

Building off of the groundwork set by external cognition, **Distributed Cognition (DCog)** shifts the focus from a single person's cognitive model to multiple people in a "cognitive system" that are collaborating to accomplish a shared goal (Hutchins 1995). Examples include a crew of people working together to operate a ship (Hutchins 1995) and a team of healthcare providers working together to care for a patient (Kaufman et al. 2015). In an attempt to provide an implementable framework for the application of DCog principles in healthcare, Furniss et al. (2015) describe an implementable framework called the Distributed Cognition for Teamwork (DiCoT) which was used to assess a single medical device (glucometer) during its implementation within a health system.

3.2.1.3 Practices

Each of the models and theories mentioned above build upon one another in complexity to help understand how HCI can be used to analyze and improve upon the interactions between humans and technology. As best described by Bederson and Shneiderman (2003), the general reasoning behind learning these principles and their contextual relevance is to:

- describe plainly and regularly for collaboration;
- explain and educate;
- predict performance in current state/ideal state to maximize gains;
- prescribe guidelines and best practices while warning about concerns; and
- generate novel ideas.

With such objectives in mind, many of the discussions throughout the rest of this chapter build—at least in part—upon one or more of the foundational principles listed above. Through use of rigorous user-centered design techniques and adoption of best practice

designs into interface standards, the hope is to continue to push HCI forwards at a pace that can match and help manage the rapid technology gains seen today.

3.2.2 HCI EVALUATION, USABILITY TESTING, STUDY DESIGN AND METHODS

Laura Kneale

Human computer interaction (HCI) is increasingly important in the development and deployment of health information systems. HCI is the "study of interaction between people (users) and hardware, software, websites, and mobile devices" (United States Department of Health and Human Services 2017). Evaluating HCI influences the design of a system, maximizes the impact the system has on the intended user population, and ensures that a system meets organizational goals. A large component of HCI evaluation is **usability** testing. Usability is "the effectiveness, efficiency, and satisfaction in which the intended users can achieve their tasks in the intended context of product use" (Middleton et al. 2013).

Recent studies have shown that usability is a significant problem in many health information systems. These problems cause frequent user errors that contribute to a range of undesirable outcomes including adverse patient events and low user satisfaction. Lower user satisfaction has been linked to slow adoption of important technology, increased costs associated with training and redevelopment work, and individuals developing complex workarounds to accomplish common tasks (United States Department of Health and Human Services 2017; Middleton et al. 2013).

For example, one famous set of studies evaluated the implementation of two **computerized physician order entry** (CPOE) modules in two different pediatric intensive care units (PICUs). Although the CPOE module was built and installed by the same vendor, the two PICUs experienced vastly different outcomes. Using a pre/post study design, the first PICU that implemented the CPOE module observed a significant increase in mortality following the implementation. A study of the installation was conducted to determine potential causes, and found many issues with the initial design of the CPOE module. Usability problems that contributed to the undesired outcome included the inability to have critical orders available prior to patient arrival on the floor, the increase in provider time it took to prescribe medications, and the incompatibility between the CPOE module and the existing pharmacy systems (Holden and Karsh 2010). The other PICU had the opportunity to learn from the first hospital's implementation, and also evaluated mortality following their CPOE deployment. This second pre/post study found a non-significant drop in mortality rates after implementation. In contrast to the first implementation, the second PICU took extra steps to evaluate the usability of the final design, involve users in the design process, and thoroughly test the system prior to go-live (Han et al. 2005).

Because of studies such as the ones described above, the **American Medical Informatics Association (AMIA)** advocates developing a greater understanding of the importance of usability among its community membership. AMIA recommends formal usability testing during system development and prior to implementation. In fact, in 2013 AMIA released a list of 14 usability principles that all **electronic health records** should adhere, to in order to ensure that the system follows best usability practices, and the design of the system minimizes adverse events (United States Department of Health and Human Services 2017).

Human-computer interaction and usability are often associated with the concept of "**user-centered design**." User-centered design is the process in which the users' goals, motivations, and environment are considered throughout the design and development phases (Del Beccaro et al. 2006). Usability testing can be used to ensure that the assumptions that the system developers made during the design of a system are consistent with the requirements of the users. Figure 7-3 shows one framework for implementing user-centered design during a system development process (Del Beccaro et al. 2006). User-centered design is currently considered to be best practice when designing new health information systems.

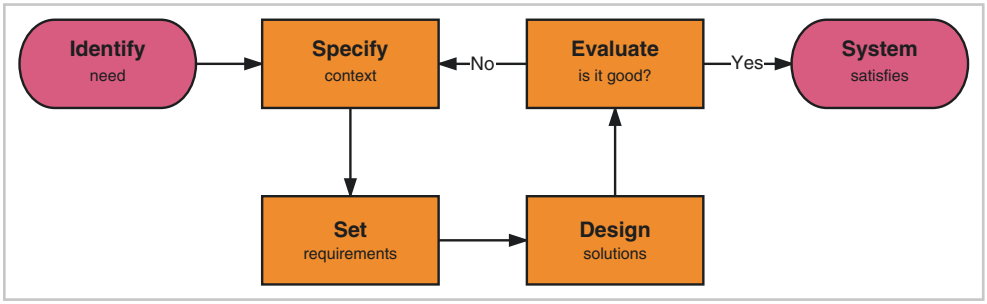


FIGURE 7-3

User-centered design process as modeled on Usability.gov (United States Department of Health and Human Services 2017)

3.2.2.1 Types of Usability Testing

Usability testing can occur at any stage of system development. **Formative usability evaluations** are conducted during the development of the system. Formative usability studies provide developers with early insights into user reactions to design decisions, and help to identify usability problems before the design has been finalized. Because the main goal of these evaluations is to understand user opinions, formative usability evaluations can be conducted on low-fidelity **prototypes** (including paper prototypes) (Usability Professionals Association 2010).

In contrast, **summative usability evaluations** are conducted after the system has been developed, but before the system is implemented. Summative evaluations are usually the final test to ensure that the system meets the project's usability benchmarks, goals, and user satisfaction standards. Summative evaluations may be helpful in finding usability issues, such as compatibility with existing workflows and technology, which may only be apparent when evaluating the entire system. In addition, summative evaluations can be used to compare usability of a new system to a benchmark, such as a gold standard or previous system (Usability Professionals Association 2010).

Because of the iterative nature of user-centered design, both formative and summative usability evaluations should be completed during the design and evaluation of a clinical information system. Formative evaluations are most helpful in gathering early user opinions, and ensuring that early decisions made by the development team are consistent with user goals and motivations. Summative evaluations, on the other hand, are the last assessment to ensure that all user requirements have been considered and the entire system works as intended.

3.2.2.2 Locations for Usability Testing

Usability testing can be conducted in a laboratory setting or in the user natural environment. Today a **usability laboratory** may include a wide range of setups. Traditionally, usability testing was conducted in a laboratory that had two rooms: a room where the usability participants conducted the test and an observation room. More recently, usability laboratories often contain sophisticated technology that automatically collects data on the participant as he or she conducts the usability test. These technologies can track participant's eye movements, calculate time between participant actions, and log user clicks. Conducting usability tests in laboratory environments can be particularly useful if the organization wants to collect a particular type of data on participants using usability software, if the system is expensive or includes a large footprint, and/or if the data in the system is sensitive or proprietary (United States Department of Health and Human Services 2017).

Usability testing can also be conducted in the user's natural environment. This means that the user is testing the system in the same environment that he or she will use the final system. Conducting tests with the user in their natural environment may provide insight into how the new system will integrate with existing tasks and systems. In addition, this method eliminates the need to have a central place to administer the tests, which may be a resource burden on the organization or reduce the organization's ability to recruit diverse study participants (United States Department of Health and Human Services 2017).

Often, depending on the needs of the organization, systems are tested in both laboratory and natural environments throughout the development process. Each location is associated with unique benefits and challenges, and the organization's goals, budget, and user constraints should be considered before deciding between potential locations.

3.2.2.3 Participants in a Usability Test

There are two groups of people who are needed to conduct a usability evaluation. The first group is the team that develops the usability testing conditions, creates the testing protocol, and administers the study procedures. This group may consist of **designers**, **human-computer interaction** experts, **domain experts**, and **developers.** The decisions made by this team will affect whether the outcome of the usability tests produce accurate and useful results.

Secondly, an organization will need to recruit people to perform the usability evaluation. Depending on the testing methods chosen, **participants** may include experts or potential users. Human-computer interaction experts can compare the usability of a new system against a gold standard, previously defined best practices, or help identify common mistakes in the systems' design. A domain expert can provide insight into user preferences and goals, even if he or she is not part of the group of potential users. For example, when designing a system for a PICU, an experienced pediatric provider may be involved in testing the usability of a system, even if he or she is not currently working in the unit where the system will be implemented.

Although both experts and users can bring valuable insight to the usability testing process, each type of evaluator may also bring biases to the results. For example, the intended users of the system will be able to provide information about their goals and expectations of the system. In addition, they will be able to help identify problems with the system that may be unique to their work environment. Users may not, however, be as good at articulating their needs for the system or be able to help brainstorm more optimal design choices without structured facilitation by the usability testing team. On the other hand, experts will be able to bring insights from similar systems, and help organizations benchmark their system against best practices. Experts will not be able to talk about the nuance expectations of a system's users, or identify issues that may be unique to a particular organization (United States Department of Health and Human Services 2017).

Both experts and users will likely expect compensation for their time. Many usability experts work as consultants and advertise their hourly rate. Internal experts will need to set aside time from their regular duties to conduct a usability evaluation. Recruiting from the intended user population may take even more effort. Depending on the user population, the usability study may need to be advertised to a large audience (e.g. the general public), provisions made to provide travel compensation, and additional compensation will be needed for users who complete the usability test. These costs should be considered when evaluating the different usability testing methodologies. Although it may be a tempting way to reduce costs, it is also important to remember that the people who design the system are not the best candidates for participating in usability studies. People who are closely tied to the system, including developers, healthcare provider champions, and individuals that designed the usability protocol, may unintentionally bring biases to the usability test and reduce the effectiveness of the usability testing data (United States Department of Health and Human Services 2017).

3.2.2.4 Usability Testing Methods

Selecting the appropriate method for usability testing depends on the organization's goals, timeline, budget, and resources. Knowing the organizational goals and constraints will help you select the best method(s) for your usability evaluation. Many organizations use different usability testing methods at different points in the development process to gather a range of data about the system, and provide multiple opportunities to engage with users.

TABLE 7-1

EXAMPLE USABILITY TESTING METHODS

COMMON EXPERT METHODS	COMMON USER METHODS
• Heuristic evaluation • Cognitive walkthrough • Role-playing and simulations	• Focus groups/interviews • Surveys • Think-aloud protocol • A/B testing

There are hundreds of tools that have been developed to help teams evaluate the usability of a system. Table 7-1 displays a list of commonly used strategies for gathering information from experts and potential users.

3.2.2.4.1 Expert Conducted Usability Methods

As described above, experts can provide insight into how a new system compares to known usability best practices. In addition, domain experts can help system developers understand user needs and goals, even if he or she is not in the user population.

A **heuristic evaluation** is a process that involves expert evaluators testing a system against a predefined list of potential usability problems (United States Department of Health and Human Services 2017). Heuristic evaluations can be completed for general audiences (e.g. Nielsen's heuristics (Nielsen 1994)) or for specific user populations (e.g. heuristics for older adult smartphone users).

Heuristic evaluations are most effective when being used to detect obvious usability problems, such as small font or inactive buttons. Completing a heuristic evaluation first may increase the effectiveness of user tests. Eliminating the obvious problems can allow users to focus more on the nuances of the system instead of being distracted by glaring issues. In order to ensure that the heuristics are correctly applied, and the review is comprehensive, it is recommend that multiple experts use the heuristics to review a single system (Martin and Hanington 2012).

Cognitive Walkthroughs:

A **cognitive walkthrough** asks experts to evaluate a system by walking through a series of common user tasks (i.e. "scenarios") and anticipate how the system should act during each step. Experts using this method are able to tell system designers where the system acts unexpectedly, which in turn may point to areas that may confuse potential users. This method is particularly useful with systems that will provide minimal user training, or where users will be expected to quickly adopt the system. Similar to the heuristic evaluation, this method is most effective when used before user evaluation to allow users to focus on system details during their evaluations (United States Department of Health and Human Services 2017; Martin and Hanington 2012).

Role-Playing and Simulations:

Sometimes it is difficult or not feasible to recruit actual system users for usability studies due to user availability and organizational resource constraints. In these situations, experts may try to act as the user for usability testing purposes. Using role-playing exercises or simulating a user experience may help experts empathize with user perspectives, and identify potential usability problems for that population. These methods will be most effective if the design team spends time ensuring that the scenarios used in the role-play or simulation is as realistic as possible. This may involve collecting data from users, conducting market research, or validating the scenarios with end-users (Martin and Hanington 2012).

3.2.2.4.2 User Conducted Usability Methods

Potential users are often asked to test systems to gain early feedback and identify issues during the formative evaluation stages. Gathering feedback from potential users can be challenging; however, because potential users may not be used to providing constructive feedback on systems. There are several usability testing methods that have been designed to help potential users express feedback.

Focus Groups, Interviews, and Surveys:

The most common way to elicit user feedback is to ask potential users to try a new system, and then ask them their opinion about the experience. Focus groups, interviews, and surveys are all tools that help users to express their opinions.

Individual **interviews** are a straightforward method for gathering qualitative from a usability test. After a user reviews the system, he or she is asked to sit down with a moderator to talk about the experience. Interviews can be structured (with the same questions asked to each participant), semi-structured (starting with the same questions but allowing the moderator to ask follow up questions), or open-ended (allowing the user to direct the conversation). Interviews can be used alone, or to supplement other testing methods. The advantage of an interview is that the facilitator can individualize the conversation to meet the needs of the participant, and spend the time to gather all the important details of an individual user's opinion. Disadvantages of this method include a large time investment to schedule and conduct the interviews, and the difficulty in projecting how close one participant's opinion is to other users (United States Department of Health and Human Services 2017; Martin and Hanington 2012).

Focus groups are sessions where a group of users (about 5–10) are brought together to talk about their experience at the same time. Examples of focus group participants include a multidisciplinary team of clinical providers, diverse users from the general population, or several people who perform the same job at different organizations. The advantage of conducting group sessions is that users can comment on each other's opinions. This interaction may highlight similarities and differences of opinions between users, allow users to explain their positions more thoroughly, and develop a consensus about a design choice. Focus groups are more difficult to conduct than individual interviews. Focus group moderators must be sensitive to potential power dynamics that may inhibit users from expressing honest opinions, and lead the discussion in a way where participants aren't able to derail the group with side conversations (United States Department of Health and Human Services 2017; Martin and Hanington 2012).

Surveys are a standard way to gather user opinions for a usability test. Surveys can be taken in person or remotely, and can be combined with another usability testing method. Surveys are most helpful when they are "validated," which means that the survey has been previously shown to produce reliable results over repeated tests. Surveys are relatively easy and inexpensive to administer. There is also little cost associated with increasing the sample size of a survey to reach broad communities of participants. Disadvantages of surveys include the preparation needed to ensure that the data collected from the survey will be comprehensive enough to be actionable, and identifying a survey that has already been validated and will meet your usability testing goals or validating your own survey (Martin and Hanington 2012).

Think-Aloud Method

The **think-aloud method** asks potential users to verbalize what they are thinking, feeling, and doing as they complete a series of assigned tasks. The think aloud method can be either concurrent (the participant verbalizes their thoughts as they complete the tasks) or retrospective (tasks are video recorded and the participant provides commentary at the end of the task sequence). This method allows the team to collect data on what the participant was thinking or feeling as he or she made decisions on how to navigate the system. The advantage of the think-aloud method is that the moderator does not have to guess why a participant made the choices that they did, and to uncover areas of confusion within the system. Not all participants will be comfortable with this method, and a skilled moderator may be needed to know when and how to prompt the user to verbalize their thoughts (United States Department of Health and Human Services 2017; Martin and Hanington 2012).

A/B Testing

The **A/B testing** method involves prototyping two different interfaces for the same task or series of tasks. Participants are randomly assigned one of the two prototypes (A or B), and

the usability testing team records the outcomes with that interface. After all participants have used either the A or B prototype, the outcomes from the different participant groups are compared. A/B testing is most useful when an organization wants to make a decision between two interfaces, and has specific goals for what the user should accomplish from a particular interface (e.g. purchase a product or complete a task within a set timeframe). A/B testing is not as useful for iterating on design choices or for gathering a nuanced understanding of user preferences.

3.2.3 INTERFACE DESIGN STANDARDS AND DESIGN PRINCIPLES

John Manning

3.2.3.1 Design Standards

Since the late 1980s, The International Organization for Standardization (ISO) has taken an active role in helping define and improve on our understanding of usability, human-centered design/user-centered design (UCD), and the user experience (Holden et al. 2016; Jokela et al. 2003; Bevan et al. 2015). Various ISO guidelines exist to describe and provide guidance on evaluation/implementation of human-computer interaction (HCI) principles. As a general rule, ISO standards are reviewed every 5 years and may be revised or replaced to accommodate current best practices in thinking. A brief summary of the relevant ISO standards for HCI can be found in Table 7-2.

The concepts of usability and UCD are critical to HCI discussions. While their current use is covered in more detail in Sect. 3.2.2, it is worth noting that the each of these concepts has experienced a shift in how it is defined. One simple example is the definition of usability, which has had the following definitions:

- **Nielsen** (1994)—a system's learnability, efficiency, memorability, error avoidance, and recovery (Nielsen 1993).
- **ISO 9241-11 (1998)**—the ability to accomplish goals with *"effectiveness, efficiency, and satisfaction in a specified context of use"* (Holden et al. 2016; International Organization for Standardization 1998).

TABLE 7-2

BRIEF OVERVIEW OF THE PERTINENT INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO) STANDARDS FOR USABILITY AND HUMAN-CENTERED DESIGN

ISO STANDARD	YEAR	KEY PRINCIPLES
9241-11	1998	Defines usability and its subcomponents: effectiveness, efficiency, satisfaction, context of use Establishes concepts of goals and tasks Provides characteristics of user interfaces ISO/draft International Standard (DIS) 9241-11.2 currently under development to replace this
13407	1999	Defines human-centered design and its rationale Helps guide the planning, principles, and activities of the design process Later replaced by ISO 9241-210
9241-210	2010	Defines the human-centered design approach for interactive systemsEstablishes user-centered design and evaluation methodsEncourages multidisciplinary design teams

Adapted from Holden et al. (2016), Jokela et al. (2003), and International Organization for Standardization (1998, 1999, 2010)

TABLE 7-3

COMPILATION OF COMMON HUMAN-COMPUTER INTERACTION (HCI) DESIGN PRINCIPLES

CONTEXT	PRINCIPLE	DESCRIPTION
Layout	Keep it simple	Limit clutter and distractions whenever possible Provide enough visual information for the task at hand Eliminate unnecessary physical and mental steps Allow for shortcuts and automated action sequences
	Keep it consistent	Design using conventions and standards that persist across various menus and interfaces
	Keep it familiar	Systems should resemble the user's world/mental models Buttons should look like buttons Cultural standards (e.g. reading left-to-right, cultural mappings of colors to concepts) should be upheld
Navigation	Make it logical	Sequences of steps and overall progress should be clear Provide user feedback when a task is complete
	Make it interactive	Following important actions and changes to the system state, the user should know this has happened immediately and without confusion
	Make it helpful	Design to avoid user and system errors whenever possible (e.g. using colors, bold, etc. for identical patient names) When errors occur, they should be auditable and reversible Alerts should be clear, descriptive, and used deliberately Help documentation should be easily accessible, logical, and searchable

Adapted from Holden et al. (2016) and Gibbons et al. (2011)

- **Task, User, Representation, Function (TURF; 2011)**—something that is *"useful, usable, and satisfying*" (Zhang and Walji 2011). Note that the TURF framework specifically focuses on usability in electronic health record (EHR) design.

Design Principles

Various recommendations and design principles exist within HCI. These were covered in part in Sect. 3.2.2 with discussions of Nielsen's heuristics, with AMIA's usability design principles, and with Usability.gov's recommended UCD process. A summary of the recurring themes seen within these and related principles has been compiled and adapted into Table 7-3 below.

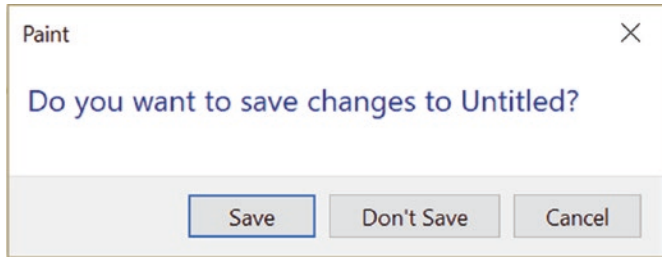
3.2.4 USABILITY ENGINEERING

Usability engineering is the process of making software more usable. Although usability engineers often make design and interface recommendations, their focus is on assessing and measuring how well end-users interact with the system. This is done through direct observation, click-counting, written surveys and evaluation of system logs.

A usability test ensures that an application meets user expectations with respect to meeting requirements (effectiveness) easily (efficiently) in a simplistic and satisfying manner. A usable application should be:

1. Easy to use
2. Easy to learn
3. Satisfying to the user

Safari (Apple)



Paint (Microsoft)

FIGURE 7-4

Example of two dialog boxes in Safari and Paint, copyright Apple and Microsoft, respectively. Note that Apple has the Cancel button on the left while Microsoft has it on the right

Ease of use is commonly measured by counting the number of minutes, keystrokes, mouse clicks or other interactions that are required for common tasks. One emerging method of analysis is to track users' eye movements, to see where they spend the majority of their attention. In general, the most common use-cases should benefit from the most optimization.

Ease of learning is accomplished by adhering to common programming paradigms, and having a straightforward menuing system. Consider the following dialog boxes belonging to two very common mainstream applications (Fig. 7-4). In Apple's Safari, the OK button is on the bottom right of the dialog box. In Microsoft's Paint, the Cancel button is on the bottom right. A user switching from application to application would be frustrated that the buttons are not where he expects them to be.

User satisfaction is much harder to measure. It is more about the user's experience while using the application and his/her feeling towards it. This is usually measured by survey or direct observation.[1] One simple rule is that users want to feel valued. An application's responsiveness is a key factor. Providing positive feedback for actions and avoiding lag are important. It goes without saying that applications with programming errors that crash frequently can challenge even the most dedicated user.

In commercial web sites, poor usability will result in lost sales.[2] In the case of an Electronic Health Record, user dissatisfaction will cause users to develop workarounds or revert to downtime procedures when the application doesn't perform to their expectations. It is up to the usability engineer to prevent this from happening.

1 See https://www.surveymonkey.com/mp/software-evaluation-survey-template/ for an example.
2 In one extreme case, a removing a single button was credited with an enormous increase in sales. See Spool JM. The $300 Million Button 2017. https://articles.uie.com/three_hund_million_button/ (accessed March 16, 2017).

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Scott Mankowitz

3.3 Health Information Systems and Applications

CHAPTER OUTLINE

3.3.1 TYPES OF FUNCTIONS OFFERED BY SYSTEMS

Computer systems are ubiquitous and protean in healthcare. The following is a representative but by no means exhaustive list of the ever expanding functions offered by computer systems.

1. Electronic Health Record (EHR). The definition of an EHR is evolving. In its strictest sense, it is the electronic analog of a paper chart—a place to store observations and procedures relating to a given patient. In practice, it includes many other things (including items listed below). Some EHR functions include patient tracking, laboratory and radiology result tracking, clinical decision support, order sets, order entry with interaction checking, discharge instructions, chart templates, macros, care plans, clinical decision support and many others.
2. Radiology Information System (RIS) and Picture Archiving and Communication System (PACS). Although the distinction between RIS and PACS is becoming less distinct, a RIS generally manages the workflow of radiologists and technologists while a PACS stores and retrieves images. Reports are usually stored in both systems.
3. Laboratory Information System (LIS). A LIS generally manages laboratory workflow, such as collecting reports from laboratory instruments and correlating them with orders received from the EHR. It provides a mechanism for laboratory specialists to disseminate results to providers.
4. Supply chain management and materiel management. Caring for patients requires great deal of supplies and equipment to be available at the point of care. Making sure that these items are present in sufficient quantities and in good repair is often assisted by logistics and inventory management software. Maintaining a list of available hospital beds falls into this category.

5. Pharmacy management. Like other supplies, pharmaceuticals must be ordered, received, stored, dispensed and returned. Pharmacy tracking software can help perform these functions. In a well-integrated system, as a physician orders a medication, the EHR performs clinical checks (dose, allergy, drug interactions, etc) and releases it from a mechanized dispensary (e.g. Pyxis, Omnicell). At the same time, a message is sent to patient billing to charge for the medication and another message is sent to the pharmacy inventory computer to see if more drug has to be purchased from the manufacturer.
6. Scheduling. Scheduling software helps coordinate the activities of many providers and patients. It can also be used to create and distribute work schedules for nurses, providers and others.
7. Medical Staffing. A medical staff office may use a database to keep track of providers' credentials, Continuing Medical Education, disciplinary actions, privileges, staff dues, insurance policies, office hours, languages spoken and other items.
8. Personal Health Record (PHR). Patients often compile their own health records in the form of a PHR. PHR's can be designed to receive information from other sources, such as personal fitness devices, community health information exchanges, immunization servers or EHRs.
9. Scanning and archiving. Documents that are not stored as structured data can be stored as scanned images. These documents may contain clinical information or may be any other kind of stored data, such as purchase orders or contracts.

3.3.2 TYPES OF SETTINGS WHERE SYSTEMS ARE USED

Electronic Health Records (EHRs) are most commonly used in clinical settings, such as hospitals, clinics and doctors' offices. As discussed elsewhere, they may contain more or less structured data on patient's conditions, allergies, treatments, medications, demographics, insurance and billing information, advance directives, etc. This wealth of information is extremely valuable for secondary analysis by researchers seeking to find new associations between treatment and outcomes. It is often used by public health experts to complete epidemiological studies.

Patient Portals are public-facing systems where patients are able to interact with their EHR. At a minimum, they are able to review clinical information to learn more about their condition or to share it with other health care professionals. In more advanced systems, patients may annotate or contest items found in their EHR to provide newer or more correct information. Some portals allow payment, scheduling and other non-clinical tasks as well.

There are also many home-based health records. The term **Personal Health Record** (PHR) has been advocated for systems which manage data provided and maintained primarily by the patient himself. Perhaps the best known example of this is the MedicAlert bracelet. The patient (or family member) populates a database with patient information, including all information that may be relevant in the case of an emergency where the patient himself is unable to communicate. The patient wears a bracelet engraved with some of the information (e.g. "diabetes") and also an ID number which is linked to his personal health record. By calling a toll-free number, a healthcare professional can gain access to this information in an emergency.[1]

Data Reliability in Non-clinical Settings

The major pitfall to patient-maintained data is that it may be out of date or incomplete, especially when it comes to current medications and dosages. Data from clinical settings tends to be more accurate. Some glucometers, scales and blood pressure monitors offer mechanisms to transfer data directly to a PHR. The majority of these systems also allow the user to edit

1 See https://www.medicalert.org/how-our-medical-ids-work for more information.

the data for correctness, which also may allow the user to hide embarrassing information or exaggerate some findings.

Personal activity monitors ("fitness trackers") are small, battery-powered devices generally worn on the body to measure physical activity. Most are able to upload data to a repository so that users can track their workouts, or those of their friends. Some health plans give discounts to their customers who exercise regularly. As with other PHRs, social and financial pressure may lead to fraudulent data.

3.3.3 ELECTRONIC HEALTH/MEDICAL RECORDS SYSTEMS AS THE FOUNDATIONAL TOOL

We have seen that the variety of information contained in an Electronic Health Record (EHR) is voluminous. As a result, the EHR has become the foundational tool (i.e. the primary data repository) for all healthcare related information.

EHRs commonly contain modules for registration, documentation of patient interactions, laboratory reporting, order entry, clinical decision support, electronic communication among patients and healthcare professionals, public and population health reporting, financial and administrative reporting, patient support (such as a patient portal). With this vast amount of knowledge, the EHR has become the foundation for other entirely non-clinical processes, such as shipping and receiving, materiel management, utilization review, calendar and meeting scheduling, infection control, nutrition and dietary services.

An example of end-to-end control provided by an EHR: A physician places an order for metoprolol. The EHR checks for harmful interactions and accepts the order. The patient's nurse is alerted to the new order and the site dispensing machine (e.g. Pyxis, Omnicell) automatically releases the medication. The nurse confirms the correct patient and correct medication via barcode scan and administers the medication to the patient. The EHR records the time of administration as well as the blood pressure before and after the medication was given, reporting this data back to the physician. It also computes the charge for the medication and adds it to the patient's bill. At the same time, the EHR notes that the clinic's supply of metoprolol is running low and notifies the pharmacy to restock the dispensing machine. It also orders more metoprolol from the manufacturer when the par levels fall below a predetermined standard. By comparing the cost of administration of metoprolol compared with the hospital acquisition cost, the EHR provides a report to the pharmacy and therapeutics committee showing that the clinic makes a 10% markup on metoprolol, and a 55% markup on atenolol, possibly suggesting a therapeutic interchange, which it also manages.

3.3.4 TELEMEDICINE

Daniel Ostermayer, M.D. and Irfan Husain, M.D., M.P.H.

Overview

Telemedicine or telehealth defines a clinical practice of medicine where the provider and the patient are separated geographically but interact through the use of a variety of telecommunication tools. Broadly, telemedicine is categorized as either **synchronous** (real-time) or **asynchronous** (non-real-time). As internet access and internet based communication software has become increasingly ubiquitous, telemedicine has experienced a rapid rise in popularity and use cases.[2] In addition to internet connectivity driving growth, a desire to reduce healthcare costs, advance care availability and quality, and patients' desire for convenience have all contributed to telemedical deployment in a multitude of healthcare settings. Hospital systems can take advantage of consolidated expertise of specialty services and provide those

2 Greenstein S, McDevitt R. Evidence of a modest price decline in US broadband services. Inf Econ Policy 2011;23:200–11.

services to a greater geographic area through telemedical services. Frequent and rapid interactions with patients can potentially decrease overall costs by managing chronic diseases and providing continued patient education.

Historically, telemedicine was first employed in the setting of acute conditions such as stroke care. The **telestroke** programs, as one of the earliest telemedicine services, provided acute stroke care from a remote neurologist to a patient in an emergency department without neurologic services.[3] The main goal was facilitation of the time sensitive administration of thrombolytic therapy during an acute stroke where a formal neurologic evaluation could be performed by a telemedicine physician in coordination with the emergency department providers. Since these first applications, telemedical services have moved outside of hospitals to involve settings ranging from outpatient clinics to prehospital care. Healthcare applications have also expanded to include medical consultations with home health physicians, paramedic and field provider triage, radiologic and pathology interpretation, and telepresent surgical assists to name a few. The overall dominant trend in telemedicine is a diversification in delivery models since no method will fit the needs of all specialty services and settings.

Technological and System Components

Depending on the nature of the telemedicine system (synchronous or asynchronous) a set of technological and systems components must be in place to ensure adequate usability in the local and remote location. Both sides of telemedicine communication systems require the ability to perform **data capture, storage and transmission**. Often for large files such as video and high resolution imaging, **caching** is required especially during **synchronous** communication in order to ensure quality of real-time communications. Similar to online video streaming, caching provides the buffer for variations in the **latency and reliability** of the network. Data is encrypted in transit and while at rest to ensure patient privacy and security. Many third-party services provide either long-term or temporary data storage for both caching and historical review, especially for video conferencing. Synchronous systems, to ensure **quality of service (QoS)** often rely on dedicated transmission pathways, such as traditional **plain old telephone service** (POTS)**, Integrated Service Digital Network connections** (ISDN) (128 kb/s)**, T1** (1.544 Mbit/s) or **T3** (44.736 Mbit/s) lines. Newer and often less expensive systems utilize consumer or business grade **broadband connections** (5 Mbps–1 Gbps). With a broadband connection, a single transmission pathway carries both the telemedical service data as well as other internet data. Broadband based systems require implementation of **QoS** rules that can prioritize the telemedicine service over other data transmissions. QoS controls can occur at the local networking level or via the internet using **end-to-end QoS** implementation provided by the service provider.

Delivery Models

Although modern telemedicine often utilizes synchronous voice, video, and messaging as a single software service for patient and staff communication, all or some of the modalities can be employed at a given time depending on the desired level of interaction. The main components of a telemedicine system include, **Video, Voice, Messaging,** and **Data Visualization**. For example, teleICUs, where physicians monitor intensive care units, the healthcare provider often communicates by voice and messaging with nursing staff, views synchronous data from patient monitoring, and then may use voice or video to communicate with patients and family members. U.S. Poison control centers, in contrast, only use telephone systems to communicate directly with the physician requesting the consult. Home health services generally use video and voice systems interacting directly with the patient or an onsite caregiver. Teleradiology systems utilize data visualization mainly in an asynchronous fashion and synchronous based telephone systems for communication with a consulting physician.

3 Schwamm, L.H., Holloway, R.G., Amarenco, P., Aude- bert, H.J., Bakas, T., Chumbler, N.R., et al. A review of the evidence for the use of telemedicine within stroke systems of care: A scientific statement from the American Heart Association/American Stroke Association. Stroke. 2009). 40, 2616–2634.

Synchronous Systems

Psychiatry, toxicology, home health, emergency medicine, general medicine, and neurology are all specialties utilizing synchronous telemedicine systems. Most utilize a combination of video and voice only depending on the clinical interaction but all require bidirectional real-time communication. Such channels must be encrypted and often don't involve storage of the video data. Tele-trauma and remote specialty consultations have been used to provide telehealth to rural or less specialized acute care centers by utilizing physicians in tertiary emergency centers to advise on the **remote monitoring,** management or transfer of critically injured children and trauma patients. Neurologists can videoconference with a less familiar provider on performing a National Institute of Health Stroke Scale (NIHSS) prior to administration of thrombolytic for acute ischemic strokes. General medicine physicians consult with correctional facilities, which are often remote, to provide guidance and diagnostic management for ill prisoners. Psychiatrists as demonstrated by the South Carolina Department of Mental health and New York State Psychiatric Institute have established telepsychiatry networks to increase the availability of mental health evaluations and services, especially in rural locations. Home health systems often utilize both POTS and videoconferencing to provide daily checkups and guidance for patients with the intention of preventing hospital visits and ensuring medical compliance and advancing patient education.[4]

Asynchronous Systems

Asynchronous telemedicine systems, those where communication functions in a store-and-forward fashion, are used for remote interpretation systems. Teleradiology, teledermatology, teleophthalmology, and telecardiology, are the most common fields utilizing asynchronous telemedicine. The decreasing storage cost of data, increasing speed of internet communications and the advances in high resolution display technology all contributed to the widespread adoption of these systems, especially in the fields of telepathology and teleradiology. Both **structured data** and **unstructured text data** and images are recorded at one location, stored locally and transmitted or accessed remotely. Images which can exceed hundreds of megabytes are often cached during transmission for faster access and to ensure reliability of transmission. The asynchronous telemedicine systems also allow for **batched interpretation** of data where a radiologist or pathologist will review multiple patient images after capture has occurred.

Reimbursement

Countries employing single-payer health insurance and integrated care organizations have been the most progressive adopters of telemedicine services since reimbursement happens seamlessly within the national or provincial healthcare system. The Ontario Telemedicine Network, funded by the Ontario government has worked to provide telemedicine services throughout the entire province of over 13 million people. The services have demonstrated reduced travel time for patients, reduced hospital admissions and improved care efficacy. Kaiser Permanente of Northern California, due to its integrated financial model provides education and patient checks using telephone and video telemedicine services to reduce hospital admission and provide close patient follow-up. The system, however, employs the physicians and advanced practice providers who staff the telemedicine services rather than using the traditional fee for service model. TeleICU services that exist outside of an integrated healthcare model are reimbursed using a contractual model where a physician group provides the ICU services for a fixed rate over a set timeframe. Commercial and consumer-health focused companies that offer telemedicine services for minor acute complaints often contract with company healthcare plans in order to establish a sufficiently large customer base or market directly to consumers and bill outside of traditional insurance, charging for service based on the number or duration of services used.

4 Daschle T, Dorsey ER. The return of the house call. Ann Intern Med 2015;162: 587–8.

Teleradiology and Telepathology

Radiology, one of the first specialties to utilize telemedicine, also pioneered reimbursement for asynchronous remote interpretation. Like all store and forward systems, encrypted data originates from the sender and remains encrypted in transit and while stored at rest on the remote system to ensure HIPAA compliance. Similarly, telepathology for slide and specimen viewing utilizes a store and forward asynchronous system for remote specialist interpretation. Both teleradiology and telepathology have grown rapidly due to the implementation of image storage and transmission standards such as **Digital Imaging and Communication in Medicine (DICOM).** Such standards make interoperability between systems and vendors more feasible and more robust.

Telepresence

With advances in 3D graphics and feedback mechanics such as **haptic** and **force feedback**, telepresence systems have been advancing rapidly to allow clinicians to interact with remote environments. For example, surgeons have performed procedures remotely using robotic equipment. The technical limitations are still numerous. Low latency data connections, robotic equipment and sensors remain expensive. However, the future benefits may be to broaden the reach of specialized providers to regions where a specific intervention would not have otherwise been possible.

Limitations and Barriers

Prior to ubiquitous internet and computing resources, high cost limited adoption of telemedicine systems. Today, the major limiting factors are generally no longer technical, but rather financial, clinical, legal, and social. The most significant of these limitations are those related reimbursement and legal liability. As of 2016, 30 states have **parity laws** that require private insurers to cover telehealth services to a similar reimbursement level as in-person care. Also, 48 state Medicaid programs provide a provision for telemedical care reimbursement.[5] Medicare, however, only provides reimbursement for telemedicine services if the patient was cared for in an underserved or understaffed region with the concern being that coverage of telemedicine services on par with physician visits will lead to excessive use before true clinical benefits of telemedicine have been demonstrated.[6,7]

On the legal front, state licensure laws often require telemedicine providers to be credentialed at multiple sites and states if care is provided outside of the provider's physical location or home state. In order to increase the adoption and ease of implementing tele services, the **Interstate Medical Licensure Compact** proposed enacting the TELE-MED Act of 2015 to enable providers licensed to bill for Medicare patients to provide telemedical services to any Medicare patient. Healthcare systems such as Kaiser Permanente and the Veterans Affairs hospitals have worked within their systems to allow for physician care privileges to include all participating telehealth sites regardless of the physician's primary practice location. Private companies such as Doctors on Demand have required multiple state licenses for all participating telemedicine physicians. Even though the Federation of State Medical Boards adopted the Interstate Medical Licensure Compact in 2014 to facilitate multistate provider licensure, states such as Texas require patients to see a physician in person prior to providing Internet-facilitated patient care.[8]

Clinically, sparse research has provided evidence that telemedicine provides a similar level of patient care as in-person visits. Most current research has focused on the potential for cost savings. Also, some fear that telemedicine services increase the potential to casually prescribe substances to patients who do not have an in-person patient-doctor relationship. Socially, telemedicine may benefit patients with the least access to healthcare resources. The

5 Bashshur, R.L., Shannon, G.W., Krupinski, E.A., Grigsby, J., Kvedar, J.C., Weinstein, R.S., et al. National telemedicine initiatives: Essential to healthcare reform. Telemedicine and e-Health. 2009. (15). 600–610.

6 Neufeld JD, Doarn CR. Telemedicine spending by Medicare: a snapshot from 2012. Telemed J E Health 2015;21:686–93.

7 Dorsey, E.R., Topol, E.J., State of Telehealth. NEJM.2016. 375(2). 154–61.

8 114th Congress (2015–2016). H.R.3081—TELE-MED Act of 2015 (https://www.congress.gov/bill/114th-congress/house-bill/3081).

underserved demographics, however, are the patients most likely to have poor internet connectivity and least likely to opt to take advantage of telemedicine services. Also, patients with infrequent contact with physicians are more likely to require a full physical exam that cannot take place using a telemedicine service.

Future Developments

The future for telemedicine centers around validation of the service as beneficial to the patient and healthcare system. This requires studies focused on patient centered outcomes rather than feasibility and new uses. Collaboration between physicians and treatment teams will allow for telemedicine to grow as one tool for healthcare delivery, whether synchronously or asynchronously. Also, as the legal and financial environments continue to evolve, the barriers to deployment will decrease and provide means for financial stability. As telemedicine systems become increasingly common, usability and availability will become a standard expectation among patients and healthcare providers.

Scott Mankowitz

3.4 Clinical Data Standards

CHAPTER OUTLINE

3.4.1 STANDARDS DEVELOPMENT HISTORY AND CURRENT PROCESS

Abigail Watson

The history of standards development in healthcare is the history of consensus building through the use of the scientific method. It is the history of scientific invention, first-to-market, natural monopolies, snake oil salesmen, regulatory oversight, market consensus, and international treaties. And its modern history traces back over 400 years.

The longest running healthcare standard still currently in use is the International Classification of Diseases (ICD-10), which began in London by The Worshipful Company of Parish Clerks, who kept weekly mortality statistics from 1592 to 1595 and then continuously from 1603. These London Bills of Mortality were simple ledgers and tallies of all the ways people passed away… Plague, Spotted Fever, Consumption, Childbearing, and so forth.

As a city practice, London kept these ledgers out of public interest. But in so doing, the records allowed the different parishes to begin to standardize the language they used in describing disease. A person didn't simply die of fever. But they died of Yellow Fever or Scarlet Fever. And that *shared language* would eventually prove critical to the standardization of medical practice around the world.

Over the years, the London Bills of Mortality were extended by luminaries such as John Snow, William Farr, François Bossier de Lacroix (Sauvages), Carl Linnaeus, and William Cullen to include hierarchical classification, indexes, codesets and other *structured data* elements.

By the 1800s, the Scientific Revolution had spread to both the European Continent and to the Americas; and the field of medicine was being transformed from a practice of barber-surgeons, grocers, and apothecaries into the beginnings of the field of study we know today. Critical to this process was a rigorous survey of both the Body and Mind.

While Greek theories of the four humors continued to be widely taught through the 1700s, the work of William Harvey on the mechanisms of blood circulation began the systematic mapping of the Body, resulting in Henry Gray's seminal work

Anatomy of the Human Body. This work, in turn, laid the foundation for modern Pathology, as it provided a *reference model* for practitioners to use.

The College of American Pathologists would eventually take the ideas present in Gray's Anatomy, and develop the Systematized Nomenclature of Medicine, which includes anatomy, diseases, findings, procedures, microorganisms, and other substances. It includes structural representation of human and veterinary subjects, and provides a topographic axis to locate disease according to body organ.

Outside the field of medicine, the steam engine was transforming the world, and railroads tracks were being laid across nations. Rail gauge was a continual source of interoperability problems, preventing cars from one rail line from traveling on another, causing accidents, and costing the industry untold amounts of losses. The problems lasted for decades, eventually prompting Charles Dudley to form ASTM International, a standards group to test materials used in rails, and later influencing rail gauge agreements and the size of the standard boxcar and shipping container.

Also of note was the invention of electricity, which gave rise to the telegraph and standardized the way we communicate. The early Morse code alphabet eventually gave way over the years to the 5 bit Baudot code used in teleprinters (with support for lowercase characters!), the 6-bit TeleTypeSetter (TTS) code of early modems, the 7-bit ASCII code that has punctuation, and the 16 bit Unicode character sets with support for Cyrillic, Greek, Hebrew, and other alphabets.

Meanwhile, the clinicians working in sanitariums, asylums, and debtor's prisons were making their progress in surveying the Mind. Like the earlier parish clerks who kept records of weekly mortality statistics; the stewards of public incarceration systems began keeping statistics of the mental states of their wards. And like the efforts of the London Parish Clerks and the Surgeon Pathologists, they began creating a shared language for describing mental states.

Eventually, theorists such as Sigmund Freud, Carl Jung, and Magnus Hirschfeld began synthesizing their data into theories of cognition and thought. They also began developing judgements on what behavior is typical or normal, and what behavior is atypical. The American Psychiatric Association compiled these observations into the standard now known as The Diagnostic and Statistical Manual of Mental Disorders (DSM).

Ethical medical progress took a large step backwards during the World Wars, wherein the eugenics movement in Europe lead to widespread genocide and war crimes. The Nuremberg Code resulted, which was the first worldwide standard on how (not) to conduct medical research. Facing the fallout of the second world war—both literally and figuratively—the international community began devoting huge amounts of resources during post-war reconstruction to creating new processes for consensus building and governance.

Organizationally, these efforts resulted in the United Nations and International Organization for Standardization (ISO). And of particular note is the development of the international balloting process. Much attention was given to balloting and voting systems in the late 40s and 50s as part of academia's contribution to postwar reconstruction. Not only was there a need to incorporate countries into a new world order, but the consequences of mismanaged outcomes in light of nuclear warfare gave game theory an urgency it never had before.

Consequently, post-war reconstruction led to the modern standards balloting process that is still used today by the ISO, Institute of Electrical and Electronics Engineers (IEEE), ASTM, Health Level Seven (HL7), and other standards bodies.

As the world was settling into post-war reconstruction, a new era of commodity electronics began, which resulted in an explosion of development in audio/video devices. And while most people trace the history of the Digital Imaging and Communications in Medicine (DICOM) standard through the history of radiologic sciences; it was the work of the Institute of Electrical and Electronics Engineers that resulted in the laserdiscs and coaxial cables that eventually became the CD-ROM format and Ethernet cables that allow modern radiology equipment to be networked together; and it was the work of the Joint Photographic Experts Group which defined the digital formats that allowed images to be digitally stored and visualized on televisions, discs, and network cabling.

Meanwhile, the International Organization for Standardization (ISO) and the International Telegraph and Telephone Consultative Committee (CCITT) were both developing models for describing electronic switchboard and telecommunication routing infrastructure. In the late 70s they independently created network interconnection models; and in 1983 these documents were *merged* to form the standard called the Basic Reference Model for Open Systems Interconnection.

More commonly known as the ISO 7 Layer Network Model, the model includes the following layers: Physical, Data Link, Network, Transport, Session, Presentation, Application.

With the electronics and networking technology in place, the 1980s saw the first modern interoperability standard of electronic medical record systems. Begun as a project at the University of California at San Francisco Medical Center, the UCSF protocol eventually became the Health Level Seven (HL7) working group by 1987 and a full blown standards development organization by the early 90s.

Thirty years later, the HL7 organization is still going strong, developing modern interoperability standards such as the Continuity of Care Document (CCD) and the Fast Healthcare Interoperability Resources (FHIR) standard.

Once hospital systems began managing their clinical records and billing systems with computers, it was only a matter of time before people realized that everybody was duplicating effort and continuously reinventing the wheel. So organizations set about *harmonizing* these efforts, much like ASTM had done for the railroads. Like the railroads, standardization was a process that came about *after* the networking did.

Early efforts harmonizing clinical terms were conducted by the National Library of Medicine and the Regenstrief Institute in Indiana…. institutions whose missions are to catalog and improve the nation's health. While we tend to think of these institutions nowadays as being repositories and curators of genomics and pharmacogenomics research. However, prior to the personal computer revolution and the Human Genome Project, the challenging problems of the day were coordinating health measurements, observations, and documents commonly used in laboratories; and managing large inventories and catalogs of pharmaceuticals by hand.

So it was the early 1990s when the Regenstrief Institute published the Logical Observation Identifiers Names and Codes (LOINC) data dictionary. And a few years later, the National Library of Medicine used the Unified Medical Language System to publish the RxNorm dictionary, which incorporates data from First Databank, Gold Standard Drug Database, and Multum.

In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act kicked off health care reform in the U.S. Providing $25.9 billion to promote the adoption of health information technologies, it provided incentives for every hospital in the nation to adopt an electronic health record (EHR) system. However, while the Act encouraged hospitals to adopt EHR systems, in the interest of promoting free-market solutions, it didn't specify *which* EHR system. Accordingly, hospitals implemented many dozens of different solutions, setting the stage for a need for interoperability initiatives.

The first such initiative was the BlueButton initiative. The Veterans Administration had been an early adopter of EHR systems; and at the time of the HITECH Act was arguably the largest electronic health network in the country. The BlueButton initiative helped veterans download their health records from VistA (the EHR of the VA). However, while it provided data in an easy-to-read format that veterans could understand, it was difficult to import into other systems.

As the HITECH Act was being implemented, the Medicare EHR Incentive Program (administered by the Centers for Medicare & Medicaid Services) selected the HL7 Continuity of Care Document (CCD) as the extract format for clinical care summaries. Effectively, the HL7 group took the data that the Veterans Administration was exporting in the BlueButton initiative, and used it as a starting point for a more structured file format that could be both exported and imported between EHR systems.

The HL7 Group had its eyes on a larger initiative though…. adoption of modern web standards and web services as the default transport and exchange format for EHR systems. Using the moniker Fast Healthcare Interoperability Resources (FHIR), the HL7 Group

began marshaling the resources and industry support for adopting standard protocols such as HTTP, REST, OAuth, and OpenId for their next generation interoperability standard. The FHIR standard is expected to go normative in 2018.

As of this writing, future directions and trends in interoperability appear to be heading towards distributed ledger systems and blockchains, as well as swarm file systems such as Interplanetary File System (IPFS). These technologies are trying to address the underlying interoperability problem of unsynchronized data by creating distributed networks where data cannot be accessed unless it is already synchronized and distributed across the entire network.

Concisely, we can describe the standardization process as involving the formation of consensus around shared language, structured data, and reference models. Formation of consensus can be difficult though; and often requires the identification of pain points that incentivize stakeholders to engage in the merging and harmonization of competing standards.

Once stakeholders are on board to sponsor a standard, a more structured balloting process can be initiated. Such a process involves creating working groups, creating drafts of the standard, balloting and voting, subsequent revisions, finalizing and distributing the standard, and then maintaining the standard. These activities can involve hundreds or thousands of participants and take years to accomplish. Yet, they reliably produce standards that have wide consensus, support, and adoption.

And this is exactly what is happening in healthcare with the adoption of electronic medical records. We are currently developing consensus around which shared languages, which vocabularies and ontologies to use, which exchange formats to support, and which reference models to adopt as standard. The HL7 group is leading the effort to ballot these things and create official standards. It's an exciting time to be involved in healthcare IT!

3.4.2 DATA STANDARDS AND DATA SHARING

Data standards are the methods, protocols, terminologies and specifications for the collection, exchange, storage and retrieval of information associated with healthcare applications.[1] Standards exist for nearly every type of medical data, such as: electronic health records (EHRs); clinical decision support instructions; pharmacy data; laboratory orders and results; radiological images and interpretations; billing, coding and reimbursement data; quality metrics; administrative processes; scheduling; medical devices and remote monitoring systems; and many others.

There are several key components of data standards which enable sharing[2]

1. Data definition—what data are collected and exchanged
2. Data interchange formats—the methods for encoding data into binary format so that it may be transmitted among disparate systems.
3. Terminologies—the medical terms that are used to describe the data as well as the relationships among terms and concepts.
4. Knowledge representation—the way that medical evidence (i.e. literature, guidelines, etc) are structured for clinical decision support systems.

Data Elements and Data Types

Data elements are individual pieces of information related to healthcare, such as a glucose measurement, systolic blood pressure, date of birth, etc. **Data types** define the form that such information takes. Simple data types include date, time, strings, integers, real

1 Aspden P, et al. eds. Health Care Data Standards. In: Patient Safety: Achieving a New Standard for Care. Washington, DC: National Academies Press; 2004.

2 AHIMA Work Group. Data Standards, Data Quality, and Interoperability (2013 update). Journal of AHIMA 84(11):64-69 [expanded web version].

numbers, etc. In addition to the form, data types should indicate the units of measurement. For example, glucose is measured as milligrams per deciliter[3] (mg/dL) and so on. To achieve **interoperability**, message formats must also include encoding specifications which define the relationships between data elements, architectures, and clinical templates. For example, in a fully interoperable system, a glucose measurement of 126 mg/dL in taken at 11:15 PM in New York would be automatically translated to 7.0 mmol/L at 16:15 in London.

OID

The first step in translating concepts from one terminology to another is identifying the terminology itself. The Object ID repository was jointly developed by the International Telecommunications Union—Telecommunication standardization sector (ITU-T) and the International Organization for Standards (ISO) for naming of objects in a permanent and unambiguous way. Nearly any item can be listed, but for our purposes, the OID is used for referencing standards, terminologies, algorithms, templates, rules, protocols, file formats and the like. For example, Logical Observation Identifiers Names and Codes (LOINC) is given the code 2.16.840.1.113883.6.1. The OID dot notation is hierarchical and specifies that this particular object is an external code system defined by HL7 in the USA.[4]

3.4.3 TRANSACTION STANDARDS

There are several transaction standards which are prevalent in healthcare. From a technical standpoint, there is not much difference between transactions and messages. For our purposes, transactions typically involve systems external to our facility (e.g. a retail pharmacy or insurer) while messages refer to communications within our facility (order entry, lab results, etc.)

National Council for Prescription Drug Programs (NCPDP)

The National Council for Prescription Drug Programs (NCPDP) is an American National Standards Institute (ANSI) accredited Standards Development Organization (SDO) which is responsible for outpatient pharmacy communications (inpatient pharmacy orders generally use HL7 V2—See Sect. 3.4.4). Some of the many standards the NCPDP has developed relate to: Benefit Integration; Billing Units; Formulary and Benefit; Manufacturer Rebates; Medicaid Subrogation; Medical Rebates Data Submission; Pharmacy ID Cards; Prescription File Transfer; Product Identifiers; Prior Authorization Transfer; and Universal Claim Forms.[5]

There are two important versions of NCPDP Script. Version 8.1 was required for HIPAA compliance, and version 10.6 is required for Meaningful Use. Figure 9-1 shows an example SCRIPT transaction.

```
UNA:+./*'
UIB+UNOA:0++1234567+++77777777:C:PASSWORDA+7701630:P+19971001:081322'
UIH+SCRIPT:008:001:NEWRX+110072+++19971001:081322'
PVD+P1+7701630:D3+++++MAIN STREET PHARMACY++6152205656:TE'
PVD+PC+6666666:0B+++JONES:MARK++++6152219800:TE'
PTT++19541225+SMITH:MARY+F+333445555:SY'
DRU+P:CALAN SR 240MG::::240:ME+EA:60:38+:1 TID+85:19971001:102*ZDS:30:804+0+R:1'
UIT+110072+6'
UIZ++1'
```

FIGURE 9-1

SCRIPT message in United Nations/Electronic Data Interchange for Administration, Commerce and Transport (UN/EDIFACT) format. This format is very similar to the HL7 V2 format discussed in Sect. 3.4.4. Some interesting things to note about this message: The first line starts with the characters UNA and specifies the delimiters that will be used for the rest of the message: component data element separator (: in this sample); data element separator (+ in this sample); decimal mark (. in this sample); escape character (/ in this sample); the asterisk is not used; segment terminator (' in this sample). In the UIH segment, we see that this is a SCRIPT message and it is creating a new prescription (NEWRX). Emphasis mine.

3 At least in the United States.

4 For much more information on OID's see http://oid-info.com/

5 For much more information, see https://www.ncpdp.org/Standards/Standards-Info

FIGURE 9-2

Example of an X12N 276 message—a request for claim status. Segments begin with 2–3 letter descriptors and end with an exclamation point. Line breaks are added for readability, but would not exist in an actual message. ST and SE signify the begin and end of a transaction, respectively. The reference number 0046 is repeated on the first and last line to indicate a closed loop. Modern X12 messages can also be transmitted in eXtensible Markup Language (XML) format, which uses open and close elements for the same purpose. (i.e. <transaction> </transaction>)

```
ST*276*0046!
BHT*0010*13**20030109!
HL*1**20*1!
NM1*PR*2*PAYER NAME*****21*9012345918341!
PER*IC*PROVIDER CONTACT INFO*TE*6145551212!
HL*2*1*21*1!
NM1*41*2******46*111222333!
HL*3*2*19*1!
NM1*1P*2*PROVIDER NAME*****FI*FEDERAL TAX ID!
NM1*1P*2*PROVIDER NAME*****XX*NPI NUMBER!
NM1*1P*2*PROVIDER NAME*****SV*PROVIDER NUMBER!
HL*4*3*22*0!
DMG*D8*19191029*M!
NM1*QC*1*DOE*JOHN****MI*R11056841!
TRN*1*500!
REF*1K*940922!
REF*BLT*131!
AMT*T3*28.00!
DTP*232*RD8*20020501-20020501!
SE*18*0046!
```

ASC X12

The Accredited Standards Committee X12[6] (also known as ASC X12) is an SDO chartered by ANSI. It produces the X12 Electronic data interchange (EDI) standards that facilitate electronic interchange of all sorts of business transactions, such as order placement and processing, shipping and receiving information, invoicing, payment and cash application data.

The X12N subcommittee is responsible for developing standards related to insurance. Of those, the following transaction types are of interest to healthcare:

- 837: Medical claims with subtypes for Professional, Institutional, and Dental varieties.
- 820: Payroll Deducted and Other Group Premium Payment for Insurance Products
- 834: Benefits enrollment and maintenance
- 835: Electronic remittances
- 270/271: Eligibility inquiry and response
- 276/277: Claim status inquiry and response
- 278: Health Services Review request and reply

Figure 9-2 shows an example of an X12 transaction.

3.4.4 MESSAGING STANDARDS

Health Level Seven International (HL7)

Health Level Seven International is a standards developing organization (SDO) which is accredited by the American National Standards Institute (ANSI) and International Organization for Standards (ISO) which creates and maintains interchange formats for healthcare information. Its eponymous protocol, HL7 version 2 (V2) is the primary clinical messaging standard in the US, and is used in over 90% of hospitals. When people say "HL7 message", they generally mean V2. There are four basic types of HL7 Messages:

1. ADT: Admit, Discharge, Transfer—for tracking when patients enter, leave or move within a facility
2. ORM: ORder Management—placing or cancelling orders

6 Incidentally, the 12 in X12 doesn't mean anything. It was assigned sequentially by ANSI when ASC was accredited.

```
MSH|^~\&|CE|001|RD|001|201704080113||ORM^O01|212358388404784272|P|2.2|||AL|AL
PID|||000587355||DOE^John^A||19491104|M||B|300 CENTRAL AVE^FL 2^EAST ORANGE^NJ^07018||(973)266-
3307|(973)266-3307|EN|S|CA|3251075|580485125||||VI
PV1|||I|5I^523^1^EOGH||||7111^WELBY^MARCUS^W|7111^WELBY^MARCUS||MED|||||||7111^WELBY^MARCUS^W|||
|||||||||||||||||||||||201703272145
ORC|NW|39084339||9483357^ICC-
EO|NW||001^^^201704080113^^S||201704080113|E300454^NIGHTENGALE^FLORENCE^^RN||7111^WELBY^MARCUS^
W~7111^WELBY^MARCUS^W|5I||201704080113||||^NIGHTENGALE^FLORENCE^^RN||||||||||^^^^^^^^V
OBR||39084339||4367104^CHEST X-RAY--PORTABLE ONCE
S^^^^PHDICT||||||||||7111^WELBY^MARCUS^W|||||||CR|||1^^^201704080113^^S||||chest tubes
placement.|||||201704080113|||||||^^^^CHEST X-RAY--PORTABLE^ILW-
XSERVC||PERFORM_IMMEDIATE_FLG^Y^LEOEXT~GE_FIRST_SERVICE_DTTM^2017-04-
08:01:13:00^LEOEXT~REASON_FOR_EXAM^chest tubes placement.^LEOEXT
NTE||P
```

FIGURE 9-3

Example of an HL7 V2 message sent when Dr. Welby ordered a portable chest x-ray for his patient John Doe. Emphasis mine. See text for explanation

3. ORU: Observation Result—lab results, radiology results, vital signs
4. DFT: Detail Financial Transaction—financial transactions that are sent to a billing system

The V2 standard was the first commonly used messaging standard and has been embraced and extended by many developers. As a result, the standard often differs somewhat between implementations and offers limited interoperability. V2 messages are separated by vertical bars and carets (i.e. |'s and ^'s), commonly called pipes and hats.[7] Figure 9-3 is a message which was sent when a doctor ordered a portable chest x-ray after placing a chest tube.

The message is composed of several **segments**. In this message, the segments are MSH (Message Header), PID (Patient IDentification), PV1 (Patient Visit), ORC (ORder Common), OBR (OBservation Request) and NTE (Note). Each segment has a number of **fields** (also called **composites**) which are separated by vertical bars. The order of these fields is determined by specification (although implementations vary somewhat). Consider the PID segment:

```
PID|||000587355||DOE^John^A||19491104|M||B|300 CENTRAL AVE^FL 2^EAST ORANGE^
NJ^07018||(973)266-3307|(973)266-3307|EN|S|CA|3251075|580485125||||VI
```

To parse this, we have to review the HL7 specification. Table 9-1 shows the first few fields for the PID segment.

Each of the field data types is also explicitly defined, and can be further separated into **components** by the caret delimiter. For example, Extended Patient Name (XPN) in field 5 has 14 components. The first few are shown in Table 9-2.

DICOM

Digital Imaging and Communications in Medicine (DICOM) is an ANSI accredited SDO which is responsible for handling, storing, printing, and transmitting medical images. DICOM is actually a collection of standards which has evolved over many years, and includes file formats, network communications protocols and even definitions of grayscale necessary for printing and screen display.

7 Actually, the first five characters following the letters MSH in the beginning of the message will serve as delimiters for the remainder of the message. They are: Field Separator (normally |); Component Separator (normally ^); Subcomponent Separator (normally &); Field Repeat Separator (normally ~); Escape Character (normally \).

TABLE 9-1

EXAMPLE OF HL7 PID SEGMENT DEFINITION

SEQ	CONTENTS	DATA TYPE	REQUIRED	LENGTH
1	Set ID	SI	O	4
2	Patient ID	CX	B	20
3	Patient identifier list	CX	R	250
4	Alternate patient ID	CX	B	20
5	Patient name	XPN	R	250
6	Mother's maiden name	XPN	O	250
7	Date/time of birth	TS	O	26
8	Administrative sex	IS	R	1

Explanation of data types: *SI* Set Identifier, *CX* Extended composite ID, *XPN* Extended Person Name, *TS* Time Stamp. *IS* coded value from a table. For field #8, this is a one-character code for sex: *M* Male, *F* Female, *O* other, *U* Unknown. The *required* column has three choices: *O* Optional, *R* Required, *B* only present for backwards compatibility. In our example, we can see that fields 1, 2, 4 and 6 are blank, which is consistent with the specification. Field 3 tells us that the patient identifier is 000587355. From field 5, we learn that his name is John A. Doe (more on this below). Field 7 gives his date of birth as November 4, 1949. Field 8 tells us he is male. Thus, although some of the HL7 message can be interpreted from context, its full explanation requires reviewing the implementation standard

TABLE 9-2

EXAMPLE OF HL7 XPN COMPOSITE FIELD DEFINITION

SEQ	CONTENTS	DATA TYPE	REQUIRED	LENGTH
1	Family name	FN	O	194
2	Given name	ST	O	30
3	Second and further given names or initials thereof	ST	O	30
4	Suffix (e.g., Jr. or III)	ST	O	20
5	Prefix (e.g., Dr)	ST	O	20
6	Degree (e.g., MD)	IS	B	6

Explanation of Data Types: *FN* Family Name, *ST* String data, *IS and ID* coded values from a table, *TS* Time Stamp. Continuing our example, we see that field 5 of PID is DOE^John^A. According to the message header (MSH), components are separated by the caret character. The first component is Family Name (DOE); the second component is Given Name (John); and so on

A DICOM message is a stream of **elements** which are composed of an **element tag**, optional **value representation**, **value length** and **value**.

1. Data Element Tag: a 4-byte number identifying the type of data. In the past, this was separated into separate group and element codes, but today that distinction is only historical. The tag is usually expressed in hexadecimal notation. For example, (0010,0010) corresponds to Patient Name. The canonical list of data types can be found in the data dictionary.
2. Value Representation (VR): an optional 2-character string identifying the format of the data. (e.g. PN is Person Name, DA is date, and so on)
3. Value Length (VL): the length of the value in bytes
4. Value Field: the actual data. Some fields are unrestricted, and contain nearly anything, while others are constrained to a restricted vocabulary. For example, patient sex is constrained to be one of Male, Female or Other.

DICOM files are stored as binary streams, without any human-readable punctuation, although some implementations use XML internally to make it more editable. Figure 9-4 is an example of the first few bytes of a DICOM file for a chest X-Ray.

Element	Binary	Meaning
1	08 00 00 00	Data Element: (0008,0000) - Group Length
	04 00 00 00	Value Length: 4 bytes
	1E 01 00 00	Value: 286
2	08 00 08 00	Data Element: (0008,0008) - Image Type
	10 00 00 00	Value Length: 16 bytes
	4F 52 49 47 49 4E 41 4C 20 50 52 49 4D 41 52 59	Value: ORIGINAL PRIMARY
3	08 00 12 00	Data Element: (0008,0012) - Creation Date
	0A 00 00 00	Value Length: 10 bytes
	31 39 39 35 2E 30 37 2E 32 30	Value: 1995.07.20
4	08 00 13 00	Data Element: (0008,0013) - Creation Time
	08 00 00 00	Value Length: 8 bytes
	31 31 3A 32 32 3A 30 37	Value: 11:22:07

FIGURE 9-4

DICOM image format with explanations. DICOM files are machine readable, but not human readable. This fragment of a chest x-ray shows that the file was created on July 20, 1995 at 11:22:07 and has a total of 286 elements. Only the first four are shown here

3.4.5 NOMENCLATURES, VOCABULARIES, AND TERMINOLOGIES

Terminologies

A **terminology** is a controlled, limited **vocabulary** used to express all the **terms** or **concepts** in a domain. For example, in HL7 V2, the gender of a person is limited to one of Male, Female, Unknown or Other. According to the designers of V2, all persons may be assigned to one of these values, and there is no person that can claim to be more than one of these. This type of vocabulary is often encountered in surveys where the subject is allowed to select an item from a menu of choices.

A **code** is a short, usually alphanumerical representation applied to a term so that it can be more easily processed (e.g. M for male). In a **nomenclature**, concepts can be combined according to specific rules to form more complex concepts, such as in the Systematized *Nomenclature* of Medicine (SNOMED, which is an ontology—see Sect. 3.4.6).[8] A **thesaurus** is a network of terms that relate to each other in more or less complex ways.

ICD-10

ICD-10 is the tenth revision of the International Statistical Classification of Diseases and Related Health Problems, a vocabulary created by the World Health Organization (WHO). It contains codes for diseases, symptoms, physical findings, external causes of injury and social problems.

In 2016, ICD-10 Clinical Modification (ICD-10-CM) replaced the 9th revision as the standard method for encoding diagnoses in the US. Some of the differences between ICD-9 and ICD-10 are shown in Table 9-3.

8 de Lusignan S. Codes, classifications, terminologies and nomenclatures: definition, development and application in practice. Inform Prim Care. 2005;13(1):65–70.

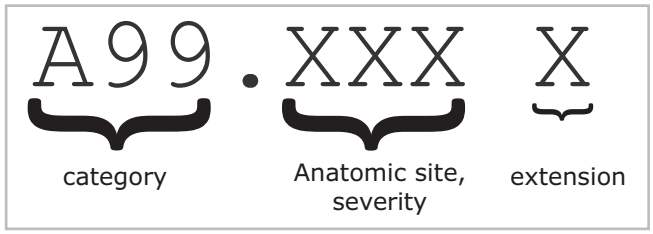
TABLE 9-3

DIFFERENCES BETWEEN THE NINTH AND TENTH REVISIONS OF THE INTERNATIONAL CLASSIFICATION OF DISEASES

	ICD-9	ICD-10
Number of codes	13,000	68,000
Length of code (chars)	3–5	5–7
Specificity	Somewhat detailed	Very detailed
Laterality (i.e. right or left)	Not specified	Specified
Visit type (i.e. initial, repeat)	Not specified	Specified
Max codes reported	4	12

FIGURE 9-5

Anatomy of an ICD-10 code. Key: A, letter; 9, number; X, alphanumeric character



ICD-10 is arranged in a hierarchical format by organ system and etiology. There is no multi-hierarchy, meaning that a code can only exist in only one branch of the hierarchy. In general, the longer the code, the more specific is the meaning. Payors often demand the most specific code possible for billing purposes. The code is 5–7 characters in length. The first character, a letter, specifies the major class (usually organ system involved). The next two characters, which are numbers, complete the category. A decimal point separates the next few characters which, if present, provide additional information. Figure 9-5 shows the anatomy of an ICD-10 code, and the list of major categories is shown in Tables 9-4 and 9-5.

Some examples:

C50.212, Malignant neoplasm of upper-inner quadrant of left female breast.
I80.01, Phlebitis and thrombophlebitis of superficial vessels of right lower extremity.

One of the key features of ICD-10 codes is that they provide justification for hospitalization, procedures and other services. For example, a patient with diagnosis code H66.001 (Acute suppurative otitis media without spontaneous rupture of eardrum, right ear) may justify the performance of Myringotomy with insertion of ventilating tubes (Current Procedures and Terminology code 69436). Without this diagnosis (or another qualifying diagnosis), an insurer may question the necessity of the procedure and may refuse to pay.

Diagnosis Related Group

Originally developed at Yale in the 1970s, this list of 745 principal diagnoses are meant to describe hospital inpatient episodes of care, in terms of the amount of resources required and the intensity of services provided. They are used by the Center for Medicare and Medicaid Services (CMS) to determine reimbursement under the inpatient prospective payment system (IPPS). Computer programs called **groupers** are used to classify discharges into one of the DRG codes. The current set of DRGs is known as the Medicare Severity Diagnosis Related Groups (MS-DRGs). DRGs are grouped into 25 body systems, known as Major Diagnostic Categories (MDCs). Severity of diagnosis is specified as having Major Comorbid Conditions (MCC) or Comorbid Conditions (CC) or without comorbid conditions. Since patients with comorbidities require more resources, they typically stay in the hospital longer (greater length of stay, LOS). As a result, the reimbursement weights are higher. In general, the LOS is reported as a geometric mean instead of an arithmetic mean because the geometric mean better accounts for outliers.

TABLE 9-4

MAJOR CATEGORIES FOR ICD-10 CODES

A00-B99	Certain infectious and parasitic diseases
C00-D49	Neoplasms
D50-D89	Diseases of the blood and blood-forming organs
E00-E89	Endocrine, nutritional and metabolic diseases
F01-F99	Mental, behavioral and neurodevelopmental disorders
G00-G99	Diseases of the nervous system
H00-H59	Diseases of the eye and adnexa
H60-H95	Diseases of the ear and mastoid process
I00-I99	Diseases of the circulatory system
J00-J99	Diseases of the respiratory system
K00-K95	Diseases of the digestive system
L00-L99	Diseases of the skin and subcutaneous tissue
M00-M99	Diseases of the musculoskeletal system and connective tissue
N00-N99	Diseases of the genitourinary system
O00-O9A	Pregnancy, childbirth and the puerperium
P00-P96	Certain conditions originating in the perinatal period
Q00-Q99	Congenital malformations and chromosomal abnormalities
R00-R99	Symptoms, signs and abnormal clinical and laboratory findings
S00-T88	Injury, poisoning and other consequences of external causes
V00-Y99	External causes of morbidity
Z00-Z99	Factors influencing health status and contact with health services

Don't memorize these

TABLE 9-5

EXAMPLE ICD-10 CODES SHOWING INCREASING SPECIFICITY

CODE	EXPLANATION
H66	Suppurative and unspecified otitis media
H66.0	Acute suppurative otitis media
H66.00	Acute suppurative otitis media without spontaneous rupture of eardrum
H66.001	Acute suppurative otitis media without spontaneous rupture of eardrum, right ear

The letter H specifies diseases of the eye, ear and mastoid process. H65-H75 are disease of the middle ear and mastoid process

There are four guiding principles for creation of DRGs[9]

1. The data used to calculate the DRG should be routinely available
2. The overall number of DRGs is relatively small
3. Each DRG contains patients with similar resource requirements
4. Patients within a DRG should be clinically similar

9 These are the academic reasons for creation of DRGs. The practical reason was actually financial. Prior to the introduction of DRGs, hospitals were paid on a per diem basis for inpatient care, which created an incentive for long hospital stays and increasing the intensity of inpatient services. When payors shifted to the prospective payment model with DRGs, they were paid a flat rate based on the DRG code, which is why hospitals are now incentivized to discharge patients as soon as possible.

TABLE 9-6

EXAMPLES OF SEVERAL MEDICARE SEVERITY DIAGNOSIS RELATED GROUPS (MS-DRG)

MS-DRG	MDC	TYPE	TITLE	WEIGHT	GMLOS	AMLOS
280	05	MED	Acute myocardial infarction, discharged alive w/MCC	1.7289	4.7	6.0
281	05	MED	Acute myocardial infarction, discharged alive w/CC	1.0247	3.0	3.7
282	05	MED	Acute myocardial infarction, discharged alive w/o CC/MCC	0.7562	2.0	2.4

Abbreviations: *MDC* Major Diagnostic Category, *GMLOS* Geometric Mean Length Of Stay, *AMLOS* Arithmetic Mean Length Of Stay, *MCC* Major Comorbid Condition, *CC* Comorbid condition. Major Diagnostic Category 05 refers to diseases of the circulatory system

TABLE 9-7

SELECTED EMERGENCY DEPARTMENT PROCEDURES WITH CURRENT PROCEDURAL TERMINOLOGY CODES AND RELATIVE VALUE UNIT WEIGHTS

SERVICE	CPT CODE	RVU
EKG rhythm interpretation	93042	0.22
Application of finger splint	29130	0.83
Single laceration up to 2.5 cm (scalp, neck, axillae, external genitalia, trunk-including hands and feet)	12001	1.27
Level III ED exam	99283	1.75
Single laceration repair 2.6–7.5 cm (scalp, neck, axillae, external genitalia, trunk-including hands and feet)	12002	2.08
Endotracheal intubation	31500	3.24
Critical care (30–74 min)	99291	6.31
Treatment of shoulder dislocation	23650	8.18

Examples[10] (Table 9-6):

Current Procedural Technology®

Current Procedural Technology® (CPT) is a set of codes maintained by the American Medical Association (AMA) for the purposes of describing procedures and services for billing and analytic use. Although the AMA maintains an exclusive copyright, these codes are used by nearly every insurer, including the Centers for Medicare and Medicaid services (CMS), which means that most users of these codes must pay yearly licensing fees to the AMA.

Each code has an associated Relative Value Unit (RVU) weight associated with it which roughly correlates to the degree of skill, risk and/or time required for the procedure. The total RVU for a procedure can be broken down into separate measurements for the work, the practice expense and the professional liability insurance cost (PLI). Table 9-7 shows some common Emergency Department procedures with RVU. Some codes are **bundled** and can not be billed together. For example, when a physician bills for critical care (99291), he can not separately bill for a regular ED exam (99283) because it is assumed that a regular exam is part of critical care services.[11] There are many complex rules about what codes can be included on the same bill. These rules vary from payor to payor.

10 CMS. Table 5.—List of medicare severity diagnosis-related groups (MS-DRGs), relative weighting factors, and geometric and arithmetic mean length of stay—FY 2015 final rule, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2015-FR-Table-5.zip accessed 4/20/17.

11 Critical care subsumes many other ED activities. The following is a list of items that can not be billed separately when critical care is included: Interpretation of cardiac output measurements (93561, 93562). Pulse oximetry (94760, 94761, 94762); Chest X-ray interpretation (71010, 71015, 71020); Blood gases (99090); Gastric intubation (43752, 91105); Transcutaneous pacing (92953); Ventilator management (94002-94004, 94660, 94662); Vascular access procedures (36000, 36410, 36415, 36591, 36600).

RVUs are used by insurers to determine reimbursement. They are also used to compute the relative contribution of physicians to a group practice, and are frequently used as the basis for determining raises, bonuses and other accolades.

Other Terminologies

There are many other noteworthy terminologies and many being created each day. The following terminologies are somewhat less common.

Universal Medical Device Nomenclature System

The Universal Medical Device Nomenclature System (UMDNS) is a hierarchical terminology for medical devices including both device types and specific make/model records.

Examples

CODE	SHORT NAME	DESCRIPTION
16652	Defibrillators, implantable	Defibrillators that are permanently inserted (implanted) abdominally, pectorally, or subcutaneously. Pectoral and abdominally implanted defibrillators are connected to the patient's heart through a set of epicardial or transvenous leads. These defibrillators consist of a hermetically sealed container, including a lightweight battery, electronic circuitry to sense cardiac activity and produce the electrical pulses (shocks), and electrode leads that conduct the myocardial signals to the defibrillator and the electrical defibrillating pulses to the patient, when needed. Implantable defibrillators are used to sense ventricular fibrillation and initiate defibrillation by applying an electric shock to the heart to depolarize the myocardium. Some of these stimulators have memory modules for storage and retrieval of the cardiac electrical activity, and some have programmable capabilities. Subcutaneous implanted defibrillators that are connected to leads and electrodes anchored under the skin above but not touching the heart are also available. Implantable defibrillators are used as life saving devices mainly for tachycardia, ventricular fibrillation, and cardiac arrest
17428	Dressings, nonimpregnated, synthetic, film	Synthetic dressings made of synthetic polymers (typically polyurethane). These dressings are usually transparent films coated with an adhesive that is permeable to water vapor and oxygen but impermeable to liquids and bacteria. Synthetic film dressings do not absorb usually wound exudates; they are used mainly in wound management

National Drug Code

The National Drug Code (NDC) is a unique identifier for the approximately 10,000 labelled drugs approved by the Food and Drug Administration. Barcodes that appear on drug vials are typically the NDC. The NDC is a 10-digit number broken into three segments. The first four digits identify the labeler (manufacturer, packager or distributor). The next four digits are the product code which specify the strength, formulation and dosage form. The last two digits are the package code which describes the size and contents of the package. The first four digits (labeler code) are assigned by the FDA, while the product and package codes are assigned by the labeler.

Example

CODE	MEANING
0777-3105-02	0777 is the labeler code for Dista Pharmaceuticals 3105 is the product code for Prozac (fluoxetine) 20 mg tablet 02 specifies a bottle of 100 pills

Health Care Financing Administration Common Procedure Coding System

The Health Care Financing Administration Common Procedure Coding System (HCPCS) provides codes for products and services not mentioned in CPT.

Examples

CODE	MEANING
PL001007	Progressive addition lenses
Q6001007	Service furnished by a locum tenens physician
UE001007	Used durable medical equipment
A0998001003	Ambulance response and treatment, no transport
A4267001003	Contraceptive supply, condom, male, each

3.4.6 ONTOLOGIES AND TAXONOMIES

A **classification** is an arrangement of concepts into groups according to established criteria, such as the International *Classification* of Disease. The term **taxonomy** is also used this way to mean a rigidly hierarchical structure where each child concept inherits characteristics from a parent concept. For example, tuberculosis is a kind of pneumonia which is a kind of infectious disease. An **ontology** is an extension of a taxonomy where concepts can be related in multiple different ways in addition to simple parent-child relationships.[12] For example, a taxonomy may assert that tuberculosis (is a kind of) pneumonia. An ontology defines its concepts by relationships to other concepts, and would add that tuberculosis (is caused by) *Mycobacterium tuberculosis;* tuberculosis (has symptom) cough; tuberculosis (has symptom) hemoptysis, etc. One way to think of the difference between a taxonomy and an ontology is that a taxonomy is a family tree, while an ontology is Facebook.[13]

Ideal ontologies have several characteristics[14]

1. Concept orientation—elements of the terminology are coded concepts with hierarchical relationships to other coded concepts. Redundant, ambiguous and vague concepts are excluded
2. Concept permanence—coded concepts remain in the dictionary forever. Codes are never deleted or reused
3. Nonambiguity—coded concepts have only one meaning.
4. Explicit versioning—each version of the dictionary is given a version number
5. Meaningless identifiers—the codes themselves are unrelated to the hierarchy or relationship among concepts. (i.e. codes themselves are non-semantic)
6. Multihierarchy (or polyhierarchy)—concepts may be reached through multiple different paths. (e.g. viral meningitis could be found under the classification of infectious disease or neurological disease or related to the presenting symptom of headache)
7. Formal definitions—concepts are defined in a formal way so as to make detection of duplicates easier
8. Multiple granularities—concepts have varying degrees of specificity for different users. (e.g. a family practitioner may be satisfied with code for "coronary artery disease" while a cardiologist may benefit from a more specific code, such as "history of acute anterolateral myocardial infarction with posterior extension")
9. No residual categories—concepts are defined with as much specificity as possible, so that containers such as "not otherwise specified" are not needed.
10. Nonredundancy—coded concepts must be unique so that even if multiple terms refer to the same entity, only one code is found in the dictionary. Alternatively, when redundant codes do exist, they are easily recognized as aliases or synonyms.

12 A nice review of some common ontologies can be found in Cimino JJ, Zhu X. The practical impact of ontologies on biomedical informatics. Yearb Med Inform. 2006:124–35.

13 Academically speaking, taxonomy and ontogeny are different terms. Practically speaking, the distinction is blurred in modern literature.

14 One of the seminal papers in this area is Cimino JJ. Desiderata for Controlled Medical Vocabularies in the Twenty-First Century. Methods Inf Med. 1998 Nov; 37(4–5): 394–403.

TABLE 9-8

TERM TYPES FOR RXNORM, PUBLIC DOMAIN BY NATIONAL LIBRARY OF MEDICINE

TTY	NAME	DESCRIPTION	EXAMPLE
IN	Ingredient	A compound or moiety that gives the drug its distinctive clinical properties. Ingredients generally use the United States Adopted Name (USAN)	Fluoxetine
PIN	Precise ingredient	A specified form of the ingredient that may or may not be clinically active. Most precise ingredients are salt or isomer forms	Fluoxetine hydrochloride
DF	Dose form	How the drug is used	Oral solution
SCDC	Semantic clinical drug component	Ingredient + strength	Fluoxetine 4 MG/ML
SCDF	Semantic clinical drug form	Ingredient + dose form	Fluoxetine oral solution
SCD	Semantic clinical drug	Ingredient + strength + dose form	Fluoxetine 4 MG/ML oral solution
BN	Brand name	A proprietary name for a family of products containing a specific active ingredient	Prozac
SBDC	Semantic branded drug component	Ingredient + strength + brand name	Fluoxetine 4 MG/ML [Prozac]
SBDF	Semantic branded drug form	Ingredient + dose form + brand name	Fluoxetine oral solution [Prozac]
SBD	Semantic branded drug	Ingredient + strength + dose form + brand name	Fluoxetine 4 MG/ML oral solution [Prozac]

RxNorm[15]

RxNorm is a project of the National Library of medicine to normalize the format of clinical drugs. It is based on what type of drugs a clinician might order and what form those drugs take when administered to a patient (as opposed to the form produced by the manufacturer).[16] It relies on a combination of 14 commercial and noncommercial sources of drug information, such as the Food and Drug Administration product labels, Medical Subject Headings (MeSH), Micromedex®, First Databank® and others. In order to remove redundant entries, drug components are placed into a semantic normal form (SNF) which expresses the active ingredient(s), strength, dosage and unit of measurement. Each component is assigned a Concept Unique Identifier (CUI).

From here, the concept is expanded into many different term types (TTY) which include varying types and amounts of information, some of which are shown in Table 9-8.

In RxNorm, concepts are linked to each other using several bidirectional relationships. For example Zyrtec is a tradename of Cetrizine, and Cetrizine has a tradename of Zyrtec. Figure 9-6 shows some of the relationships among the CUI's associated with this medication.

There are approximately 80,000 items in the RxNorm database.

SNOMED CT[17]

Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) is a comprehensive, hierarchical medical vocabulary that was initially developed by the College of American Pathologists and England's National Health Service. Since 2007, it has been distributed by the International Health Terminology Standards Development Organization (IHTSDO).

15 See http://www.nlm.nih.gov/research/umls/rxnorm/overview.html for more information.

16 For example, amoxicillin is produced as a powder which is reconstituted by a pharmacist to create a suspension. Prescribers will request a certain dosage of amoxicillin suspension to treat a child with acute otitis media. It is of no interest to the prescriber how that suspension came into being. Thus, when producing a list of prescribable drugs, it would not make sense to include amoxicillin powder, but it would make sense to include amoxicillin suspension.

17 For much, much more information, see http://www.snomed.org/. Also, visit the IHTSDO SNOMED browser, at http://browser.ihtsdotools.org/

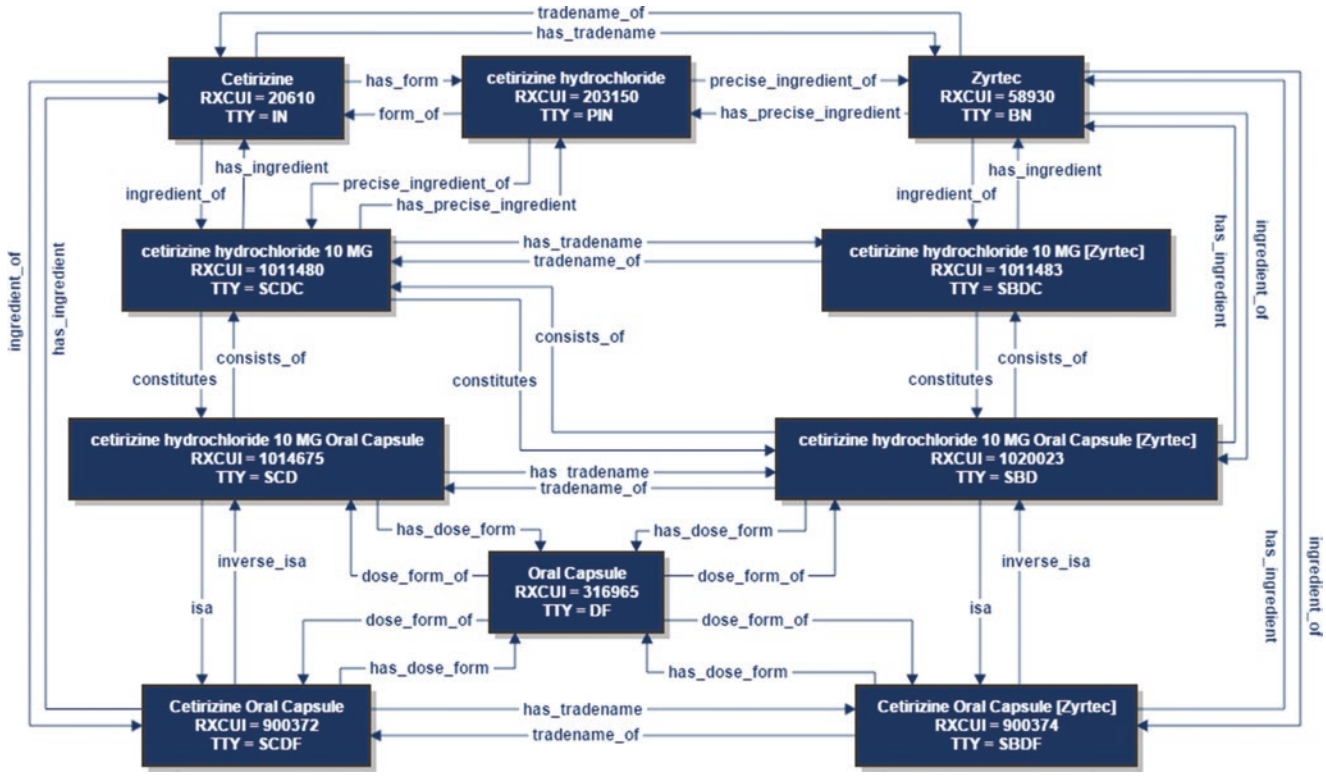


FIGURE 9-6

Semantic map of cetrizine, public domain by National Library of Medicine. Abbreviations: RXCUI, prescription Concept Unique Identifier; For explanations of TTY, see Table 9-8

TABLE 9-9

CORRELATION BETWEEN A CLINICAL NOTE AND SNOMED CONCEPTS

44 year old man complains of moderate, constant pain in the bilateral lower back for the past 3 weeks	Age more than 40 years (699716008); Male (248153007); Constant pain (426206001); Lower back (37822005); Moderate Severity (6736007); 3 weeks (4831000175101)
Past medical history: pulmonary embolism	History of pulmonary embolus (161512007)
Medications: Xanax 1 mg bid	Administration of substance via oral route (434589000); Alprazolam 1 mg tablet (371281008); Twice a day(229799001)
Lab results: Hgb 15 mg/dL	Hemoglobin normal (165399006)
CT scan of head: negative	Computerized axial tomography of brain without radiopaque contrast (396205005); Has interpretation (363713009); Negative (260385009)
Plan: follow up with Dr. Hinds 1 week	Referral to doctor (306253008); Private doctor (310174000); 1 week (4791000175109)

SNOMED includes concepts and the relationships between concepts. There are 19 top-level hierarchies, including body part, clinical finding, procedure, substance, event and others. The most common concepts are assigned by **pre-coordination**, where each concept is assigned a number (SCTID). For example, the SCTID for headache is 25064002. Newer or more complicated concepts are identified by **post-coordination**, where terms are defined by a combination of two or more basic codes. (e.g. Head = 69536005, Ache = 410711009).

Table 9-9 is the author's attempt to extract SNOMED concepts from a brief clinical note.

Each SNOMED concept is related to one or more other concepts. The most common relationship is the parent-child relationship (called **is_a** in SNOMED). For example,

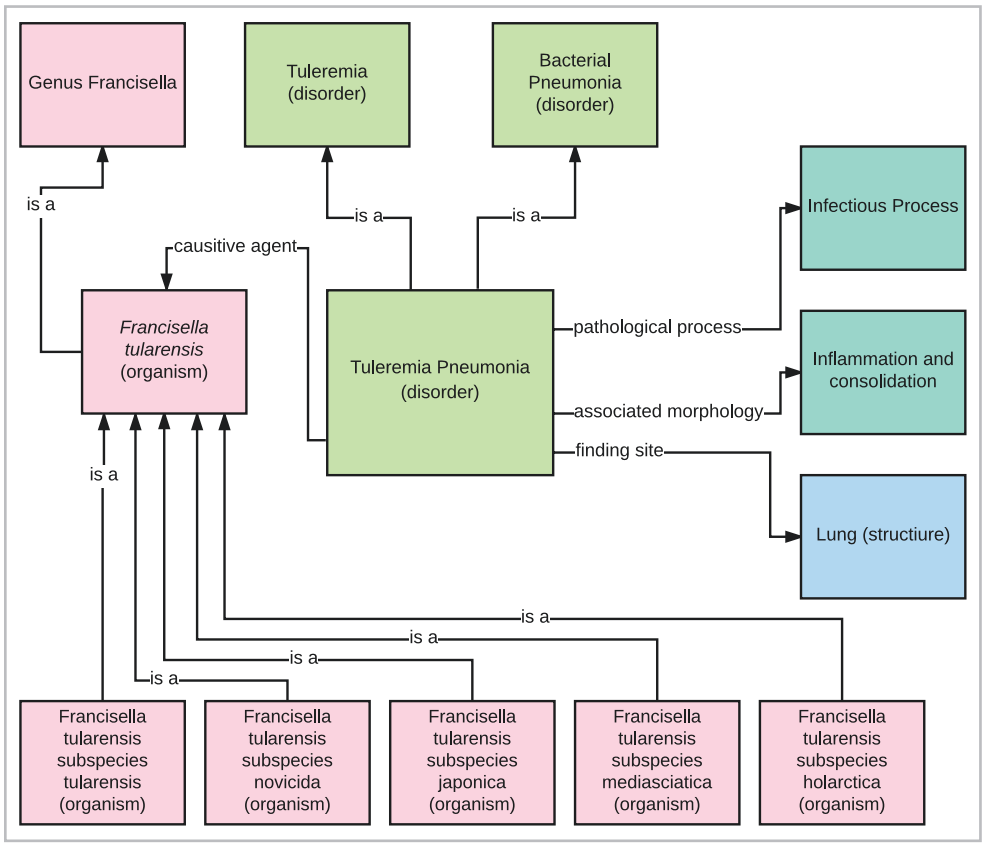


FIGURE 9-7

Diagram of ontological relationships in SNOMED, with Tularemia in the center

Glioblastoma multiforme (393563007) is a Primary malignant neoplasm (372087000), which in turn is a Malignant neoplastic disease (363346000), which is a Neoplastic disease (55342001) which is a Neoplasm and/or hamartoma (399981008) which is a Disease (64572001) which is a Clinical Finding (404684003) which is a SNOMED Top Concept (138875005). SNOMED is also multi-hierarchical, which means that a concept can inherit from multiple parents. Glioblastoma multiforme (393563007) also is a Glioma (393564001) which is a Neoplastic disease (55342001), and so on.

SNOMED concepts can also be linked by non-hierarchical terms. Consider, Pulmonary Tularemia (45556008) which is linked to *Francisella tularensis* (51526001) as *causitive_agent*. It is also linked to Lung (39607008) as a *finding_site*. Some of these links are depicted in Fig. 9-7.

In total, the there are 311,000 concepts, 800,000 descriptions, and almost a million relationships in the latest release of SNOMED CT.

LOINC

Logical Observation Identifiers, Names, and Codes (LOINC) includes 80,000 defined entries for laboratory and clinical observations.[18] LOINC is maintained and distributed by the Regenstrief institute, and is free for all users. The current code set includes laboratory terminology, vital signs, hemodynamics intake/output, EKG, obstetric ultrasound, cardiac echo, urologic, imaging, endoscopic procedures, ventilator management, and selected survey instruments.

Some of the most common LOINC codes are shown in Table 9-10. By convention, LOINC codes are six digits long, with a hyphen between the fifth and sixth digit.

18 As of LOINC version 2.59, released 2/21/17, there are 83,377 terms.

TABLE 9-10

SEVERAL OF THE MOST COMMONLY USED CODES IN LOINC (LOGICAL OBSERVATION IDENTIFIERS, NAME AND CODES)

ID	NAME	CLASS
02160-0	Creatinine [mass/volume] in serum or plasma	CHEM
00718-7	Hemoglobin [mass/volume] in blood	Hem/BC
02823-3	Potassium [moles/volume] in serum or plasma	CHEM
02345-7	Glucose [mass/volume] in serum or plasma	CHEM
02951-2	Sodium [moles/volume] in serum or plasma	CHEM
03094-0	Urea nitrogen [mass/volume] in serum or plasma	CHEM
02028-9	Carbon dioxide, total [moles/volume] in serum or plasma	CHEM
02075-0	Chloride [moles/volume] in serum or plasma	CHEM
00789-8	Erythrocytes [#/volume] in blood by automated count	HEM/BC
00786-4	Erythrocyte mean corpuscular hemoglobin concentration [mass/volume] by automated count	HEM/BC

3.4.7 INTEROPERABILITY STANDARDS

In order for computers to communicate effectively, system designers must ensure that the terminologies and vocabularies used in each system can be directly and unambiguously mapped from one to another.

HL7 V3 and RIM

Health Level Seven Version 3 (HL7 V3) bears little resemblance to V2. V3 is encoded as eXtensible Markup Language (XML) and is not backward-compatible to V2. The major thrust in developing V3 was to create **semantic interoperability,** or the ability to exchange data with unambiguous shared meaning. The foundation for semantic interoperability in V3 is the **Reference Information Model** (RIM), which is composed of four base classes: entities (people, places, things), roles, participations and acts. As an example, suppose that Dr. Welby performs a cholecystectomy on Mr. Doe in Operating Room 6. Mr. Doe, Dr. Welby and OR-6 would be entities. Mr. Doe would have the role of patient and Dr. Welby the role of surgeon. The act would be a cholecystectomy, and participation would link all of the above. By extending these four classes, and combining them with standardized vocabularies and data types, nearly any kind of health information can be encoded and transmitted.

Different kinds of healthcare communications have different requirements. For example, a lab report must have a patient identifier and at least one result. An order for a chest x-ray must have a patient identifier, an ordering doctor, a reason for exam, etc. The set of rules defined for a particular type of communication is known as a **constraint.** By rigorously defining what can, should and can't be in a communication, the system of constraints can be used to ensure that the receiver will be able to interpret and use the message.

As of 2017, V3 has not been widely adopted as a messaging standard, nor has it supplanted V2 as expected. One notable exception is the **Clinical Document Architecture (CDA)**, a hierarchical text-based format for medical record interchange. One example of the CDA is the **Continuity of Care Document (CCD)**, which became immensely popular when it became a requirement for Meaningful Use in 2010.

```
<observation classCode="OBS" moodCode="EVN">
   <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
   <id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>
   <code code="3141-9" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Patient Body Weight - Measured"/>
   <statusCode code="completed"/>
   <effectiveTime value="20170514"/>
   <value xsi:type="PQ" value="86" unit="kg"/>
   <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
</observation>
```

FIGURE 9-8

A section of a Continuity of Care Document (CCD), which is a constraint on the Health Level 7 (HL7) Reference Information Model (RIM). The template and encoding are specified using numeric identifiers (e.g. 2.16.840.1.113883.6.1) as well as textual names (e.g. LOINC) which makes the document both human-readable as well as unambiguous enough for semantic interoperability. This observation shows that the patient's weight is 86 kg

```
<observation classCode="OBS" moodCode="EVN">
   <code code="50373000" codeSystem="2.16.840.1.113883.6.96"
         codeSystemName="SNOMED CT" displayName="Body height measure"/>
   <statusCode code="completed"/>
   <effectiveTime value="20170514"/>
   <value xsi:type="PQ" value="1.77" unit="m"/>
</observation>
```

FIGURE 9-9

Another section from the same CCD. This document uses a SNOMED CT term instead of LOINC to describe the finding. In this case, the patient's height is 1.77 m, and was recorded on May 14, 2017

Figures 9-8 and 9-9 show a small part of a CCD, specifically the height and weight of a patient. Observations are a child class of the act class. There are a few important things to note in this fragment. The first is that these messages follow a particular template. In this case, the template ID is 2.16.840.1.113883.10.20.22.4.27, which is an OID object corresponding to vital sign measurement. The specific measurement is *Patient Body Weight—Measured*, which corresponds to code 3141-9 in the LOINC vocabulary (The LOINC vocabulary, in turn is coded as OID 2.16.840.1.113883.6.1). The actual weight is 86 kg, which has interpretationCode of N. If you look up code system 2.16.840.1.113883.5.83, you will see that the code N means Normal.

FHIR

Fast Healthcare Interoperability Resources (FHIR, pronounced "fire") is a relatively new standard for transfer of medical information. It relies on well-established web technologies, such as Hypertext Transport Protocol (HTTP) with representational state transfer (REST) endpoints for transport; Hypertext Markup Language (HTML) and Cascading Style Sheets (CSS) for presentation; Javascript Object Notation (JSON) and extensible markup language (XML) for data representation; and Atom for publication and syndication.

FHIR supports transmission of documents, messages and services using RESTful endpoints. While many other standards support these paradigms, FHIR was designed to use identical content for all message types, meaning that there is no need to build a separate interface when transferring information from a message into a document. The fundamental building block of FHIR is a **resource**. Resources are atoms of information that have standard elements and consistent meaning across all contributors. This is accomplished through using reusable data types and common metadata. In addition, all resources also contain a human-readable component.

As of this writing (December 2017), FHIR v3.0.1 is classified as a Standard for Trial Use (STU) which means that the standard is likely to change before it becomes final (Fig. 9-10).

FIGURE 9-10

Example of a FHIR resource expressed in Javascript Object Notation (JSON), public domain by Health Level 7 International. Note that there is a human readable component with Hypertext Markup Language (HTML) markup in the text section


```
{
  "resourceType": "Patient",
  "id": "genetics-example1",
  "meta": {
    "lastUpdated": "2012-05-29T23:45:32Z"
  },
  "text": {
    "status": "generated",
    "div": "<div xmlns=\"http://www.w3.org/1999/xhtml\">Everywoman, Eve. SSN:\n
444222222</div>"
  },
  "identifier": [
    {
      "type": {
        "coding": [
          {
            "system": "http://hl7.org/fhir/v2/0203",
            "code": "SS"
          }
        ]
      },
      "system": "http://hl7.org/fhir/sid/us-ssn",
      "value": "444222222"
    }
  ],
  "active": true,
  "name": [
    {
      "use": "official",
      "family": "Everywoman",
      "given": [
        "Eve"
      ]
    }
  ],
  "telecom": [
    {
      "system": "phone",
      "value": "555-555-2003",
      "use": "work"
    }
  ],
  "gender": "female",
  "birthDate": "1973-05-31",
  "address": [
    {
      "use": "home",
      "line": [
        "2222 Home Street"
      ]
    }
  ],
  "managingOrganization": {
    "reference": "Organization/hl7"
  }
}
```

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Scott Mankowitz

3.5 Information System Lifecycle

CHAPTER OUTLINE

3.5.1 INSTITUTIONAL GOVERNANCE OF CLINICAL INFORMATION SYSTEMS

The board[1] of a healthcare facility has three primary roles: to establish policies, to make significant and strategic decisions, and to oversee the organization's activity. Since the investment in an EHR is often a very large capital expense, the board is frequently involved in the EHR selection process. In most cases, the board will maintain oversight during implementation and beyond. The day-to-day management of the EHR is left to the management team, usually in the person of the Chief Information Officer or his designee.

Policies and procedures regarding the use of clinical information should cover the following topics:

1. Access—the institution should have very clear rules about who may access which parts of the EHR. Most systems have a large number of security checkpoints scattered throughout the application, and when a user attempts an operation, the system checks the user's access level to determine if he may proceed. These security clearances are often grouped into particular roles, so for example if a new doctor is brought on staff, he is assigned the security clearance of "doctor" which allows him to write notes, enter orders, etc. Similarly, when a nurse is brought on staff, she is given permission to view orders, but not to enter them. Finally, a data scientist may want to review epidemiological data, and may be given read-only access to a replica of

1 In most organizations, the "board" represents the highest level of authority. It is composed of a group of stakeholders who are either owners or industry experts or community representatives who hold fiduciary responsibility for the organization. Typically the Chief Executive is selected by and answers to the board. The board is sometimes called a board of directors, board of governors, board of trustees, bored of meetings, etc.

the database (e.g. a shadow copy) but not to live data. In each of these cases, the user is given enough access to do his job, but no more.

2. Use of clinical data—The primary use of clinical data is to provide care and support clinical decisions. The secondary usage of clinical data for research purposes must be guarded closely to prevent against intentional or unintentional dissemination of protected health information. A well-constructed policy and review board can serve to encourage research without exposing the institution to undue risk. A **data steward** is a person who monitors and controls use of an institution's data.
3. Downtime procedures—Routine maintenance tasks as well as unexpected system failures will require some or part of the system to be inactive from time to time. During these periods, there must be ironclad fallback procedures (such as reverting to a paper-based system) that permit uninterrupted clinical operations.
4. Agreements with other entities—User agreements cover the expectations and responsibilities of users, while business associate agreements (a HIPAA requirement) perform the same function with business partners. **Service level agreements** (SLAs) help manage expectations between software vendors and the institution. SLAs often include provisions for timely updates and response to errors. When an institution selects a software package, the SLA may be more important than the program features or price.
5. Change control (also called **configuration management**)—No system can run indefinitely without active management. From time to time, users will identify bugs, request changes or demand new features. Also, vendors may issue updates in response to changing technology or regulation. The institution must have a standard forum to approve and prioritize these changes. In some institutions, there is a change control board which is composed of clinical and informatics experts who can prioritize or reject modifications to the system.

Further reading: For a great governance policy, see the data governance policy from Vanderbilt University at https://www.vanderbilt.edu/datagovernance/files/Data_Governance_Policy_v1.0.pdf

3.5.2 CLINICAL INFORMATION NEEDS ANALYSIS AND SYSTEM SELECTION

Choosing a clinical information system is a costly and time-consuming endeavor. Integrating a new system usually follows some variation of the system development lifecycle (SDLC), which is an organized, systematic framework for building and delivering information systems.

1. The process begins with **analysis** of a business need. This may be something quite simple like measuring a patient's heart rate, or much more complex, like the need for a comprehensive an Electronic Health Record (EHR)
2. When the needs are known, developers begin to **design** the system. This includes building user interfaces, creating data storage models, coordinating transfer of information in and out of the system and many other tasks. Unless the business need is quite unique, most organizations will purchase software that has already been established or negotiate with an Application Service Provider (ASP). Rarely, the organization may decide to design the system in-house or contract with an outside software developer.
3. **Implementation** involves putting the system into action, such as installing hardware and software, establishing policies and procedures regarding its use and training users.
4. Once the system is in place, **testing** is required to validate the system and make sure that it meets all requirements.
5. All systems require **maintenance** to remain healthy. This may include making regular backups, installing upgrades, dealing with programming errors (bugs) or implementing new features. Maintenance and support run for the longest amount of time and typically consume 80% of the project's budget.

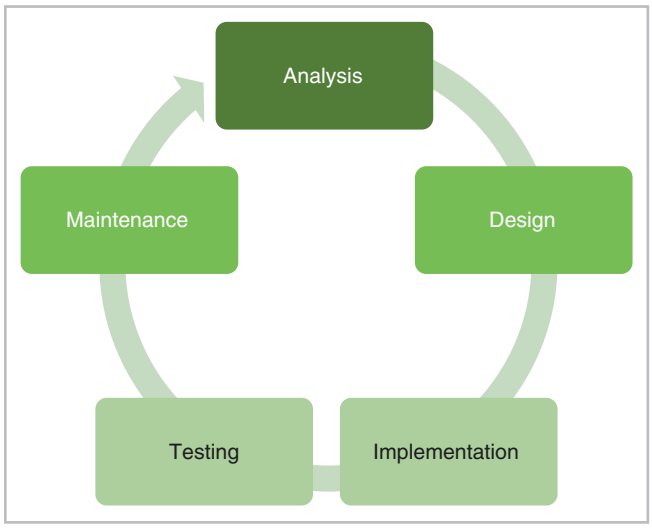


FIGURE 10-1

The Systems Development Life Cycle (SDLC)

At some point, the system will undergo evaluation, and new needs will be identified. This information is fed back into the analysis phase, thus continuing the cycle. If the business need has disappeared or if the cost of the system exceeds its benefit, the organization may replace the system.

There are many variations of the SDLC, some including many more steps in the cycle. The terms chosen here mirror the chapter headings of this book (Fig. 10-1).

3.5.2.1 Methods for Identifying Clinician Information System Needs

The first step in deciding what kind of system is required is to identify the clinical information needs of the organization. This can be accomplished in several ways.

1. Workflow analysis (See Sect. 2.3.1) is the process of examining how work is done in an organization and what information is required at each step.
2. Focus groups or individual interviews can be used to gain insight into what kinds of information are needed at each step. Interviews should include all relevant stakeholders, including physicians, nurses, registrars, billers, transcribers, executive staff, technologists, etc.
3. If focus groups or workflow analysis is too expensive, it may be reasonable to administer written surveys to stakeholders to assess their needs.
4. Since most systems will be purchased instead of built, it pays to research all the relevant vendors, as they may be able to provide ideas that staff haven't even thought of yet. Another option is to visit alternative sites that already have information systems installed to see what their information needs are and how they are meeting those needs.
5. Review medical literature on the specific project type. There may be new or emerging information needs which will need to be handled.
6. Analyze the strategic goals of the organization, as these may suggest information needs. If the organization wants to improve the quality of care, the information needs may include evidence-based standards presented at the time of treatment. If the strategic plan calls for providing more rapid care, perhaps the goal of the system is simply to make providers more efficient.

Once the information needs are identified, they must be returned to the organization's leadership in order to prioritize them. This ranked list of requirements will eventually form the basis of the **request for proposal** (RFP).

3.5.2.2 Assessment of Clinical Process Changes That Will Be Required

When planning an information system, some of the manual processes performed by staff will be replaced with digital ones. In addition, the information system may engender new requirements that did not exist before. This type of workflow redesign (See Sect. 2.3.2) can be complex and require inservice training of staff. Depending on how dramatic the change is, it may eliminate staff or create new staffing needs.

3.5.2.3 Elements of a System Requirements Specification Document

The system specification document lists all the requirements that the organization has for this project.

1. Technical specifications include the hardware and software requirements, system capabilities and functions, including required networking and workstations.
2. Intellectual property (IP). If the system is being developed specifically for the organization, they may have some IP rights (e.g. patents or copyrights) related to the product. Similarly, the vendor may wish to retain copyrights on the code they produce in order to sell it to another organization. Another area of IP is the data collected by the system. Some vendors may wish to monetize patient records and sell them for secondary analysis.
3. Licensing. If the software is owned by the vendor, they may grant a limited license to use and or modify the software. Those modifications may be owned by the vendor or the organization or both. Software licenses often specify how many simultaneous users the system can have or how many patients can be managed by the system.
4. Contracting. The agreement between organization and vendor must be clearly delineated in writing. Contracts help ensure both parties that there will be no changes in what is being provided and at what cost.
5. Confidentiality. Healthcare information system vendors are quite familiar with HIPAA and other confidentiality rules. They may have signed a Business Associate Agreement, which can specify what should happen in the event of a data breach.
6. Training and Support. Clinical information systems can be highly technical and unfamiliar to users. The requirements document would not be complete without adequate provisions for training users to operate the system, and technical support for when the system acts in unexpected ways.

These requirements are usually consolidated into a request for proposal (RFP). This request will be submitted to available vendors to begin a competitive bidding process. Other options are a **Request for Information** (RFI), which is a less-detailed version of the RFP, or a **Request for Quotation** (RFQ) when the nature of the system is already well known and the organization is just seeking a price point.

Contents of an RFP

The RFP should contain enough information for the vendor to make a reasonable offer. When complete, it includes information provided by both the organization and the vendor (Table 10-1).

Once the RFPs are sent out and returned, the organization will apply a standard rubric so that it can make an apples-to-apples comparison. An example is shown in Table 10-2.

Eventually, this kind of comparison will result in selecting a vendor. Contract negotiation can be a complex and intricate process, and will require legal counsel. Contracts can specify levels of service, timelines for installation and payment, penalties and remedies for failures on either side, as well as a reasonable mechanism to disengage should the process not work out.

TABLE 10-1

PROVIDED BY ORGANIZATION	PROVIDED BY VENDOR
Instructions for vendors: In order for the organization to be able to review different offers in an organized manner, there should be a deadline for the RFP and instructions for how it is to be submitted. The RFP may contain a confidentiality agreement or a non-disclosure agreement iwf the organization has significant intellectual property or trade secrets they wish to protect. There may be other specifications that the vendor must adhere to, such as adopting an environmentally friendly policy	
Background on the organization: The vendor will need to know more about its potential client, such as the type of organization, types of services offered, patient volumes, staffing matrix and financial stability. Perhaps more importantly, the vendor must know how the potential product aligns with the organization's mission and vision	Vendor background: Just as it is important for the vendor to understand the organization, the organization must learn about the vendor. This would include the number and type of similar projects, professional references, successes and failures
System requirements: A prioritized list of needs and desires for the new system	Proposed solutions. The vendor would explain how it intends to satisfy the needs of the organization. It may also include alternatives and enhancements that it feels would be superior to the organization's proffered list. This may also include proposals for training staff, providing updates, guarantees and warranties
Criteria for evaluation: The organization should spell out the rubrics and mechanisms it will use to select the best option	Quote: a detailed price list including all mentioned options, payment plan, timeline for installation or delivery

TABLE 10-2

EXAMPLE OF A RUBRIC TO COMPARE THREE HEALTH SYSTEM VENDORS

CRITERIA	VENDOR 1	VENDOR 2	VENDOR 3
1. Compatible with organization's single sign on	x		x
2. Clinical context aware	x		x
3. Interface with legacy laboratory system	x	x	x
4. Provide electronic prescribing with pharmacy list	x	x	x
5. Patient room displays		x	
6. Patient portal	x		
7. Formulary items	2000	4500	1000

3.5.2.4 Risk Analysis and Mitigation

The purpose of a risk management program is to protect the organization and ensure that it is able to carry out its mission.[2] Risk assessment involves investigating vulnerabilities to determine both their probability of occurring as well as their likely impact. It requires managers to balance the costs of protective measures against the operational capability. Analysis of risk must be integrated into all phases of the SDLC, as shown in Table 10-3.

2 For quite a bit more information on this, see the National Institute of Standards and Technology Special Publication 800–30, revision 1: Risk Management Guide for Information Technology Systems; see https://doi.org/10.6028/NIST.SP.800-30r1

TABLE 10-3

RISK MANAGEMENT MUST BE INCORPORATED INTO ALL PHASES OF THE SOFTWARE DEVELOPMENT LIFE CYCLE (SDLC)

PHASE	RISK MANAGEMENT
Analysis	Risks and security concerns are identified and built into the system requirements document
Design	During development, new risks, such as programming errors or interface vulnerabilities are found and mitigated
Implementation	When the system is installed into a new environment, new risks and security problems can become evident, such as securing physical access to a server room or networking cabinet
Testing	Vulnerability testing is a key part of risk analysis. Some organizations will hire "white hat" hackers to see if they can break into their system. Other system tests may involve intentionally disabling part of the system or removing network capacity
Maintenance	Periodic risk assessment of a running system ensures continued functioning. This becomes especially important whenever the system is modified, such as when new upgrades are applied or interfaces are added
Disposal	When the system is decommissioned, the protected data must be appropriately transitioned to the new system or destroyed in a reliable way

3.5.2.5 The Costs of Health Information and Communications Technologies

The putative benefits of health information systems are well known: decrease in inappropriate utilization; fewer adverse drug events due to drug-drug and drug-disease interaction checking; improved screening for diseases and many others. Many published studies have demonstrated an overall cost savings for patients and health systems (although there is probably quite a lot of selection bias for these studies). One systematic review[3] found that the implementation of an information system could result in anywhere from a 75% decrease to a 69% increase in targeted costs. Review of the peer-reviewed literature rarely includes the capital costs for the implementation, maintenance, training and testing of these systems, which makes a true cost-benefit calculation very difficult.[4] Complicating matters is the Federal EHR incentive payment programs which have encouraged providers and institutions to quickly buy health information technology. These massive payouts with short timeframes can make an otherwise unattractive IT investment quite compelling, especially for a cash-strapped institution.

Some have sought to estimate the total cost of ownership of an EHR. One study[5] in 2012 found that a typical multiphysician practice spent about $162,000 to implement an EHR. The first-year maintenance cost was $85,000 with an additional 611 staff hours spent getting ready for the transition. Providers required an average of 134 h to become comfortable enough with the system to use it daily. Increasing the time required to provide care can be costly. A busy internist may see up to four patients per hour. If the EHR adds only 1 min to each visit, that amounts to 28 min per day, or approximately two patients, or about $150 in billing. Over the course of a year, that comes to $30,000 in lost revenue.

Larger institutions can have much greater costs.[6] In 2011, Henry Ford Health System spent $353 million on an EHR overhaul. Of that, approximately $100 million was spent on

3 Jones SS, Rudin RS, Perry T, Shekelle PG. Health Information Technology: An Updated Systematic Review With a Focus on Meaningful Use. Ann Intern Med. 2014;160:48–54.

4 Chaudhry B, Wang J, Wu S, Maglione M, Mojica W, Roth E, et al. Systematic Review: Impact of Health Information Technology on Quality, Efficiency, and Costs of Medical Care. Ann Intern Med. 2006;144:742–752.

5 McBride M. Understanding the true costs of an EHR implementation plan. Medical Economics. July 25, 2012.

6 Akanksha J. Unpacking hospitals' EHR implementation costs: What's behind the million-dollar price tags? Becker's Health IT & CIO Review. May 18, 2016.

improving the data center, and the remainder on vendor-specific processes and fees. To offset those costs, the health system expects to receive about $50 million in federal EHR incentives.[7]

3.5.3 CLINICAL INFORMATION SYSTEM IMPLEMENTATION

Once the system is selected, plans for installing and initiating the system must begin. The day that the system first becomes operational is called the **activation day,** or, more commonly, **go-live.** Preparation for go-live involves many moving parts, and requires significant dedicated planning in order to be successful.

3.5.3.1 Elements of a System Implementation Plan

While most vendors have strong opinions about how to best utilize their products, collaboration with the host institution is an absolute requirement. Implementations vary, but most will follow this general pathway

1. Project Management—overall management will require input from both vendor and customer. This requires a dedicated project manager who is familiar with the host institution's resources. See Chap. 4.4 for more information.
2. Workflow and process redesign—before bringing in a new system, it is important to optimize the current processes and workflows in the context of the new system's capabilities. (See Chap. 2.3 for more information on workflows)
3. Create the implementation plan—Vendors tend to come prepared with a plan of their own, identifying what they intend to accomplish by what timeframes. They will also have expectations of the host institution which are based on their experience elsewhere and may not be totally appropriate to the current client. When developing the implementation plan, care must be taken to synthesize the vendor's plan with the capabilities and interests of the institution.
4. Issues management—an important part of project management is handling problems when they arise. Many implementors utilize a database to keep track of trouble tickets in order to prioritize efforts.
5. Data Center—most clinical information systems require a central database to be installed locally, which means that the institution's data center will require upgrading or at least, provisioning. Some implementations will use an off-site (i.e. "in the cloud") data center. Cloud databases may be more appropriate for implementations where network latency is not an issue.
6. Local Hardware—the selection of appropriate workstations requires careful consideration. For example, if most of the computing work is done in the data center, relatively low-cost computers (or dumb terminals) may be used. However, if that work is shifted to the users' computers, the technical requirements (and cost) of the workstations become higher. In addition to workstations, the system may include input and output devices, such as barcode scanners, label printers, page printers, etc.
7. Network—The linkage between the datacenter and the users' workstations must be adequate for the expected network traffic. In general, older, text-based interfaces require minimal bandwidth, while remote displays of virtual machines require more. If the datacenter is located remotely, there must be secondary access methods if the primary method becomes unavailable. The network engineer must assure that there is adequate address space as well as wiring to support the clinical system. Wireless networks offer

7 Greene J. Henry Ford Health debuts electronic records system. Crain's Detroit Business. November 13, 2011.

greater portability, but are slower, more prone to lost connections, and can be easier to hack than wired networks.

8. Security risk analysis—Hospital systems are becoming increasingly popular targets for hackers and there are reports of medical systems being hijacked and rendered inoperable until a ransom is paid. In addition, local and federal laws demand data security and privacy. Conducting a security analysis will help identify threats to data availability, integrity and privacy. These threats can be minimized by the creation of new policies or enforcement of previous policies (see Sect. 3.1.4).
9. Super user training—users who are "early adopters" of technology are often given special training on the new system in order to be available as trainers for other users when the system goes live. They may also assist in tailoring the software for the institution.
10. System installation—installing software is ideally a fairly simple matter, since the hardware was specifically chosen to meet the software's requirements. When an institution chooses an Application Service Provider (ASP) or some other form of co-location, the vendor is usually responsible for the installation.
11. Software configuration (also called "system build")—Most applications come with pre-built workflows which are useful for the majority of implementations. However, there will always be some modification and customization for each client.[8] In addition, the application's data tables have to be loaded with relevant data, such as medical staff names, formulary medications, clinical orders and order sets, decision support tools, and other items. If the new system is replacing another system, it may be necessary to transfer historical patient data from the old system to the new one.
12. Interface development—The new system must be able to send and receive data from other clinical systems. This may require construction of new interfaces and new integrations. (See Sect. 3.1.6.1 for more information).
13. Testing—Various forms of testing must be carried out to ensure that the system runs as expected. (Sect. 3.5.4 deals with this more specifically). End users are recruited to use a test system to perform common actions. If all the tests succeed, the modifications are advanced to the production system.
14. End user training—even the most well-designed and intuitive programs require training in order to ensure that end users will feel comfortable with the new system. (See Sect. 3.5.3.2 below)
15. Go live—The majority of the configuration errors will be discovered shortly after go live, so it is important to have as much technical staff as possible on hand during the days to weeks after implementation. In addition, there must be sufficient support for end users who have not used the system since they did their training, which may have been months prior. Most organizations see an immediate drop in clinical productivity when a new system is implemented and it is prudent to increase clinical as well as technical staff in preparation for go-live.
16. Lessons learned—after go live, the implementation team should gather together to discuss the successes, near-misses and failures of the implementation. These discussions are often beneficial to the vendor as well, for planning future implementations.
17. Monitoring progress—after the initial problems are solved and early bugs are fixed, the team needs to monitor the efficiency of the new system, in order to justify its continued usage. This may include measuring how often users revert to downtime procedures, which aspects of the system are underused, the amount of time required for common tasks and other measurements. Monitoring is an ongoing process and will last for the life of the system.

8 Modern, mature EMRs have pre-built implementation workflows based on years of implementation experience as well as scientific evidence. While some tailoring is necessary for smooth functioning, there are several reasons for minimizing local modifications: (1) Changing one template may have an effect on many others; (2) Tailoring is costly and may create incompatibilities in future upgrades; (3) Many of the modification requests actually come from users who wish to revert to the workflows they had before the implementation, which may derail the efficiencies the system was designed to provide.

18. Optimization strategies—The monitoring process should reveal several opportunities for improvement. These should be analyzed on the basis of cost, safety and potential for increased efficiency or effectiveness of the system. Just like monitoring, the optimization step is continuous and ongoing.

3.5.3.2 Models of User Training and Support Processes That Can Meet Clinician Needs

Training of users can take many forms. Most institutions use a combination of on-line videos and classroom frontal presentation combined with challenge testing. In some cases, the vendor will set up a test environment which is similar to the user's work area. The instructor will issue a series of common clinical tasks, such as ordering a lab test or requesting a consultation. The users are allowed to try things out on the test system until they gain mastery. When the class is finished, the test system is refreshed to its original state for the next class.

For complex systems such as an electronic health record, training usually lasts from 6 to 24 h, and can be quite expensive. However, the cost of *not* training can be even higher. Failing to provide adequate training is a very common reason for end-user dissatisfaction. It can also result in users developing shortcuts, workarounds or inappropriately resorting to downtime procedures just to avoid a clinical system.

3.5.3.3 Processes and Mechanisms That Obtain and Respond to Clinician Feedback

A reliable issues management system (sometimes called trouble ticket system) is mandatory for a successful implementation. Once a problem is addressed, the fix should be broadcast to other users, as there is a reasonable chance that other users are experiencing the same problem.

There are several mechanisms to collect user feedback. During go-live, technicians should be readily available for both training and support. When clinical issues arise, they can be quickly addressed with a face-to-face interaction. If the problem is related to training, the technician can instruct the user on how to use the system. If a misconfiguration or data error is identified, the problem can be escalated to the appropriate higher-level technician for correction. Technical staff will have to prioritize requests from educational needs to feature requests, system enhancements and bug fixes.

After go-live, the technical staff will have much less physical presence in the clinical units, however, support must still be readily available. A telephone support system (e.g. helpdesk) should be available during all hours of clinical operation. For less emergent needs, the system should have a online feedback mechanism built into the system so that users can submit problem tickets for later review. Technical staff should be able to provide rapid and personalized responses to users.

3.5.4 CLINICAL INFORMATION SYSTEM TESTING, BEFORE, DURING AND AFTER IMPLEMENTATION

Most development is done in three replicated environments commonly referred to as dev, test and prod.

1. The **development environment** (dev) includes software that is still under construction. Programmers and designers change software continuously as they try new architectures, methods, algorithms, interfaces and protocols. There is very little actual data in this environment. When the software is relatively stable, it is advanced to the test environment.

2. The **test environment** is modeled to look like the real world, but is populated with sample data instead of real-world information. It often contains the unusual ("edge") cases that provide for meaningful tests. Rigorous testing usually occurs in this environment.
3. The **production environment** (prod) is the one that is published to the users. Orders and transactions placed in the production environment are expected to have real and reliable consequences. Changes made in this environment will affect all users currently engaged with the system. Testing should be done in the dev and test environments, but never in the production environment.[9]

Static and Dynamic

Testing falls into two categories. **Static testing** involves examining the source code, data architecture and wireframes of user interfaces. **Dynamic testing** involves actually executing the software in a variety of environments. Although static testing is useful in the initial phases of a project, the overwhelming majority of testing is dynamic.[10]

White-box testing (or clear box testing) involves creating tests that evaluate small segments of source code for applicability to a certain purpose, such as validating that a calculation function gives the right answer when certain pre-defined inputs are provided. White box testing assumes knowledge of the inner workings of the program and access to source code. The alternative is called **black box testing**, where the tester has no knowledge of how the software works, but designs tests according to what the software is supposed to do.

Types of Tests

- **Unit testing** refers to tests that verify the functionality of a very specific section of code, such as might be found within a single method, function or class. Most commonly, this is a form of white box testing. **Integration testing,** on the other hand, is a form of testing that seeks to test the interaction between two or more separate units of code.
- **Performance testing** assesses the system's capabilities when there are a high number of simultaneous users.
- **System testing** refers to the evaluation of the system as a whole as opposed to just a small subsection. For example, this may include a user logging in, placing orders, transferring a patient, printing results and then logging off.
- **Operational acceptance testing** (also called user acceptance testing or operational readiness testing) is a type of pre-release testing which ensures that the product meets all listed requirements. This is generally done as part of the development process, but is also done by the customer to ensure that the product meets their needs.
- **Installation testing** ensures that the system is installed correctly and working on the customer's hardware.
- **Compatibility testing** refers to testing the system to make sure that it works well with other applications on the same system.
- **Regression testing** focuses on detecting problems that could arise after an upgrade. Specifically, making sure that old functions still work and that items that have been patched in the past continue to work.
- **Usability testing** is concerned with ensuring that the user interface is intuitive and easy to use. **Accessibility testing** is a type of usability testing aimed at users with physical impediments in accordance with accessibility standards such as the Americans with Disabilities Act.

Testing Before Implementation

Testing a clinical information system should reveal that the proposed solution generally achieves the goals that the clients specified. The system should

- Respond appropriately to inputs
- Be designed intuitively so that users can learn the system easily

9 Of course, some bugs will remain undetected despite thorough testing and will only be found by users who are actively using the system. Hence the saying, "there is not test like prod".

10 For the biologists out there, Static testing is like *in vitro* testing, while dynamic testing is *in vivo*.

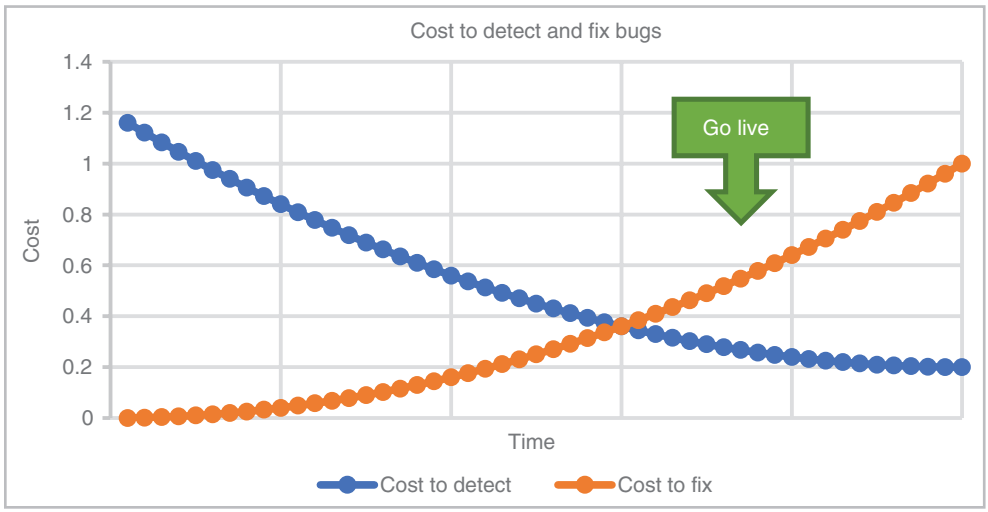


FIGURE 10-2

The cost to repair bugs increases as the project progresses. This is inverse to the cost of detecting bugs, which is relatively easy after go-live, but harder in the initial phases of the project

- Run on its intended hardware and within its expected software ecosystem
- Perform its functions in a reasonable timeframe

Testing During Implementation

Testing during implementation usually involves interacting with users who are using the system for the first time. Active feedback is sought to improve the user experience and reduce errors. All connected systems are checked to make sure that the system communicates with them as expected. Bugs are more easily detected during this phase because the system is being put to actual use by many simultaneous users. Bugs detected after go-live are generally harder to fix because of the increased number of moving parts (Fig. 10-2).

Tests After Implementation

After implementation, testing is continuous to ensure that the product functions as expected. This may include routine samples of data or monitoring of log files. In many instances, maintainers will set up a suite of tests that are run periodically to ensure that the system is functioning as expected. As new capabilities are added to the system, new tests are added to the maintenance queue.

3.5.5 CLINICAL INFORMATION SYSTEM MAINTENANCE

Maintenance of clinical systems is ongoing and is just as important as the initial setup and implementation.

1. **Preventive maintenance** is any activity designed to prevent system failure. It includes performing backups, applying operating system upgrades, virus scanning, resetting passwords, providing regular inservice training, reviewing log files, ensuring drive capacity, measuring network latency, performing security testing and many other tasks. Some of these items can be described as **system administration.**
2. **Corrective maintenance** refers to any steps needed to correct problems with the clinical information system, including hardware, software, networks and remedial training of users. These problems are usually detected by users and are reported to the system maintainer through a helpdesk or an issues management (i.e. trouble ticket) process. Having appropriate local staff to deal with this variety of issues is not always necessary, especially when an application service provider (ASP) or Software as a Service (SaaS) model is used.
3. **Customized maintenance** or **tailoring** is the process of modifying the clinical information system to adapt to changing needs. This may involve creating new screens for various

specialty providers, or adding new formulary drugs. It is important to have a reliable change control process to prioritize the elements of the system that need to be tailored.

4. **Enhancement maintenance** involves improving the hardware, software or network which comprises the information system. Most enhancements are made to meet the needs of evolving technology. For example, a new radiology system may require installation of a faster network and training of staff in the use of a new database.
5. **Data Quality Management** and **Data Stewardship** include processes meant to ensure that the clinical information system has accurate data. This may include: performing regular audits of certain types of clinical information to detect incorrect or potentially misplaced data; review clinical decision overrides to make sure that the alerts remain relevant; examine free-text fields to see where structured data input is not being used; run various sanity checks on clinical data to detect data entry problems.

3.5.5.1 Disaster Recovery and Downtime

When any part of a clinical information system becomes unusable, there should be alternative (i.e. **downtime**) procedures that can take the place of the system until it returns to normal function. In most institutions, this involves reverting to a paper-based system. In some cases, the clinical information system will have a read-only replica which is available while the production system is down.

The majority of downtime is planned, which means that all staff members know approximately when it will start and end, and are therefore able to organize their activities around the loss of system function. A very common hospital example is when the Electronic Health Record has to be deactivated in order to upgrade to the newest version. Prior to the downtime, portions of the clinical charts are printed out so that providers will have access. Orders are written on paper and lab reports are faxed or emailed. When the system is back up again, many institutions will backfill the information system with data that was gathered on paper during the downtime.

Disaster recovery refers to attempting to resuscitate a system after catastrophic data loss, such as an operating system failure or a hard drive crash. The simplest way to recover lost data is to utilize backups. If backups are not available, it may be possible to reconstruct a data store from original sources. For example, if an EHR suffers a data loss, it may be possible to recover laboratory data from lab equipment or from log files or from archived messages.

3.5.5.2 Clinical Information System Transitions and Decommissioning of Systems

When a system no longer provides a favorable cost-benefit position for the organization, it will be **decommissioned**. Most of the time, a new system will be installed to replace the functionality of the previous system. Transitioning from one clinical information system to another is rarely simple. The same semantic interoperability which is required for sharing data between two live systems must be present when transferring data from a legacy to a newer system. When this is impossible (or too expensive), the data from the old system will be stored in a less-accessible format. For example, when transitioning from a paper system, lab reports may be stored as scanned images instead of structured data.

3.5.6 CLINICAL INFORMATION SYSTEM EVALUATION

The last phase of the software development lifecycle is the evaluation phase. In this phase, the organization decides if the system is consistent with its mission and vision. If the system is successful, we return to the analysis phase to determine how to make it better. If it is not successful, it may be decommissioned or replaced. We return to the analysis phase to determine what to replace it with.

The best time to evaluate an information system is when it has been fully implemented and providers are just beginning to get comfortable with it, usually about 1 month after go-live. Here are some questions to ask:

1. Did we learn anything about our corporate culture in the process?
2. Have all providers "bought in" to the EHR, or are there still some stragglers?
3. How accurate was our workflow analysis? Does it need to be adjusted after go-live?
4. Was our training adequate? Are there groups of people who should have training but didn't?
5. Are we capturing all the data we hoped to? Are we able to leverage that data to make business or clinical decisions?
6. What are the unintended consequences of our new implementation? Are there workers who are overloaded? Are there workers with no work to do?
7. Was our internal and external network adequate for the job?
8. Have we been able to address the issues brought up by users?
9. Are there physical locations in the facility which lack technology? That have too much?
10. Was our initial HIPAA security assessment accurate? Do we need to modify anything?
11. Did our vendor deliver as promised? What issues need to be worked on? More importantly, have we saved any lives?

3.5.6.1 Outcomes Relevant to the Clinical Goals and Quality Measures

It is important to come up with relevant questions to determine if the clinical information system has achieved its goals. The outcomes should be relevant clinically and should also reflect the organization's values. Measuring clicks and EHR utilization or counting the number of orders placed with the CPOE system does not tell a complete story. A more pertinent question might be: Does the newly implemented sepsis order set result in better compliance with the surviving sepsis guidelines? More importantly, have we saved any lives?

3.5.6.2 Qualitative and Quantitative Methods for Evaluating Clinical Information Systems

Most reliable methods of evaluation are quantitative. Numerical results can be analyzed statistically to determine significance. Qualitative methods can be useful for non-numerical measures, or when the numbers of patients are insufficient for statistical analysis.

Continuing our sepsis example, we could examine how often the guidelines are followed before and after the order set (quantitative), or we could ask providers if they felt the order set made their practice safer, easier or better (qualitative).

3.5.6.3 Evaluation Plan Design

Like a scientific study, designing an evaluation plan requires explicit inclusion and exclusion criteria, verifiable and objective measures, careful analysis and responsible reporting regardless of the result. If the clinical information system helps the organization achieve its clinical goals, it is considered a success.

In our example, we could identify sepsis patients by International Classification of Diseases (ICD-10) code, including only those that were discharged during a particular timeframe. Once our population is identified, we could review the logs of the Electronic Health Record (EHR) to see if the sepsis order set was used. We could then check each patient to see which of the sepsis related core measures (SEP-1) were met. This information would be gathered and analyzed and presented at the next meeting of the quality department. In general, the number of patients in the population being studied is called the denominator and the

number of patients who successfully met criteria are called the numerator. The resulting quotient, therefore, is the success rate.

Suppose we collect the following information:

	USED ORDER SET	DID NOT USE ORDER SET
SEP-1 criteria met	85	155
SEP-1 criteria not met	8	72

We can see that 91% of patients where the order set was used met the SEP-1 criteria, while only 68% of those met criteria when the order set was not used. This would be powerful evidence in favor of using the order set. We could further analyze this population to measure morbidity and mortality (which are truer outcome measures). If we chose to use a qualitative method, we could pool responses from users of the system and report the common threads.

PROVIDER	COMMENT
1906	The order set saved time
2366	It reminded me to order lactic acid
5521	It calculated fluid requirements for me
1809	I found it cumbersome
1766	I don't need to be told how to practice medicine

This anecdotal data is not as powerful as quantitative data, but is still valuable in the evaluation process.

Part IV
Leading and Managing Change

The knowledge and skills that enable clinical informaticians to lead and manage changes associated with implementing clinical information systems and promoting adoption by health professionals.

Scott Mankowitz

4.1 Leadership Models, Processes, and Practices

CHAPTER OUTLINE

4.1.1 DIMENSIONS OF EFFECTIVE LEADERSHIP

There are many aspects to effective leaders. Several have been identified by Lowder[1]

1. **Personal effectiveness dimension.** Successful leaders have certain personal characteristics such as trustworthiness, a strong moral compass, intellectual fortitude and optimism. They tend to be self-motivated, goal-oriented and work towards self-improvement. They manage time effectively and set priorities for important issues.
2. **Interpersonal relationship effectiveness dimension.** To make peace among other workers, leaders must embody trust, compassion, empathy, fairness and objectivity. They encourage, guide and motivate. People with these attributes are often perceived as charismatic and influential. In any charismatic leader, there is always a potential to pursue self-interest at the cost of the organization.
3. **Managerial effectiveness dimension.** The leader exudes team spirit, improves the productivity of other people, delegates authority, empowers others, communicates with candor, seeks organizational improvement, and emulates high organizational values.
4. **Operational effectiveness dimension.** The leader is an expert in relationship building, understands customer needs, propagates the organizational vision and mission, promotes organizational stability, and maintains customer satisfaction. Using these tools, he improves numerical measures like net profit, return on investment, earnings per share, etc.
5. **Societal effectiveness dimension.** The leader (or the organization) positively impacts the environment, communities, governments, suppliers, or consumers through community involvement, public relations and environmental stewardship.

1 Lowder, B. Tim, Five Dimensions of Effective Leadership: A Meta-Analysis of Leadership Attributes & Behaviors (March 21, 2007). Available at SSRN: https://ssrn.com/abstract=975559 or http://dx.doi.org/10.2139/ssrn.975559.

Barsch et al. list five dimensions of "centered leadership":[2]

1. Meaning: finding strengths and putting them to work in the service of a purpose that inspires.
2. Positive framing (or optimism): adopting a more constructive way to view your world and convert even difficult situations into opportunities.
3. Connecting: building a stronger sense of community.
4. Engaging: pursuing opportunities disguised by risk
5. Energizing: practicing ways to sustain your energy on a long leadership journey.

Much distinction is made between the **manager** and the **leader**. In general, managers are appointed in an organization and have people who work for them on a transactional basis. For example, if the subordinate works for 40 h, the manager will pay him a salary. Leaders, on the other hand, don't have subordinates, and may occupy no official office in their organization. Rather, they inspire followers with promises of transformation (i.e. follow me to a brighter future). Managers tend to seek a stable environment and are focused on getting work done. Leaders are often risk-takers and focus on people.

The following table shows some of the differences between managers and leaders.[3]

SUBJECT	LEADER	MANAGER
Essence	Change	Stability
Focus	Leading people	Managing work
Have	Followers	Subordinates
Horizon	Long-term	Short-term
Seeks	Vision	Objectives
Approach	Sets direction	Plans detail
Decision	Facilitates	Makes
Power	Personal charisma	Formal authority
Appeal to	Heart	Head
Energy	Passion	Control
Culture	Shapes	Enacts
Dynamic	Proactive	Reactive
Persuasion	Sell	Tell
Style	Transformational	Transactional
Exchange	Excitement for work	Money for work
Likes	Striving	Action
Wants	Achievement	Results
Risk	Takes	Minimizes
Rules	Breaks	Makes
Conflict	Uses	Avoids
Direction	New roads	Existing roads
Truth	Seeks	Establishes
Concern	What is right	Being right
Credit	Gives	Takes
Blame	Takes	Blames

2 Barsh J, Mogelof J, Webb C. The value of centered leadership: McKinsey Global Survey results [Internet]. McKinsey & Company. [cited 2017Mar28]. Available from: http://www.mckinsey.com/global-themes/leadership/the-value-of-centered-leadership-mckinsey-global-survey-results.

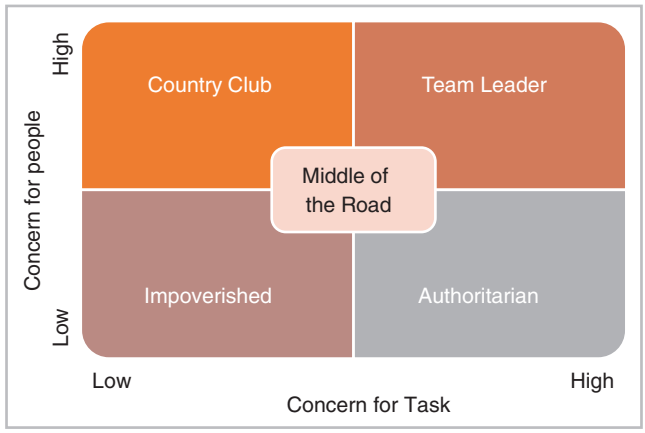
3 This table and much more useful information comes from changingminds.org. See http://changingminds.org/disciplines/leadership/articles/manager_leader.htm.

Leadership Models

There are many leadership models with varying degrees of academic basis. The **Great Man Theory**, proposed in the 1840s for example, believed that great leaders were born, not made.[4] The **Trait Theory** listed certain traits (e.g. assertiveness, dependability, persistence, adaptability, etc.) which were correlated with great leaders. Most of these traits were considered innate, though some skills (such as being knowledgeable, tactful, or organized) could be learned.

Blake and Moulton proposed the **leadership/managerial grid** to describe four types of leaders based on their concern for results and people.

1. The **authoritarian** (or **autocratic**) leader is concerned with results, but not with people. He issues edicts and expects them to be followed. He does not tolerate negotiation or collaboration.
2. The **country club** manager is concerned with people but not with results. He is affable and political and people like working with him. He is not the most effective leader.
3. The **impoverished** (or laissez-faire) manager has no interest in either people or results. He allows his teams to work without guidance or punishment.
4. According to the authors, the best kind of manager is the **team leader,** who has concern for both people and results. He inspires confidence and people want to work harder because they are inspired by his motivation.



Situational Leadership

The **Situational Leadership® Model**, developed by Paul Hersey and Ken Blanchard states that different tasks and different people require different kinds of leadership. They list four degrees of **Performance Readiness** (or Maturity):

1. M1—(lowest maturity) lack skills to perform the job at hand
2. M2—willing to work at the task, novice and enthusiastic
3. M3—experienced, but lack confidence to take responsibility
4. M4—mature, willing to do the task and take responsibility for it.

These maturity levels roughly correlate with four levels of supervision

1. S1—Directing; the manager tells the subordinate exactly how to do the task
2. S2—Coaching; the manager is providing direction but is working with the subordinate on the task

4 Since business school involves teaching people how to be leaders, this has not been the most popular of the leadership theories in academia.

3. S3—Supporting; the manager and subordinate employ shared decision making
4. S4—Delegating; the manager is still involved in monitoring the process, but the subordinate makes most of the decisions.

4.1.2 GOVERNANCE (E.G., PROCESSES; RESPONSIBILITY VERSUS AUTHORITY)

Governance is the way the rules, norms and actions in an organization are structured, sustained, regulated and enforced. This is distinct from **process governance,** which is the use of rules to manage programs and initiatives in order to optimize business process and to make workflow more efficient. For more information on governance of health information systems, see Sect. 3.5.1)

Authority is the power to give orders and have them obeyed; the power to make decisions. **Responsibility** is being accountable for an obligation, trust or debt, such as the obligation to complete an assignment.

Authority and responsibility operate hand in hand. Having responsibility without authority leaves a person incapable of finishing the work because he lacks the ability to make others work with him or to utilize resources. Having authority without responsibility is equally problematic, as it leads a person to make decisions that affect others without taking into account the impact on the project.

Governance requires structure. In most American corporations, the board of directors are elected by shareholders and hold fiduciary responsibility for the organization.[5] They select the Chief Executive Officer (CEO) and often other members of the management team. The organization will also have divisions based on regions or function, each with their own hierarchy answering to different members of the management team. In addition, there may be various committees which are drawn from across the organization and empowered to manage certain aspects of the business.

Governance should include fixed policies and procedures which are fair and predictable, the governing body for should include important stakeholders as well as members of the executive team. Including representatives from many different disciplines enables the body to understand problems from different angles. Some of the values of good governance include:

1. Standardizing the process of decision making helps establish expectations for all stakeholders. This can be especially important in large organizations with many different departments.
2. Decisions that are made according to a fair process have greater legitimacy than those that are made arbitrarily or capriciously. Employees are much more likely to respect a process that has internal and external consistency.
3. Governance has the ability to align decisions with the organization's mission and vision.
4. When all large purchases are passed through a single body, there is a much smaller likelihood of duplication. For example, two departments simultaneously recognize the need for a specific technology. Instead of allowing both departments to purchase it independently, they create a system where they can share it.
5. Workers are much more likely to invest their time and energy into an organization when they perceive it as predictable and fair.

4.1.3 NEGOTIATION

Negotiation is a dialogue between two or more parties intended to reach a mutually beneficial outcome or to resolve a conflict. Negotiation is a skill, and seasoned negotiators tend to fare better than new ones. It has been said that the object of negotiation is to show the other party a way to solve its problem by doing things your way.

5 In European corporations, the board is broken down into a supervisory board and a management board.

Negotiation is not always successful, and when the parties are unwilling to agree, there are several further options: mediation, arbitration and finally, litigation.

Mediation is when an independent third party is brought in to help find a resolution. Often, the mediator will suggest a resolution. Ultimately, however, both sides must agree to the proposed solution. **Arbitration** involves hiring a third party to effectively act as a judge and dictate a solution to the problem. In binding arbitration, both sides agree, *a priori,* to follow the decision of the arbitrator. **Litigation** involves using the traditional court system to resolve the matter. Arbitration and mediation are desirable because they tend to be significantly less expensive than litigation. Collectively, any solution that avoids expensive litigation is called **alternative dispute resolution.**

Distributive Bargaining and Integrative Bargaining

There are two common forms of negotiation: distributive bargaining and integrative bargaining. **Distributive bargaining** (also called **zero-sum**) is encountered when there are a fixed number of resources that are to be divided among participants. There is no expectation of a further relationship. For example, when purchasing a car, the buyer wants to keep as much money as he can, while the seller wants to collect as much money as he can. In **integrative bargaining** (also called **win-win**), the parties are building a lasting relationship and have to make sure that both sides will thrive under the new agreement. An example of integrative bargaining, is hiring a new employee and deciding on compensation, benefits, work expectations, etc. One way to think about the difference between distributive and integrative negotiations is that distributive negotiation is about how to fairly cut up a pie for all to share, while integrative negotiation seeks to enlarge the pie so that everyone comes out with more.

Techniques for effective bargaining

There are many techniques which can enhance a negotiator's position:

1. **Research the opposition.** It is very important to know what resources the opposition brings to the table. Asking for things that they can not provide will not bring about a successful negotiation. Perhaps more importantly, knowing the opposition's wants and needs enables the negotiator to develop more effective strategies. Asking open-ended questions during the negotiation can help. When doctors negotiate with patients, this is a very effective means of figuring out not only the medical issue, but also the social ramifications and the patient's emotional context.
2. **Research the alternatives.** Before initiating a negotiation, know the fallback options. This is often called BATNA (Best Alternative To a Negotiated Agreement). In salary negotiations, the BATNA may be an offer from another employer. For a patient selecting treatment options, the BATNA may be watchful waiting.
3. **Nearly everything is negotiable separately.** When one party offers a package deal, it need not be accepted as a whole. Unbundling various parts can make for a more equitable agreement. For example, in a salary negotiation, the salary itself may be fixed by an institutional rule, but the employer may be willing to pay for other benefits, such as medical staff dues, moving expenses, computers and continuing medical education.
4. **Know the range.** Identify each of the issues which are important and set minimum, optimum and target goals for each. The **optimum** is the best deal one could reasonably expect. The **minimum** is the lowest acceptable level before selecting the BATNA. **Target** is somewhere in the middle and represents the expected endpoint for the negotiation.
5. **Identify the leverage points.** Knowing the opposition's needs and desires is important as it can help the negotiator prioritize his offers. Similarly, it is important to know what items are of lesser value to the negotiator himself, as these can be easily given up in trade for items that are more valuable.
6. **Only negotiate with the decisionmaker.** A classic dodge in negotiation is for one party to make an appeal to a higher authority. (e.g., "this offer sounds good, but I have to ask my wife") This tactic effectively stalls the negotiation. Before starting the dialog, ensure that the person capable of making the decision is at the table.

7. **Start with common ground.** The experienced negotiator begins the discussion with items that are already mutually agreed upon. By doing this, the negotiator has built trust and the opposition has gotten comfortable saying yes. This makes it much easier to find agreement when more contentious items are raised.
8. **Don't ignore the hard points.** The goal of negotiation is to find a complete solution. Some aspects may be painful to mention, but if they are not addressed up front, they will be much harder to rectify later.
9. **Bring data to the table.** Nothing argues a point as well as independently verified evidence. This may take the form of scientific literature, comparable real-estate sale prices, national salary surveys, etc.
10. **Separate problems from solutions.** Discussion of potential problems needs to be complete before searching for suitable solutions. Failure to fully understand the problems at hand may lead to a premature agreement which must be later revised.
11. **Do not compare external offers at the negotiating table.** Regardless of how many competing offers are available, the current deal is the only one that can be negotiated right now. It must be accepted or rejected on its own. If it is rejected, both parties must resort to their BATNA.
12. **Delayed gratification.** In most cases, it is preferable to defer a reward until a later date rather than give it up entirely. For example, while negotiating with an insurer, a physician is offered $6.45 per RVU, even though his target was $7.00 per RVU. Instead of ceding the point, he agrees to $6.45 for the current year with an automatic raise to $7.15 for the second year. In this way, he shows confidence that the relationship will be successful.
13. **Create a win-win.** Another possible solution the previous scenario is that the physician agrees to $6.45 with a bonus of up to $1.00 if certain productivity thresholds are met. In that way, when the physician benefits, the insurer benefits as well. This is called a win-win situation, and is the most effective type of negotiation.

4.1.4 CONFLICT MANAGEMENT

Conflict is inevitable in any organization, but not all conflict is bad. Sometimes, conflict can be used to discover shortcomings, inspire teamwork and generate novel approaches to problems. **Conflict resolution** aims to end conflicts completely, while **conflict management** attempts to preserve the positive aspects of conflict while minimizing the negative ones.

Positive conflict encourages employee interaction. Managers who identify positive conflict should encourage it.

1. Competition can often be a positive force in the workplace. Consider a pharmaceutical company where two sales representatives vie with each other to be the lead seller. Managers should beware that too much competition may have undesirable results, such as cheating, cutting quality or frustrating a section of the workforce who are not as successful.
2. Conflict can spur creativity as employees seek new answers to problems. As these solutions become established, overall productivity for the group increases (Fig. 11-1).

Negative conflict is, unfortunately, more familiar to most of us than positive conflict.

1. Personal conflict results from issues entirely unrelated to the workplace and may have roots in personal dissatisfaction, emotional problems or substance abuse. Managers must attempt to intervene as soon as possible to ensure productivity of other workers. Human Resources may be involved in remediation. When personal conflict becomes severe, it may result in mobbing, bullying or harassment, which are punishable under state and federal law.

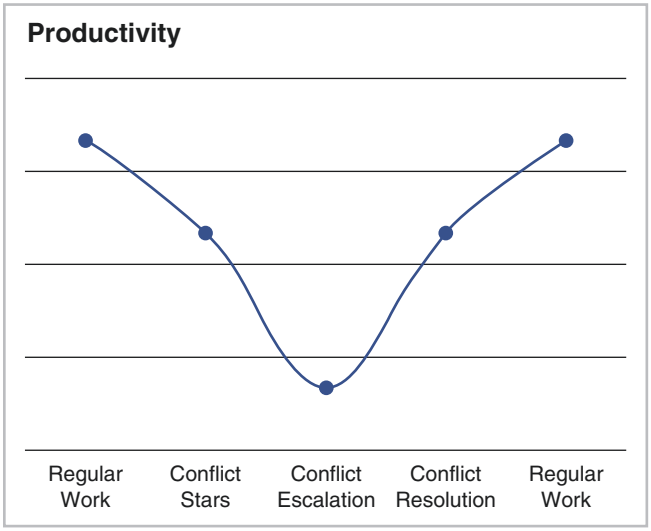


FIGURE 11-1

Productivity declines with conflict and returns after resolution

2. Discrimination exists when selected populations of workers experience unjust treatment based on biological or social differences unrelated to their work capacity. For example, a group of nurses from a particular country believe that they are given work schedules that are less desirable than those of their colleagues. To resolve this issue, a manager could objectively review all the work schedules to ensure fairness. If he finds significant anomalies, he would have to change the method by which schedules are assigned.
3. Performance Review can generate conflicts when workers receive ratings below their expectations. If not addressed, this can lead to resentment and (paradoxically) worsening productivity. One way to remedy this is for the manager to provide the worker with specific instructions on how to improve performance.
4. Conflicts with customers and patients. Medical providers often have disagreements with patients when their expectations are not met. This may be due to inattention on the part of the provider or lack of understanding on the part of the patient or family, or some combination of both. The Joint Commission demands that a rigorous and impartial system be used for patient complaints. By assuring both sides that their treatment is fair and unbiased, most conflicts can be resolved.
5. Leadership disputes. Conflict often exists between managers and subordinates, particularly in terms of tactical decisions. A common healthcare example arises when a physician places an order but a nurse feels that it is unsafe or not in line with institutional policy. Sometimes, this can be resolved by having both parties sit down and learn what each other's motivations are. More likely than not, once each understands the other's concerns, a favorable solution can be found (Fig. 11-2).

Approaches to Conflict Management

Pruitt[6] classified approaches to conflict management based on two dimensions: **Assertiveness** (pursuit of a solution benefiting me) and **Cooperativeness** (pursuit of a solution benefiting all). See Fig. 11-1. By creating a 2 × 2 table, he is able to classify different styles of conflict management.

1. **Inaction** is a result of people who have low assertiveness and low cooperativeness. They are unconcerned with how the outcome affects either themselves or the other party.
2. When one party is highly assertive but not cooperative, they pursue their own victory and are called **contending.**

6 Pruitt DG. Strategic choice in negotiation. American Behavioral Scientist. 1983 Nov 1;27(2):167–94.

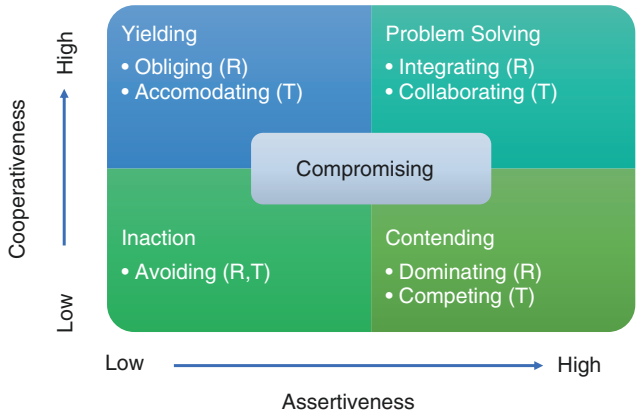


FIGURE 11-2

Graphic of Pruitt's model of conflict management where degree of assertiveness and cooperativeness determine the style of management (Yielding, Problem Solving, Inaction and Contending). Rahim and Thomas use similar ideas with different nomenclature, as noted with (R) and (T), respectively

3. The opposite end of the spectrum is the **Yielding** type who wants to find a solution—any solution—and is willing to give up his own needs.
4. When parties have both characteristics, they are called **Problem Solvers** and are most likely to find a mutually beneficial solution.

A similar model, by DeChurch and Marks[7] used **activeness** (how direct the participants are) and **agreeableness** (how nice people are) to classify conflicting parties. When studied, they found that activeness had minimal effect on ultimate resolution of the conflict, while agreeableness had a positive impact[8].

Rahim[9] suggested five different management approaches, which are very similar to Pruitt's: integrating, obliging, dominating, avoiding and compromising.

1. **Integrating**: studying differences, exchanging viewpoints and seeking alternatives in order to find a mutually beneficial solution (i.e. Problem Solving)
2. **Obliging**: minimizing differences in order to appease the other party (i.e. Yielding)
3. **Dominating**: pursuing a solution that benefits one side at the cost of the other (i.e. Contending)
4. **Avoiding**: trying to find an answer that ignores the needs of both parties, especially by pretending the problem doesn't exist. (i.e. Inaction)
5. **Compromising**: similar to problem solving, where each party gives up something to achieve peace.

Thomas and Kilmann[10] have also proposed five styles of conflict resolution which are also quite similar to those of Rahim and Pruitt. Their nomenclature is: Competing, Compromising, Collaborating, Avoiding and Accommodating. These names are summarized in Table 11-1.

4.1.5 COLLABORATION

Collaboration is the process of two or more parties working in a coordinated fashion in order to achieve some purpose. A similar term is **cooperation**, however collaboration connotes some form of leadership and coordination of efforts and is more disciplined. For

7 DeChurch LA, Marks MA. Maximizing the benefits of task conflict: The role of conflict management. International Journal of Conflict Management. 2001 Jan 1;12(1):4–22.
8 One of the reasons that this chapter is marked as Low Yield is that it would be really hard to write a board question about this material. No, really. Could you imagine a board question where the answer is "if you are in a fight, just try to be nice"?
9 Rahim MA. A measure of styles of handling interpersonal conflict. Academy of Management journal. 1983 Jun 1;26(2):368-76.
10 Thomas KW. Thomas-Kilmann conflict mode instrument. Tuxedo, NY: Xicom; 1974.

TABLE 11-1

APPROACHES TO CONFLICT MANAGEMENT WITH TERMS USED BY PRUITT, RAHIM AND THOMAS

AUTHOR	DESCRIPTION OF CONFLICTING PARTIES				
	WE BOTH WIN	I LOSE–YOU WIN	I WIN–YOU LOSE	WE BOTH LOSE	WE BOTH WIN AND LOSE
Pruitt	Problem Solving	Yielding	Contending	Inaction	
Rahim	Integrating	Obliging	Dominating	Avoiding	Compromising
Thomas	Collaborating	Accommodating	Competing	Avoiding	Compromising

example, two authors collaborate to produce a scientific study, while their kids cooperate to clean up the back yard.

Collaboration is an attempt to create a whole that is greater than the sum of its parts. By bringing together the competencies, experience and judgment of a variety of professionals with different skill sets, multidisciplinary teams are able to outperform their more homogenous rivals.

Determinants of successful collaboration have been classified as systemic factors (conditions outside the organization), organizational factors (conditions within the organization) and interactional factors (interpersonal relationships between team members).[11]

Systemic determinants include differences in power among members of the group, such as the differing roles between physicians and nurses. For physicians, professional development is characterized by the acquisition of authority, responsibility and autonomy, rather than collegiality and trust. Collaboration, however, relies on the mutual recognition by professionals of their interdependence as well as the acceptance of areas where their competencies overlap. When physicians act territorially, the result is fragmented care.

Organizational factors are determined by the organizational structure. One of the most important conditions for meaningful collaboration is establishing time and space for interaction. For example, in many community hospitals, physicians act dyssynchronously with the rest of the care team. Doctors come to the hospital at their convenience, round on their patients, enter orders, request consultations and return to their busy practices, often without directly interacting with other professionals. In academic hospitals, the organizational structure demands greater collaboration. Rounds are usually at a fixed time and there is an expectation that all resident and attending physicians will be present. In yet more collaborative environments, rounds are made with physicians, nurses, social workers, case managers and a host of other ancillary services. This degree of planning fosters better collaboration

Interactional determinants include the individual's desire to collaborate, trust, communicate with and respect other team members. Of these, trust seems to be the most important factor, as the other aspects will usually fall into place once trust is established. Physicians often devalue the time they spend communicating with other professionals. As a result, the respect is eroded and trust is never formed. When physicians realize that better outcomes are had through effective collaboration, they make time to communicate, which in turn generates trust and respect.

4.1.6 MOTIVATION

Olivia Dudley

Motivation is defined as a combination of external and internal factors that stimulate incentive and desire in people to work hard on refining their role either individually or as part of a team. Motivation is also key in inspiring an individual toward achieving a goal. Teamwork has the potential to take individual based motivation and apply it to a collaborative group. If

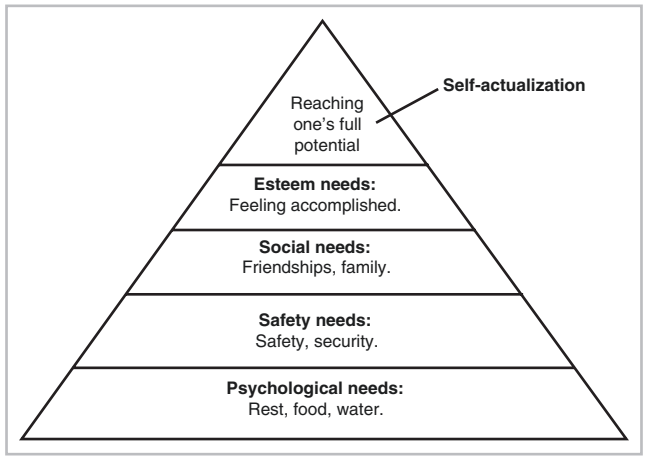
11 Martín-Rodríguez LS, Beaulieu M-D, D'amour D, Ferrada-Videla M. The determinants of successful collaboration: A review of theoretical and empirical studies. J Interprof Care. 2005;19(sup1):132–47.

all individuals of a team are motivated, then their collective work will be greater than a single individual's work alone.

Motivation is typically derived either intrinsically or extrinsically. Intrinsic motivation refers to actions driven by internal reward, such as personal satisfaction or a sense of accomplishment. Extrinsic motivation is driven by external reward, such as a promotion or employee of the month nomination.

Motivational Theories

Maslow's hierarchy of needs states that humans have certain needs which motivate them to achieve. Individual behavior is motivated first by basic needs including physical survival, safety and security. Once that is fulfilled, individuals are then motivated by psychological needs and then finally, by self-fulfillment.



The Herzberg Motivation-Hygiene theory describes two classes of motivators: hygiene factors and motivation factors. Hygiene factors are required to prevent dissatisfaction, but are not positive motivators themselves. They are factors that cannot be avoided nor prevented such as job security, working conditions, and salary. Motivation factors like recognition, advancement, and growth are most important to inspire a team. They are most closely related to job satisfaction.

McClelland's acquired needs theory states that an individual's specific needs are acquired over time and shaped by personal life experiences. These needs influence a person's motivation and can be categorized into three classes:

1. Need for achievement—a strong need to excel by setting and accomplishing challenging goals.
2. Need for affiliation—an individual's need to belong to a group, be liked by the group, and be accepted by others.
3. Need for power—the need to be strongly influential, lead, and make a lasting impact on others.

Motivation is a result of both unconscious and conscious factors including personal achievement, individual needs and desires, individual expectations, personal growth, and incentive or reward. Motivators are drivers of human behavior and are essential to inspire individuals to accomplish a goal. By understanding what motivates not only one's self, but a team of people, it will make for a more successful, enriched, and productive workplace.

4.1.7 DECISION MAKING

The job of a manager is, above all, to make decisions. There are several common classifications of decision makers. The first distinction is based on how much information is required to feel comfortable making a decision. **Maximizers** are people who research exhaustively

before coming to a conclusion. The alternative is called **satisficing,** in which research is conducted only until an acceptability threshold is met. Presumably, this level is lower than that of the maximizer.

Another axis to classify decision makers is the number of options that they pursue. Single focus decision makers routinely pick the single best option. Multifocussed deciders may pursue several options at a time to see which one shakes out. Single focus deciders put their energy and resources into making things turn out how they see fit, while multifocus people are more adaptive to changing circumstances.[12]

With these two axes in mind, we construct yet another 2 × 2 table (See Fig. 11-3).

Decisive. People using the decisive style want few options and minimal information. They value action, speed, efficiency, and, most of all, brevity. Once a plan is in place, they stick to it. Emergency physicians tend to be decisive.[13]

Flexible. Flexible decision makers keep the information burden at a minimum, also keep their options open. They focus on speed and adaptability. If they choose an option and it becomes undesirable, they quickly change course. Surgeons tend to be flexible.

Hierarchic. Hierarchic people collect much more data than decisives or flexibles. They involve others in their thought process and expect to arrive at decisions that will last. Radiologists and pathologists fall into this category.

Integrative. The integrative person seeks copious information before taking a first step, but even then, he is not committed to the decision. He tends to continuously evaluate many different choices and may pursue multiple different valid opportunities at the same time. Decision making for the integrative is not an event, but a process. Think Internal Medicine.

Gleason has also proposed an alliterative classification of decision makers:[14]

1. Command. Command decisions are made quickly with minimal information and minimal consultation. This is most similar to the Decisive style.
2. Collaborative. The leader seeks counsel from all stakeholders before making the decision.
3. Consensus. All team members are invited to contribute ideas and majority rules. This is different from the collaborative approach where the leader makes the decision.
4. Convenience. Sometimes, the best decision is to allow someone else to decide. This is also called “complete delegation”.

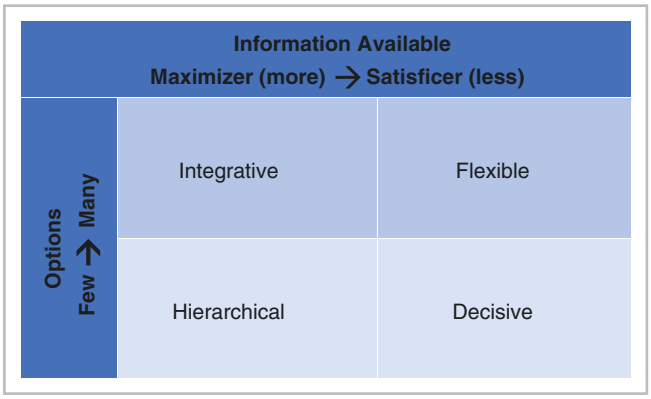


FIGURE 11-3

Types of decisionmakers are classified based on the amount of information they require and how many options they pursue

12 Brousseau KR, Driver MJ, Hourihan G, Larsson R. The Seasoned Executive’s Decision-Making Style. Harvard Business Review. 2006 Feb;

13 Grouping physicians’ personalities by specialty training is mostly a false stereotype. But it’s still fun. See Maron BA, et. al. Ability of prospective assessment of personality profiles to predict the practice specialty of medical students. Proc (Bayl Univ Med Cent). 2007 Jan; 20(1): 22–26. and Bexelius TS, et. al. Association between personality traits and future choice of specialisation among Swedish doctors: a cross-sectional study. Postgrad Med J. 2016 Aug;92(1090):441–6.

14 Gleeson B. Four ways for Leaders to Make a Decision. Forbes 2012 Nov;

After the decision is made, it is valuable to review the decision to make sure it was correct. Sometimes, this is very easy (i.e. did the patient survive? Did the project earn money?) Other decisions require more in depth analysis. By studying the lessons learned from a decision, a manager will be more ready the next time a similar situation arises.

Scott Mankowitz

4.2 Effective Interdisciplinary Teams

CHAPTER OUTLINE

4.2.1 HUMAN RESOURCES MANAGEMENT

Managing the human capital of an organization is called human resources management. The goal is to maximize employee performance in order to achieve the organization's goals and objectives.

Hiring, Recruitment and Staffing

Recruitment is defined as a process that provides the organization with a pool of qualified job candidates from which to choose. Before companies recruit, they must implement proper staffing plans and forecasting to determine how many people and with what proficiencies they will need. The forecast is based on the annual budget of the organization and the long-term plans of the organization.

Recruiting is the process of providing the organization with qualified applicants. Some organizations will give preference to **internal candidates** (i.e. applicants who are already working for the organization in another capacity). However, other organizations may favor diversity and deliberately seek candidates from outside the organization.

INTERNAL VS. EXTERNAL CANDIDATES	ADVANTAGES	DISADVANTAGES
Internal	Rewards contributions of current staff; may save money compared with traditional recruitment; may improve morale	May reduce diversity and limit variety of perspectives; may cause badwill among employees vying for the job, or when an internal candidate is not hired
External	Brings new talent and insight to the organization; improves diversity	Recruitment can be expensive; may take longer for orientation and training

The recruiting process begins with a formal **job analysis** which is a process designed to delineate exactly what tasks a worker is expected to do. It may include reviewing similar jobs in other organizations as well as interviewing managers and current employees (if the job already exists). When the analysis is complete, the manager creates a **job description** (a list of the tasks and responsibilities associated with the job) and a **job specification** (a list of the skills and certifications required for the job). In most cases, job descriptions include job specifications.

Whereas recruiting is the process of identifying candidates, **selection** is the process of picking the best ones. Applicants submit resumes (or curricula vitae for professionals) which are impartially reviewed and assigned a score based on how well the applicant matches the job description. The top candidates may be interviewed and/or tested to further narrow the pool. The ratio of people who progress from one step to the next in the hiring process is known as the **yield ratio**.

Care must be taken to use criteria that are fair, valid and reliable. **Disparate impact** is when a particular group is unintentionally disfavored in the hiring process. For example, a fire department may demand that applicants be able to carry a 70-kg person 100 ft. This requirement would unintentionally discriminate against women. If it can be proven that this capability is materially related to job success, it is legal. **Disparate treatment** is the intentional exclusion of particular groups of people (e.g. solely based on age, race or gender) from the hiring process, and is not legal.

Personal references and interviews can be notoriously imprecise measures of a candidate's aptitude. In order to maximize fairness in interviews and improve inter-rater reliability, it is best to use a set of structured questions that are identical among different interviewers. Many of the biases present in research studies can be present in interviewing and the same methods to combat bias should be used to prevent it.

When a candidate is selected, an offer of employment must be made. In general, the offer will include a job title, salary, other compensation, benefits, vacation time and expected start date. Professional contracts may include non-compete clauses and expectations about how much notice must be given before either side exits the agreement.

Performance Reviews and Feedback

It is important to provide periodical and timely feedback to employees on their performance in order to maintain motivation and to correct any performance issues before they get out of hand.

Routine performance appraisal can be costly. It may require up to 3 h of a manager's time to evaluate each employee. When a manager has 15 people reporting to him, it's easy to see that a week's time is consumed with the process. As with recruiting, it is important to make a fair and unbiased system for performance review. Employees should be invited to participate in creating the rubrics for evaluation, and should be notified whenever they are changed. In general, the topics should be based on the job analysis performed in the recruiting phase and ultimately tied to the organization's strategic plan. The appraisal system should be based on actual job performance, and devoid of unmeasurable factors (such as manager's feelings about the employee). All evaluators should be similarly trained and, when possible, the ratings of multiple observers should be used.

Sources of information for performance review

1. Manager— The manager is usually the best source of information as he is familiar with the employee's work and skill. However, he be subject to personal bias and favoritism
2. Self—Some companies have employees evaluate themselves. While introspective employees may benefit from this, the conflict of interest is plain.
3. Peers—Co-workers may have insight into workers' behavior when the boss isn't looking. However, personal relationships may create unfair bias, especially when salary is involved.

4. Customers—This is often a good source of information, but can be difficult to obtain. Customer satisfaction surveys may disproportionately represent the very satisfied and very unsatisfied.[1]
5. Subordinate—Using survey information from subordinates can help a manager assess his own progress and possibly detect favoritism in his department. However, subordinates may fear retribution and could inflate ratings to gain favor from their manager.

There are many types of negative performance issues, such as:

1. Timeliness—employee arrives late or leaves early
2. Personal things at work—employees spend too much time on their phone or computer tending to personal matters instead of work projects. This may include "legitimate" issues, such as caring for a child or parent, or may just be surfing the web.
3. Nonperforming—employees who are unable to complete their work assignments may be distracted by other obligations or may lack tools, training, equipment or ability to do their jobs.
4. Conflicts—employees may have repeated disagreements with managers or other co-workers which impair efficiency
5. Substance abuse—employees using drugs or alcohol will not be able to perform at peak efficiency and may put customers or co-workers in danger.
6. Conduct outside the workplace—many organizations have strict policies stating that employees must maintain a positive image outside the workplace. For example, an employee may be disciplined if he makes disparaging statements about his company on social media.
7. Protected information—employees can be careless with personal health information or company trade secrets. In the case of PHI, regulatory penalties may apply.
8. Harassment—bullying, mobbing, sexual harassment and other forms of intimidation not only decrease overall productivity, but may be illegal.
9. Ethics violations—employees may lie, cheat or steal from the organization, customers or co-workers. In some cases, this may be "minor" such as claiming to be ill in order to take a day off work. In other cases, such as embezzlement, there may be criminal activity.

Corrective Actions

If an employee is not meeting corporate expectations, he may need to be redirected through the process of corrective action, or discipline. It is critically important that all infractions be completely documented as well as all attempts to improve the situation. These rules must be codified and easily available to all employees and managers. If the rules are applied partially or unfairly, an employee may be able to sue the company for discrimination. If an employee is fired, he may have a claim for wrongful termination.

Mandated issues are employee behaviors that require immediate action because they violate a law or regulation (e.g. a HIPAA violation). These cases are relatively simple because the company is *required* to respond.

Most cases, however involve more subtle problems. The first time an employee breaks a rule, it is called a **single incident**. If this is not corrected, the employee may feel that the action is acceptable and it becomes a **behavior pattern**. If the behavior continues, even after the employee has been addressed, it is called a **persistent pattern**. At this point, progressive disciplinary actions are used.

1 Physicians tend to be notoriously unsatisfied with customer satisfaction surveys because they believe that patients may not adequately understand the care they have received and may not be appropriate judges of quality. For example, a woman may claim that her hysterectomy was of poor quality based solely on the appearance of her abdominal scar. Moreover, physicians have complained that using satisfaction surveys places them in conflict between patients and good medical practices, such as antibiotic stewardship.

EXAMPLE OF A PROGRESSIVE DISCIPLINE PROCESS	
Counseling	Manager meets with employee to discuss the performance problem and to restate expectations. A timeline is created with specific consequences of noncompliance. A written record is signed by employee and manager and kept in the employee's file. In some cases, mandatory training may be required
Written warning	If counseling does not have the desired effect, the manager writes a formal letter of reprimand to the employee specifying exactly which rules were broken
Suspension	If the employee continues to exhibit the undesired behavior, he may be prohibited from working for a defined period of time, usually without pay
Termination	When all the above efforts fail, the employee is involuntarily separated from the company

Compensation and Rewards

Compensation plans should match the company's overall strategy. First, salaries should be competitive enough to attract top talent. Second, compensation has to have a positive trajectory in order to maintain good employees. Third, compensation can be used to improve morale, motivation and satisfaction among employees. Rewards can be used to motivate individuals or teams to operate at their peak performance. Motivated employees will provide better customer service and may be less likely to take sick days or make disability claims. In service industries, compensation may be the single largest corporate expense. In hospitals, for example, salaries represent an average of 54% of the operating budget[2]

Types of compensation

PAY	ATTRIBUTES
Fixed salary	Fixed compensation per pay period
Hourly wage	Employees are paid on the basis of number of hours worked. The Fair Labor Standards Act (FLSA) requires employers to pay 1.5 times the normal salary ("time and a half") for any hours over 40 per week. Managers and some other employees are considered "exempt" from this rule
Piecework	Employees are paid based on the number of items that are produced
Commission	Employees are paid a percentage of profits for every unit of work. For example, a broker may make 5% of the value of a sale
Bonus plans	Extra pay for achieving certain goals. Bonus plans can consist of cash or other benefits, such as time off or gift certificates
Profit-sharing plans	Annual bonuses paid to employees based on the amount of profit the organization earned
Stock options	Employees are given the option to purchase company stock at a particular cost ("strike price"), usually lower than the current trading value
Benefits	Health, dental and vision insurance are common benefits. In most cases, both the employer and employee share the contribution to the cost of insurance. Disability and life insurance are also commonly offered. Fringe benefits may include sick leave, paid time off, health club memberships, daycare services, discount plans and others
Retirement	The employer sets up a relationship with a financial services company to allow employees to deduct a part of their pay to be saved for retirement. Some employers will directly contribute to retirement savings plans, while others may match an employee's contribution. One method of retaining employees is to create a "vesting" period where the employee gains access to the employer-contributed savings only if he stays with the company for a certain time

2 Herman B. 10 Statistics on Hospital Labor Costs as a Percentage of Operating Revenue. Becker's Hospital CFO. December 10, 2013.

In addition to the above, employers are federally mandated to pay for social security, medicare, unemployment insurance, worker's compensation insurance and COBRA (extension of health insurance after employment ends).

Retention

Employee turnover refers to the monthly percentage of employees that separate from the employer, either voluntarily or involuntarily. Turnover costs can be high because they include the cost of recruiting and training a replacement as well as the costs associated with lost knowledge, lost motivation and potentially even lost trade secrets.

Common reasons for voluntary turnover

1. Culture mismatch—the employee does not fit with the corporate culture, or does not feel that his manager supports him.
2. Skills mismatch—the employee feels that his skill set does not correlate with his responsibilities
3. Lack of growth—the employee feels stuck in his job and does not see any upward mobility
4. Pay equity—the employee feels that his compensation is unfair when compared to others
5. Workload—the employee's workload is so high that it interferes with his ability to function or with his personal life.

Training and Professional Development

Formalized employee orientation has several purposes. It can reduce anxiety and start-up costs and can help reduce turnover. It gives an opportunity for the new employee to meet his supervisor and coworkers, and it sets expectations and attitudes. Many employers have a list of training sessions that must be completed before working, such as ethics, sexual harassment, multiculturalism, customer service, and others. In addition, there is usually training specific to the job, such as how to use special equipment or software.

Professional development is the process of grooming employees to greater levels of skill and responsibility. **Mentoring** is the process of assigning a new employee to a seasoned veteran of the organization to help guide development. **In-service training** includes training for current employees on new policies or equipment required for their job.

For the most part, professionals are required to support their own development (e.g. with continuing medical education) although their employer may share some of these costs. In general, these costs are tax-deductible for the employee.

Industrial Relations

The majority of employees in the United States are "at-will" employees, which means that their employment can be terminated at any time by the employer or employee. The is no requirement for justification for separation, as long as it is not based on discrimination[3]. Employees who are involuntarily terminated may be eligible for unemployment benefits, even if they are terminated for a good reason, although state laws may vary on this.

Employees who are part of a union may benefit from collective bargaining, and can not be fired without due process. In many cases, some of the responsibilities of the employer are shifted to the union, such as medical insurance or addressing grievances between employees and management. In general, negotiations about wages and working conditions are handled between the organization's management and its union representatives instead of on an employee by employee basis.

3 Many professionals enjoy protections in their employment contracts which require a notification period of up to several months prior to separation. Professors are often given tenure, which significantly restricts the ability of the university from firing them.

4.2.2 TEAM PRODUCTIVITY AND EFFECTIVENESS

Teams that work together will be more effective and will have increased productivity. These teams tend to have individual and group understanding of the team's goals and objectives. This enables them to work together to develop new ideas and divide work equitably amongst team members, benefitting from each other's strengths.

Creating a powerful team begins by selecting great team members. The ideal team members have varied skills, are respectful of each other's ideas and are willing to compromise in order to benefit the project. Team members should have no overt or hidden conflicts of interest with the team's goals or with each other.

Articulating Team Goals
In order for a team to be effective, it has to have a solid direction from its managers. The team's objectives should be SMART: Specific, Measurable, Assignable, Realistic and Time-related. The team members should be individually and jointly motivated to achieve success. Since it is very easy for team members to assume that a particular task was "someone else's responsibility," all tasks should be clearly laid out for all members. Instead of assigning tasks randomly, highly optimized teams will assign tasks to team members with the greatest relevant skill.

Defining Rules of Operation
Almost as important as articulating the team goals is defining the rules of operation. Each team member should be held individually accountable to the group. For example, all team members must be present for meetings; if they are unable to complete a task, they must ask for help or have the task re-assigned. Without solid rules, one or two team members may end up doing most of the work. As a result, motivation and dissatisfaction will increase and the team's productivity will fail. Most team members will work hard for the success of the team, but if they suspect that the rules are unfair or are changing unpredictably, they begin to feel cheated.

Clarifying Individual Roles
The team leader must make sure that every team member is aware of the extent and limitation of his role in the group. For example, some personalities work well together, while some clash. It is up to the team leader to make sure that the rules of operation are followed rigorously to minimize this potential conflict.

The following is a list of ways that a manager can boost his team's productivity[4]

1. Set the example. In order for team members to manage their time effectively, the manager must also be expert in time management and serve as a role model.
2. Set goals. The manager should set reasonable goals and boundaries for team members to stay effective.
3. Clarify expectations. The manager should meet with team members individually and remain in constant contact. It is important for team members to know the relative importance of each of their tasks so they can prioritize their time.
4. Open communication. Team members must feel free to express their difficulties as early as possible so that they can be redirected appropriately.
5. Autonomy. In order to feel valuable, employees have to be able to make their own decisions. Micromanaging their work will make them feel impotent.
6. Meetings. Many organizations fall into the practice of having regular meetings without having a distinct purpose or agenda for those meetings. Some meetings, especially early in a project may be necessary for brainstorming. Subsequent meetings should serve a particular purpose, should be as short as possible, and should invite only those people required to contribute.
7. Downtime. Team members who feel that they must be available 24/7 will ultimately show symptoms of burnout. Downtime should be scheduled and respected.

4 Knight R. How to Boost Your Team's Productivity. Harvard Business Review. January 29, 2016.

4.2.3 GROUP MANAGEMENT PROCESSES

When groups convene, many people from different backgrounds are involved in the decision-making process. Creating an efficient and productive method of solving problems is a managerial challenge.

There are several different methods of group decision making[5]. The traditional and most common method is sometimes called the "interacting group" method. The typical format involves the manager opening the meeting with a statement of the problem. The group then has an unstructured discussion with each person contributing as much or as little as he feels pertinent to the problem. After the dialog is complete, there is some form of voting or consensus procedure and the meeting ends.

There are several drawbacks to this type of meeting[6]. (1) Significant effort is required to organize and maintain a group. (2) Groups are often motivated to reach a conclusion and may not fully evaluate all options. This can result in the **central tendency effect** (also called **groupthink**) in which members of the group will favor harmony at the expense of expressing their own viewpoints. (3) Group members who are lower on the hierarchy than others may feel pressured to stay silent, even when their superiors are incorrect; (4) Aggressive or likable personalities tend to have an exaggerated influence on the group's deliberations. The major benefit to this method is that it is easy and unstructured. Most collaborators enjoy human interaction and have high levels of satisfaction with this method.

Another method of group management is the **nominal group technique** which follows a much more structured pathway

1. The problem is stated by the group leader.
2. Each team member silently writes down one or more ideas on a sheet of paper.
3. After everyone has written their ideas, each member of the team presents his ideas to the group in a round-robin order. The ideas are presented without interruption and a one-line summary is written on a whiteboard.
4. When every member has presented his ideas, a group discussion ensues to clarify and expand on each of the ideas on the whiteboard.
5. After the discussion, there is a silent voting period where each team member ranks each of the ideas from best to worst.
6. The team leader collects the votes and pronounces the group's decision.

The advantage to this method is that the opinion of all group members is heard and has the opportunity to be evaluated. The nominal group technique is sometimes known as **estimate-talk-estimate**.

The **Delphi method** is another method of obtaining group consensus which follows a completely asynchronous architecture. It begins when the group leader sends out anonymous, open-ended questionnaires to all participants. The responses are then aggregated and summarized for the group and redistributed again. This continues for 3–5 rounds until a consensus is achieved. Unlike the interacting group or the nominal group, the Delphi method does not require all members to be present at the same time, or even know who the other participants are.

Consensus mapping is a particular technique for sequencing and clustering a set of activities into an action plan[7]. Consensus mapping assumes that the list of ideas has already been created and vetted for accuracy.

5 Van De Ven AH, Delbecq AL. The effectiveness of nominal, Delphi and interacting group decision making process. Acad Manage J (1974) 17(4):605–621.

6 Graefe A, Armstrong JS. Comparing Face-to-Face Meetings, Nominal Groups, Delphi and Prediction Markets on an Estimation Task. Int J Forecasting (2011). 27(1):183–195.

7 Hart S, Boroush M, et. al. Managing Complexity Through Consensus Mapping: Technology for the Structuring of Group Decisions. Acad Manage Rev (1985). 10(3):587–600.

1. The master list of tasks is presented by the group leader. Everyone copies the tasks onto slips of paper, one task per slip.
2. The large group (plenary group) is broken down into smaller groups (task groups) and the task groups are then broken down into even smaller groups of 2–3 participants.
3. These small groups attempt to cluster the tasks into recognizable categories. They then work with other small groups to agree on clustering, trying to understand each other's clustering methodology. Ultimately, the small groups come to a consensus and the task group presents its results to the group leader.
4. The group leader creates a **strawman map** which is an amalgamation of all the task groups' work. After a break, the whole group reviews the newly created map.
5. The group is again divided into task groups for the **map reconfiguration** step which seeks to create a solution based on the task group's ideas as well as the strawman map. Representatives from the task groups again present their maps to the plenary group.
6. The last step is **map consolidation** where the leader blends the work of the various task groups into one consensus statement.

In **prediction markets,** participants are given a certain amount of play money with which to purchase and support various ideas. The proposed ideas are then bought, sold and traded at market rates. Ideas that are more popular will increase in price, while less popular ideas will decline. When prices reach equilibrium, the top ideas are selected. The drawback to this method is that it requires a significant degree of infrastructure to keep track of the user accounts and the value of various ideas, which is probably more trouble than it is worth for small meetings. However, with modern computers, this method can be used to canvass an entire corporation's ideas over a few weeks.

Research comparing the effectiveness of different group decision-making is contradictory, but some trends are evident.

1. More unique ideas are generated with the Delphi method, probably because participation is anonymous.
2. People tend to have higher satisfaction when interacting with other humans, such as in face-to-face meetings and in nominal groups.

4.2.4 MANAGING MEETINGS

Organizations tend to have a lot of meetings. Some are quite useful, while some are not. Occasionally, meetings may be required by organizational bylaws, such as hospitals which require regular department meetings. In other cases, meetings are arranged for a particular purpose or goal.

There are very few hard and fast rules about meetings, and the following are some simple suggestions to ensure success.

1. The purpose of the meeting must be clear. If the reason for the meeting can not be expressed in a single sentence, it probably shouldn't happen.
2. Select the attendees carefully. All attendees should be able to either benefit or contribute to the meeting. If a desired attendee is unable to go to the meeting, ensure that a reasonable substitute is available. When the meeting starts, take attendance to make sure that all stakeholders are present.
3. The meeting organizer should have a clear agenda with reasonable estimates of the time allotted to each item. The meeting should start and end on time. Failing to respect the time commitments of the attendees will erode their motivation and decrease overall productivity. In cases where there is simply not enough time to address the important points, consider establishing sub-committees and empowering them to deliberate on the more challenging issues.

4. Prepare and distribute as much information as possible before the meeting. This will allow attendees to ruminate on it so that when the meeting starts, an informed discussion is possible. (The corollary is that many people will not prepare for the meeting, no matter how much time or information you give them. Be prepared to summarize for them).
5. Decide in advance how the meeting will be run. Is the tone informal, or will it follow strict parliamentary procedure? How will decisions be made? Will there be voting or will the organizer have the final say?
6. Do not underestimate the physical aspect of the meeting. Ensure that the meeting space is quiet and accessible. It should have enough space for everyone to sit comfortably, and have appropriate audio-visual equipment. Consider providing refreshments.
7. Keep detailed minutes, including the assignments and timeframes for each of the attendees. In general, most people at the meeting should leave with a certain amount of "homework" or tasks that must be completed before the next meeting. When the next meeting begins, the first order of business should be to review and accept the minutes from the previous meeting.

4.2.5 MANAGING GROUP DELIBERATIONS

Most group deliberations remain unstructured. A leader or facilitator selects the participants and invites them to attend. This group of intelligent and respectful people are gathered around a table and each speak when they have something to contribute. During those rare occasions when the group strays off-topic, the facilitator redirects them and the meeting continues.

Unfortunately, as the topics become more important and the size of the group grows, these deliberations can descend into chaos. For this reason, many groups have adopted a set of rules which govern large meetings. The simplest example of this is classroom etiquette, where the members are not allowed to speak unless given permission by the leader (e.g. teacher).

In larger groups, it can be quite difficult to ensure that the group stays on-topic and that all participants have a chance to speak. One way to keep order in such meetings is to adhere to **parliamentary procedure**, in which a moderator follows established rules to determine who may speak at what time and on what topic. *Robert's Rules of Order* is a popular book describing parliamentary procedure. Its purpose is "to enable assemblies of any size, with due regard for every member's opinion, to arrive at the general will on the maximum number of questions of varying complexity in a minimum amount of time and under all kinds of internal climate ranging from total harmony to hardened or impassioned division of opinion."[8]

8 Robert HM, Robert SC. Robert's rules of order newly revised. 11th ed. Philadelphia, PA: Da Capo Press; 2011.

Scott Mankowitz

4.3 Effective Communications

CHAPTER OUTLINE

4.3.1 EFFECTIVE PRESENTATIONS TO GROUPS

Power Corrupts. PowerPoint Corrupts Absolutely.[1]

Slide-based presentations are ubiquitous in medical education. Here are some tips for developing effective presentations to groups.

1. Presentation—Identify the subject and purpose of your presentation. Lectures that conform to Continuing Medical Education guidelines must include learning objectives and potential conflicts of interest.
2. Audience—tailor your presentation to the audience. Use language and examples that are appropriate to this group.
3. Preview/review—Tell the audience what will be coming, then present it, then summarize it for them.
4. Organization—be sure that the presentation is unified and has an introduction, body and conclusion. This is especially important if you have multiple speakers working together.
5. Handouts—Some participants will want to take notes. Others will be grateful for prepared notes that accompany the lecture.

4.3.2 EFFECTIVE ONE-ON-ONE COMMUNICATION

In business, one-on-one communication often connotes the regular meeting between a staff member and a manager. This type of meeting is valuable to help make sure that both workplace and worker issues can be raised and addressed at the same time. The meeting should be private and uninterrupted so that both parties feel comfortable expressing their views. The meeting should address the staff member's projects, obstacles and goals as well as any new information the manager needs to provide.

1 Tufte E. Powerpoint is evil. Wired 2003;11(9).

In healthcare, one-on-one communication occurs every day between doctors, patients, nurses, clerical staff and others. These communications are rarely structured, even though it has been shown that structure leads to more concise, focused and thorough communication, especially when the responsibility for patient care is being handed off from one provider to another.

Many hospitals have adopted the SBAR method:

Situation—what is immediately wrong with the patient
Background—past medical history and other information relevant to this problem
Assessment—what the sending person thinks is wrong
Recommendation—what the receiving person should do

4.3.3 WRITING EFFECTIVELY FOR VARIOUS AUDIENCES AND GOALS

Writing is the most durable form of communication. As interns, we were reminded almost daily "If it wasn't written, it wasn't done."

Informaticists engage in writing many kinds of documents, such as

1. Journal articles and abstracts
2. Books and book chapters
3. Medical education items
4. Research grant proposals
5. Regulatory or technical specifications
6. Medical related content for health magazines, newspapers, websites or advertising

Informaticists also spend just as much time writing e-mails to the medical staff about new technologies or to vendors about how a system is going wrong.

In addition to linguistic skill, medical authors must tailor their writing to the level of their audience. The degree of technical precision required for the description of an interfacing protocol is much greater than that for, say, an article for *Cosmopolitan*. Yet both require diligence, responsible information and correct grammar.

4.3.4 DEVELOPING AN EFFECTIVE COMMUNICATIONS PROGRAM TO SUPPORT SYSTEM IMPLEMENTATION

An effective communications plan has several key steps.

Identify your objectives. When implementing a system there will be a myriad of communications that need to reach hundreds or even thousands of recipients. Before sending out any message, the first goal should be to figure out what purpose your communication should have. What is the outcome you are trying to achieve? Here are some examples:

- Establish trust between the informatics team and the medical staff
- Manage expectations so that users are not surprised or frustrated later on
- Encourage participation in new programs, policies or procedures
- Educate staff about features of the system.

Choose the target audience. Once the objectives are defined, it is important to spread the message to all the relevant stakeholders. Whom will this change affect? Who is required to effect this change? If the message is broadcast too widely, people will begin to ignore your transmissions. If it is too narrow, people will feel as though they are "out of the loop"

Design the messages. What are the key messages you want to communicate to each audience? Anticipate problems and provide clarification where possible. What sorts of questions do people usually ask when this kind of information is distributed? What do people need to understand in order to follow the directions? What are some of the roadblocks or hurdles that make this new method more difficult? What problem was being addressed that required this change? Finally, is there any information that should NOT be shared with the public?

Select the communication methods. In most corporate environments, email is the communication method of choice. It provides nearly instantaneous transmission to vast audiences with the opportunity for receipt confirmation and interactive dialog, all for a trivial cost. The downsides are also well known. People often disregard unsolicited emails, assuming that they are irrelevant, unimportant or even malicious. Other communication options include posters and flyers distributed around the campus; group meetings; individual meetings; and texting. Choosing the right combination of methods is key to reaching the desired audience. It is valuable to take advantage of communication methods that already exist, such as regular departmental meetings or a corporate newsletter. It is also advantageous to utilize trusted channels, such as respected clinicians or division heads.

Plan for two-way communication. Transmitting the message is only part of the challenge. Enabling feedback mechanisms encourage dialogs, which allows the team to refine strategy and gather new ideas. Listening to the recipients of the message allows the organization to adjust the system to better meet their needs. Feedback can be collected by email, anonymous suggestion boxes, communal meetings, or by making staff physically available or through a helpdesk.

Calculate the time and budget required. Sending a blast email is essentially cost-free, while the resources required to provide IT support staff to discuss the message could be overwhelming. It is also important to know how much time there is for the message to be sent and how much money should be spent to deliver it, as this will help determine the best method to get the message out.

Monitor the results. After any communication program, one should assess to see if the message was, in fact, received. Are users adapting to the new policy? Do the data support the change that was implemented? Are there still people who didn't get the memo, so to speak? Analysis of communication failures will ensure that the next communication is that much more successful.

Scott Mankowitz

4.4 Project Management

CHAPTER OUTLINE

4.4.1 BASIC PRINCIPLES

According to the Project Management Institute, A **project** is a temporary endeavor undertaken to create a unique product, service or result. Since a project is temporary, it has a defined beginning and end in time, and therefore defined scope and resources. Further, a project is not a routine operation, so it often includes teams of people who do not ordinarily work together, sometimes from different organizations and different walks of life. **Project management** is the application of knowledge, skills, tools and techniques to meet project requirements.

As opposed to normal operations, projects have a number of unique properties

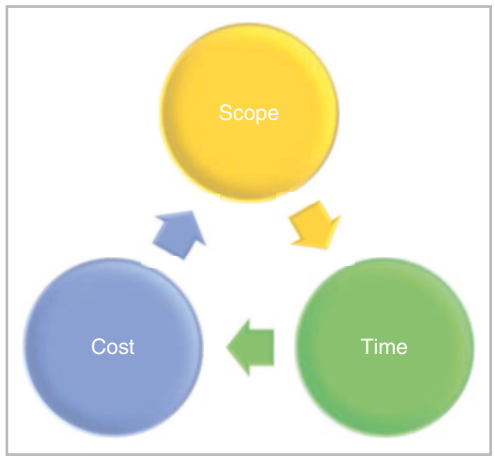
1. A project has a specific purpose. For example, the IT department will replace all the desktop computers on the 4-West nursing unit.
2. A project is temporary. For example, the computers will be replaced between January 4 and January 15.
3. A project requires resources. For example, 15 new computers, licenses for all software programs, sufficient network, power supply and cooling.
4. A project has a primary customer or sponsor who provides direction and funding for the project. For example, the IT department will provide the funding, the sponsor is the IT director and the customer is the nursing unit.
5. A project may have to adapt as it progresses when new information or new hurdles appear. Many projects involve uncertainty.

The **triple constraint** refers to the fact that projects are limited in **scope** (i.e. the work expected for the project), **time** and **cost**. These three items are in continuous balance. If one constraint is loosened, the others are able to expand. For example, if the project is given more time, more work can be done. Similarly, if the budget of a project is halved, the amount of work has to shrink as well. More recent versions of the PMBOK list the constraints as scope, time, cost, quality, resources and risk (Fig. 14-1).

Project management is a lexicon and set of procedures meant to synchronize work on various projects. As you read, you will find that the project management vocabulary is quite intuitive and quite rational. For that reason, you can expect at least one or two boards questions on these chapters. Even if you are not familiar with all the terminology, there is a good chance that you will be able to answer the questions just by knowing some key terms. Most of these chapters are based on the project management body of knowledge (PMBOK), published by the Project Management Institute (A guide to the project management body of knowledge (PMBOK® guide). 5th ed. Sydney, NSW: SAI Global; 2013). A nice read if you have the time.

FIGURE 14-1

The triple constraint



Stakeholders are people who are involved or affected by the project and include the project team, the customer, users, suppliers, vendors and sometimes even opponents to the project.

A **program** is a group of related projects which are managed in a coordinated way which results in benefits which could not be obtained if the projects were managed separately. For example, an IT department may have a user support program which includes projects like building a better help-desk, creating more training classes and producing manuals.

Project Management Knowledge Areas

1. Integration management: coordinating all the following knowledge areas to complete a project.
2. Scope management: defining the work that needs to be done
3. Time management: ensuring timely completion of the work
4. Cost management: preparing and adhering to project budgets
5. Quality management: guaranteeing that the work will meet the needs of the project
6. Human resource management: making effective use of the people on the project
7. Communications management: generating, collecting, broadcasting project information
8. Risk Management: analyzing and controlling project risks
9. Procurement Management: acquiring goods and services for the project.
10. Stakeholder management: setting expectations and communicating with all stakeholders.

Systems are sets of interacting parts which work together to achieve some purpose. **Systems analysis** is an approach which involves defining the scope of the system, dividing it into components, and identifying its problems, constraints and needs. Whenever new solutions are investigated, they are seen in the context of the whole system. **Systems management** involves the work of creating, maintaining and upgrading a system. There are three spheres of system management: business; organization and technology (Fig. 14-2).[1]

For example, suppose you are installing a new software system. The business sphere involves the cost, anticipated revenue, risk reduction and business value. The Technology sphere would include technical details, such as hardware and software specifications, network traffic impact and so on. The organizational sphere is concerned with the impact on the organization, such as who will be using the system and who will require training and who will provide that training. The organizational sphere has four frames: the **structural frame** which represents the company's hierarchy (i.e. on the organizational chart, who reports to whom); the **human resources frame** which involves managing the people of the organization; the **political frame** which refers to organizational politics; and the **symbolic**

1 Schwalbe K. Information technology project management, 5th ed. Boston, Mass: Thomson Course Technology; 2007.

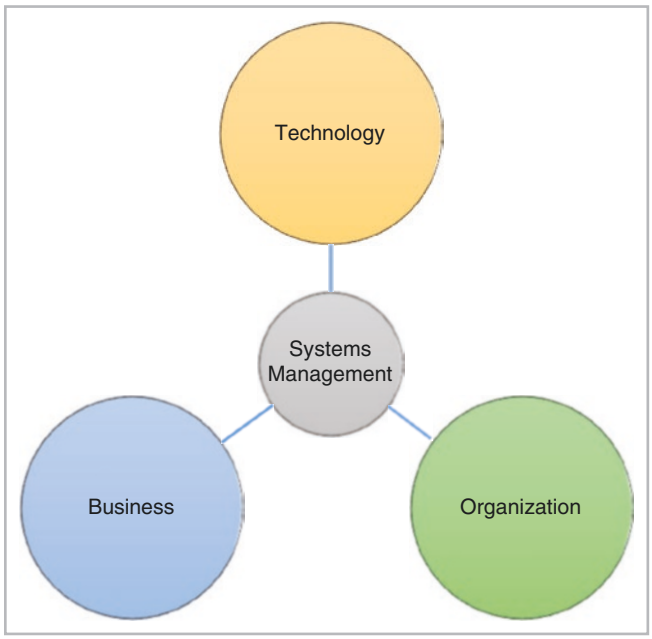


FIGURE 14-2

Systems management

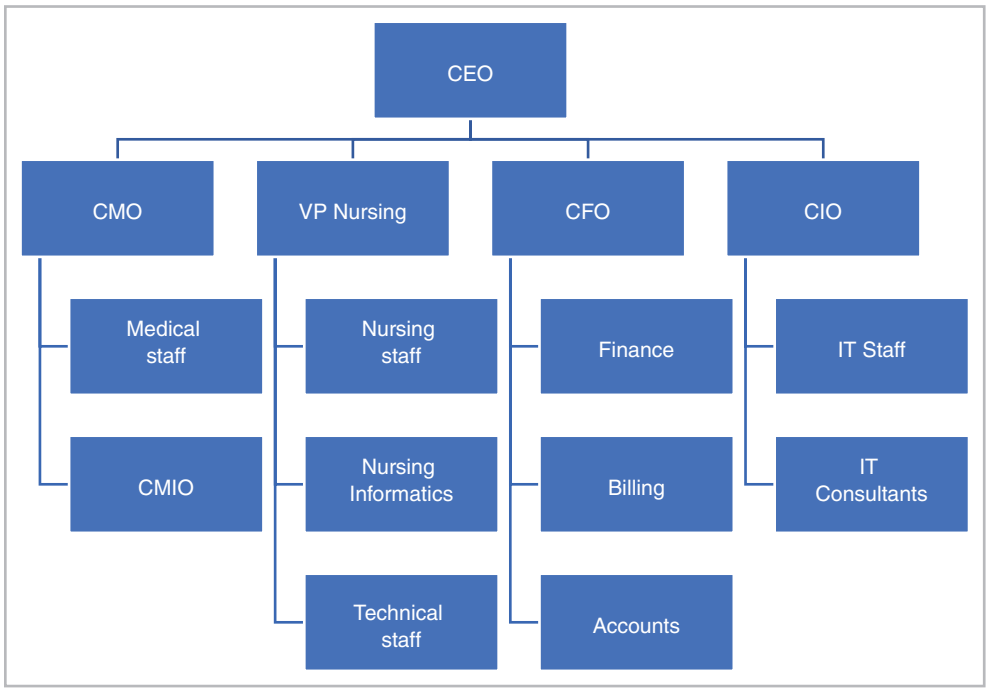


FIGURE 14-3

Functional organizational chart (most common)

frame which relates to symbols and meanings (e.g. if the CEO goes to the meeting, it must be important)

There are several common organizational structures. The most common is the **functional organizational structure** which is typically what we think of when we see an organizational chart. Each member's role is defined by their function and whom they report to in the organization. In a **project organizational structure**, project managers report directly to the CEO and staff report to them. A hybrid between the two is the **matrix organizational structure** in which each staff member reports to both a project manager as well as a functional manager. As you can imagine, the project manager's authority increases as we go from a functional structure to a project structure (Figs. 14-3, 14-4, and 14-5).

FIGURE 14-4

Project organizational structure; project staff report directly to project managers

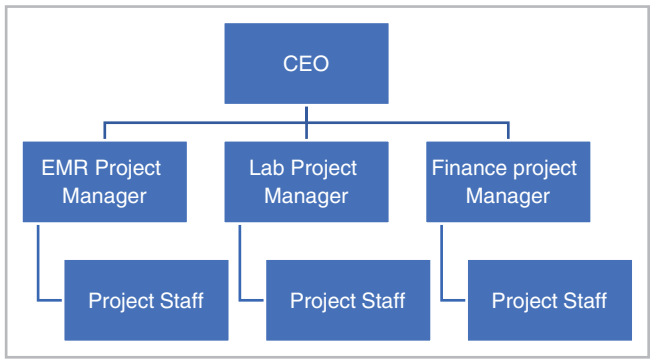
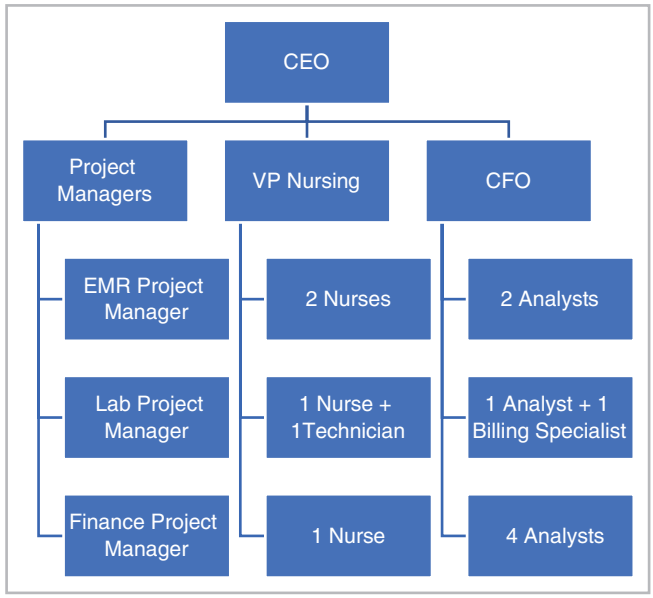


FIGURE 14-5

Matrix organizational chart; each staff member reports to a functional leader (e.g. VP Nursing) as well as a Project Manager



Probably the most important factor for the success of a project is support from top management because they have the ability to marshal organizational resources in support of a project.

1. Projects require adequate money, people and visibility to thrive.
2. Projects often require approval for unique needs.
3. Projects require cooperation from people in other parts of the organization.
4. Projects require a champion—a respected person within the organization who can promote the project.
5. IT Projects require an organizational commitment to IT at a high level
6. Projects run much more smoothly with organizational standards which allow project managers to communicate changes to all affected employees

Project Phases

A **project life cycle** is the set of phases through which a project passes on its way to completion. **Project feasibility** includes phases called *concept* and *development* which create initial cost and time estimates. **Project Acquisition** involves *implementation* (i.e. the actual work) and *close-out* (customer acceptance). During the course of the project, there are frequent management meetings called **phase exits** or **kill points**, where it is decided whether the project should be continued, modified or abandoned. Some projects have **predictive lifecycles** where great emphasis is placed on the planning phase (consider the Waterfall method in Sect. 3.1.1.3) while other projects involve more uncertainty and have **adaptive lifecycles** (consider the agile method in the same section).

Each of the knowledge areas can be broken down into five **process groups**, which include **initiating, planning, executing, monitoring and controlling** and **closing.** For the most part, these processes run sequentially, except for the monitoring and controlling process group which runs for the length of the project (Fig. 14-6).

Each of the 10 knowledge area has tasks which are related to each of the 5 process groups. Table 14-1 shows a grid demonstrating the **outputs** or **deliverables** for each combination. For example, the Integration knowledge area has an initiating phase which includes developing the project charter. In the planning phase, the management plan is developed, and so on. Some of the areas are blank because the work is minimal. For example, there is not much to do in the cost knowledge area during the initiating phase because cost estimation isn't begun until the planning phase.

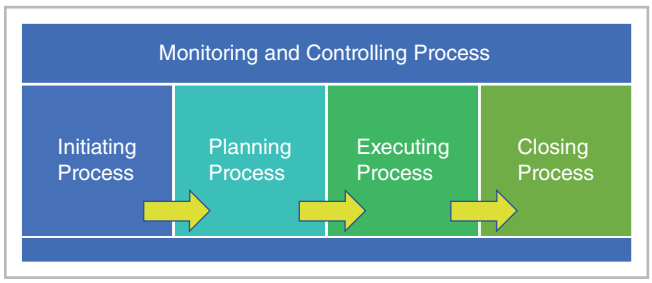


FIGURE 14-6

Process groups. Each of the knowledge areas has five processes: initiating, planning, executing, monitoring and controlling, and closing

TABLE 14-1

EACH OF THE 10 KNOWLEDGE AREAS HAS 5 ASSOCIATED PROCESS GROUPS AS SHOWN IN THE GRID

KNOWLEDGE AREA/ PROGRESS GROUP	INITIATING	PLANNING	EXECUTING	MONITORING AND CONTROLLING	CLOSING
Integration	Develop project charter	Develop project management plan	Direct and manage project work	Monitor and control work; Integrated change control	Close project
Scope		Scope Planning, definition, create WBS		Control and validate scope	
Time		Define activity and sequencing; resource and duration estimation; scheduling		Schedule control	
Cost		Cost estimation		Cost control	
Quality		Quality planning	Perform quality assurance	Control quality	
HR		HR planning	Create and develop team		
Communications		Communication planning	Manage communications	Control communications	
Risk		Identify risks; qualitative and quantitative risk analysis and response		Control risks	
Procurement		Plan purchases	Conduct procurements	Control procurements	Close Procurements
Stakeholder	Identify Stakeholders	Plan Stakeholder Management	Manage Stakeholder Engagement	Control Stakeholder Engagement	

4.4.2 IDENTIFYING RESOURCES

The primary output of the initiating phase of integration management is the **project charter**, which is a document that formally authorizes the project and gives project managers access to organizational assets. The **preliminary project scope statement** describes, in broad strokes, what work will be done. The **project management plan** describes what resources will be needed and how and when they will be used.

One of the most important things to be developed in the **scope management plan** is the **work breakdown structure (WBS).** The WBS is a deliverable-oriented grouping of the work involved in a project. A **work package** is the smallest level of task on the WBS. Each work package is assigned a start date, an expected duration and responsibility. The **WBS dictionary** gives detailed information about each work item and helps define the deliverables that are expected. Each work package is also associated with certain resources, such as people, equipment, office space, funding, etc. These resources must be made available in preparation for the work package. If the resources are unavailable, the work package may be delayed.

Human Resources

Assembling an appropriate team and making sure that the right people are in the right place at the right time can be a daunting task. A **responsibility assignment matrix (RAM)** is a 2-dimensional chart which shows the degree of responsibility each team has to each work package (Table 14-2).

Procurement (or **outsourcing**) refers to acquiring goods or services from an outside agency, such as suppliers, vendors, and contractors. There are many reasons a project manager may choose to outsource some elements of a project.

1. **Reduce costs.** Large suppliers can operate with greater economies of scale and provide products more cheaply than if they were made in house.
2. **Allow the organization to focus on its core business.** For example, by hiring an outside company to process laundry, a hospital can concentrate its executive efforts on caring for patients.
3. **Utilize limited or specialized resources.** For example, an organization may require an unusual piece of equipment for a short project.
4. **Staffing flexibility.** By outsourcing staffing, an organization can better adapt to peaks and troughs of activity.
5. **Accountability.** By adhering to a contract, organizations may be better able to solidify expectations of deliverables.

Taking these benefits into account, a project manager has to decide if outsourcing is right for this project. This is often called a **make-or-buy decision**. One of the most common make-or-buy decisions in IT is whether an application should be developed in house or purchased.

TABLE 14-2

EXAMPLE RESPONSIBILITY ACCOUNTABILITY MATRIX (RAM) FOR A MEDICATION BARCODING PROJECT. THIS PARTICULAR MATRIX USES THE RESPONSIBILITY, ACCOUNTABILITY, CONSULTATION, INFORMED (RACI) CONVENTION

	PHARMACY	NURSING	IT	RADIOLOGY	CMIO
Research symbology	I	I	R	I	A
Catalog NDC	R	C	I	I	I
Inventory drugs	R	I	A	C	I
Track implementation	C	A	C	I	R
Train staff	A	R	A	C	C

R responsibility, *A* accountability, *C* consultation, *I* informed

In order to compare an organization's internal capacity to that of a supplier, the organization will solicit information from various suppliers. These requests can take many forms. The most general request is called a **request for information (RFI)** which simply asks for the suppliers' capabilities and timelines. A **request for quote (RFQ)** is submitted when the particulars of the job are known and various suppliers compete for the contract. The most detailed request is a **request for proposal (RFP)** in which the buyer submits a statement of their need and the suppliers compete to find innovative solutions. When the responses are received by the organization, the proposals are evaluated and compared and a supplier is chosen. See Sect. 3.5.2.3 for more information.

4.4.3 RESOURCE ALLOCATION

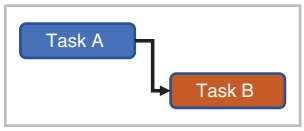
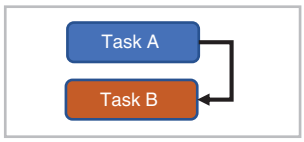
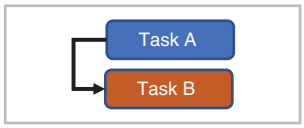
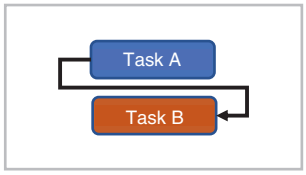
An **activity** is a defined portion of work that has an expected duration, cost and resource requirement. Defining these activities and then deciding which must be done in which order is called **activity sequencing.** It is important to remember that many activities depend on other activities to be complete before they start. For example, imagine a project involving building a data center. The new floor can not be laid until the old floor is taken up. This relationship is called a **dependency** because one activity depends on another. This particular dependency is called a finish-to-start (FS) dependency because the old floor must be completely removed before the new floor is started.

Another example: a project includes writing code and unit tests for a new module. In general, unit tests are written in conjunction with the code, so they are occurring simultaneously. However, the unit tests can not be completed until the code is complete. This represents a finish-to-finish dependency.

This can be depicted graphically as shown (Table 14-3)

TABLE 14-3

TASK DEPENDENCIES

NAME	DIAGRAM	WHAT IT MEANS
Finish to start (FS)		Task B can not begin until task A is completed
Finish to finish (FF)		Task B can not finish before A is finished
Start to start (SS)		Task B can't start until A is started
Start to finish (SF)		Task B can't finish until A is started

An arrow shows when one tasks depends on another. The left side of a box is the start and the right side is the finish. The arrowhead indicates the dependent task

Earned Value Management is a technique for estimating progress of a project. The **planned value (PV)** is the amount of money budgeted to a given activity at a certain time. For example, suppose the project involved hiring an expert for $50,000 for a 10-week contract. At 5 weeks, the PV should be $25,000. The **actual cost (AC)** is the total direct and indirect costs incurred. The **earned value (EV)** is an estimate of what the work so far is actually worth. Suppose the expert generated $30,000 in value during the first 5 weeks. The EV would be $30,000.

Occasionally, the project will progress faster or slower than expected. These differences are called **variances**. For example, suppose the project has an earned value of $7500 and a planned value of $5000. The project is now ahead of schedule, and is said to have a positive **schedule variance** of $2500. Variance can also be calculated from cost. For example, if a project has an earned value of $7500 and an actual cost of $6000, it has a positive **cost variance** of $1500.

4.4.4 PROJECT MANAGEMENT TOOLS (NON-SOFTWARE SPECIFIC)

After estimating the total number of resources and durations, a schedule can be developed. These schedules are sometimes called **network diagrams** or **process diagrams**.

Figure 14-7 represents ten tasks which are required to finish a project, however some tasks depend on others. For example, task D can not be started until task A is finished; task J can not start until tasks H, F and I are finished. The numbers adjacent to the tasks represent the amount of time required to complete the task. For example, task A takes 1 day; task B takes 2 days; task C takes 3 days, and so on.

The circles, called **nodes,** represent start and endpoints for the tasks. **Bursts** are nodes that have multiple activities dependent on them, such as nodes 1 and 3. **Merges** are nodes that depend on multiple activities, such as 5 and 6.

The **critical path** is the *minimum* time required to complete the project. Since all tasks must be completed in order to finish the project, the critical path is calculated by finding the *longest* path from beginning to end. In our example, there are four paths. The first path is $1 \rightarrow 2 \rightarrow 5 \rightarrow 6 \rightarrow 8$. In order to traverse this path, four tasks must be done, namely A, D, H and J. Each task has an assigned length. By adding all these task lengths, we get the total length of the path.

$$A = 1; D = 4; H = 6; J = 3$$
$$A + D + H + J = 1 + 4 + 6 + 3 = 14$$

So, the length of path ADHJ is 14. The complete list of paths is as follows:

$$ADHJ = 1 + 4 + 6 + 3 = 14$$
$$BEHJ = 2 + 5 + 6 + 3 = 16$$
$$BFJ = 2 + 4 + 3 = 9$$
$$CGIJ = 3 + 6 + 2 + 3 = 14$$

The longest path is BEHJ, which requires a total of 16 days. This is the critical path. If the project manager wants to deliver the project sooner, he should focus on accelerating the activities along the critical path. If he is able to shorten an activity along the critical path, a new critical path may emerge. For example, suppose the project manager shortens task E from 5 days to 1. Now ADHJ and CGIJ are the critical paths.

A more common method of diagramming a schedule is a **Gantt chart**. Tasks from the WBS are listed hierarchically with a calendar showing start and end times. Arrows on tasks indicate dependence. Task groups are depicted with heavy umbrella-shaped lines and extend from the beginning of the earliest task to the end of the latest task in the group. These are also called **summary tasks.** A **milestone** is a significant event on the schedule that has no

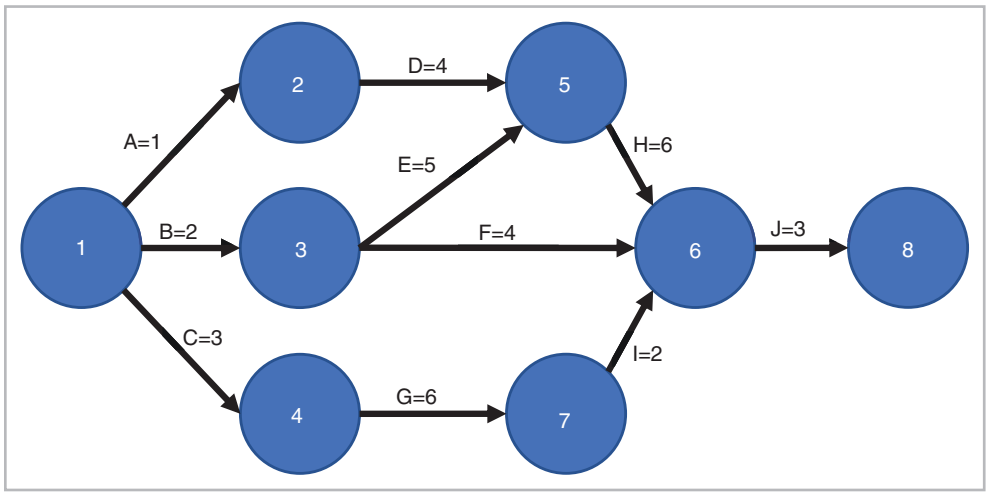


FIGURE 14-7

Node diagram showing tasks using the Activity Over Arrow (AOA) method. The duration of the activity is listed next to the name of the task

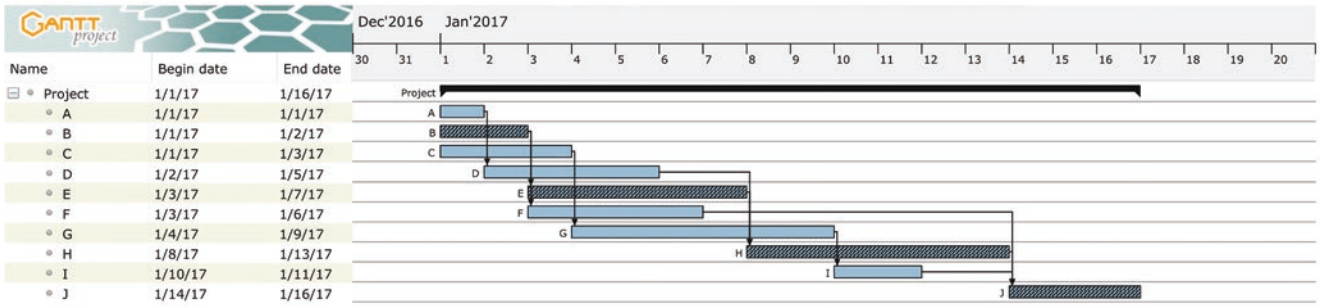


FIGURE 14-8

Gantt chart showing start and end time for several tasks. Arrows indicate dependencies. The critical path is shaded

duration of its own, but represents the completion of some important part of the project. In a Gantt chart, this is commonly drawn as a diamond shape (Fig. 14-8).

Activities that are not along the critical path often have built in leeway when they can start or finish. In our example, let's assume that the project starts on 1/1/17. If we assume that the schedule is as efficient as possible, there should be no delay between tasks B, E, H and J, and the project will finish 16 days later, on 1/17/17.

What about the other tasks? If task A is started 2 days later, task D will also be delayed by 2 days. It can not be delayed more than 2 days, because that would affect task H, which is part of the critical path. This variability in starting time is called **slack** or **float.** Using this knowledge can help with resource planning. For example, suppose that tasks A and B both require the use of an expensive consultant. If the plan is followed as written, the project manager would require two consultants to start the project. However, if task A is postponed and starts on 1/3 instead of 1/1, the same consultant can be used for both tasks A and B, potentially saving money in the project. This process is called **resource levelling**

A **Monte Carlo analysis** attempts to estimate total risk based on the risk of its components. For example, suppose a project has three tasks named A, B and C, which must run sequentially. Although we don't know exactly how long each task will take, we can make an estimate. Task A has a 30% chance of taking 5 days, 40% chance of taking 6 days, 20% chance of 7 days and 10% chance of 8 days as shown in Fig. 14-9.

Let us further assume that tasks B and C have the following distributions (Figs. 14-10 and 14-11)

By choosing numbers at random, we create a simulation of how long each task will take. For example, suppose task A takes 6 days; task B takes 13 days and task C takes 5 days. The

total duration of the project is 24 days. By repeating this simulation many times, we can get a rough estimate of how long the project will take See Table 14-4.

After 1000 iterations, we get the following histogram (Fig. 14-12):

The bars indicate the distribution of project durations. The S-shaped line tells us the cumulative probability that the task will be completed by a certain day. For example, in 50% of iterations, the job is finished on day 20.

Good news. There is no way that the board will ask you to do a Monte Carlo simulation on the exam—it's way to computationally difficult. But you should be familiar with the concept and at least know *how* to do one.

A **sensitivity analysis** allows us to vary input parameters to determine the optimum result. For example, a person looking to equip a team with computers may investigate several options by varying the amount of memory, the size and type of hard drive and the number of peripherals. At some point, he will determine the best combination of characteristics for the best cost. This type of analysis only works where a discrete formula exists to predict utility.

FIGURE 14-9

Probability distribution for time to complete task A

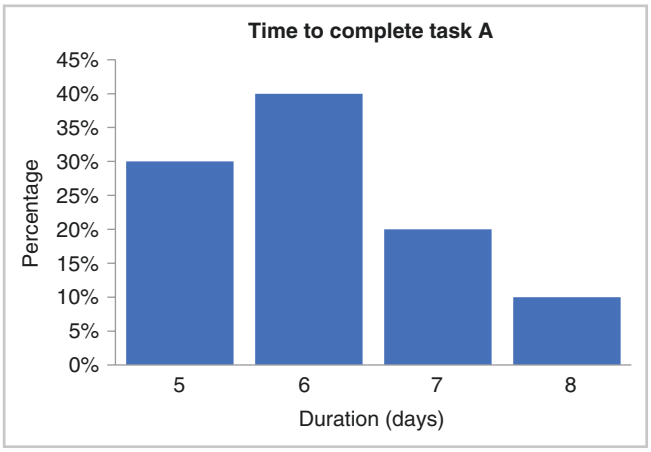
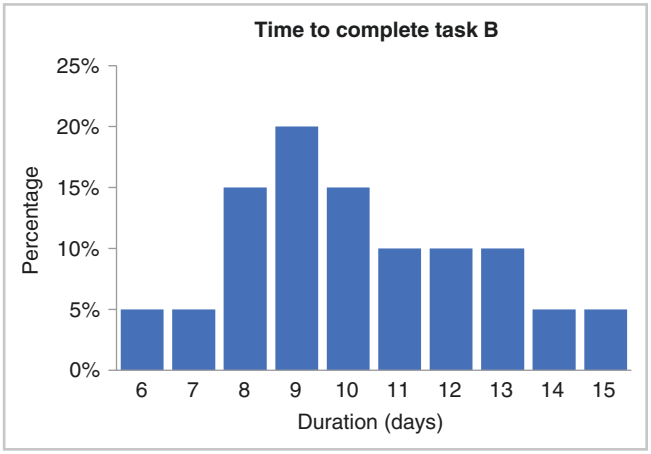


FIGURE 14-10

Probability distribution for time to complete task B



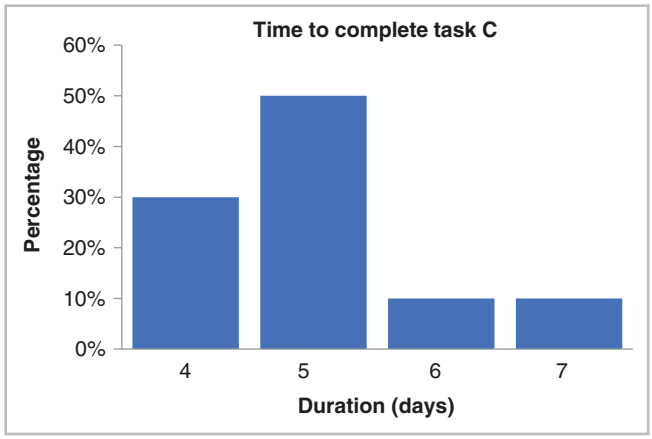


FIGURE 14-11

Probability distribution for time to complete task C

TABLE 14-4

MONTE CARLO SIMULATION SHOWING RANDOMLY SELECTED LENGTHS FOR THREE TASKS BASED ON THE PROBABILITY DISTRIBUTIONS ABOVE

ITERATION	A	B	C	TOTAL
1	6	13	5	24
2	6	10	5	21
3	5	6	4	15
4	5	9	4	18
5	6	13	4	23
6	5	8	5	18
7	8	6	4	18
8	7	11	5	23
9	5	9	7	21
10	7	9	5	21
…				…

Only the first 10 iterations are shown here

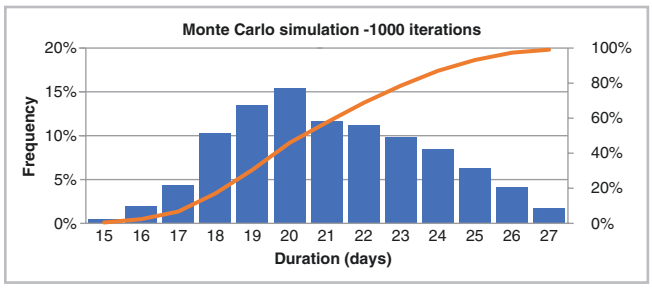


FIGURE 14-12

Cumulative Monte Carlo simulation based on 1000 iterations of the data in Table 14-4

4.4.5 INFORMATICS PROJECT CHALLENGES

4.4.5.1 Scope Creep

All projects, but especially technology projects which have no physical limitations are subject to the ever-expanding expectations called **scope creep**. As a project develops, stakeholders will identify new requests and expectations for the the project. It is vitally important to have a strong change process in place to prevent this.

Integrated change control involves accepting or rejecting any changes to the scope of the work as well as coordinating those changes among workers and stakeholders. Since this process has many ramifications, there is often a **change control system** in place, and

sometimes even a predefined group of stakeholders called a **change control board** who oversee all changes in scope of the project.

4.4.5.2 Managing Expectations

Sometimes, tasks may not be completed on schedule. The difference between planned and actual performance is called **variance.** A positive variance usually means that the project is ahead of schedule, while a negative variance means it is behind. Adjusting the schedule to account for variances and other changes is called **schedule control.**

Part of scope management monitoring and controlling is ensuring that the work is done properly, such as meeting milestones, forecasting, reporting, implementing **corrective actions** (to fix problems) and **preventive actions** (to prevent problems). The resulting project management plan combined with approved changes is often called a **baseline.** In most cases, this is used in the context of one of the knowledge areas, such as the scope baseline or the schedule baseline. The process which ensures that descriptions of all products are up-to-date is called **configuration management.**

Cost estimating is the process of developing an approximate cost for the project, while **cost budgeting** is allocating the overall cost to individual work items. Keeping a project within its budget is called **cost control.**

Project Communication Management

Project team members require up-to-date information in order to coordinate their efforts. Investors and other stakeholders require status reports and progress reports to guarantee that a project is moving in the right directions. In order to make sure that the right communications reach the right people, the project manager should develop a communications management plan. The plan should include which stakeholders require which pieces of information; who will provide the information; the method of delivery; frequency of transmission; and technology to manage the security/confidentiality of messages.

Communication takes many forms, and some are much more appropriate for certain situations than others. For example, face-to-face meetings are important for sensitive issues and for conflict resolution, but their output is not durable. Similarly, policies and procedures are normally printed and stored in a binder for easy reference, but lack interactivity. In some cases, multiple communication channels will be used.

Some methods of communication are more personal than others. In decreasing order, these include: one-on-one meetings, phone calls, group meetings, video conferencing, conference calls, voice mail, email, paper mail, web site, blog. (See Sect. 4.3.4 Developing effective communications.)

4.4.5.3 Balancing Competing Priorities

Project **portfolio management** is the process of selecting projects and programs deemed beneficial for an organization's success and evaluating projects from a strategic standpoint (Fig. 14-13).

FIGURE 14-13

Project management and Portfolio management

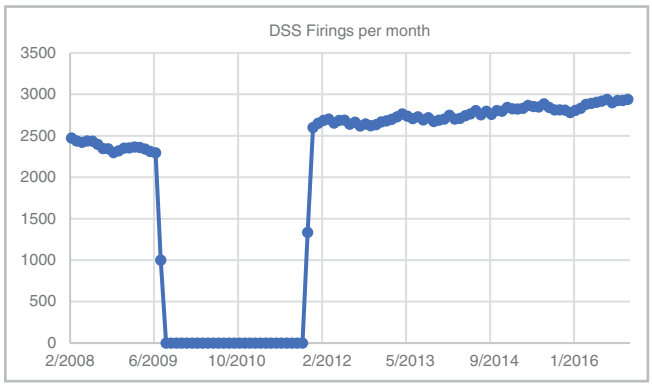


FIGURE 14-14

Run chart showing activations of a decision support system (DSS) per month. The run chart helps identify process anomalies

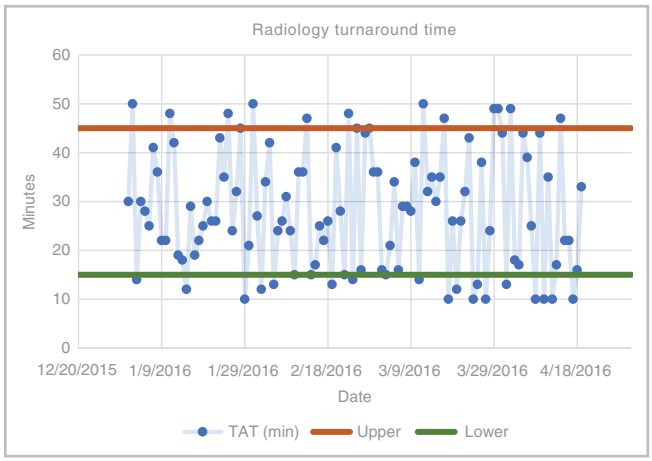


FIGURE 14-15

A control chart showing a radiology process. Many points fall outside the upper and lower control bars indicating a process that is out of control

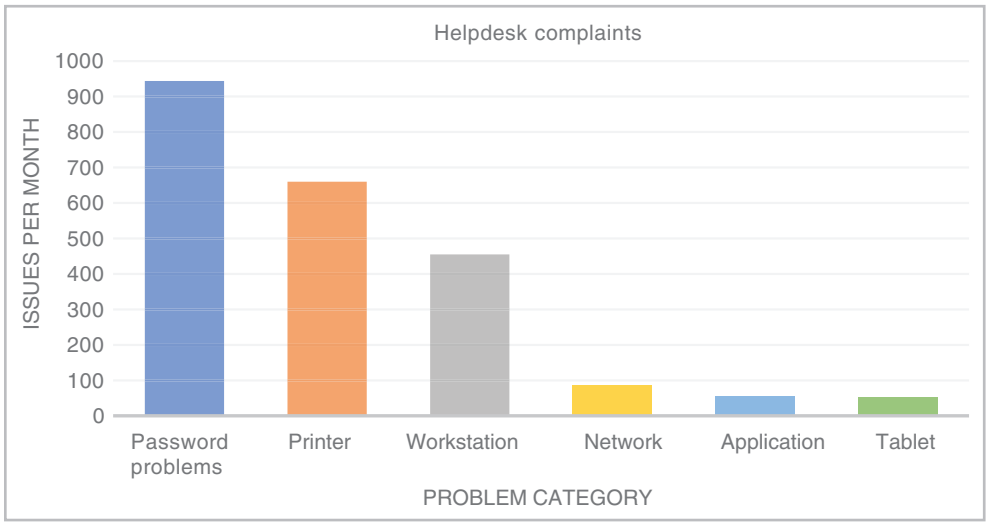


FIGURE 14-16

Pareto chart showing typical complaints received by a help-desk. Note that the problems are listed in decreasing order of incidence. This chart is used to help managers focus efforts on fixing the most frequent problems first

Maintaining quality is a key component of any project. One way to monitor quality is through **a run chart,** which graphs the variation of a process over time. For example, Fig. 14-14 shows the number of times that a decision support system (DSS) issued a warning during a particular period. This is an extreme example, but it can be seen that the DSS failed to fire from mid-2009 until early 2012. In this case it was due to a

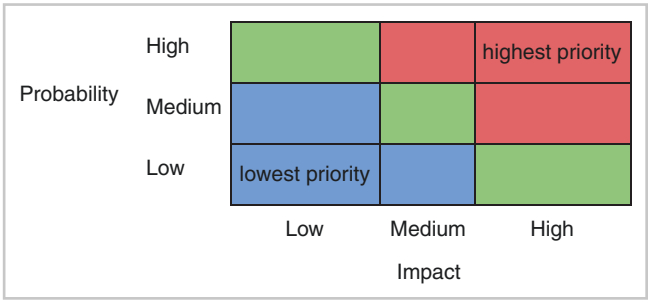


FIGURE 14-17

Probability/Impact matrix. By classifying risks along a gradient from high risk to low risk and high-impact to low impact, it is possible to prioritize risk responses

programming error. Careful monitoring of DSS firings could have detected this error much sooner.[2]

A **control chart**, similar to a run chart, depicts the results of a process over time. A control chart includes upper and lower acceptable bounds to determine if a process is in control or not. For example, the radiology department has determined that x-ray reading transcriptions should be available between 10 and 45 min after study is complete. (Fig. 14-15).

A Pareto chart is a particular type of histogram that shows problems in decreasing order of occurrence. It is useful to help prioritize efforts on finding solutions (Fig. 14-16).

Project Risk Management

A risk is an uncertainty which can lead to a positive or negative impact on a project. Risk management seeks to reduce the uncertainty by identifying and analyzing possible weaknesses and preparing for them. For example, developing solid downtime procedures guards against the risk of lost productivity should the information system fail. Purchasing insurance guards against catastrophic loss if a project harms someone.

Since all risk management requires investment, a probability/impact chart can help prioritize risk management functions. In Fig 14-17, the probability of a risk occurring is plotted against the potential impact of the risk. Low impact-low probability risks are given the lowest priority, while high-impact, high-probability risks are given the highest priority.

Risk can be classified as **positive risk** where the potential outcome is beneficial, or **negative risk** which the outcome is undesirable. There are four methods of responding to negative risk.

1. **Risk avoidance.** This is the most common method and it involves making systematic changes to a project to avoid aspects of risk. For example, patients with esophageal obstruction can be treated with orally administered meat tenderizer (papain or another digestive enzyme). However, there are safer methods of addressing this problem, such as endoscopy. To avoid this risk, a department could create a policy which prohibits the use of meat tenderizer for this indication. Creating a new policy may also create a new risk, such as a delay in care while waiting for the endoscopy suite to become available. This new risk is called a **secondary risk**.
2. **Risk acceptance.** This is the easiest approach, and is used when safer alternatives are unavailable or are too costly.
3. **Risk transference** involves shifting the risk to another entity. For example, gastric tubes commonly become dislocated and have to be replaced. This is commonly done as a blind procedure in the Emergency Department (ED), but can lead to injury if the tube is not placed appropriately. An ED that is concerned about this risk may opt to enact a policy forcing all gastric tube replacements to be done in the endoscopy suite, thereby transferring the risk to another department.
4. **Risk mitigation** is the reduction of risk by reducing the likelihood of occurrence. For example, the placement of central lines is a common risky procedure performed in the ED. The use of real time ultrasound has been shown to reduce the risk of complications.

2 see Wright A, Hickman TT, McEvoy D et al. Analysis of clinical decision support system malfunctions: a case series and survey. J Am Med Inform Assoc (2016) 23(6): 1068–1076.

Unfortunately, most risks can not be minimized into nothing, and **residual risks** may remain.

Similarly, there are four ways to respond to positive risk

1. **Risk exploitation** seeks to aggressively increase the likelihood of success by doing whatever measures it takes.
2. **Risk sharing** involves enlisting other entities to share in the risk and reward. For example, a hospital and a clinic seek to improve Medicaid enrollments so they partner on a combined financial aid office.
3. **Risk enhancement** differs from risk exploitation, but only in degree. While exploitation seeks to guarantee the positive result, enhancement only tries to increase the likelihood that the risk will occur. For example, a hospital wishes to meet a core measure threshold and employs extra personnel to make sure that they are successful.
4. **Risk acceptance** is identical to negative risk acceptance in that the project manager will accept the risk as it is without trying to modify it.

Scott Mankowitz

4.5 Strategic and Financial Planning for Clinical Information Systems

CHAPTER OUTLINE

4.5.1 ESTABLISHING MISSION AND OBJECTIVES

Any organization or any organizational unit needs a purpose. That purpose should be readily obvious to all who need to interact with that unit. Over time, as organizations take on more responsibilities or offer more services or products, they become less focused. By establishing a mission and objectives, an organization can recenter its priorities and concentrate on developing its core business.

Every major corporation has a mission and a vision statement. These are usually a few short sentences which convey what the leadership believes the business ought to become. The goals and objectives are more specific and describe what the business hopes to accomplish in the near and long term.

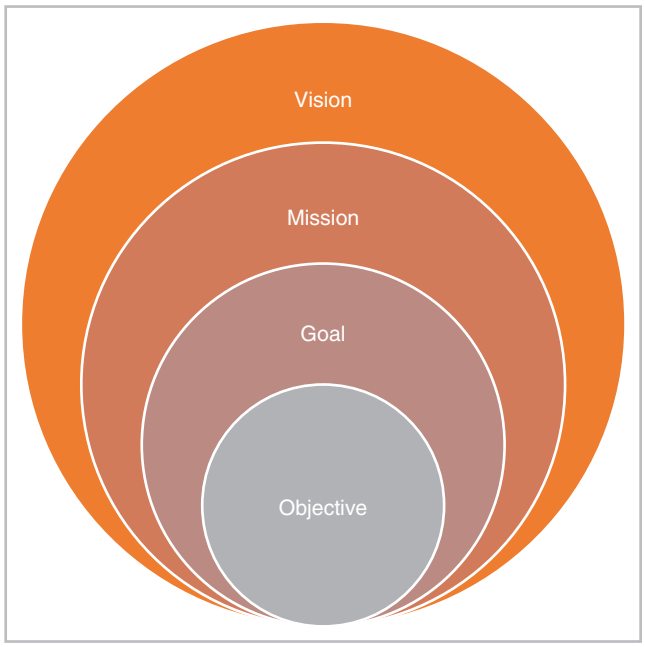
A **vision statement** describes an image or a concept. It expresses where the business hopes to be and what it hopes to achieve. The vision statement uses broad strokes to paint a rosy picture. It avoids the particulars. Richard Branson offers the following advice: “Brevity is certainly key, so try using Twitter’s 140-character template when you’re drafting your inspirational message. You need to explain your company’s purpose and outline expectations for internal and external clients alike”.

Some examples

Chapter 4.5 is an introduction to the terms that businesspeople use all the time. As a clinician, you may find that some of the terms are well-defined and others are more, well, diaphanous. As you can imagine, these airy topics do not make for good board questions. You should be familiar with the concepts, but don’t expect too much activity on the boards.

FIGURE 15-1

Vision, mission goals and objectives



- Ikea: to create a better everyday life for the many people.
- Habitat for Humanity: A world where everyone has a decent place to live.
- Creative Commons: Our vision is nothing less than realizing the full potential of the Internet—universal access to research and education, full participation in culture—to drive a new era of development, growth, and productivity.
- ASPCA: That the United States is a humane community in which all animals are treated with respect and kindness.

Mission statements tend to be more specific (although not always). They usually mention the particular type of business and the changes the business hopes to make.

- Universal health services: To provide superior quality healthcare services that: PATIENTS recommend to family and friends, PHYSICIANS prefer for their patients, PURCHASERS select for their clients, EMPLOYEES are proud of, and INVESTORS seek for long-term returns.
- Creative Commons develops, supports, and stewards legal and technical infrastructure that maximizes digital creativity, sharing, and innovation
- National Wildlife Federation: Inspiring Americans to protect wildlife for our children's future.
- American Heart Association: To build healthier lives, free of cardiovascular diseases and stroke.
- Google: to organize the world's information and make it universally accessible and useful.

It is important to remember that the foregoing discussion applies equally to a large corporation, a department within a corporation or even an individual. For example, the IT department of a hospital may have a vision statement about providing technology that promotes health and saves lives. The mission statement would have a more tangible component. It may promise to deliver excellent technology for the assessment, monitoring and treatment of patients backed up by world-class support and training.

After reviewing the mission and vision statements, the organization lays down its long-term and short term **goals.** Goals can be ambitious or purposeful but usually include specific targets. The term **objectives** is also used for goals, but tends to imply a shorter term project than a goal. For example, a goal might be to achieve 50% market share within the next

10 years. An objective may be to increase production and sales by 10% by the end of the year. *By meeting a series of objectives, we will attain our goal* (see Figure 15-1).

Unlike mission and vision, goals and objectives must be concrete items with a timeframe. The mnemonic SMART (Specific, measurable, achievable, realistic and timely) is often used to make sure that goals and objectives are appropriate.

Actions are the individual tasks undertaken to meet objectives (e.g. buying a new printer; training staff, etc.). Many actions are required to meet an objective, just as many objectives are required to fulfill a mission.

Some authors use a framework called VMOSA: Vision, Mission, Objectives, Strategies, and Action Plans. The notable addition in this structure is **strategy** which will be discussed later (see Sect. 4.5.3, Strategy Formulation)

4.5.2 ENVIRONMENTAL SCANNING

Environmental scanning is the process by which an organization systematically studies its environment in order to make better planning decisions. The scan includes two parts. The internal scan looks within the organization (i.e. the **microenvironment**). The external scan looks at the world in which the organization operates (i.e. the **macroenvironment**).

The **internal scan** should identify the factors that make the company what it is. A company's resources can be both tangible and intangible:

1. Tangible

   (a) Financial resources, such as an endowment or good credit.
   (b) Physical resources, such as a high quality physical plant.
   (c) Technological resources, such as modern medical equipment that may not be commonly available (e.g. robotic surgery apparatus).

2. Intangible

   (a) Human resources, such as highly skilled workers and well-respected managers who work together to develop efficient routines and maintain a respectful corporate culture. A good working environment will lure potential workers away from other employers.
   (b) Innovation resources, such as creative leadership that motivates workers to provide new and better services.
   (c) Reputational resources, (i.e. having a good reputation in the community) will draw customers. Even though patients may receive identical care at two facilities, they will commonly choose the one with a better reputation.

It is noteworthy that a company's intangible resources are more likely to provide a competitive advantage than tangible ones. The reason for this is simple: a well-funded competitor could easily purchase duplicate tangible resources, but would have to develop the intangible ones.

Companies also possess **capabilities**, such as the ability to treat certain ailments or provide useful services. Over time, the company learns how to apply its resources and capabilities very well and develops **core competencies**. These core competencies are the things that distinguish a company from its peers and serve as its competitive advantage. Core competencies directly add value to a product and are difficult to emulate.

Some use the VRIO (Value, Rareness, Imitability, Organization) framework to assess a company's capabilities. Suppose a hospital were evaluating its neurosurgical capability with a non-invasive stereotactic radiofrequency ablation device (e.g. Gamma Knife).

1. Value: Radiofrequency is able to treat certain neurosurgical conditions that would be otherwise untreatable.
2. Rareness: Less than 1% of hospitals have this device.
3. Imitability: For many Gamma Knife procedures, there exist traditional neurosurgical procedures which are not necessarily inferior.
4. Organization: Our hospital has a team of neurosurgeons and technicians who are very familiar with this device and we have nursing units dedicated to the recovery of these patients.

Leaders of the organization should be interviewed or surveyed for their thoughts. Where should the company be in 10 years? Does it have all the resources it needs to get there? Does it have enough resources to survive the coming year? What are the shortfalls that could prevent growth? How do employees interact with one another? What can be said about the overall morale of the company? Does the attitude of the leadership resonate with the rank and file? How well is the current strategy working? Does the company meet its financial or service objectives? How does it compare to industry averages in terms of productivity and profitability? Questions like these will help locate the organization's **strengths** and **weaknesses**.

The **external scan** will identify **opportunities** and **threats.** Factors affecting the external environment include Political, Economic, Social, Technological, Environmental and Legal. For this reason, the external scan is sometimes called a PESTEL analysis.

- Political: Healthcare is susceptible to both local and national politics. The passage of the Patient Protection and Affordable Care Act resulted in huge shifts in payer mixes, mostly through expansion of Medicaid. Similarly, local and regional legislation can affect the way patients seek care.
- Economic: When a recession decreases patients' disposable income they may be less likely to seek care, even when they are sick. When this is coupled with high-deductible insurance policies, the effect is even stronger.
- Social/cultural: Some diseases are much more common in certain demographic groups. In lower-income environments, patients may be suspicious of hospitals and doctors. There may be language issues or other cultural issues which encourage them to seek alternative care. From an IT standpoint, patients without broadband access are unlikely to utilize a personal health record at home.
- Technological: Healthcare organizations with deep investments in technology may be able to operate more efficiently. They may also be able to integrate more easily with other local providers.
- Environmental: Infectious disease, especially those that make headlines (e.g. SARS, Anthrax, Ebola, Zika) can drive patients to seek healthcare in unexpected numbers. Similarly, environmental toxins (like lead found in the drinking water in Flint, Michigan) can increase the incidence of rare diseases and present new opportunities for treatment.
- Legal: The legal environment and the threat of lawsuits can intimidate providers into practicing a form of defensive medicine which is ultimately costly and not evidence based. Note: legal can also be used here to apply to local or national laws regarding the practice of medicine, similar to Political.

A threat may come from competitors, changes in the economy, governmental regulations, shifting payer mix, or changes in habits, size or distribution of its customers. Opportunities may also be uncovered, such as a previously unidentified need or the ability to replace or supersede a competitor.

The results of the environmental scan are often represented in a 2 × 2 table called a **SWOT analysis**, which shows Strengths, Weaknesses, Opportunities and Threats (Figure 15-2).

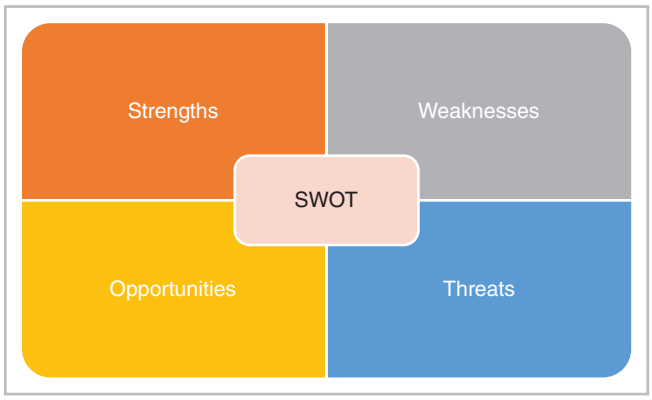


FIGURE 15-2

SWOT analysis examines Strengths, Weaknesses, Opportunities and Threats

TABLE 15-1

EXAMPLE SWOT ANALYSIS

	POSITIVES	NEGATIVES
Internal	**Strengths:** 1. I'm very creative; I often come up with novel solutions to hard problems 2. I get along with most people in the organization and I always try hard to listen 3. I work hard to get good outcomes	**Weaknesses:** 1. I can be unconventional at times and may be perceived as inexperienced. 2. People like me because I'm always agreeable, sometimes too much. 3. I often agree to do things that I don't have time for
External	**Opportunities:** 1. I am very familiar with Big Data, and our organization is moving in that direction. 2. The CIO is nearing retirement age, and there is no clear successor. 3. One of our competitors has reached out to me for advice for one of their projects	**Threats:** 1. The current CMIO is quite capable and has more experience than I do. 2. I have heard that our organization may be merging with a national chain, and jobs may be consolidated. 3. I'm concerned about my health.

Like mission and vision, A SWOT analysis can be performed on an organization, a department or even an individual. Consider the following table generated by an assistant CMIO (Table 15-1).[1]

4.5.3 STRATEGY FORMULATION

After an organization performs a thorough environmental scan and identifies its strengths, weaknesses, opportunities and threats, it must begin to create its **strategy**. A strategy is a set of decisions which should guide an organization to achieve its mission. One way to link these terms is to remember that the mission is **what** we hope to achieve and the vision is **why** it is so important to achieve it. The value network represents the people **who** are responsible for doing the work and the strategy is **how** they plan to go about doing it.

Maintaining a competitive advantage requires both **durability** and **inimitability**. Durability refers to the length of time that a product remains state-of-the art. For example, a hospital invests in a $5 million overhaul of its operating suite, installing new monitors, tables, x-ray equipment and the like. Within 10 years, however, technological advances have rendered the new operating rooms obsolete. This does not imply that the operating rooms are no longer usable—they are still fully functional. It's just that they no longer distinguish the institution from others.

1 Sometimes, you will hear executives say, "I had to SWOT myself." In general, this is what they mean. Not always.

Inimitability refers to the difficulty that competitors would have in creating the same product. For example, the fame or reputation of a single oncologist may be the basis for building an entire cancer center. It may be very difficult for a competitor to find a similar personality.

A successful strategy will develop resources and capabilities which are rare, valuable and difficult to imitate, thus maintaining a competitive advantage.

Strategy formulation tends to fall into one of five functional areas

1. Operations: the provision of medical treatments and diagnostics
2. Finance and accounting: optimizing billing and collections; managing cash and investment reserves; handling debt
3. Marketing: using media outlets to advertise the services offered
4. Human resources: recruiting, supporting and advancing the people of the organization
5. Research and Development: creating new products or services

Resource-based strategies are designed to identify resource gaps and result in investing in replenishing or augmenting the organization's resource base. For example, the orthopedic clinic has been using pre-made splints to treat fractures. When they run out, they begin fashioning splints out of plaster or fiberglass, which takes considerably more time. A potential strategy would involve maintaining a supply of splints.

Companies planning to differentiate themselves on the basis of quality must take steps to assure that the technology is in place to produce high quality products or services. This may include tighter quality control or newer equipment. Similarly, companies pursuing a low-cost strategy may embrace automation or may deliberately opt to use older equipment to minimize costs.

A **value chain** is a set of activities that an organization performs in order to deliver a product or service. Traditional value chain analysis is directed at manufacturing, but is increasingly used in healthcare. For example, a hospital is reviewing its surgical operations, specifically those involving orthopedic implants. It reviews the cost of operating room staff, maintenance, equipment, rehabilitation services, physician services and discharge planning. It discovers, to its dismay, that the cost of the implanted device actually exceeds the insurance reimbursement for the entire hospital stay. A new strategy based on this finding could include curtailing implant surgery or renegotiating rates with insurers and equipment manufacturers.

There is also value in *linking the value chain of a supplier to the value chain of an organization.* For example, many hospitals still rely on a myriad of paper forms in order to document activities. These forms are generally purchased from a forms supplier and stored within the hospital. When the forms run out, new ones are ordered from the supplier. There are several drawbacks to this procedure. Firstly, the hospital has to maintain a storehouse of forms. Second, significant care has to be taken when ordering forms to make sure that the right ones are delivered. Third, unless there is a routine par counting of the forms, the forms will run out before new ones can be ordered. One solution, employed in many hospitals, is to have the forms supplier send a representative to the hospital on a regular basis to determine the current supply of all forms. When forms are running low, the representative replenishes the forms directly from the supplier's warehouse. This process is beneficial for both the supplier and the hospital. The hospital does not run out of forms and the supplier gains additional orders.

The organizational structure (see Sect. 4.4.1) is the formal reporting pattern within the organization. When formulating a strategy, it may become necessary to reorganize the entity so as to align workers to the new policies and procedures.

4.5.4 ACTION PLANNING AND STRATEGY IMPLEMENTATION

Once strategies have been agreed on, the next step is implementation. **Strategy implementation is the translation of chosen strategy into organizational action so as to achieve strategic goals and objectives**. This is where most failures occur. It is not uncommon for organizations to draw up a strategic plan only to find that it sits unimplemented on someone's desk, and has no impact on the organization.

There are significant differences between strategy formulation and implementation (Table 15-2).

Since the plan is developed by top management, it must be communicated (or **cascaded**) to the rank and file workers in the organization. It is important to establish **buy-in** so that each member of the team knows his role and the importance of the plan to the ultimate success of the company. This is usually accomplished by having a respected member of the organization become a **champion** for the project and publically proclaim its value.

In some cases, it may be necessary to employ external consultants to manage the strategy implementation, especially when changes may disrupt a normally amicable relationship between worker and supervisor. Consider a case where the strategic plan identifies a need for a reduction in workforce. It is difficult for a department head to maintain the respect of his workers after he has fired one of their number. On the other hand, when it is an outside consultant, he may be able to salvage some respect.

Reward systems or incentive plans can be strong motivational tools to encourage acceptance of the strategic plan. These may include raises, promotions, awards or stock options. Rewards may be given to managers or to employees throughout the organization as a means of tying recognition to performance.

Even with extremely thorough planning, some uncertainty regarding resource allocation and job allocations will arise only after implementation begins. It is important to have strong leadership involved throughout the implementation process so that mid-course adjustments can be made to keep the project on target.

Developing Action Plans

Action plans are goal and objective driven recipes that tell each member of the organization what is expected of them and in what timeframe. The overall top-level action plan describes how each strategy will be implemented and how it relates to the mission. Each major division in the organization will have its own action plan which relates back to the top-level

TABLE 15-2

COMPARISON OF STRATEGY FORMULATION AND IMPLEMENTATION

STRATEGY FORMULATION	STRATEGY IMPLEMENTATION
Strategy Formulation includes the planning and decision-making involved in developing the organization's strategic goals and objectives	Strategy Implementation involves the resources, people and work required to execute the strategic goals and objectives
Strategy Formulation is an **Entrepreneurial Activity** based on strategic decision-making	Strategic Implementation is mainly an **Administrative Task** based on strategic and operational decisions
Strategy Formulation emphasizes **effectiveness** (the degree to which something is successful in producing a desired result)	Strategy Implementation emphasizes **efficiency** (the degree of effectiveness with respect to cost, resource utilization and time)
Strategy Formulation requires coordination among few individuals	Strategy Implementation requires coordination among many individuals
Strategy Formulation requires a great deal of **initiative and logical skills**	Strategy Implementation requires specific **motivational and leadership traits**

TABLE 15-3

EXAMPLE ACTION PLAN

STRATEGIC GOAL	STRATEGY	OBJECTIVE	RESPONSIBILITY	TIMELINE
Achieve 50% market share	Increase advertising in local trade journals and online	Prepare 5 print advertisements and 5 online advertisements, with budget of $1 million	Marketing team and CEO	3 advertisements by the end of 2Q with the remainder by year end
Achieve 50% market share	Improve customer service	Educate all staff members on AIDET and other customer centric philosophies	Human resources	75% of staff trained by 5/1; 90% of staff by 8/1

TABLE 15-4

COMPARISON OF CAPITAL AND OPERATING BUDGETS

	CAPITAL	OPERATING
Types of activities	Large innovations such as new plants, buildings, equipment, research projects	Day-to-day business operations
Allocation of total budget	33%	67%
Duration	Many years	Usually 1 year or less
Funding source	Retained earnings, equity or debt	Cash flow
Purpose	Grow the business	Run the business

action plan. Every manager (and maybe every employee) has a role in the action plan. Each item in the action plan should specify: the goal to be accomplished; how the goal contributes to the overall strategy; what measurable outcome is expected; what resources and or personnel are required; and the timeframe of the results (Table 15-3).

4.5.5 CAPITAL AND OPERATING BUDGETING

Companies typically have two types of budgets: the capital budget and the operational budget. The operational budget covers day-to-day items required for running the business, such as wages, rent, utilities and temporary equipment. The capital budget is used for larger purchases such as buildings and machinery that are expected to last more than 1 year. Some recommend that one third of a business's total expenditures should go to the capital budget and two-thirds for the operating budget (Table 15-4).

The Operating Budget

In order to create an operating budget, the company must be able to predict how much money it will take in. This calculation produces a projected (pro forma) income statement. The operating budget includes several parts:

- Sales budget: how much money can be expected to be earned by the sale of goods and services
- Production budget: how many units are produced and kept in inventory in preparation for sale
- Direct materials budget: the cost of raw materials that will be used to create the product.
- Direct labor budget: the cost of salary for workers who are producing the product.
- Selling and administrative budget: the cost of advertising and administrator salaries and consultants
- Manufacturing overhead budget: the additional costs of making the product which are not listed above.

Drug and device manufacturers will generally have operating budgets similar to the list above. Hospitals and medical practices are service industries, where the primary output of the organization is not a tangible product like a drug, but a service, like medical consultation. In service industries, the operating budget primarily focuses on sales and labor costs.

The sales budget predicts how much money will be earned by selling goods and services. For example, a manufacturer of implanted cardiac defibrillators will try to estimate the total number of units that they hope to sell in the coming year. By multiplying the cost per unit by the number of units, they arrive at a projected sales budget. In the case of a hospital, the majority of income comes from inpatient admissions. Annual sales would be calculated by multiplying the total number of admissions per year by the average revenue per patient. This calculation takes into account many factors, such as the reimbursement per patient (payer mix); the intensity of services provided to each patient (case mix index); the relative cost to the institution for providing that care (length of stay) and many other statistics.

The Capital Budget

Capital budgeting is also known as investment appraisal because it often involves comparing many different options of spending a company's limited funds. There are several tools which can be used to determine which capital projects are most beneficial to the organization's profitability.

The simplest method is the **accounting rate of return (ARR)** which measures the average profit over investment.

$$ARR = \frac{average\ profit}{average\ investment}$$

For example, suppose a medical office is considering buying a new electrocardiogram (EKG) machine. The cost of the machine is $1000 and is expected to last about 5 years. After that, it will be out of date and can be sold for about $200. The cost of capital investments is spread out over the time that it is used in a process called **depreciation.** Since the usable life of the product is 5 years, and it decreases in value by $800, it is said to depreciate at a rate of $160 per year.

$$annual\ depreciation = \frac{initial\ cost - scrap\ value}{usable\ life} = \frac{\$1000 - \$200}{5\ years} = \$160/\ year$$

During that time, the office expects to do 220 EKGs per year, and expects to collect approximately $5 per EKG. Thus, the sales budget for the EKG machine is 220 × $5, or about $1100 per year. ARR is usually expressed as a percentage. Using our equation above,

$$ARR = \frac{1100}{160} = 6.875 = 687.5\%$$

In this example, the EKG machine offers a fantastic return on investment, and the medical practice should definitely invest in it. (Please note that this calculation does not take into account the cost of hiring an EKG technician, the professional time required to interpret the EKG or the supplies and maintenance of the machine.)

Not all investment decisions are so easy. Let's try a more complicated example. Assume that we want to build a surgical suite that has the following expenses. Starting up will require $50,000 in construction costs and another $100,000 in equipment. The equipment is expected to last about 7 years and will have a scrap value of about $10,000. The two **recurring costs** are rent and salaries. Rent on the facility is $15,000 per year and salaries are $130,000 per year. For this case, we will assume that there will be no raises or other changes in personnel costs. During the first year, we expect to do 100 procedures and collect $1000 revenue per procedure. During each subsequent year, we expect our volume to increase by 30 procedures

TABLE 15-5

EXAMPLE SPREADSHEET SHOWING COSTS AND REVENUES FOR A HYPOTHETICAL CLINIC. NUMBERS EXPRESSED IN THOUSANDS. NEGATIVE NUMBERS IN PARENTHESIS

YEAR	0	1	2	3	4	5	6
Equip cost	($100)	$0	$0	$0	$0	$0	$10
Construction	($50)	$0	$0	$0	$0	$0	$0
Rent	($15)	($15)	($15)	($15)	($15)	($15)	($15)
Personnel	($130)	($130)	($130)	($130)	($130)	($130)	($130)
Revenue	$100	$130	$160	$190	$220	$250	$280
Profit	($195)	($15)	$15	$45	$75	$105	$145
Total return	($195)	($210)	($195)	($150)	($75)	$30	$175

per year. Thus, in year 2, we will have 130 procedures. In year 3, we will have 160 procedures, and so on. The following spreadsheet shows our expected cash flows (in thousands). Expenses are expressed as negative numbers and shown in parenthesis. Total return (or profit since inception) shows how much money is made or lost since the beginning of the investment (Table 15-5).

If the projections are correct, the total cost of the project over 7 years is $1,155,000 and it will generate $1,330,000 in revenue, resulting in a net profit of $175,000. On an annual basis, that comes to $165,000 per year in expenses and $190,000 in revenue. Using our ARR formula from above, we can see that this investment yields about 15%.

$$ARR = \frac{profit}{investment} = \frac{190{,}000 - 165{,}000}{165{,}000} = 15.152\%$$

Another useful metric is the **payback period.** This calculates the approximate amount of time required to completely recoup the initial investment. By looking at the total return in the above table, we can see that this occurs sometime between the fourth and fifth year. A shorter payback period indicates a better investment.

One of the drawbacks to using the payback period and the ARR as investment metrics is that they do not account for the **time value of money**, which states that money that is available now is more valuable than the same amount of money in the future because of its potential earning capacity. This is because money that is tied up in one project is subject to inflation and effectively limits the organization's ability to invest in competing projects.

Discounted cash flow (DCF) calculations enable us to account for the time value of money. Let's assume that we have an asset that is worth $100 right now. We can say that its **Present Value (PV)** is $100. If we invest it, and we make 5% interest over the course of a year, we would end up with $105. Using financial terms, the **Future Value (FV)** of $100 in one year is $105, assuming a **discount rate** of 5%. Since the interest applies every year, the FV rises exponentially, as is seen in the following equation, where r is the discount rate and n is the number of years.

$$FV = PV \cdot (1 + r)^n$$

Using this equation, the FV of $100 in 5 years is $128. This calculation can also be used to calculate the PV of a future return. How much should you pay right now to get $100 in 5 years? Using the same equation, we see that the PV of $100 5 years from now is $78, assuming a 5% discount rate.

Going back to our spreadsheet, let's calculate the PV of our revenues and expenses. In year 0, there is no discounting, and FV=PV. At the end of year 1, the FV of our revenue is $130,000. Using our equation, we calculate the PV.

$$\mathrm{FV} = \mathrm{PV} \cdot (1 + \mathrm{r})^{\mathrm{n}}$$

$$130{,}000 = \mathrm{PV} \cdot (1 + 0.05)^{1}$$

$$\mathrm{PV} = 123{,}810$$

TABLE 15-6

EXAMPLE SPREADSHEET INCORPORATING DISCOUNTED CASH FLOW

YEAR	0	1	2	3	4	5	6
Equip cost	($100)	$0	$0	$0	$0	$0	$7
Construction	($50)	$0	$0	$0	$0	$0	$0
Rent	($15)	($14)	($14)	($13)	($12)	($12)	($11)
Personnel	($130)	($124)	($118)	($112)	($107)	($102)	($97)
Revenue	$100	$124	$145	$164	$181	$196	$209
Profit	($195)	($14)	$14	$39	$62	$82	$108
Total return	($195)	($209)	($196)	($157)	($95)	($13)	$95

Similarly, for the second year, the FV of revenue is 160,000.

$$160{,}000 = \mathrm{PV} \cdot (1 + 0.05)^2$$
$$\mathrm{PV} = 145{,}125$$

It is important to note that both revenues as well as expenses are discounted. Since rent is a fixed cost in our example, we can see that its PV declines from $15,000 at inception to $11,193 at the beginning of year 6 (Table 15-6).

By adding the PV of all the revenues and expenses, we can compute the **net present value (NPV)**, which tells us the value of the entire investment in today's dollars. If the NPV is positive, it is considered a good investment. If the NPV is negative, it is a poor investment. In our case, the NPV is $95,370. Using this data, we can also compute the discounted payback period, or the amount of time it takes for the NPV to reach zero. In our case, this happens between year 5 and 6.

In our example, we used a discount rate of 5%. In real-world calculations, the discount rate should approximate the organization's cost of capital. For example, a company with a good credit rating may be able to borrow money at a low interest rate, while a company that is struggling will have to pay much more. Since companies often have multiple sources of financing, the **weighted average cost of capital (WACC)** is often used as the discount rate. Thus, when using the NPV as an appraisal metric, an investment may be profitable with one discount rate and unprofitable with another.

As the discount rate rises, the NPV decreases. At some point, the NPV reaches zero. This discount rate at this point is called the **internal rate of return (IRR)**[2]. The IRR can be calculated for different projects and used to compare their profitability. Like the ARR, investments with higher IRR are more profitable.

4.5.6 PRINCIPLES OF MANAGERIAL ACCOUNTING

Managerial accounting is the collection of financial data within an institution to enable strategic corporate decision making. There are several key differences between financial and managerial accounting (Table 15-7):

Job Costing

One of the most important tasks for the managerial accountant is to calculate how much it costs the organization to provide its goods and services. This data can be used to determine pricing or to decide which products and services should be offered. For example, an ambulatory surgery center (ASC) wishes to calculate its costs for performing a colonoscopy. Direct labor costs include nursing and technician time. Supplies include intravenous (IV) lines and medications. Overhead includes all other costs, amortized over many procedures and

2 In our example, the IRR is 13.85%, although the calculations required are fairly complex.

TABLE 15-7

FINANCIAL AND MANAGERIAL ACCOUNTING

	FINANCIAL ACCOUNTING	MANAGERIAL ACCOUNTING
Purpose	Describe the financial condition of the business on a particular date	Assist management by providing financial information that is used to plan, implement and evaluate performance
Target audience	External parties, such as shareholders, lenders and regulatory agencies	Managers within the organization
Segment reporting	Pertains to the entire organization. Certain figures may be broken out for materially significant business units	Pertains to individual departments in addition to the entire organization
Timeframe	Historical—reports on the prior quarter or year	Current—data is as up-to-date as possible and often includes forecasts for the future
Format	Financial reports are legally mandated and are presented in a specific format, consistent with the Generally Accepted Accounting Principles (GAAP)	May be presented in any format deemed useful by managers. There is no legal requirement or format
Reporting period	Externally mandated, usually annually or quarterly	Whenever needed. May be annual, monthly or even daily

difficult to quantify by themselves, such as maintenance of the facility, housekeeping, supervision and others. After adding the individual costs, the ASC estimates that it costs approximately $1200 to provide a colonoscopy. This number is very useful as it can inform decisions on how much to charge or whether or not to participate with an insurer.

Margin Analysis

In large production environments, there exist economies of scale. What this means is that when a corporation produces 100,000 items, it can do so more efficiently than it could if it were producing only one or two. However, if the company ramps up production to 100,000 units, it then has to expand its other operations which might be costly. Moreover, it has to be sure that it can actually sell 100,000 units in order to stay profitable.

For example, A nursing home has a capacity of 35 beds, of which 20 are currently occupied. The maximum patient-nurse ratio is 8:1, so there are three shifts of three nurses each day to care for the patients. Let's assume that the staffing cost for nurses is $60 per nurse per hour (3 nurses; 24 h per day; $60 per h; $3 \times 24 \times 60 = \$4320$ per day), and the revenue for 20 patients at $220 per patient is $4400 per day. The managerial accountant performs a **margin analysis** to calculate the total profit per unit of care. It turns out that the nursing home makes only $4 per patient per day.

The CEO of the nursing home is interested in expanding his business. A doctor offers to bring in 5 more patients to the nursing home. Is this a good idea? Raising the census to 25 would raise the revenue to $5500. However, 25 patients would require 4 nurses instead of 3, which raises the nursing costs to $5760 per day, which outstrips the revenue.

The nursing home's CEO asks the managerial accountant for a **breakeven analysis** which is the point at which the profit is exactly zero. The accountant replies that the next break-even point occurs when the census is 26.18 patients. The CEO returns to the doctor and tells him that if he brings 6 patients, the nursing home would lose money, but if he brought 7, they would have a profit (Figure. 15-3).

Trend Analysis/Forecasting

One of the tasks of the managerial accountant is reviewing the trendline for costs and investigating unusual variances or deviations. This data may be costs paid to vendors, salaries for employees, taxes, regulatory fees or any other business expenses. Income must also be carefully examined. Creating realistic forecasting of income is necessary for developing an operating budget.

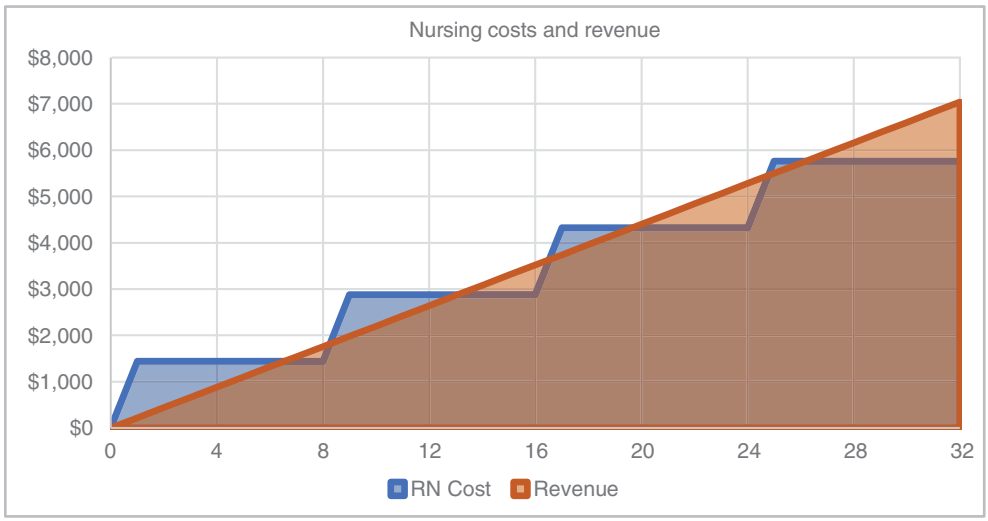


FIGURE 15-3

Example of margin analysis. For some patient volumes, nursing costs preclude making a profit. As volume increases, this happens less frequently

Anomaly detection is a key value of managerial accounting. For example, a managerial accountant is reviewing the cost of medications for an arthritis clinic. He notes that the cost of colchicine has increased nearly 50-fold since last year.[3] As a result, he recommends that the medical executive committee re-asses the value of the drug.

4.5.7 EVALUATION OF PLANNING PROCESS

After the plan is complete, and numerical methods have been applied to ensure success, it becomes time to step back and reassess the plan as a whole and in the context of the organization. The following questions may help guide analysis.

1. Does the plan reflect the mission and vision? Do all the strategies bring the organization closer to the desired outcome? If there are parts of the plan that seem extraneous or misdirected, they must be removed.
2. Is the plan realistic? Can everything really be accomplished within the time and cost constraints?
3. Is the plan balanced? Does it support ALL the organizational goals, or just some of them?
4. Is the plan clear and complete? Does it specify all the tasks that need to be done? Does it include all the details that are required for others to understand and execute it?

3 Lee J. Gout-drug competition returning to market after court fight. Modern Healthcare. January 15, 2015.

Scott Mankowitz

4.6 Change Management

CHAPTER OUTLINE

4.6.1 ASSESSMENT OF ORGANIZATIONAL CULTURE AND BEHAVIOR

An **organizational culture** is the values and behaviors that describe the psychological environment of a company. It is more than the mission or vision statement; it is the sum of the attitudes and feelings of the people that make up the organization. It can include the organization's experiences, philosophy, self-image and expectations. It is based on the shared beliefs, customs and rules that have evolved over time. Written policies and procedures, rules and regulations contribute to the culture but do not define it. Culture extends into the inner workings and sense of community embodied by the organization.

Organizational culture is unique for every organization and can prove quite difficult to change. **Organizational climate** is the current mood (zeitgeist) of the company in light of recent events.

Subcultures are the peculiarities of culture that exist for small groups within a larger organization. For example, engineers often have different ways of interacting and showing strength than do receptionists.

Assessment of Corporate Culture

Here are some questions to ask employees, management and consultants when trying to understand the culture of an organization.

Architecture. What does the physical plant look like? Is it clean and modern or is it run-down? Does it have the latest in technology? Is it located in the city center where others can see it, or is it located remotely, away from civilization?

Employees. How do the employees behave? Is there a dress code? Do people dress formally or informally. Do they arrive on time, or are the hours "flexible"? Or, does nobody check when people are late? How do workers treat each other? Is there a visible hierarchy? Do employees hang out together at the water cooler, or are they sequestered in their offices? How do they communicate with each other? Do they talk, have meetings, send text messages, emails or written memos?

Impression. What is the reputation of the company in the business community? Does the company excel for any particular service or behavior? Is it generally honorable, or does it operate deceptively. Does it always pay its debts? How does the company advertise itself?

Operant conditioning. By what factors are employees measured and rewarded? Are these reward mechanisms publicized or are they a closely held secret? Would the company be proud or embarrassed if their methods were widely known?

Unmentionables. What are the company taboos? Are there certain things that this company would *never* do? Are there things that employees are not allowed to talk about? What are the company rumors, legends and stories? Do the workers really believe them?

The Organizational Culture Profile[1] popularized by O'Reilly et al. in 1991 list seven "orientations" of corporate culture, some of which overlap.

1. Innovation (Risk). Innovative organizations encourage risk-taking to advance the company. Risk-averse companies invest heavily on training and regulation. Organizations in risky environments, such as hospitals, tend to place a low value on innovation where any mistake could result in significant harm.
2. Attention to detail (Precision)—Employees are expected to be accurate in their work. Hospitals tend to place a high value on precision.
3. Emphasis on outcome (Achievement)—Employees are expected to do "whatever it takes" to get the desired outcome. An example might be a high-profile realtor.
4. Emphasis on people (Fairness)—Companies place a high value on treating their employees with respect and dignity. For example, ice cream manufacturer Ben & Jerry's famously limited compensation by establishing a rule that the highest paid employee could not earn a salary more than five times that of the lowest paid employee. As a result, the company had very well paid janitors and modestly paid executives.
5. Teamwork (Collaboration)—Work activities are organized around teams instead of individuals.
6. Aggressiveness (Competitive)—Employees are encouraged to be assertive when dealing with clients and competitors.
7. Stability (Rule)—The organization values steady output and predictable service levels.

4.6.2 CHANGE THEORIES

Kelly Bookman

Diffusion of Innovation

Everett Rogers defines **diffusion of innovation** as "the process by which an innovation is communicated through certain channels over time among the members of a social system".[2] An **innovation** is an idea or practice that is *perceived* as new. It is the perception of newness that is the key to diffusion and it involves uncertainty or the recognition of alternatives and their probabilities. Rogers describes mostly technology innovations which have both hardware (the tool) and software (the knowledge behind the tool) components. The uncertainty associated with a new idea or technology drives individuals to seek *innovation-evaluation* information to help assuage that uncertainty. The rate of adoption of an innovation is determined by relative advantage, compatibility, complexity, trialability and observability.

Communication channels can be mass media type which are more effective in disseminating knowledge of innovations or interpersonal type which are more effective in developing and shaping attitudes towards them. These attitudes directly influence the decision to adopt or reject the new technology. Most people make these decisions not based on scientific information but rather by subjective evaluation by others who have tried the innovation. The

1 O'Reilly, C. A., Chatman, J. A., & Caldwell, D. F. (1991). People and organizational culture: A profile comparison approach to person-organization fit. *Academy of Management Journal, 34*, 487–516.
2 Rogers E. Diffusion of Innovation. 3rd ed. New York: The Free Press; 1983. p.5.

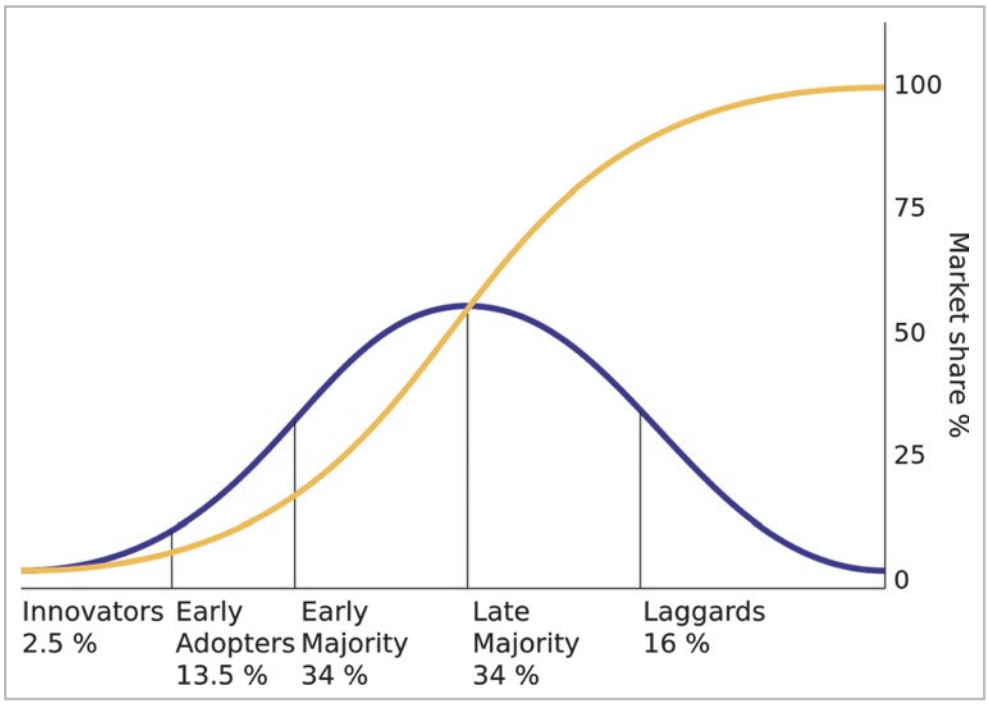


FIGURE 16-1

Adopters tend to fall into a bell-shaped curve. Based on Rogers, E. (1962) Diffusion of innovations. Free Press, London, NY, USA, Public Domain, https://commons.wikimedia.org/w/index.php?curid=18525407

innovative-decision process has five steps: knowledge, persuasion, decision, implementation and confirmation.

Individuals are characterized by innovativeness based on relative earliness of adoption compared to other members of the social system and there are five categories which include innovators, early adopters, early majority, late majority and laggards (Fig. 16-1). The rate of adoption varies from innovation to innovation but is always a sigmoid (s-shaped) curve with innovators on the lower part of the s and laggards at the top. Innovators actively seek information about new technologies, have a high degree of mass media exposure and an extensive interpersonal network. They can cope with higher degree of uncertainty and do not depend on others for subjective evaluation of the new idea. Late adopters and laggards are often regarded as resistant to change and sometimes individually blamed for not adopting an innovation. There is some research that laggards often do adopt a change but then discontinue it due to disenchantment. Status motivators seem to be less important for late majority and laggards than for innovators, early adopters and early majority. Laggards will generally move from initial trial to full usage more rapidly than innovators or early adopters as they have the benefit of having seen the outcomes of adoption by the earlier groups.

Diffusion occurs within a social system and individual innovativeness is based on individual characteristics as well the nature of the social system and its norms. Since innovators are often deviant from the norms their role in diffusion is often limited whereas there are other individuals who have opinion leadership and can drive attitudes about specific new ideas. These opinion leaders may be informal leaders and they maintain their influence by virtue of their competence, accessibility and conformity to the social system's norms.

There are three different ways for changes to be implemented. Optional (individual) where the individual person opts for the change; collective (consensus) where the group opts for the change; and authoritative (top-down) where the leader imposes the change on subordinates. While the authoritative method results in the fastest change, it often fails during implementation due to lack of buy in. Decisions are also based on consequences which can be desirable versus undesirable, direct versus indirect and anticipated versus unanticipated. Change agents promote innovations with desirable, direct and anticipated consequences.

Transition Theory

Transition occurs with every change and is much slower than change itself. William Bridges[3] describes transition as "the state that change puts people into" with change being the external difference in process and transition being the internal psychological reorientation that people have to undergo for the change to be accepted. He explains the process of transition as three phases: saying goodbye (endings), the neutral zone (explorations) and moving forward (new beginnings). Saying goodbye requires letting go of the way things were and shifting to neutral. Once the loss of how things used to be is accepted, people enter the very uncomfortable neutral zone which is where Bridges says the creativity and energy of transition occur and hence real transformation. It is important to note that change itself can continue but transition must be attended to or the change won't be sustainable. People need to understand what the new process is and what is being required of them before they can move forward. Reasons people fail to transition include not making an ending, becoming confused in the neutral zone and not doing the work required to transform and not being able to behave in the new way. The third phase "moving forward" requires behaving in a new way that might challenge one's previous sense of competence. It is especially hard to complete this final phase when an organization is known for punitive reactions to mistakes and people become concerned about their ability to perform in the new process.

Leaders tend to move through the change process quickly because they can envision the end goal of the change. It is important that leaders remember, understand and recognize that transition is occurring for the front line workers and lead through it. Bridges discusses the 4 P's of transition communications: the purpose (why we are doing this), the picture (what it will look and feel like when we get there), the plan (details on how we will get there) and the part (what you can do to help). It is important that leadership articulates and models the new attitudes and behaviors needed to sustain the change. Leaders need to be collaborative and function as coaches.

Lewin Change Theory

Lewin[4] had many themes to his work including Field Theory, Group Dynamics, Action Research and the three step model of change—all of which he thought were necessary to bring about "planned change". Lewin's **Field Theory** states that an individual's behavior is a function of one's own characteristics as well as the group environment (the "field"), where a group is defined as individuals who have an "interdependence of fate". His **group dynamics** concept stresses that change efforts should be directed at group and not individual behaviors and should be focused on norms, roles and interactions to effect the change. Members of the group should be engaged and committed to changing their behavior. **Action research** recognizes that change requires successful action which must incorporate correct analysis of the situation, identification of alternative solutions and the choice of the most appropriate solution. Lewin said that there must be a "felt need" by the individual that change is necessary but for change to be sustained, it must encourage collaboration and participation at the group level.

Lewin is best known for his three step change model. Step 1 is "unfreezing" from the current state so old behavior can be discarded and new behavior adopted. This includes preparing for change and overcoming inertia and resistance. Step 2 is "moving" to the change and should include trial and error of all available options and reinforcement of the change. Step 3 is "refreezing" to stabilize the new equilibrium and assure that the new behaviors are sustained and don't regress. This requires that group norms and routines be transformed to augment the new process with changes to organizational culture and policies.

Precede/Proceed

Planning models like the precede/proceed model[5] can be thought of as a structure for organizing change rather than being a specific theory of change like Bridges' or Lewin's theories.

3 Bridges W, Bridges S. Managing Transitions: making the most of change. 4th ed. Boston, MA: Da Capo Press; 2016.

4 Burnes B. Kurt Lewin and the Planned Approach to Change: A Re-appraisal. J Manage Stud. 2004;41(6):977–1002.

5 Green LW, and Kreuter MW. Health Promotion Planning: An Educational and Ecological Approach. (4th ed.) New York: McGraw-Hill, 2005.

The purpose of the precede/proceed model developed Green and colleagues is not to explain relationships among factors that affect change; rather it is to provide a framework for systematically applying change theories to assist in planning and evaluating success of health behavior change programs. The PRECEDE (Predisposing, Reinforcing and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation) framework developed in the 1970s is based on the idea that an educational "diagnosis" should precede an interventional plan. In 1991, the PROCEED (Policy, Regulatory and Organizational Constructs in Educational and Environmental Development) framework was added to emphasize the importance of environmental factors in health behaviors. In 2005, the model was revised to acknowledge that ecological and participatory approaches are relevant to public health initiatives in general and to bring in the contribution of genetics. Overall, according to Green, it is important that the intended audience participates in defining the priorities and goals for any intervention (Fig. 16-2).

Phase 1 is social assessment, participatory planning and situation analysis. Phase 2 is epidemiological, behavioral and environmental assessments. Phase 3 is educational and ecological assessment which looks at predisposing, reinforcing and enabling factors. Phase 4 is where there is administrative and policy assessment and intervention alignment. Phases 5–8 are all about implementation and evaluation. Data is needed around process, impact and outcome.

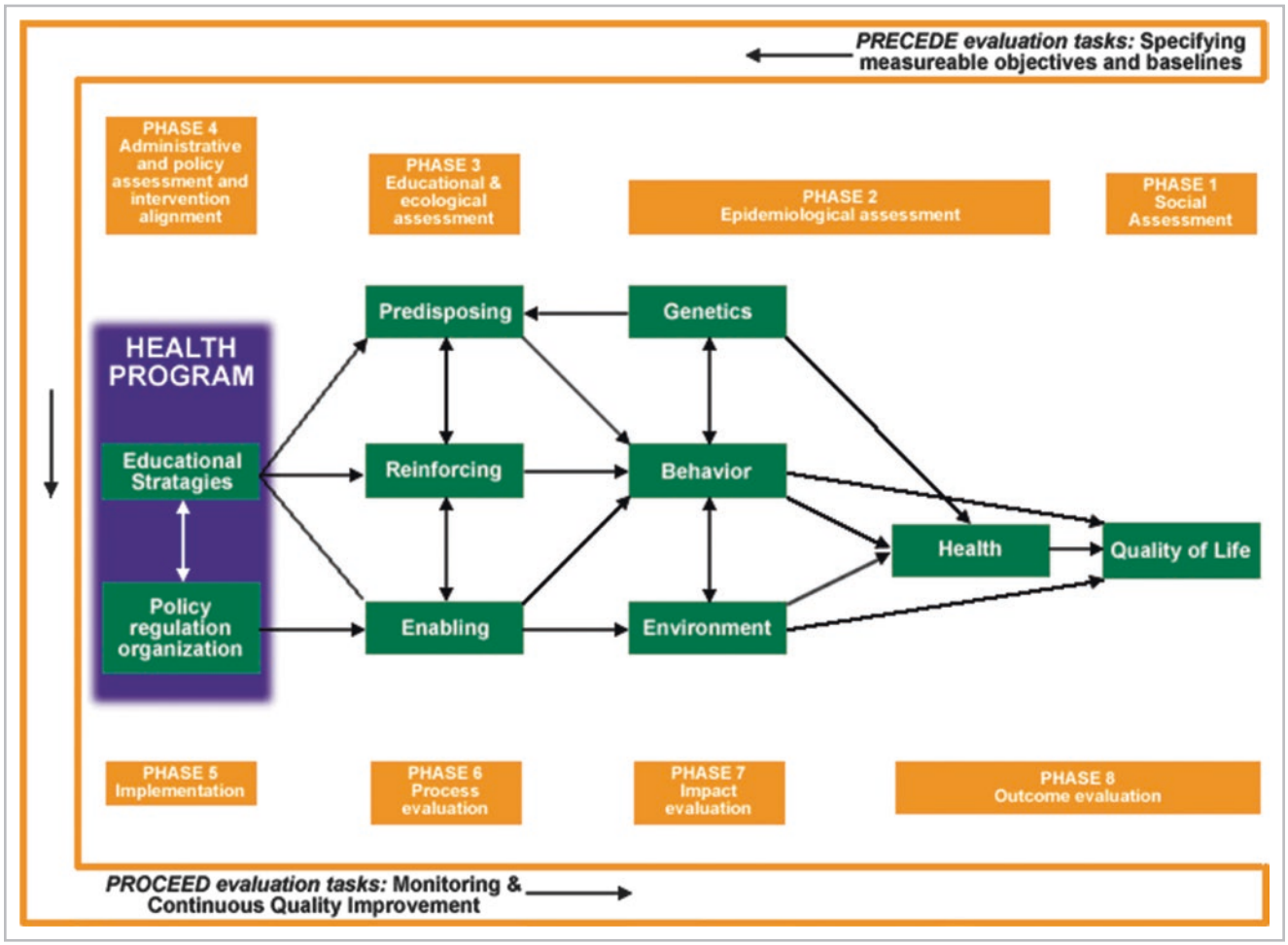


FIGURE 16-2

Generic representation of the precede-proceed model. From L. Green and M. Kreuter. (2005). Health promotion planning: an educational and ecological approach (4th ed.). Mountain View, CA: Mayfield Publishers

This model is heavily data driven and may require more financial and human resources than are available depending on the situation. Further, it does not get down into the details of the specific interventions. Using this model ensures that programs can be replicated and documented for review as well as providing a systematic framework for setting priorities and evaluating outcomes.[6]

Social Influence Theory

Social influence is any change in which a person's relations with other people affects his activities, emotions or actions.[7] For most people, there are three central motivations: to be accurate; to affiliate; and to maintain a positive self-concept. Compliance refers to the response of acquiescence when the target knows he/she is being asked to respond in a certain way. A person needs to have an accurate perception of a situation in order to respond appropriately and effectively and tends to use his feelings as cues for effective responses. Some have suggested that unconventional requests are more subject to variations in mood than conventional requests.

Behavior in accordance with authority can be due to compliance or obedience and is generally related to whether the authority is gained by means of expertise (compliance) or relative position in a hierarchy (obedience). Soft influences are factors which originate from within the authority such as credibility. Harsh influences originate from an external social structure. Since volition is associated with compliance, authorities who demonstrate consideration for subordinates' needs and treat them with fairness and respect generally find more compliance with their requests.

Social norms influence individuals to respond to situations especially when there is uncertainty. There are norms which tell people what is acceptable or unacceptable (injunctive norms) and what is typically done (descriptive norms). That said, actions are relatively unaffected by norms unless they are salient. Those attempting to influence behavior must bring the relevant norms to the forefront of the target's consciousness to be successful.

Individuals are motivated to develop and foster social relationships. There is a clear relationship between a target's fondness for the influencer and the likelihood of compliance with any request. Further, in person requests and perceived similarity to the requestor lead to greater compliance. Ingratiation is another way to influence people and improve compliance. Reciprocation is considered one of the strongest and most pervasive forces in social culture.

People are motivated to maintain their self-concepts by behaving in ways consistent with who they believe themselves to be. Thus, compliance can be driven by getting people to behave in a certain way and then asking them to continue to behave that way to maintain their self-perception of consistency in beliefs and actions. This assumption of consistency based compliance may not be true across all cultures. Consistency needs are more influential in individualistic cultures than in collective cultures.

Conformity is another important component of social influence theory. It refers to changing one's behavior to match the responses of others and it is based on the desire to behave correctly and obtain approval from others. A strong "goal of accuracy" can counteract normative pressures to conform if the person making the decision to conform has accountability for the decision's correctness or if it is against the decider's beliefs. However, perception of consensus among group members can exert significant influence. The goal of affiliation can drive some people to exhibit conscious behavioral mimicry or even more obvious forms of conforming to gain social approval and enhance or protect their self-esteem.

Complex Adaptive Systems

Health care is a complex system, the components of which interact in a nonlinear fashion in multiple ways and create unexpected results. Complexity comes from the interaction of elements within a system and between a system and its environment. Complex adaptive

6 Glanz K, Rimer B, Viswanath Eds. Health Behavior and Health Education: Theory, Research and Practice. 4th ed. Jossey-Bass. CA. 2008.

7 Cianldini RB and Goldstein NJ. Social influence: compliance and conformity. Annu Rev Psychol. 55:591–621. 2004.

systems (CAS) are dynamic and evolve with the changing environment.[8] The idea is to understand the intrinsic properties of a CAS and use them to drive behavioral change.

Key characteristics of a CAS are diverse agents that learn, nonlinear interdependencies, emergence of self-organization and coevolution. Health care organizations have providers, patients and other stakeholders who are diverse and who learn and absorb uncertainty. Relationships are nonlinear and outputs are often disproportional to inputs. This combination of diverse learners and nonlinear interactions drives self-organization and coevolution. Through agent interactions, self-organization creates ever changing organizational patterns with no single, centralized control that governs system behavior. Actions by one part within the system influence all other related parts but not uniformly. Coevolution is when a system's response to its environment changes both the system and the environment. This, in and of itself, sometimes causes the original change to no longer be adaptive. CASs are by their nature fundamentally unpredictable and are always poised to change or on the "edge of chaos".[9]

4.6.3 CHANGE MANAGEMENT STRATEGIES

There are many popular *change management strategies*. John Kotter, in his book *Leading Change*, highlights an eight-stage process to manage change.[10]

1. Create a sense of urgency. The business case for implementing change has to be unequivocal, and leaders have to explain why delaying the change is not an acceptable option. For example, the US government awarded large sums of money to providers who made meaningful use of EMRs, but only if they did so by a certain deadline.
2. Create a guiding coalition. Change requires leaders who are both representative of and respected by the people who are subject to the changes. The coalition must be responsive to problems and stalwart in their endorsement.
3. Developing a vision and strategy. Marching forward without a clear destination is a recipe for failure. See Sect. 4.1.5 for examples of vision and strategic formulation.
4. Communicating the change vision. Even the best strategy is useless if it remains in the ivory tower of the leadership. There must be effective and comprehensive means of transmitting this message to the workers.
5. Empowering employees. Leaders may lose touch with the day-to-day hassle of a new change. They may not be able to foresee problems because they are too invested in the ultimate success of the project. For this reason, it is critical to empower employees to raise implementation issues and, in some cases, to pause progress until a better solution can be found. With power comes responsibility, and empowered employees will ultimately support the change.
6. Generating short-term wins. Employees want immediate feedback that the change process is beneficial, even if they do not reap the reward themselves. Without this, they will believe that their efforts are valueless. For example, nurses in a hospital are asked to teach patients how to use a patient portal as part of their discharge teaching. Many nurses feel that it is a waste of time because this patient population is not technically literate. When a manager announces that the portal has been accessed 1000 times during the past month, the nurses realize that their efforts were successful and approach their task with renewed vigor.
7. Consolidating gains to produce more change. Once early gains are seen, there is a temptation to rest on one's laurels and assume that the rest of the project will simply fall into place. Unfortunately, the short-term wins that were selected in stage 6, were chosen

8 Lipsitz LA. Understanding health care as a complex system: the foundation for unintended consequences. JAMA. 308(3): 243–244. 2012.
9 McDaniel RR, Lanham HF and Anderson RA. Implications of complex adaptive systems theory for the design of research on health care organizations. Health Care Manage Rev. 34(2): 191–199. 2009.
10 Kotter JP. Leading Change. Boston, MA: Harvard Business School Press; 1996.

because of their relative simplicity. More complex changes to interdependent systems require even greater leadership. This is where empowered employees will make the most difference. If leadership has clearly expressed its vision, employees will be able to figure out how to continue the project to completion.

8. Anchoring new approaches in the culture. People who initially resisted change likely remain in the organization. After successful change, they may still wonder if the change was beneficial for them or their work unit. If the new processes are not anchored in the corporate culture, they are unlikely to result in long-lasting change.

In addition to the above, there are several key organizational factors required for success.

1. Strong leadership commitment. Since change often impacts more than one department, the top leadership of an organization must be involved to smooth out negotiations and compromises between departments. When leadership appears lackadaisical, users will tend to revert to more comfortable processes.
2. Communication. The process of informing all stakeholders about the benefits and value of the change must be methodological and comprehensive. If people are impacted by the change without adequate warning and the ability to voice concerns, they will retaliate.
3. Planning. It is said that a clever man can escape an unpleasant situation that a wise man would never have gotten into. Careful planning and early involvement of all stakeholders and end-users can help prevent problems further down the line.
4. Champions. Having respected members of the organization in addition to corporate leaders is invaluable for motivating employees to embrace changes. If they feel that average users such as themselves can benefit from change, they are more likely to be involved.
5. Ensure local benefits. Users are more likely to enjoy change if it makes their lives easier. For example, a hospital decides to revamp its material acquisition process in order to allow executives to more closely monitor the hospital's spending. In the past, the manager filled out a requisition form, had it signed by a department head, brought it to the acquisition manager who ultimately processed the order. In a new, electronic, system, the manager fills out essentially the same form, but now it is sent automatically to purchasing and to the department manager. Since it is now easier for the manager to do her job, she is more likely to use the system. In truth, the system was installed for the benefit of the executives, but the implementation would not have been nearly as successful had it not made an immediate benefit to the end-user.
6. Training. When change is introduced, many end-users will fail to implement it simply because they do not know how. Training on a new system must be complete and backed up by competent and timely support services.

4.6.4 STRATEGIES FOR PROMOTING ADOPTION AND EFFECTIVE USE OF CLINICAL INFORMATION SYSTEMS

The preceding discussion provides generic instruction for change management. In this chapter, we focus on one of the most common tasks of the modern clinical informaticist, facilitating the install of a new clinical information system, specifically a new electronic medical record (EMR).

Involvement of top leadership is critical to success. EMRs tend to be fantastically expensive when considering the total cost of ownership, and mobilizing the amount of resources required for successful implementation is key. The organizational leadership must be involved from the beginning of the planning phase through implementation and beyond.

One of the first steps in implementing a new technology is to assess the current organizational climate (see Sect. 4.6.1) and workflow (see Chap. 2.3). From this vantage point, we can see what needs to be changed and how best to do it.

Physically installing technology can be a challenging task, and although it is obviously necessary to success, it is not sufficient. Moreover, technology does not provide any value to the organization until the system is used. The real benefits only appear when the users implement and adapt the system in order to deliver actual results.

Providing reasonable expectations for the new technology must be done very carefully. If the value of the system is overstated, it will be regarded as a failure. If it is understated, people will think it's more trouble than it's worth and will not embrace it.

Recruiting respected members of the staff to become champions of the new project will help improve credibility. Champions should not be selected based on their technical prowess. On the contrary, champions should be the clinical leaders of the organization, whose clinical acumen is sought routinely. After all, technology is only a tool to provide patient care, much like a stethoscope. If a clinical leader convincingly argues that this technology will benefit his patients and his practice, others will follow. Meanwhile, if a clinically poor but technically adept doctor espouses a new EMR, his opinions will be quickly discarded as irrelevant.

End-user input is critical for correct implementation. No system is perfect and testing will reveal problems that need to be fixed. Before the system is released, there will be many tradeoffs between efficiency, security, safety and accuracy, as well as countless other concerns. If end users are involved in the compromises that are made, they are more likely to tolerate an inefficient system than if they were never involved at all.

Regarding users, both desire and capability must be aligned in order for successful adoption. If the software doesn't work or the users don't know how to use it correctly or the users aren't properly motivated, success will be impossible. This can be shown in a simple Skill versus Will matrix (Fig. 16-3).[11]

Just as champions can address users without motivation, training can address users who lack skills. Training should be specific to the user's work function and provided in a stress-free environment away from work site. Although on-the-job training can be used, users who are expected to simultaneously learn and use a new system will develop shortcuts and workarounds just to get through the day. In addition, training should be backed up by solid and available support systems. For example, if an order entry system fails to print out orders at 2:00 AM, an entire nursing unit may be brought to a halt. Without rapid technical support, downtime may last days and the lack of faith in the system could last years.

In summary, with any technology adoption, the organization must demonstrate value, provide training, establish expectations, engage and involve users and continually reinforce the new process. If the organization is unable to create synergy, users will ultimately develop workarounds that undermine the EMR.

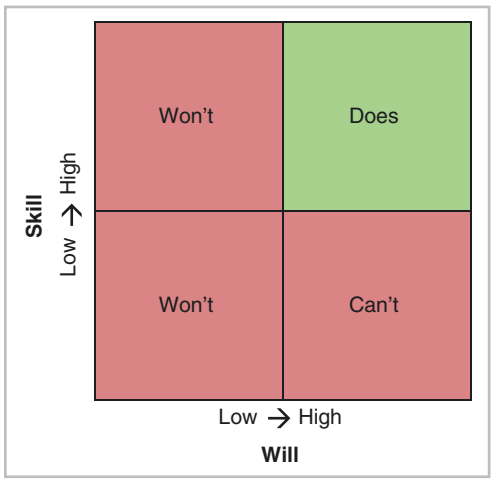


FIGURE 16-3

Skill versus Will matrix

11 McCarthy C, Eastman D. Change management strategies for an effective EMR implementation. Chicago, IL: HIMSS; 2010.

Numerical Methods

TEST CHARACTERISTICS

The accuracy of a screening test determined by comparing its results to a highly accurate test called a **gold standard** (or **criterion standard**). When the tests agree, the result is called true (i.e. true positive or true negative). A Type I error occurs when the screening test mistakenly shows a relationship. A Type II error occurs when the screening test mistakenly indicates that there is no relationship (see table below).

	TEST (+)	**TEST (–)**
Disease (+)	**True positive (TP)**	**False Negative (FN)** (type II error)
Disease (–)	**False positive (FP)** (type I error)	**True negative (TN)**

There are several different test characteristics that can be computed from the above. For the probability column, P(T) is the probability that the test is positive. P(T′) is the probability that the test is not positive. P(D) is the probability that the disease is present. The vertical bar in probability means "given that", so P(T|D) means the probability that the test is positive given that the disease is present.

MEASURE	**WHAT IT MEANS**	**MATH**	**PROBABILITY NOTATION**
Prevalence	How common is the disease?	*TP*+*FN*	P(D)
Sensitivity or recall or True positive rate	How many people with the disease will be detected with the test?	*TP*/(*TP*+*FN*)	P(T|D)
Specificity or true negative rate	How many people without the disease can be ruled out with this test?	*TN*/(*TN*+*FP*)	P(T′|D′)
Fall-out or false positive rate	Of all the healthy people, how many will be incorrectly diagnosed with this test?	*FP*/(*TN*+*FP*) 1-specificity	P(T|D′)
Accuracy	How often is the test correct?	(*TP*+*TN*)/*Total*	
Positive predictive value or precision	When the test is positive, how often is it right?	*TP*/(*TP*+*FP*)	P(D|T)
Negative predictive value	When the test is negative, how often is it right?	*TN*/(*TN*+*FN*)	P(D′|T′)
Positive likelihood ratio or LR(+)	How much does a positive test increase the odds of having the disease?	$\frac{TP/(TP+FN)}{FP/(FP+TN)}$	

MEASURE	WHAT IT MEANS	MATH	PROBABILITY NOTATION
Negative likelihood ratio or LR(–)	How much does a negative test decrease the odds of having the disease	$\frac{FN/(FN+TP)}{TN/(TN+FP)}$	

No tests are perfect, and nearly all will have a trade-off between sensitivity and specificity, so some tests are better in certain situations. For example, consider the diagnosis of HIV. There are two stages of tests: screening tests and confirmatory tests. Asymptomatic patients are given routine screening tests. If the test is positive, the patient is given a confirmatory test. If the confirmatory test is positive, treatment is begun.

Screening tests tend to be highly sensitive and relatively inexpensive. False positives are common, and the person ordering the test must use this knowledge when interpreting the results. Confirmatory tests tend to be more expensive and are designed to minimize false positives (i.e. have high specificity)

BAYES THEOREM

Bayes theorem explains the relationship between prevalence, risk factors and outcome. Mathematically, it can be expressed as

$$P(D|T) = \frac{P(T|D)\cdot P(D)}{P(T)}$$

In medicine, the most common application of Bayes theorem is in predicting the likelihood of a particular outcome considering various risk factors or test results. For example, suppose there is a screening test for breast cancer that is 80% accurate (i.e. sensitivity and specificity are both 80%). Further, let's assume that the prevalence of breast cancer in our population is 5%. If a woman has a positive screening test for cancer, what are the chances that she actually has the disease?

Using our formula above, we are solving for P(D|T), where D is having cancer and T is having a positive screening test. Given an accuracy of 80%, we can figure out the frequency of true positive and false positive tests. The frequency of true positives is the frequency of cancer times the frequency that the test is correct.

$$\begin{aligned} P(T|D) &= \text{probability of having a positive test when cancer is present (i.e.test accuracy, 80\%)} \\ &= 0.8 \end{aligned}$$

$$\begin{aligned} P(D) &= \text{probability of having cancer (i.e.prevalence of the disease, 5\%)} \\ &= 0.05 \end{aligned}$$

$$\begin{aligned} \text{True positives} &= (\text{probability of test being RIGHT})\cdot(\text{incidence of cancer}) \\ &= P(T|D)\cdot P(D) \\ &= 0.8\cdot 0.05 \\ &= 0.04 \end{aligned}$$

$$\begin{aligned} \text{False positives} &= (\text{probability of test being WRONG})\cdot \text{incidence of NOT having cancer} \\ &= P(T|D')\cdot P(D') \\ &= (1-P(T|D))\cdot(1-P(D)) \\ &= (1-0.8)\cdot(1-0.05) \\ &= (0.2)\cdot(0.95) \\ &= 0.19 \end{aligned}$$

$$\begin{aligned} P(T) &= \text{probability of having a positive test} \\ &= \text{true positive tests} + \text{false positive tests} \\ &= 0.04 + 0.19 \\ &= 0.23 \end{aligned}$$

Plugging it all in, we get:

$$P(D|T) = \frac{P(T|D) \cdot P(D)}{P(T)} = \frac{(0.8)(0.05)}{0.23} \approx 0.174$$

Which means positive predictive value of this test is about 17%. In other words, even if a person has a positive screening test, the chances of having cancer are still only 1 in 6 because of the relatively low prevalence of the disease.

Said another way, we can calculate the likelihood ratio using the following formula:

$$\begin{aligned} LR(+) &= P(D|T) / P(D|T') \\ &= 0.8 / (1 - 0.8) \\ &= 4 \end{aligned}$$

Which means that the odds of having cancer increase 4-fold when the test is positive.

MEASURES OF RISK

There is a big difference between odds and probability. They are not the same thing, although they are often confused with one another. Suppose you flip a coin. The probability of getting heads is 50%, but the odds of getting heads are 1:1. More mathematically,

Probability = (chance of desired outcome)/(total number of possible outcomes)

Odds = (chance of desired outcome)/(chance of all other outcomes)

Going back to our 2 × 2 table,

	OUTCOME (+)	**OUTCOME (–)**
Study group	a	b
Control	c	d

The **odds** of someone in the study group having the desired outcome is a/b

The **probability** (or **risk**) of someone in the study group having the desired outcome is a/(a + b)

So, what's the difference? When can we use odds ratio, and when do we use relative risk? The odds ratio is used in cohort and case-control studies, where the prevalence in the population is not known. Risk is used in RCT's where the prevalence of disease is known. In other words, if I deliberately pick controls to match my study group, I can make no guesses about what percentage of the whole population actually has the disease, so I can only tell someone their odds. However, if I randomly select from the population, I can calculate the prevalence of disease in the study group as well as the control group, and thereby assess their risk.

MEASURE	**WHAT IT MEANS**	**MATH**
Relative risk	How many times riskier is the study than the control?	$RR = \frac{risk\ in\ study\ group}{risk\ in\ control\ group} = \frac{a/(a+b)}{c/(c+d)}$
Absolute risk reduction	How much less risk is in the study group compared to control?	$ARR = risk\ in\ control\ group - risk\ in\ study\ group$ $= a/(a+b) - c/(c+d)$
Relative risk reduction	How many times less risky is the study group compared to the control group?	$RRR = \frac{risk\ in\ control\ group - risk\ in\ study\ group}{risk\ in\ control\ group}$ $RRR = \frac{ARR}{a/(a+b)} = \frac{a/(a+b) - c/(c+d)}{a/(a+b)}$
Number needed to treat (harm)	How many people would have to have the intervention to benefit one person?	$NNT = \frac{1}{RRR} = \frac{a/(a+b)}{a/(a+b) - c/(c+d)}$

MEASURE	WHAT IT MEANS	MATH
Odds ratio	What are the odds in the study compared to control	$OR = \frac{odds\ in\ study\ group}{odds\ in\ control\ group} = \frac{a/b}{c/d}$

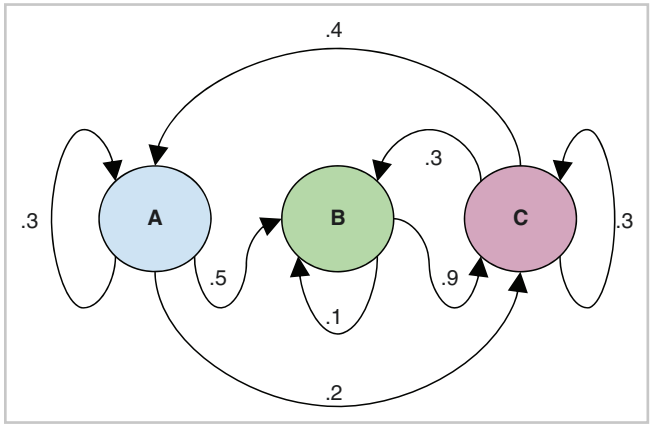
Some points to remember

1. The RR is similar to the OR when the outcome is rare.
2. ARR is usually smaller than RRR.
3. Likelihood ratios can be directly applied to odds, not risk (unless using a nomogram)

MARKOV CHAINS

Markov chains are a diagrammatic way of showing how a population shifts from one state to another. Consider the following diagram. In this population, each individual exists in one of three states: A, B or C. In each generation some members of group A will remain in group A; some will join group B and some will join group C. The numbers over the arrows indicate the fraction of the population that will shift. For group A, 0.3 will remain A; 0.5 will become B; and 0.2 will become C. The sum of all the outgoing arrows should be 1.0. Suppose that our population starts with 100 members in each state. What will be the population for each group the next generation?

One way to calculate this is to look at the inputs to a particular node. Node A receives inputs from A and C. (There is no arrow from B to A.) If the initial population of C is 100, and 0.4 of that population goes to A, that represents 40 individuals. If the initial population of A is 100, and 0.3 remain in A, that represents another 30 individuals. Summing those inputs gives us 70 individuals. So, at the end of the second generation, A has 70. Using similar calculation, we find out that C has 140 individuals. By repeating the process, we can calculate the populations for the third generation, as shown in the table.



GENERATION	A	B	C
1	100	100	100
2	A: 0.3 × 100 = 30 B: 0 × 100 = 0 C: 0.4 × 100 = 40 Total = 70	A: 0.5 × 100 = 50 B: 0.1 × 100 = 10 C: 0.3 × 100 = 30 Total = 90	A: 0.2 × 100 = 20 B: 0.9 × 100 = 90 C: 0.3 × 100 = 30 Total = 140
3	A: 0.3 × 70 = 21 B: 0 × 90 = 0 C: 0.4 × 140 = 56 Total = 77	A: 0.5 × 70 = 35 B: 0.1 × 90 = 9 C: 0.3 × 140 = 42 Total = 86	A: 0.2 × 70 = 14 B: 0.9 × 90 = 81 C: 0.3 × 140 = 42 Total = 137

Questions

1. If actual system users are unavailable for usability testing, what is the next thing a development team should consider?
   (a) Consider postponing the system deployment until the users become available
   (b) Explore methods, such as role-playing, to simulate user responses
   (c) Implement the system without any usability testing (usability testing can only be conducted with the user population)
   (d) Scrap the system—it would be too dangerous to implement a system without usability testing with the end users

2. Which of the following determinants contributes the most to a population's health?
   (a) Literacy
   (b) Medical care
   (c) Personal behaviors
   (d) Social circumstances

3. Given that A and B are independent events, which of the following is true?
   (a) P(A) + P(B) = P(A and B)
   (b) P(A) + P(not A) = 0
   (c) P(B) = P(A and B) + P(not A and B)
   (d) P(A) + P(B) + P(C) = P(A and B and C)

4. Process mining is a specific technique of workflow analysis which involves
   (a) Analysing medical records to identify patients with a particular phenotype
   (b) Calculating the failure rate in an industrial process
   (c) Merging database tables using a common key
   (d) Reviewing the event log of an information system

5. What are Bridges 4P's of transition communications?
   (a) pain, pallor, pulselessness, paresthesias
   (b) people, places, purpose, philosophy
   (c) purpose (why we are doing this), picture (what it will look and feel like when we get there), plan (details on how we will get there), part (what you can do to help)
   (d) punctuation, periodicity, perplexity, punitiveness

6. Complex adaptive systems
   (a) tend towards disorder
   (b) have nonlinear interactions which create unexpected results
   (c) have a central discipline
   (d) do not evolve based on their environment

7. Aspects of a well-designed electronic health record interface might include:
   (a) A color mapping scheme that follows cultural norms (e.g. red means stop)
   (b) Avoid providing direct user feedback, as it can be distracting
   (c) Different modules should have design standards most appropriate to their particular task
   (d) Provide as much information as possible in the interface

8. Given the matrix below, what is the positive likelihood ratio LR(+)

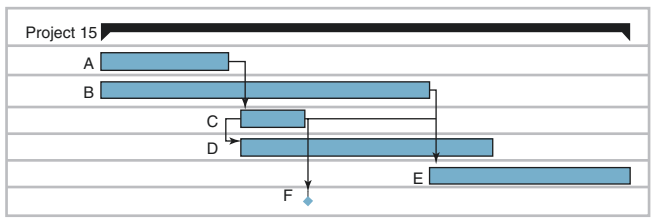
	DISEASE	NO DISEASE
Test +	20	25
Test –	5	100

   (a) 0.2
   (b) 1
   (c) 4
   (d) 8

9. Which of the following is LEAST likely to result in successful workflow reengineering?
   (a) Analyze the process from the perspective of the desired outcome instead of the individual tasks
   (b) Hiring a product line supervisor to ensure that all protocols are correctly followed
   (c) Relieve a process bottleneck by employing more resources
   (d) Using a stepwise (i.e. graduated) approach to revise workflows

10. Which of the following is true?
    key:
    PPV = positive predictive value;
    TP = true positive;
    FN = false negative;
    NPV = negative predictive value;
    TN = true negative;
   (a) PPV = TP/(TP + FN)
   (b) NPV = TN/(TN + FN)
   (c) Sensitivity = TP/(TP + TN)
   (d) Specificity = TN/(TP + TN)

11. Fast Health Interoperability Resources (FHIR) is an emerging standard based on
   (a) Digital Imaging and Communications in Medicine (DICOM) protocols
   (b) Inexpensive commodity hardware
   (c) Standard web technologies (e.g. hypertext transport protocol, cascading style sheets)
   (d) Unbreakable encryption techniques

12. 

    In the Gantt chart above, which task has the LEAST slack (or float)
   (a) A
   (b) B
   (c) C
   (d) D

13. A doctor is considering dating a nurse who works in the same hospital. He is concerned about his possible exposure to HIV and other sexually transmitted diseases, so he reviews her chart in the Electronic Medical Record (EMR). Has a breach of confidentiality occurred?
    (a) NO: Since the doctor himself is at risk, he may review the chart to protect his own health, according to the doctrine of self-preservation
    (b) NO: Since the doctor has administrative privilege to access medical records, he is ethically justified to do so
    (c) YES: Since the relationship between the doctor and nurse is not a doctor-patient relationship, the doctor has no right to review her record
    (d) YES: Since the nurse knew in advance that her records would be available to medical professionals in the hospital, she tacitly agreed to routine chart reviews

14. Environmental scanning is performed by an organization to
    (a) Identify competitive advantages
    (b) Create vision and mission statements
    (c) Propose budgets
    (d) Ensure ethical behavior

15. Which of the following user feedback requests should receive the highest priority
    (a) Non-critical bug fix
    (b) Password reset
    (c) System lag
    (d) Training request

16. By what mechanism do hospitals pay for indigent care?
    (a) capitation
    (b) cost-shifting
    (c) pay-for-performance
    (d) requiring co-payments

17. A Pareto chart is useful for identifying
    (a) Budgeting and cost controls
    (b) Most common problems requiring attention
    (c) Staffing hierarchies
    (d) Whether or not a process is in control

18. The predictive model that describes the shortest time required to move a mouse to an object on a computer screen is called:
    (a) Fitts Law
    (b) Hick-Hyman Law
    (c) Model Human Processor
    (d) Norman's Theory of Action

19. The purpose of managerial accounting is to
    (a) Assist managers in financial decision making
    (b) Describe historical financial performance
    (c) Meet the needs of regulatory agencies
    (d) Report the financial condition of a business

20. A multispecialty medical group is evaluating two proposals, A and B, for adding a new service line. Which of the following statements makes B a better investment?
    (a) The accounting rate of return is 5% for A and 4% for B
    (b) The internal rate of return is 5% for A and 4% for B
    (c) The net present value is $5000 for A and $4000 for B
    (d) The payback period is 5 years for A and 4 years for B

21. Logical Observation Identifiers, Names, and Codes (LOINC) and Systematized Nomenclature of Medicine (SNOMED) are controlled vocabularies. Which term is most likely to appear in both?
    (a) Dysuria (symptom)
    (b) Fall from height (cause of injury)
    (c) Right Femur (body part)
    (d) Systolic Blood Pressure (physical finding)

22. Which of the following informatics specialists and tasks is LEAST likely to be involved in wearable computers
    (a) A Consumer Health Informatics specialist will help physicians manage workflow
    (b) Data visualization specialists will create novel methods for visually representing data
    (c) Interface specialists will manage the transfer of data from one platform (e.g the wearable computer) to another (e.g. an EMR)
    (d) Translational informatics specialists will be involved in the collation of large amounts of data into usable formats

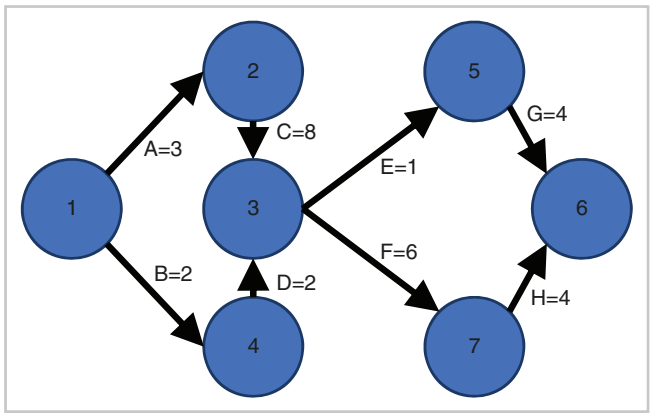
23. Clinical decision support interface issues are present
    (a) In both data entry and data output
    (b) In data entry alone
    (c) In data output alone
    (d) When used as a stand alone system

24. Which of the following is an explicit part of the Institute Of Medicine recommendations for clinical practice guidelines?
    (a) Consists of a series of alternative algorithms to reflect gaps in consistency of studies and reports
    (b) Explains the parts that values, opinion, theory, and clinical experience play in deriving recommendations
    (c) Is developed by a panel of specialists in the field pertinent to the disease process in question
    (d) Should be published in the federal register to ensure adequate access to the guidelines

25. Of the following determinants of health, which of the following is the hardest to change
    (a) Access to quality medical care
    (b) Alcohol consumption
    (c) Carriage of BRCA1 gene
    (d) Exposure to lead

26. In workflow analysis, one way to visually evaluate a process for parallelization
    (a) Collect all paper forms and design electronic equivalents
    (b) Draw process maps for all relevant processes
    (c) Remove outliers from the dataset
    (d) Train workers to expand their scope of practice

27. Limiting the number of choices one has on a menu decreases the user's decision time according to which theory?
    (a) Distributed Cognition
    (b) Fitts Law
    (c) Hick's Law (or the Hick-Hyman Law)
    (d) Norman's Theory of Action

28. 

A project has the activity-over-arrow node diagram above, starting at node 1 and ending at node 6. What is the critical path?

(a) 7
(b) 9
(c) 14
(d) 21

29. An outcomes researcher is studying the health of low-income patients after the opening of a new congestive heart failure clinic. Which of the following measures is likely of MOST interest to the researcher?

(a) Degree of ST-segment depression on resting electrocardiogram (ECG)
(b) Left ventricular end-diastolic volume (LVEDV)
(c) Median dosage of furosemide in the population
(d) Number of blocks patient is able to walk

30. A hospital chooses to use telemedicine to read inpatient electrocardiograms (ECG). The ECGs are scanned throughout the day and read remotely in batches by an off-site cardiologist. What telemedicine technology is being utilized?

(a) Real-time communication
(b) Remote monitoring
(c) Store and forward
(d) Synchronous

31. A corpus of information holds 25 documents which are labeled with the letters from A to Y. The set of documents related to a certain disease are: A, B, C, D, E, F, G, H and I. What is the recall of a search algorithm that yields A, I, K, M, N, O, T and W?

(a) 11%
(b) 22%
(c) 50%
(d) 100%

32. Which of the following is the best example of workflow reengineering?

(a) Improving quality so that failure is extremely rare
(b) Reducing clinical staff on a nursing unit to save money
(c) Replacing paper forms with electronic equivalents
(d) Revising a clinical process to be more efficient

33. This standard format from HL7 International is intended to facilitate the transfer of patient charts between Electronic Health Records and Personal Health Records and includes vital signs, family history, plan of care, and similar data
    (a) Commission on Accreditation of Ambulance Services
    (b) Continuity of Care Document
    (c) Healthcare Common Procedure Coding System
    (d) Joint Commission on Accreditation of Healthcare Organizations

34. What is a reason for practicing defensive medicine (e.g. ordering tests of low expected yield)?
    (a) To decrease the risk of future litigation
    (b) To honor the fiduciary relationship between physician and patient
    (c) To improve patient satisfaction by increasing utilization
    (d) To reward colleagues for taking call

35. Being able to determine what kind of information is required and how to obtain it is part of a core competency known as
    (a) Computer competency
    (b) Controlled Vocabulary
    (c) Informatics management
    (d) Information literacy

36. Which of the following is LEAST LIKELY to encourage interoperability
    (a) Common data definitions
    (b) Enhanced image compression
    (c) Established protocols
    (d) Shared terminologies

37. Clinical Practice Guidelines are LEAST LIKELY to have which of the following effects?
    (a) Quicken the pace of translation of research into practice
    (b) Improve healthcare quality
    (c) Reduce inappropriate practice variation
    (d) Reduce the cost of care

38. Typically, clinical practice guidelines have several parts. Which of the following is LEAST LIKELY to be included?
    (a) A foundation consisting of a systematic review of the research evidence bearing on a clinical question
    (b) A set of recommendations, involving both the evidence and value judgments regarding benefits and harms of alternative care options
    (c) A set of rules outlining exactly how to treat a certain type of patient given certain circumstances
    (d) Recommendations intended to optimize patient care

39. Patient B has lung cancer and has been given 3 years to live without therapy during which time he will continue to have symptoms of chronic shortness of breath and cough. There is a new treatment which promises a cure but has a certain mortality rate associated with it. The patient is asked if he would accept the treatment knowing that there is a 50% risk of mortality. He declines. He is then asked if he would accept the treatment if there were a 30% chance of mortality. He still declines. The question is asked multiple times, each time lowering the risk of mortality. Ultimately, when the

rate is 5%, the patient is unable to choose one option over the other. Making this decision is an example of:
(a) Quality Adjusted Life Years (QALY)
(b) Standard gamble
(c) Time trade off
(d) Visual analogue

40. Which of the following is the best measure to use in evaluating a clinical information system?
(a) Clinical outcomes
(b) Network latency
(c) Number of hits on patient portal
(d) Terminology domain coverage

41. Which of the following tasks is considered preventive maintenance?
(a) Disaster recovery
(b) Making backups of configuration data
(c) Replacing a broken printer
(d) Upgrading radiology monitors to improve resolution

42. A non-clinical benefit to an electronic health record is
(a) better communication among caregivers
(b) improved legibility and clarity of progress notes
(c) more appropriate prescribing
(d) rapid collection of aggregate health information for investigational trials

43. The risk of maintaining a software product is transferred from the institution to the vendor by means of a
(a) Business Associate Agreement
(b) End-User Licensing Agreement
(c) Open source model
(d) Service Level Agreement

44. Reducing defects is the hallmark of the six-sigma quality improvement methodology. What is the target defect rate?
(a) 50%
(b) 6%
(c) 0.0004%
(d) Zero

45. A cancer patient is told that he has a 35% chance of surviving his illness. His oncologist offers him various treatment strategies, each with their own chances of success and failure. The patient opts out of all treatment, believing that 35% is as good as he is going to get. This response to risk analysis is best described as
(a) Risk Acceptance
(b) Risk Avoidance
(c) Risk Exploitation
(d) Risk Transference

46. The best mechanism to control scope creep is
(a) Integrated change control
(b) Risk avoidance
(c) Run chart
(d) Sensitivity analysis

47. Poorly designed healthcare information systems have been known to contribute to
    (a) Adverse clinical events
    (b) Satisfied users
    (c) Streamlined workflows
    (d) Workforce reduction

48. In an ontology, relationships between terms
    (a) Are limited to parent-child (or class-instance) relations
    (b) Are not explicitly stated, as they are inferred from the concept names
    (c) Exclude synonyms or aliases
    (d) Formally define those terms

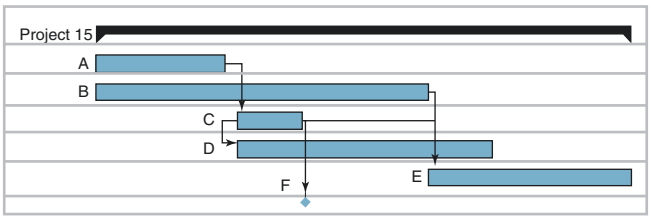
49. A researcher performs a meta-analysis. Her search algorithm retrieves eight documents, of which two are relevant and six are not relevant. In addition, there is one other study which was not detected by her algorithm. What is the recall of information retrieval algorithm?
    (a) 25%
    (b) 33%
    (c) 66%
    (d) 100%

50. Assuming a discount rate of 10%, what is the future value of $100 in 2 years?
    (a) $90
    (b) $100
    (c) $110
    (d) $121

51. What type of database access is MOST APPROPRIATE for a researcher examining secular trends in *Pneumocystis jirovecii* pneumonia?
    (a) File system access
    (b) Live database, read-only
    (c) Shadow (i.e. replica) only
    (d) System administrator access

52. A software tester is evaluating an application, but has no access to the source code. She designs tests based on what the software is *supposed* to do, according to the project requirements. One characteristic of this type of testing is:
    (a) It is a form of static testing
    (b) It is composed of code reviews and structural assessment
    (c) Testers generally do not have to have technical knowledge of the relevant programming languages
    (d) Tests usually involve small code fragments, such as a module or a class

53. Although information retrieval primarily deals with unstructured data, queries often benefit from the use of supplementary information which accompanies documents, known as
    (a) Corpus
    (b) Index
    (c) Metadata
    (d) Relevancy

54. 

In the Gantt chart above, which of the following tasks is part of the critical path

(a) A
(b) B
(c) C
(d) D

55. An implementer of Electronic Health Records requires using the New York Heart Association's Classes of Heart Failure (shown below) to stratify patients. This is an example of a/an

CLASS	PATIENT SYMPTOMS
1	No limitation of physical activity
2	Slight limitation of physical activity
3	Marked limitation of physical activity
4	Unable to carry on any physical activity without discomfort

(a) Controlled vocabulary
(b) Ontogeny
(c) Semantic encoding
(d) Taxonomy

56. Certain users of a clinical information system are often provided with early or extra training. These "super-users"
(a) Are responsible for maintaining passwords and access levels
(b) Attenuate security concerns
(c) May help train other users
(d) Set up interfaces with other clinical systems

57. A test for lupus is 90% sensitive and 90% specific in a population where the prevalence of Lupus is 10%. If a patient has a positive test, what is the approximate likelihood that he has lupus?
(a) Zero
(b) Less than 1%
(c) 50%
(d) 99%

58. The Leapfrog group, founded with support from the Agency for Healthcare Research and Quality, was created in response to:
(a) Multiple large failed EHR implementations
(b) The 1999 Institute of Medicine report, "To Err Is Human"
(c) The death of Libby Zion, a young woman who died possibly as a result of harmful drug interactions
(d) Wachter's "Digital Doctor" discussion of alert fatigue

59. A novel therapy claims that it can reduce the incidence of palpitations in patients using albuterol. In a small study, 20 individuals were evenly divided into two groups. One group received therapy and the other did not. Five patients in the therapy group and six in the control group had palpitations. What is the relative risk reduction associated with the therapy?
    (a) 5%
    (b) 17%
    (c) 50%
    (d) 500%

60. Ideas from Sigmund Freud, Magnus Hirschfeld and Carl Jung were gathered by the American Psychiatric Association when compiling this standard:
    (a) The Criminal Justice Mental Health Standards (CJMHS)
    (b) The Diagnostic and Statistical Manual of Mental Disorders (DSM)
    (c) The National Alliance on Mental Illness (NAMI)
    (d) The Standards of Reporting of Neurological Disorders (STROND)

61. Which of the following methods of alternative dispute resolution requires the LEAST intervention from parties not involved in the conflict?
    (a) Arbitration
    (b) Litigation
    (c) Mediation
    (d) negotiation

62. When recruiting employees, internal candidates are associated with:
    (a) Better morale as a result of promoting from within
    (b) Greater recruiting costs
    (c) Improved diversity
    (d) Newer and fresh insights

63. Which of the following is LEAST important in promoting safety of Clinical Decision Support systems?
    (a) comprehensive auditing facility
    (b) downtime procedures
    (c) updated medical knowledge repository
    (d) usability testing

64. Which of the following is least likely to be an explicit part of a controlled vocabulary?
    (a) Concept identifiers (codes)
    (b) Definitions of terms
    (c) Post-coordinated terms
    (d) Relationships between terms

65. Syntactic Ambiguity refers to a/an
    (a) Inconsistency or conflict in recommendations
    (b) Word that can be pronounced differently
    (c) Word with more than a single meaning
    (d) Sentence constructed with more than one meaning

66. A journal with a high impact factor
    (a) Has a wide circulation
    (b) Is referenced more frequently than other journals
    (c) Is the journal most highly respected in a field
    (d) Offers free access to all original research

67. An example of intrinsic motivation is:
    (a) A nurse feeling a sense of pride after helping care for a critically ill patient
    (b) A doctor seeking to see more patients per hour to receive a bonus
    (c) A physician assistant staying after her shift because her attending doctor offered her a raise to do so.
    (d) A respiratory therapist following an institutional policy

68. A company's tangible resources could include
    (a) A modern facility
    (b) A positive reputation
    (c) A productive corporate culture
    (d) Creative leadership

69. The net present value is roughly equivalent to
    (a) The average cost for a company to borrow money
    (b) The cost of the investment
    (c) The total profit over the life of the investment corrected for today's dollars
    (d) The total profits divided by investment

70. In a case where a misconfigured order set ultimately resulted in harm to a patient, who has the most legal liability?
    (a) The creator of the order set
    (b) The company that sold the Electronic Health Record (EHR)
    (c) The hospital
    (d) The ordering physician

71. Transactions between hospitals and outpatient pharmacies are usually governed by standards established by
    (a) Accredited Standards Committee X12
    (b) American National Standards Institute (ANSI)
    (c) Health Level Seven International (HL7)
    (d) National Council for Prescription Drug Programs (NCPDP)

72. Innovators, early adopters, early majority, late majority and laggards are:
    (a) characteristics of an individual's "complexity"
    (b) characteristics of an individual's "innovativeness"
    (c) descriptions of parts of a social order
    (d) descriptions of parts of a complex adaptive system

73. Which of the following represents a bidirectional dataflow?
    (a) Clinical decision support advises a physician order
    (b) Insurer requests explanation of care which is provided by patient accounts
    (c) Research is incorporated into the medical literature
    (d) Utilization review committee tracks expensive drug orders

74. Which terminology is most commonly used for inpatient hospital reimbursement for Medicare?
    (a) Current Procedural Terminology (CPT)
    (b) Diagnosis Related Group (DRG)
    (c) National Drug Code (NDC)
    (d) The ninth revision of the International Classification of Diseases (ICD-9)

75. After a corporate merger, two hospitals are required to share patient information. Each hospital is firmly entrenched with their own proprietary electronic health record. What method of sharing information is most likely to be successful
    (a) Anonymization
    (b) Certification
    (c) Integration
    (d) Interfacing

76. A network in which multiple nodes are directly connected to each other node is often called a/an
    (a) Mesh
    (b) Point-to-point
    (c) Snowflake
    (d) Star

77. Which of the following models, theories, and frameworks seeks to define usability in the context of electronic health record design?
    (a) Distributed Cognition
    (b) Goals, Operators, Methods, and Selectors (GOMS)
    (c) Learning Healthcare Systems
    (d) Task, User, Representation, Function (TURF)

78. Which of the following questions is best answered by project portfolio management?
    (a) How can the project stakeholders be managed?
    (b) How many personnel are required to complete this project?
    (c) What is the timeframe for the successful completion of this project?
    (d) Which projects should be undertaken to best further the organization's long term strategy?

79. You should consider a focus group methodology over individual interviews when:
    (a) The moderator is inexperienced with focus groups
    (b) The user schedules are difficult to align with each other
    (c) The user population contains complex power dynamics
    (d) Your goal is to obtain consensus on a design decision

80. In a Prediction Market, how are ideas selected?
    (a) All group members must unanimously agree on the best choice
    (b) Group members "purchase" ideas they find favorable with fake money
    (c) Ideas are presented anonymously, and each group member has one vote
    (d) The group leader works collaboratively with the group, but ultimately makes the decision

81. When transitioning data from a legacy system to a new one, semantic interoperability ensures that
    (a) Data will have the same meaning on both systems
    (b) Patient information will be securely encrypted
    (c) Usernames and passwords will be identical on the old system to the new one
    (d) The period of overlap between the systems will be short or non-existent

82. The Japanese philosophy of "kaizen" espouses the belief that all systems can be made better, all the time. This dogma is most consistent with
    (a) Continuous Quality Improvement (CQI)
    (b) LEAN methodology
    (c) Six-sigma
    (d) Value Stream Mapping

83. Research shows that one therapy is 95% successful, while another therapy for the same disease is 98% successful, but costs nearly 10 times as much. According to the Institute of Medicine' report *Crossing the Quality Chasm: A New Health System for the 21st Century*, this represents a conflict between which pillars of quality?
    (a) Effectiveness and Efficiency
    (b) Equity and Timeliness
    (c) Patient-centeredness and timeliness
    (d) Safety and Effectiveness

84. How do quality organizations, such as the Joint Commission, affect physician behavior?
    (a) By defining clinical measures that impact reimbursement
    (b) By rescinding the license of doctors who violate standards of care
    (c) By spending lavishly to educate physicians about their products and services
    (d) By sponsoring classes in medical schools

85. According to social influence theory, compliance and conformity are driven by
    (a) goal of happiness
    (b) goal of achieve
    (c) goal to degrade self-concept
    (d) goal of affiliation

86. Which of the following must be removed from a document in order for it to be considered de-identified according to Safe Harbor?
    (a) Age: 23 years
    (b) Medical History: Diabetes
    (c) Email address: mankowitzs@evh.org
    (d) Vital Signs: P 85; T 99.5; R 15; BP 133/63

87. According to Roger's Diffusion of Innovation theory, the rate of adoption of an innovation is determined by:
    (a) acceptance, tolerability, understandability
    (b) ease of access, maintenance, accessibility
    (c) likability, ease of use and cost
    (d) relative advantage, compatibility, complexity, trialability and observability

88. The difference between data and information is:
    (a) Data are pictorial representations, such as charts and graphs while information is purely numerical
    (b) Data must be encrypted while information does not
    (c) Data are measurements or observations while information is the interpretation of data
    (d) Data are pedagogic tools while information reflects real-world constructs

89. What is the most common scenario for inappropriate disclosure of medical information
    (a) Accidental disclosure, such as when a doctor gives verbal orders to a nurse while another person is nearby
    (b) Intentional theft, such as when a hacker breaks into the Electronic Health Record and steals patient data
    (c) Insider theft, such as when a unit clerk makes photocopies of medical records for sale to a medical liability law office
    (d) Legitimate curiosity, such as when a physician reviews his patient's chart for history of substance abuse

90. Using audit controls to keep track of data modification is an example of what kind of safeguard?
    (a) Administrative
    (b) Physical
    (c) Protective
    (d) Technical

91. Which of the following budget items is LEAST affected when implementing an Application Service Provider model?
    (a) Data center
    (b) Network infrastructure
    (c) Printers
    (d) Workstations

92. Metadata ensures interoperability of data through
    (a) Accurate timestamps
    (b) Data definition
    (c) Error correction
    (d) Origin validation

93. According to the HIPAA privacy rule, in what cases may a covered entity share data with another (non-covered) entity?
    (a) When the data is created by the entity
    (b) When the data is maintained by the entity
    (c) When the data is relevant to the non-covered entity's workflow
    (d) When the non-covered entity signs a business associate agreement

94. A project requires all team members to eat together, but none may eat until the CEO sits down to eat. What type of dependency is this?
    (a) Finish to finish
    (b) Finish to start
    (c) Start to finish
    (d) Start to start

95. A software developer creates a Clinical Decision Support system which suggests an inappropriate medication and dosage for a patient, who is ultimately injured. Which of the following arguments (if true) would provide the BEST protection to the software developer?
    (a) The clinician should have known that the suggested dosage was incorrect
    (b) The hospital has a service-level agreement with the vendor
    (c) The user agreed to an End User License Agreement when he logged in
    (d) The software was provided AS IS with no warranty

96. In the process of making a decision, satisficing is
    (a) Choosing an acceptable result instead of searching for an optimal result
    (b) Making a rapid "gut feeling" decision with little to no research at all
    (c) Maintaining multiple opportunities in order to eventually select one
    (d) Performing extensive research prior to deciding

97. What is one disadvantage of a survey methodology for understanding user perspectives:
    (a) Surveys are time consuming and expensive to administer
    (b) Surveys can only reach a limited number of participants
    (c) Surveys require expert moderators to administer
    (d) Surveys may not be detailed enough to capture a user's true feelings or complete opinions about the system

98. The branch of informatics which involves teaching patients to manage their own health and make their own healthcare decisions is
    (a) Applied Informatics
    (b) Clinical research informatics
    (c) Consumer health informatics
    (d) Translational bioinformatics

99. The System Development Life Cycle has been described by many authors. Which of the following is LEAST likely to be one of the phases?
    (a) Analysis
    (b) Design
    (c) Disposal
    (d) Payment

100. After installation of an Electronic Health Record (EHR), all physicians with a degree of Doctor of Osteopathy (DO) find that they are unable to enter orders, while doctors with a degree of Medical Doctor (MD) are still able. A review of the hospital by laws shows that there is no distinction made between different types of doctors. What is the most likely cause of the problem?
    (a) DOs are not legally allowed to order medications
    (b) Physician Assistants (PAs) have order-writing capability
    (c) The EHR permission system has become corrupted
    (d) There was an error in setting up role-based permissions for DOs

101. The majority of clinical research in the US is sponsored by
    (a) Academia
    (b) Charity
    (c) National Institute of Health
    (d) Industry

102. The Interstate Medical Licensure Compact proposed enacting the TELE-MED Act of 2015 in order address which of the following barriers to the adoption of telemedicine?
    (a) Cost
    (b) Legal
    (c) Social
    (d) Technology

103. Which of the following message types is least human-readable in its common form?
    (a) Continuity of care document (CCD)
    (b) Digital Imaging and Communications in Medicine (DICOM)
    (c) Fast Healthcare Interoperability Resources (FHIR)
    (d) Health Level Seven (HL7) V3 document

104. Which of the following is an intentional activity that realigns the performance of the project work with the project management plan?
    (a) Corrective action
    (b) Integrated change control
    (c) Project acquisition
    (d) Risk control

105. Which regulatory task is generally managed by state government
    (a) Accreditation of hospitals
    (b) Administering board certification examinations
    (c) Licensure of physicians
    (d) Permission to begin clinical trials on a new drug

106. The purpose of Clinical Decision Support is to
    (a) Decrease third party payments
    (b) Display web-based prompts leading to medical websites
    (c) Reduce physicians' cognitive burden
    (d) Show Pop-up alerts interrupting work flow

107. Selecting the best usability method depends on:
    (a) Effective role-playing and cognitive walkthroughs
    (b) Security concerns
    (c) Using software developers as testers
    (d) The organization's goals and constraints (e.g. budget, timeline, etc.)

108. Normalized database tables
    (a) Are prone to data anomalies, such as when deletion of one row of data causes loss of other data
    (b) Contain indexes to make database queries more accurate
    (c) Have less duplicated data and tend to take up less space on disk
    (d) Tend to be faster to query than denormalized databases because the process by which the database searches for matching fields is very efficient

109. According to the the Institute of Medicine' report *Crossing the Quality Chasm: A New Health System for the 21st Century*, educating patients, providing comfort, involving friends and family are all aspects of which quality component?
    (a) Effectiveness
    (b) Efficiency
    (c) Patient-centeredness
    (d) Safety

110. Clinical Decision Support systems are most likely to give inappropriate advice in which situation?
    (a) When users become inured to its alerts
    (b) When used with patients having unusual constellations of symptoms
    (c) When the system requires structured data input
    (d) When the CDS is physically removed from the patient bedside

111. A researcher evaluates eight patients with a novel disease and wishes to publish his findings. This type of article would most likely be considered
    (a) Case series
    (b) Editorial
    (c) Method Paper
    (d) Original research

112. Which of the following is the first step in improving a team's effectiveness?
    (a) articulating team goals
    (b) Beginning the work
    (c) clarifying individual roles
    (d) defining rules of operation

113. The waterfall software design method
    (a) Is designed to allow users to change project requirements at any time during the design process as long as the delivery date is not changed
    (b) Is modeled after manufacturing design methods
    (c) Is sometimes called a "top-down" process because design starts with a user interface prototype
    (d) Stresses user interaction during the software writing process

114. In an ideal ontology, meanings should refer to no more than one concept. This is known as
    (a) Nonambiguity
    (b) Nonredundancy
    (c) Nonvagueness (specificity, definition)
    (d) Versioning

115. Which of the following falls OUTSIDE the realm of a practitioner of public health
    (a) Creating laws to limit spread of illicit drugs
    (b) Educating people on the risks of sun exposure
    (c) Syndromic surveillance
    (d) Advising government to restrict travel of persons infected with contagious illness

116. At the midpoint of a project, the project manager estimates that the work already done is worth about $100,000. He has spent $75,000 of his budget. On his timeline, he expected to have $85,000 of the work done by this point. How is the project progressing?
    (a) The project is ahead of schedule and under budget, which means there is a positive schedule variance and a negative cost variance
    (b) The project is ahead of schedule and under budget, which means there is a positive schedule variance and a positive cost variance
    (c) The project is behind schedule and under budget, which means there is a negative schedule variance and a negative cost variance
    (d) The project is ahead of schedule and under budget, which means there is a negative schedule variance and a negative cost variance

117. A hospital turns to a member of the medical staff to lead a project by setting a good example and encouraging his colleagues to follow. This person is referred to as a
    (a) Champion
    (b) Designer
    (c) Developer
    (d) Officer

118. Which network topology is most resistant to a single point of failure?
    (a) Mesh
    (b) Point-to-point
    (c) Snowflake
    (d) Star

119. Which of the following is true of statistical methods used in meta-analysis?
    (a) The mean difference (MD) is used for binary events, such as death, complication, and recurrence of disease
    (b) The mean difference (MD) is used for numeric events such as measurements
    (c) An odds ratio equal to 1 generally indicates there is a treatment benefit
    (d) The narrower the range of the confidence interval, the more general the study's estimates, and the more confident you can be that the result is due to chance

120. One of the problems that has been "solved" by the transition from paper records to electronic records is:
    (a) auditing access to medical records is more reliable
    (b) physicians documentation is considerably easier
    (c) privacy has been improved
    (d) standard vocabularies and terminology have been widely implemented

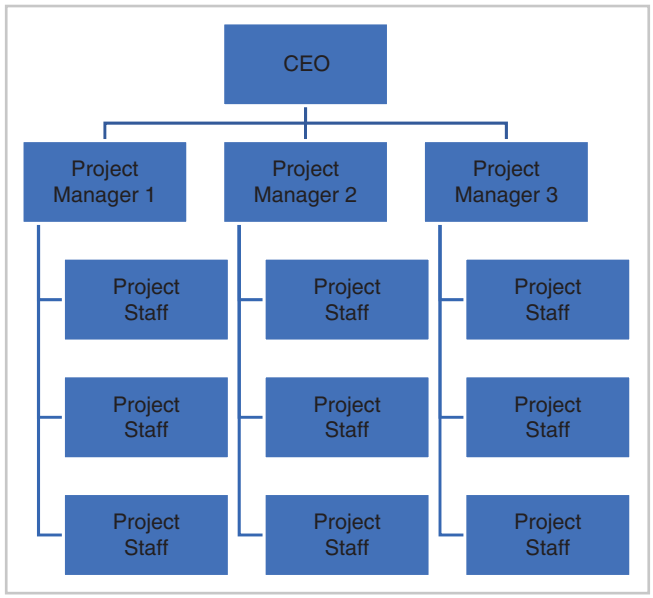
121. Which of the following would be detected by an internal scan of a SWOT analysis?
(a) Regional drought
(b) Highly skilled workers
(c) National recession
(d) Pending legislation

122. The five rights of clinical decision support refer to
(a) A framework to plan and implement Clinical Decision Support intervention
(b) A "star" network with right angles in Clinical Decision Support programming
(c) Documentation of governmental medical intercession
(d) Legal ramifications of implementing alerts

123. The rate of adoption varies from innovation to innovation but is always:
(a) logarithmic with laggards at the bottom and innovators at the top
(b) inversely proportional to accessibility
(c) an S-curve with innovators on the lower part of the S and laggards at the top i.e. slow at first as innovators begin adoption, followed by a phase of rapid acceptance, followed by another plateau as laggards join in
(d) a bell shaped distribution

124. A hospital is trying to develop a policy on whether or not to include a new drug on their formulary. The chief informaticist performs an exhaustive review of the literature, selecting manuscripts based on an explicit search strategy. He records his findings and presents them to the Pharmacy and Therapeutics Committee of the hospital. He has performed
(a) Chart Review
(b) Meta-analysis
(c) Randomized Controlled Trial
(d) Systematic Review

125.



What kind of organizational chart is depicted?
(a) Functional organizational chart
(b) Geographic organizational chart
(c) Matrix organizational chart
(d) Project organizational chart

126. Which motivational theory states that one's needs are a direct result of their previous encounters:
    (a) Herzberg's Motivation-Hygiene theory
    (b) Lewin's Change Theory
    (c) Maslow's hierarchy of needs
    (d) McClelland's acquired needs theory

127. This standard is part of the Unified Medical Language System defined by the U.S. National Library of Medicine, and incorporates medication data from products such as First Databank, Gold Standard Drug Database, and Multum, and can mediate messages between systems not using the same software and vocabulary
    (a) National Drug Code Directory
    (b) National Drug File (NDF-RT)
    (c) Protein Data Bank
    (d) RxNorm

128. A software product is upgraded from version 2.0 to 2.1, and a user notes that it is no longer able to print reports the way it used to. This defect could most likely have been detected with
    (a) Installation testing
    (b) Regression testing
    (c) Unit testing
    (d) White-box testing

129. The PRECEDE/PROCEED program:
    (a) is a planning model for change
    (b) is a single change theory
    (c) describes specific interventions in detail
    (d) does not incorporate epidemiological, behavioral or environmental assessments

130. An assembler
    (a) Converts a FORTRAN program to machine language
    (b) Is required for all interpreted languages
    (c) Makes source code more readable
    (d) Translates assembly language to machine code

131. A research study found no difference in outcome between people who had surgery for appendicitis versus those who had conservative treatment with antibiotics. The researchers then performed a post-hoc analysis and found that patients with ruptured appendicitis fared much better with surgery. In order to reach their conclusion, the researchers employed a/an
    (a) Ecological study
    (b) Hypothesis generation
    (c) Subgroup analysis
    (d) Surrogate marker

132. An informaticist is asked to debug a running system which is protected by a firewall. He connects remotely from his home using a program that makes it seem as though his home computer is actually a node on the remote network. This technique is called
    (a) Port forwarding
    (b) Remote desktop
    (c) Virtual machine
    (d) Virtual private network

133. Intentionally duplicating data within a database table to improve speed is called
    (a) Database Join
    (b) Denormalization
    (c) Query
    (d) Update anomaly

134. Writing software tests to ensure the functionality of software is a key feature of
    (a) Rapid application Development
    (b) Scrum
    (c) Test-Driven Development
    (d) Xteme Programming

135. The Reference Information Model was designed to improve
    (a) Human Readability
    (b) Patient Outcomes
    (c) Semantic Interoperability
    (d) Timely Reimbursement

136. Which of the ACID guarantees is violated when a transaction containing two separate updates is interrupted in the middle, resulting in one completed update and one failed update?
    (a) Atomiticity
    (b) Consistency
    (c) Isolation
    (d) Durability

137. An employer requires fluency in Mandarin as a job specification. This will likely result in
    (a) Disparate impact
    (b) Disparate treatment
    (c) Discrimination
    (d) Selection bias

138. Which of the following entities is LEAST LIKELY to be a stakeholder in an Electronic Medical Record (EMR) project
    (a) A competing medical center
    (b) Hospital employees who will be using the system
    (c) Member of the medical staff who is not an employee and opposes the new EMR
    (d) Regulatory agencies

139. A characteristic of horizontal system integration is
    (a) Each system is directly connected to every other system
    (b) The cost for developing this type of system includes creating an interface for each component as well as creating an enterprise service bus
    (c) The overall entity is relatively stable, because there is no single point of failure
    (d) Similar systems are grouped together, thus reducing the number of interfaces that must be created

140. A study evaluated the association between cell phones and brain cancer. The researchers discovered that brain cancer occurred in 20 of 10,000 people who had cell phones and in 10 of 10,000 people without cell phones. Approximately how many additional people would have to get a cell phone to cause one case of brain cancer?
    (a) 100
    (b) 1000
    (c) 5000
    (d) 10,000

141. In a present-day circuit switching telephony network, the connection between two nodes is
    (a) Created by transmitting quanta (or packets) of information over public networks
    (b) Established by an automatic switch
    (c) Managed by a human operator inserting a jack into a receptacle
    (d) Shared among other users of the system

142. What kind of integrity violation occurs when a database table contains a foreign key which does not exist in the primary table?
    (a) Logical or domain integrity
    (b) Physical integrity
    (c) Referential integrity
    (d) Table integrity

143. Fast Healthcare Interoperability Resources (FHIR) is a trademark of Health Level 7 (HL7), and are defined by these web protocols:
    (a) Javascript Object Notation (JSON), eXtensible Markup Language (XML), Resource Description Framework (RDF) Turtle
    (b) Hypertext Markup Language (HTML), Domain Name Service (DNS), Kerberos, Lightweight Directory Access Protocol (LDAP)
    (c) Hypertext Transport Protocol (HTTP), Representational State Transfer (REST), OAuth, OpenId
    (d) Hypertext Transport Protocol (HTTP), Simple Object Access Protocol (SOAP), eXtensible Markup Language (XML), OpenId

144. The programming control structure which instructs a computer to repeat a section of code is called a/an
    (a) If/then/else block
    (b) Loop
    (c) Recursion
    (d) Syntax

145. An information retrieval (IR) specialist is concerned with the number of non-relevant documents in his collection. He finds that his search program inappropriately retrieves 6% of the total number of irrelevant documents. What has he measured?
    (a) Fallout
    (b) Precision
    (c) Recall
    (d) Specificity

146. The typical steps in a Clinical Practice Guideline algorithm include the following:
    (a) Action, Conditional, Branch, and Synchronization
    (b) Action, Outcomes, Likelihood ratios, and Risks
    (c) Conditionals, Alternatives, Outcomes, and Synchronization
    (d) Treatments, Outcomes, Alternatives, and Odds Ratio

147. The HIPAA security rule describes an addressable regulation as one that
    (a) is a clearly defined requirement
    (b) is a selection from a menu of choices
    (c) is based on the location of the covered entity
    (d) May be met in several different ways

148. Job Costing is an important managerial accounting function which
   (a) Analyzes trends of costs and revenues to detect anomalies
   (b) Calculates the profits from various products and services
   (c) Estimates the amount of money an organization requires to produce products
   (d) Reports the estimated budget for all goods and services which will be sold in the coming year

149. A data warehouse, unlike a database
   (a) May use a combination of optical, magnetic and solid-state media
   (b) Represents data specific to a smaller organizational unit, like a department
   (c) Requires real-time data
   (d) Usually contains denormalized data for analytics

150. Which of the following federal acts introduced Meaningful Use rewards
   (a) American Recovery and Reinvestment Act of 2009 (ARRA)
   (b) Health Insurance Portability and Accountability Act of 1996 (HIPAA)
   (c) Patient Protection and Affordable Care Act of 2010 (PPACA)
   (d) The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA)

151. This format was developed in 1994 by Clem McDonald, then investigator at the Regenstrief Institute in Indiana, and is used as a standard for identifying health measurements, observations, and documents commonly used in laboratories
   (a) Current Procedural Terminology
   (b) International Society of Blood Transfusion—BarCode 128
   (c) Laboratory Code Sets Distribution
   (d) Logical Observation Identifiers Names and Codes

152. Which of the following decision-making activities is LEAST likely to be viewed as an external representation?
   (a) Sketching a diagram to assist with brainstorming
   (b) Using pen and paper to assist with a math equation
   (c) Using well-organized computer displays to retrieve information critical to patient care
   (d) Working with other healthcare providers to coordinate patient care plans in the intensive care unit

153. A 17-year old girl is treated for a sexually transmitted disease. Her mother requests online access to her medical records. Ethically, should the mother be given access?
   (a) Since the girl is an emancipated minor, she is viewed as an adult, and the mother has no right to her records
   (b) Since the girl is under the age of majority (i.e. 18), her parents act as her "personal representative" under HIPAA and can view her records
   (c) Certain conditions, such as treatment of sexually transmitted diseases, are protected from the usual rules requiring adult consent. Therefore, any information resulting from such a protected encounter must remain private. However, the rest of her medical information may be disclosed
   (d) Since the mother is the holder of insurance for the child, she is classified as a payor, and is given routine access to her medical records

154. When Electronic Health Record (EHR) data is fed directly to a regional Health Information Exchange (HIE), which of the following data provides the earliest clues to detect emerging infectious disease?
   (a) Blood culture results
   (b) Insurance utilization data
   (c) Physician referral patterns
   (d) Syndromic surveillance data

155. Computer-interpretable guidelines (CIGS) are effective if they
    (a) Allow for physician personal preferences
    (b) Are incorporated into the clinical workflow
    (c) Are endorsed by the major insurers
    (d) Match geographical social variability

156. According to the leadership/managerial grid, a person who manages by making rules and does not tolerate dissent would also have
    (a) High concern for task and High concern for people
    (b) High concern for task and Low concern for people
    (c) Low concern for task and High concern for people
    (d) Low concern for task and Low concern for people

157. When an unsigned integer is stored in memory, increasing the number of storage bits increases the
    (a) Exponent
    (b) Maximum allowed value
    (c) Minimum allowed value
    (d) Precision (significant digits)

158. A change control process is a mandatory aspect of
    (a) Data Quality Management
    (b) Downtime procedures
    (c) Preventive maintenance
    (d) Tailoring

159. Over time, we can expect the present value of cash
    (a) Increase
    (b) Stay constant
    (c) Equal the future value
    (d) Decrease

160. The best reason to consider conducting a usability test in a laboratory setting is when your team:
    (a) Expects to have a difficult time gathering users in a central location
    (b) Has a short timeline to gather user opinions
    (c) Has a small budget for usability testing
    (d) Is evaluating a system that includes sensitive information that needs to be protected

161. The distinctions between leaders and managers is best described as
    (a) Leaders inspire followers, while managers employ subordinates
    (b) Leaders usually occupy important offices in an organization, while managers tend to be lower in the hierarchy
    (c) Leaders are often very particular about how work should be completed, while managers more commonly use laissez-faire methodology
    (d) Leaders enforce logic and calculation, while managers appeal to passions and hopes.

162. Why are generic drugs often as expensive as brand name drugs?
    (a) Brand name drugs are often listed on discount formularies
    (b) Generic drugs have higher quality components
    (c) Generic manufacturers are not as efficient at producing drugs
    (d) When only a single generic manufacturer exists, it will charge whatever price it can

163. When evaluating a clinical information system, qualitative analysis is preferred to quantitative analysis when
    (a) The criteria for success are well defined
    (b) The denominator is small
    (c) The outcome studied is part of a national guideline
    (d) There is a fixed timeframe for the study

164. Health Level Seven Version 2 (HL7 V2) messages have limited use in interoperability because
    (a) Implementations of HL7 V2 vary from vendor to vendor
    (b) Extensive metadata accompanying messages enhances data context
    (c) HL7 V2 has been largely supplanted by newer protocols for healthcare messaging
    (d) The lack of binary encoding limits the transmission size

165. Reasons to use formal group management processes (as opposed to unstructured meetings) include
    (a) Allowing leaders to voice their opinions
    (b) Avoiding the central tendency effect ("groupthink")
    (c) Cost
    (d) Scheduling unstructured meetings may be difficult

166. Which of the following exists within the "Gulf of Execution" in Norman's Theory of Action?
    (a) Categorize action choices by difficulty
    (b) Define available gulfs
    (c) Evaluate sources of inaction
    (d) Perceive the state of the world

167. Clinical informatics is chiefly concerned with
    (a) Bringing knowledge from findings in the physical world to clinical practice
    (b) Building a better electronic medical record
    (c) Compilation and analysis of "big data"
    (d) Creating larger clinical trials

168. A consultant is hired to assess the corporate culture for an organization. Which of the following is the best method?
    (a) Analyze the company's product and service offerings
    (b) Evaluate the company's regulatory filings (e.g. with the Internal Revenue Service)
    (c) Examine the marketing materials produced by the company
    (d) Review the policy manual to determine what employees are expected to do

169. In the healthcare delivery system, the relationship between a state licensing board and an individual nurse anesthetist can be best described as
    (a) Exempt
    (b) Regulatory
    (c) Statutory
    (d) Supervisory

170. Research studies of clinical decision support
    (a) Are exhaustive and reassuring
    (b) Are overwhelmingly positive
    (c) Focus on changes in patient outcomes
    (d) Show that Clinical Decision Support can alter decisions and actions

171. Which of the following sources of evidence is LEAST likely to change an established understanding?
(a) All-or-none randomized controlled trials
(b) Case-control study
(c) Prospective cohort study
(d) Systematic review of randomized controlled trials

172. A corpus of information holds 25 documents which are labeled with the letters from A to Y. The set of documents related to a certain disease are: A, B, C, D, E, F, G, H and I. What is the precision of a search algorithm that yields A, I, K, M, N, O, T and W?
(a) 15%
(b) 25%
(c) 50%
(d) 75%

173. Which legislative act fueled the advancement of health informatics in the United States, attempting to catch up with other countries?
(a) Health Information Technology for Economic and Clinical Health Act (HITECH)
(b) Health Insurance Portability and Accountability Act (HIPAA)
(c) Patient Protection and Affordable Care Act (PPACA)
(d) Health Care and Education Reconciliation Act

174. This standard was developed by the College of American Pathologists, and includes anatomy, diseases, findings, procedures, microorganisms, and other substances. It includes structural representation of human and veterinary subjects, and provides a topographic axis to locate disease according to body organ.
(a) International Classification of Diseases
(b) Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT)
(c) Tournoux-Talairach Atlas
(d) Web Ontology Language

175. According to the Data-Information-Knowledge-Wisdom framework, at what phase are ethical considerations applied to clinical care?
(a) Data
(b) Information
(c) Knowledge
(d) Wisdom

176. In the Health Level 7 V2 fragment below, what do the vertical bars (|'s) and carets (^'s) represent?
MSH|^~\&|CE|001|RD|001|201704080113||
ORM^O01|212358388404784272|P|2.2|||AL|AL
PID|||000587355||DOE^John^A||19491104|M||B|300 CENTRAL AVE^FL 2^EAST ORANGE^NJ^07018||(973)266-3307|(973)266-3307|EN|S|CA|3251075|580485125||||VI
(a) Error flags
(b) Field Delimiters
(c) Missing values
(d) Unprintable characters

177. The Worshipful Company of Parish Clerks kept weekly mortality statistics in London from 1592 to 1595 and then continuously from 1603. These London Bills of Mortality were developed by John Graunt, William Farr, Sauvages, Linnaeus, and William Cullen into the standard that we know now as:
(a) The Diagnostic and Statistical Manual of Mental Disorders
(b) The International Classification of Diseases
(c) The Nuremberg Code
(d) The World Health Organization Global Epidemiological Surveillance Standards

178. Which of the following is a component in calculation of the work Relative Value Unit (RVU) for concepts in Current Procedural Terminology?
(a) Cost of liability insurance
(b) Cost of materials required for the procedure
(c) Geographical location where procedure is performed
(d) Technical skill required for the procedure

179. Which of the following is the MOST important factor for creating effective collaboration?
(a) Extensive training
(b) Individual dominance
(c) Similar education among team members
(d) Trust among participants

180. A medical student notices that a comatose patient twitches his hand on occasion. Despite no change in the neurologic exam, he reports that the muscle twitch is a sign that the patient is improving. This suboptimal interpretation of events could be due to:
(a) Anchoring Bias
(b) Blois' decision making
(c) Confirmation Bias
(d) Value Bias

181. Which of the following can be used to ensure logical integrity in a database
(a) Column values are limited by a sanity check
(b) Database access is restricted to database administrators (DBAs)
(c) Every table has a primary key
(d) Regular backups are made

182. Which of the following allows a project risk manager to prioritize resources among several identified risks?
(a) control chart
(b) Monte Carlo simulation
(c) probability impact chart
(d) responsibility activity matrix

183. Gathering new information (past history, family history, etc.) from an admitted patient that helps define that patient's pretest probability of having a certain disease state, and then using this prevalence of disease to interpret diagnostic testing, is an example of what model of decision making?
(a) Additive model
(b) Algorithmic model
(c) Bayesian model
(d) Blois' model

184. An informaticist is reviewing national data for incidence of stroke using an Online Analytic Processing database. She decides to compare different regions to each other. What type of data manipulation does she need?
(a) Dice
(b) Drill-down
(c) Pivot
(d) Roll-up

185. According to Bridges' Transition Model, what is "transition"?
    (a) A stage of delivery
    (b) A word used to mark a new paragraph
    (c) An environmental shift
    (d) The state that change puts people into

186. Maintaining Clinical Decision Support requires
    (a) A knowledge base that is unchanging
    (b) Autonomously functioning physicians
    (c) Little to no physician involvement
    (d) Ongoing resources and provisions

187. A database schema
    (a) Consists of one indivisible piece of information
    (b) Defines the type of data that each column in a table can accept
    (c) Delineates the order in which database rows are stored on disk
    (d) Ensures that data are normalized

188. Which of the following is MOST LIKELY to be a corporate vision statement for a healthcare company?
    (a) To complete purchase of a new building
    (b) To increase sales by at least 50% compared to last year
    (c) To protect the world's health
    (d) To upgrade the computer system to version 2.4 on all workstations by the end of the month

189. When a hospital verifies a patient's insurance, which standards development organization (SDO) is most likely involved?
    (a) Accredited Standards Committee X12N
    (b) American National Standards Institute (ANSI)
    (c) National Electrical Manufacturers Association (NEMA)
    (d) United States Food and Drug Administration (FDA)

190. Which term best describes the sum of the products, services, and results to be provided as a project?
    (a) Activity
    (b) Milestone
    (c) Program
    (d) Scope

191. A search algorithm results in precision = 60% and recall = 40%. There are 125 items in the corpus. What is the F1 score?
    (a) 24%
    (b) 40%
    (c) 48%
    (d) 100%

192. Medicare's Inpatient Prospective Payment System (IPPS)
    (a) reimburses hospitals based on the complexity of the diagnosis
    (b) reimburses hospitals on a per-diem basis
    (c) reimburses hospitals on a per-service basis
    (d) reimburses physicians based on the complexity of the diagnosis

193. The need for achievement based on McClelland's acquired needs theory could be best satisfied by:
   (a) Becoming an influential leader
   (b) Being accepted by a group
   (c) Being well liked
   (d) setting/achieving challenging personal goals

194. A researcher is studying asthma. Using a population database from a Health Information Exchange database, he identifies 1000 people with asthma. He then reviews the demographics for those patients and identifies another group of 1000 patients with roughly the same age, socioeconomic status and geographical distribution. He then reviews the patient records for evidence of lead exposure. The type of study performed is
   (a) Case-control study
   (b) Cross-sectional study
   (c) Prospective cohort study
   (d) Randomized study

195. Which of the following is a constraint on the Reference Information Model (RIM)?
   (a) Continuity of Care Document (CCD)
   (b) Extensible Markup Language (XML)
   (c) Health Level Seven (HL7) V2.5.1 messages
   (d) Systematized Nomenclature of Medicine (SNOMED)

196. According to the Strength of Recommendation Taxonomy (SORT), recommendations based on which of the following would have the BEST strength?
   (a) Consensus of world experts
   (b) A case series of 21 patients
   (c) A study showing that treatment resulted in statistically significant decrease in counts of fungal cells on days 3, 7 and 21.
   (d) A study showing that treatment resulted in statistically significant fewer days off work

197. According to the Situational Leadership Model,
   (a) Highly effective leaders should delegate decision-making responsibility in most situations
   (b) Great leaders have particular traits, many of which are innate
   (c) Situational Awareness is the ability to stay focused on a task in a particular situation
   (d) The leader varies the degree of supervision based on the maturity of the subordinate

198. Physicians tend to increase the intensity and diversity of services in which of the following payment models?
   (a) accountable care organization
   (b) capitation
   (c) fee for service (FFS)
   (d) inpatient prospective payment system (IPPS)

199. "When you hear hoofbeats, think of horses, not zebras" is a warning to avoid what type of cognitive bias?
   (a) Anchoring bias
   (b) Belief bias
   (c) Representativeness bias
   (d) Value bias

200. Of the following group management processes, which does not require face-to-face communication?
   (a) Consensus Mapping
   (b) Delphi
   (c) Groupthink
   (d) Nominal Group

201. Several authors have developed classifications for styles of conflict management. Which of the following is likely to be most successful?
   (a) Contending/Dominating/Competing
   (b) Inaction/Avoiding
   (c) Problem Solving/Integrating/Collaborating
   (d) Yielding/Obliging/Accommodating

202. Increased use of Clinical Decision Support in the United States is fueled by
   (a) Funding and policy initiatives
   (b) Patient survey responses
   (c) Physician mandates
   (d) Stabilization in technology

203. A researcher performs an observational study on pancreatic cancer in an inner city population and makes some conclusions about the population as a whole. Which of the following would indicate a lack of external validity?
   (a) The device used to measure pancreatic enzymes is not very accurate
   (b) The device used to measure pancreatic enzymes has not been calibrated and consistently measures approximately 50% too high
   (c) The inner city population has very poor access to healthcare and many untreated comorbidities when compared to the general population
   (d) There was essentially no blinding in the study

204. Below are listed several research projects. According to the GRADE criteria, in which of the following cases would the results of the study WEAKEN the strength of evidence?
   (a) A researcher performs a systematic review in order to compare drug A with drug B. He finds five studies comparing drug A with placebo and eight studies comparing drug B with placebo
   (b) A researcher notes that for every milligram of drug A that is given over a certain range, there is a small but measurable change in outcome
   (c) A researcher studies medication compliance in patients with and without hip fracture by measuring attendance at routine office visits. He notes that patients with hip fracture are more likely to come to clinic than those without
   (d) A researcher studies a new drug for cardiac arrest. He finds that 8/8 patients given the drug survive, while 0/9 who are not given the drug survive

205. The health information organization most closely associated with the board exam in clinical informatics is
   (a) Health Level Seven International (HL7)
   (b) The American Medical Association (AMA)
   (c) The American Medical Informatics Association (AMIA)
   (d) The Healthcare Information and Management System Society (HIMSS)

206. After completing a research study, an investigator finds no difference between the standard of care and a novel therapy. His manuscript is rejected by a leading journal because the editor feels that his finding is not interesting enough for his readership. This is likely an example of
(a) Peer review
(b) Publication bias
(c) Rejection bias
(d) Selection bias

207. A novel drug claims that it can reduce leg cramps in people taking electrolyte solutions. The absolute risk reduction is 7% and the 95% confidence interval is −4.5% to 16%. Which of the following can be concluded about the utility of this drug?
(a) The number needed to treat is 7
(b) The number needed to harm is 18
(c) The hazard ratio is 1.66
(d) The findings are not statistically significant at the $p < 0.05$ level

208. The most important function of an index in information retrieval is
(a) Decrease fallout
(b) Facilitate tokenization
(c) Improve query speed
(d) Increase recall

209. PCR testing is used as a screening tool to rule out HIV infection before allowing potential donors to give blood. As the prevalence of HIV in a the population increases, the negative predictive value of this test will:
(a) Decrease
(b) Increase
(c) Not enough information to say
(d) Stay the same

210. Which telemedicine category and application are correctly paired?
(a) Remote Monitoring—teleICU
(b) Telephone—Picture Archiving and Communication System (PACS)
(c) Telepresence—US Poison Control
(d) Video Conferencing—scheduling

211. According to the Institute of Medicine' report *Crossing the Quality Chasm: A New Health System for the 21st Century*, what is one way to improve the health care system?
(a) Expand information technology
(b) Increase governmental oversight
(c) Promote use of non-physician providers
(d) Reduce costs

212. Which of the following negotiation techniques can be used to deliberately stall a negotiation
(a) appeal to a higher authority
(b) bringing external evidence to the negotiation
(c) create a win-win situation
(d) unbundle negotiable components

213. The p-value reported in a study indicates the likelihood that the results could be
    (a) Improperly measured
    (b) A result of bias
    (c) A result of pure chance
    (d) Published

214. Which of the following statements is most accurate with respect to grading of evidence?
    (a) Basic science studies have greater precision because the vagaries of human behavior are removed from the analysis
    (b) Case series are more accurate because all patients are evaluated by the same observer, eliminating inter-observer variation
    (c) Expert clinical opinion is based on multiple independent and well educated observers
    (d) Systematic reviews of multiple trials have the lowest risk of bias compared to other study types

215. From an ethical standpoint, Electronic Health Records tend to be better than traditional systems in which of the following categories?
    (a) Beneficence—An EHR is significantly better than a paper-based system in preventing misdiagnosis
    (b) Honesty—An EHR provides all information without deception
    (c) Justice—since electronic access is essentially free, all have equal access to modify their medical records
    (d) Least Intrusive Alternative—EHR's provide very fine access granularity so that only individuals with certain roles are able to access sensitive aspects of the chart

216. The board of directors as asked the CEO to purchase new technology but has refused to enlarge the budget, thus preventing the CEO from completing the task. This is an example of
    (a) authority without responsibility
    (b) responsibility without authority
    (c) responsibility with authority
    (d) neither authority nor responsibility

217. A nursing manager constructs a mathematical model for the productivity of a coronary care unit based on the number of staff members of different types. She determines that the impact of increasing the nursing staff by two nurses would nearly eliminate delays in care while increasing by one nurse would have only a modest benefit. This type of calculation is called
    (a) control chart
    (b) Monte Carlo analysis
    (c) run chart
    (d) sensitivity analysis

218. A study compared 90 cocaine users with 900 non-users and found that the hazard ratio for developing acute myocardial infarction was 8. If 15 people in the control group had acute MI, How many patients in cocaine group had an acute MI?
    (a) 9
    (b) 12
    (c) 15
    (d) 90

219. The most important benefit of good organizational governance is
    (a) increasing profits
    (b) rewarding workers for jobs well done
    (c) providing workers with a predictable and stable environment
    (d) ties with local municipal governments

220. Strategy implementation differs from strategy formulation in that
    (a) Strategy formulation involves more people than strategy implementation
    (b) Strategy formulation is an administrative task while strategy implementation is a primarily entrepreneurial activity
    (c) Strategy formulation is creative while strategy implementation is productive
    (d) Strategy formulation is less theoretical than strategy implementation

221. A medical clinic is interested in purchasing an MRI machine using its capital budget. The usable life of the MRI is 10 years. The accounting technique used to spread the cost of MRI over the length of its usable life is
    (a) Depreciation
    (b) Direct materials budget
    (c) Mortgage
    (d) Operating expense

222. A researcher discovers a new treatment that cures age related macular degeneration. When the treatment is applied, 100% of his subjects regain complete normal vision. Since his results are so successful, he opts not to use a control arm. He publishes a paper describing the success of seven patients. Which term best classifies this paper?
    (a) All-or-None study
    (b) Ethics violation
    (c) Ecological study
    (d) Randomized Controlled Trial

223. This standard supports workflow between machines such as microfiche readers, laser disk video players, and MRI scanners, and incorporates best practices from the International Organization for Standardization, the Joint Photographic Experts Group standards, and the Institute of Electrical and Electronics Engineers.
    (a) Compact Disc, Read Only Memory
    (b) Digital Imaging and Communications in Medicine
    (c) Ethernet Category 6
    (d) World Wide Web Consortium (W3C)

224. Which of the following would have the greatest effect on the health of a population?
    (a) Aggressively treating patients with resting systolic blood pressure between 180 and 200
    (b) Building more parks so that children have the option to play outside
    (c) Educating prospective parents about Tay-Sachs disease to prevent carriers from having children
    (d) Increasing restrictions on tobacco sales so that cigarettes are modestly harder to obtain

225. The means by which an organization sets out to achieve its goals is known as a/an
    (a) Resource
    (b) Strategy
    (c) Value chain
    (d) Vision

226. Persons table (version 1)

PERSONS		
ID	**FIRST_NAME**	**LAST_NAME**
1	Sal	Zindenbleourf
2	Scott	Mankowitz
3	Mark	Blake

Persons table (version 2)

PERSONS		
ID	**FIRST_NAME**	**LAST_NAME**
1	Sal	Zindenbleourf
2	Scott	Mankowitz
3	Mark	Mankowitz

Which of the following SQL commands will bring the **persons** table from version 1 to version 2?
(a) ALTER TABLE persons WHERE id = 3
(b) DELETE FROM persons WHERE First_Name = 'Mark'
(c) UPDATE persons SET Last_Name = 'Mankowitz'
(d) UPDATE persons SET Last_Name = 'Mankowitz' WHERE id = 3

227. Peer-reviewed journals are considered more reliable than non-peer-reviewed journals because
(a) Experts in the field of study are involved in the editorial process
(b) Journal editors are selected from more prestigious institutions
(c) Only randomized controlled studies can be published in peer-reviewed journals
(d) Peer reviewed journals require publication of all raw data

228. Physicians are distinguished from other providers of medical care in that physicians
(a) Can be sued for medical malpractice
(b) May perform complex surgical operations
(c) Must complete Continuing Education courses after graduation
(d) Possess doctoral degrees

229. Which of the following is LEAST likely to affect a make-or-buy decision?
(a) competitor's share of market
(b) cost of a pre-made product
(c) levels of expertise in current staff
(d) local availability of resources

230. The overarching desire to remove non-value-added aspects of a process is characteristic of which quality improvement methodology?
(a) Delphi
(b) Lean
(c) Plan-Do-Study-Act
(d) Six-sigma

231. This format was an early attempt at government led interoperability standards, and helps veterans download their health records from VistA, a health record system based on Cache/MUMPS (the same database used by Epic Systems)
(a) BlueButton
(b) Continuity of Care Document
(c) HL7 v2.x
(d) Veterans Analysis and Statistics (NCVAS)

232. In service industries, such as hospitals, a Human Resource Management objective would be
   (a) Decrease revenues
   (b) Improve customer loyalty
   (c) Minimize labor cost
   (d) Product innovation

233. As software creation progresses from development to implementation and beyond, software defects (bugs) become
   (a) Covered by various warranties and assurances
   (b) Easier to detect, but harder to fix
   (c) More costly to both detect and fix
   (d) More likely to be detected by static than dynamic testing

234. In assessing a company's capabilities, the VRIO (Value, Rareness, Imitability, Organization) framework is often used. Which of the following represents the WEAKEST capability?
   (a) A product which is easily made of expensive raw materials
   (b) A product made using a patented process
   (c) A service which is highly sought after
   (d) A service which can be provided on a large scale

235. When de-identifying a document, why is date of birth considered more significant than a patient's account number?
   (a) A patient may have several account numbers but only one date of birth
   (b) Duplicate testing is less likely when both name and date of birth are given
   (c) Date of birth may be found in publicly accessible databases
   (d) Treatment of medical illness can change based on the patient's age

236. A physician practice is considering a commodity software purchase. Which request is most appropriate?
   (a) Request for Information
   (b) Request for Proposal
   (c) Request for Quotation
   (d) Software Development Life Cycle

237. Lewin's three steps of change include:
   (a) plan, do, act
   (b) unfreezing, moving, refreezing
   (c) disassemble, reassemble, assimilate
   (d) ungroup, group, regroup

238. Information processing tools which are used to quickly decide the best course of action or decision and often lead to shortcuts in evaluation and occasionally suboptimal results are called:
   (a) Bayes Theorem
   (b) Cognitive bias'
   (c) Decision support systems
   (d) Heuristics

239. In the Systematized Nomenclature of Medicine (SNOMED), integer codes are assigned to terms which are unrelated to their position in the hierarchy (e.g. non-semantic encoding). Which of the following is the LEAST compelling argument for using non-semantic concept identifiers?
(a) Assuming the ontology respects concept permanence, the code can never be reclassified if the meaning evolves or the classification scheme changes
(b) Hierarchical terminologies, such as the International Classification of Diseases (ICD-10) with limited code sizes may run out of space
(c) In an ontology that supports multihierarchy (polyhierarchy), a code can be assigned to only one hierarchy
(d) Integers allow for significantly more rapid data processing

240. Given the matrix below, if a patient has a positive test, what are the chances that the patient has the disease being tested for?

	DISEASE	NO DISEASE
Test +	19	1
Test –	2	439

(a) 10%
(b) 27%
(c) 73%
(d) 95%

241. Which of the following is an established Change Management strategy?
(a) Communicate the expected behaviors to rank and file while maintaining need-to-know secrecy regarding the ultimate vision
(b) Consolidate all decision-making with as few as possible highly-trained individuals
(c) Establish a guiding coalition of organizational leaders to champion the change
(d) Use short term wins to define the mission and vision for the project

242. An operational budget is most likely funded with
(a) Cash flow
(b) Debt
(c) Equity
(d) Retained earnings

243. In the Open Systems Interconnect (OSI) network model, which of the following would be the lowest layer?
(a) Distributed Applications
(b) Fiber optic cable
(c) Networking protocols
(d) Passwords

244. Which of the following activities is a part of the initiating phase of integration management?
(a) Conduct procurements
(b) Create and develop the project team
(c) Human Resource planning
(d) Write the project charter

245. A/B testing is most effective when used to:
   (a) Allow users to express their expectations for the system
   (b) Determine which of two alternatives is better received by users
   (c) Gather user opinions on how an interface should be designed
   (d) Understand how the system interacts with existing workflows and technologies

246. Conflict management is generally better than conflict resolution because
   (a) Conflict management minimizes the negative aspects of conflict while preserving positive ones
   (b) Conflict resolution is better in high-stress environments
   (c) Conflict resolution is more likely if the parties show high assertiveness and high cooperativeness
   (d) Negotiation often fails to bring resolution

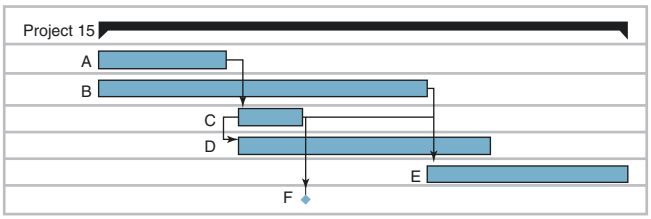
247. Which of the following operators is LEAST likely to be seen in the Keystroke-Level Model (KLM)?
   (a) Mental preparation of an action
   (b) Pointing the mouse to a target
   (c) Pressing a key
   (d) Sketching a diagram to assist with brainstorming

248. A clinical study involving Drug X was criticized for lack of appropriate blinding. Which of the following could have been the reason?
   (a) Patients were excluded from the study if they did not make follow-up appointments
   (b) Patients were selected from a single ethnic group
   (c) The investigator knew which patients received drug X and which did not
   (d) The statistical methods used did not report confidence intervals

249. A medical journal specialized in application or method papers. Which of the following titles most likely belongs to a method paper
   (a) An unusual case of pulled hamstring and sarcoidosis
   (b) Epidemiology of pulled hamstrings in the US: 2012–2016
   (c) Hamstring injury during acrobatics: case report and review of the literature
   (d) Technique to apply infiltrated lidocaine to pulled hamstrings

250. Clinical Decision Support has shown benefits in
   (a) Aiding in diagnosis, treatment guidelines, clinical pathway adherence
   (b) Improving patient outcomes and decreasing morbidity
   (c) Improving physician efficiency and satisfaction
   (d) Decreasing errors in data entry

251. Which of the following is the most valid outcome measure of a process to maintain an active medication list for all patients?
   (a) attainment of meaningful use status
   (b) demonstrating that over 90% of patients have at least one medication listed in the medical record
   (c) fewer adverse drug interactions
   (d) reduction of medication costs

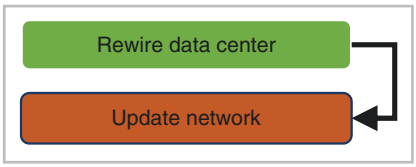
252. 

In the Gantt chart above, what does F represent?
(a) Milestone
(b) Float
(c) Start-Start dependency (SS)
(d) Summary Task

253. Which of the following is an example of distributive bargaining (distributive negotiation)
(a) defending a medical malpractice case
(b) forming a partnership
(c) hiring a consultant
(d) setting a price for a new x-ray machine

254. A video tool is being employed by a rural hospital without on-site trauma services that allows for the emergency medicine physician to share real-time video of possible traumatic emergencies. This an example of which form of communication:
(a) Asynchronous
(b) Remote monitoring
(c) Store and forward
(d) Synchronous

255. Given that a certain patient has a disease, the probability of a test being positive is known as
(a) Sensitivity
(b) Specificity
(c) Positive Predictive Value
(d) Negative Predictive Value

256. 

The above diagram represents a dependency on a Gantt chart. Which statement below is equivalent?
(a) The data center must be rewired after the network is updated
(b) Do not begin updating the network until the data center is completely rewired
(c) The network must be updated before the data center can be rewired
(d) The network update can not be completed until the data center is completely rewired

257. An informaticist is concerned about how users are interacting with a clinical information system. She finds that patient temperature is sometimes stored in the temperature field and sometimes in a free text field. She beings an inservice training program in order to improve
(a) Data Stewardship/Data Quality
(b) Usability
(c) Referential Integrity
(d) Syntax

258. Unlike the ninth revision of the International Classification of Diseases (ICD-9), ICD-10
    (a) Allows for greater specificity
    (b) Has fewer concepts
    (c) Includes external causes in addition to diseases
    (d) Is hierarchical

259. Which telemedicine medium typically requires the highest amount of bandwidth and lowest latency?
    (a) Messaging
    (b) Remote monitoring
    (c) Telephone
    (d) Telepresence

260. User-centered design should:
    (a) Avoid evaluation of the system against organizational benchmarks
    (b) Be conducted only when health information systems are to be used by patients
    (c) Consider user goals, motivations, and environment throughout the design and development phases
    (d) Use market research as the main source for understanding user perspectives

Answers

1. **THE ANSWER IS B.** User testing is important to the development process, however there are surrogates to having actual users, such as role-playing. Delaying or discarding the system are inferior choices, as is implementing the system with no testing at all. (REF: Sect. 3.2.2—HCI Evaluation)

2. **THE ANSWER IS C.** Of all the determinants of individual and population health, the most significant contributors to morbidity and early mortality are behavioral, such as smoking, sedentary lifestyle, etc. The next most significant is biology, followed by social, medical and environment. (REF: Sect. 1.2.1—Determinants of Health)

3. **THE ANSWER IS C.** The probability of B can be expressed as the probability of A and B occurring together plus the probability of (not A) and B occurring together. The probability of A and B occurring is equal to the probability of A times the probability of B, given A. (REF: Sect. 2.1.2—Decision Science)

   $P(A \text{ and } B) = P(A) * P(B|A)$
   $P(A) + P(\text{not } A) = 1$
   $P(A \text{ and } B \text{ and } C) = P(A + B + C)$

4. **THE ANSWER IS D.** Process mining is a method of workflow analysis which involves researching the event log of an information system to find out how effective various processes are. Merging database tables using a common key is usually called a **join**. (REF: Sect. 2.3.1 Methods of Workflow Analysis)

5. **THE ANSWER IS C.** This question tests a simple definition, but even if you did not know the answer, you could probably eliminate some choices. We are looking for terms that convey communications as well as transition. A and D are quite unlikely. Choice C seems to express both those concepts well. (REF: Sect. 4.6.2—Change Theories)

6. **THE ANSWER IS B.** You should know a little about CAS, but even if you didn't, you should be able to eliminate choices A and D. A system which is adaptive should evolve and it should tend towards order. A system which is complex is more likely to be nonlinear than have central discipline. (REF: Sect. 4.6.2—Change Theories)

7. **THE ANSWER IS A.** Using familiar designs, such as a color scheme that follows cultural norms can shorten the learning process. Design should be consistent across the EHR and interfaces should not be cluttered with information. Feedback is important to notify the user that his task was successful. (REF: Sect. 3.2.3—Interface Design Standards and Design Principles)

8. **THE ANSWER IS C.** The Positive likelihood ratio is defined as the true positive rate divided by the false positive rate. (REF: Sect. 2.1.2—Decision Science)

$$\text{LR}(+) = \text{sensitivity} / (1 - \text{specificity}) = \text{TPR} / \text{FPR}.$$

$$\text{LR}(+) = \frac{TP/(TP+FN)}{FP/(FP+TN)} = \frac{20/(20+5)}{25/(25+100)} = 4$$

9. **THE ANSWER IS D.** Workflow reengineering involves finding different paths to the same goal. Hiring another manager to oversee production simply reinforces the original protocols. Similarly, hiring new employees to relieve a bottleneck may ultimately be a part of process reengineering, but not necessarily. Workflow reengineering can not be accomplished in a stepwise fashion, It is an all-or-none proposition. (REF: Sect. 2.3.2 Principles of Workflow Re-engineering)

10. **THE ANSWER IS B.** The negative predictive value is equal to the number of true negatives divided by the number of total negative test results, i.e. TN/(TN + FN). Likewise, PPV is equal to TP/(TP + FP). Sensitivity is a measure of the test being used and is equal to the true positives divided by all patients who have the disease being tested for, i.e. Sens = TP/(TP + FN). Likewise, Specificity is the number of true negatives divided by all the patients without the disease being tested for, i.e. Spec = TN/(FP + TN). (REF: Sect. 2.1.2—Decision Science)

11. **THE ANSWER IS C.** Fast Health Interoperability Resources is an emerging standard from Health Level Seven which uses standard well-established web technologies to transfer health information. It is expected that development costs for FHIR should be significantly less than other (proprietary) technologies. DICOM is a set of protocols for transmission of medical images. Although FHIR should run on inexpensive commodity hardware, choice C is a better answer. Alas, there are no unbreakable encryption techniques. (REF: Sect. 3.4.7 Interoperability Standards)

12. **THE ANSWER IS B.** The critical path of a project is the longest path from start to completion, which defines the minimum time required to complete the project. Slack or float is the degree to which a task can be postponed without delaying the end of the project. Tasks that fall along the critical path have no float. In this diagram, the critical path includes tasks B and E, so B has no float. (REF: Sect. 4.4.4 Project Management Tools)

13. **THE ANSWER IS C.** Review of medical records is only permitted in the context of a doctor-patient relationship, which clearly does not exist here. Even though the nurse knew that it was *possible* for people to snoop through her records, that does not give anyone permission to do so. The fact that the doctor has administrative privilege to review records does not give him ethical permission, even though his own health is at stake. (REF: Sect. 1.1.5—Ethics and Professionalism)

14. **THE ANSWER IS A.** The environmental scan identifies, among other things, strengths of the organization, such as competitive advantages. In general, vision and mission statements should be written before the environmental scan. Budgeting is done as part of setting up an action plan, after the environmental scan. Ensuring ethical behavior could be an aspect of an internal scan, but is still not as good an answer as identifying strengths. (REF: Sect. 4.5.2—Environmental Scanning)

15. **THE ANSWER IS B.** Among those items listed, the only one which would completely prevent a user from using the system is a password reset. If users do not have access to the system, they will find ways to bypass it, either by using downtime procedures or by using another user's password. Requests for additional training and non-critical bug fixes will be prioritized as resources allow. System lag is a very common complaint and is often multifactorial. A laggy system is frustrating, but still operational. (REF: Sect. 3.5.3—Clinical Information System Implementation)

16. **THE ANSWER IS B.** In general, hospitals are required to provide care for indigent patients under a number of different systems. Federal law requires emergency care to be provided regardless of ability to pay. In addition, many hospitals are required to provide a certain amount of indigent care in order to maintain their tax-free status. Finally, many hospitals have physician training programs (residencies) which are subsidized by the government in exchange for providing indigent care. In nearly all these cases, the cost of indigent care is never reimbursed at the same rate as regular services, and the cost is shifted from well-paying patients to less well-paying patients. Capitation is the process of shifting the risk of the cost of care from the insurer to the provider by paying a fixed fee per patient regardless of services provided. Pay for performance initiatives seek to link reimbursement to the achievement of certain quality measures. One way insurers disincentivize patients from seeking care is by requiring co-payments at the time of service. (REF: Sect. 1.2.5—Health Economics and Financing)

17. **THE ANSWER IS B.** A Pareto chart is a histogram which lists common problems in decreasing order of occurrence. (REF: Sect. 4.4.5 Project Management—Informatics Project Challenges)

18. **THE ANSWER IS A.** Fitts Law states that the time it takes for a person to click on an item on a screen is related to the distance to the item and (inversely) to the size of the item. Hick-Hyman Law states that the time it takes to make a decision is logarithmically related to the number of choices. Model Human Processor (MHP) is a model like Goals Operators Methods Selectors (GOMS) that determines how long it takes a person to perform a certain task. (REF: Sect. 3.2.1 Models, Theories, and Practices of HCI)

19. **THE ANSWER IS A.** Managerial accounting, unlike financial accounting is directed at managers within the organization and provides them with financial information required to plan, implement and evaluate performance. Financial accounting describes the financial condition of the business in historical format, usually during the past year or quarter. Financial reports are prepared to meet regulatory requirements according to the Generally Accepted Accounting Principles (GAAP). (REF: Sect. 4.5.6—Principles of Managerial Accounting)

20. **THE ANSWER IS D.** A shorter payback period indicates a better investment. For both the accounting rate of return and the internal rate of return, a higher percentage indicates a better investment. The present value (PV) of an item indicates its future value in today's money. (REF: Sect. 4.5.5 Capital and Operating Budgeting)

21. **THE ANSWER IS D.** The LOINC vocabulary is mainly directed at identifying laboratory and radiology tests as well as physical exam findings. SNOMED is much more expansive and seeks to have terms for every aspect of biomedical practice. The overwhelming majority of LOINC terms are also in SNOMED. Basically, this question is asking what sort of term would be found in LOINC. If you're interested, Systolic Blood Pressure is 8480-6 in LOINC and 72313002 in SNOMED. (REF: Sect. 3.4.6 Ontologies and Taxonomies)

22. **THE ANSWER IS A.** Choices B–D all match a branch of informatics with the task they are likely to perform. Choice A incorrectly pairs consumer health with physician data workflow. The key point is that a wearable computer has a potential to generate voluminous data, requires intelligent methods of analyzing and presenting that data, and is likely to be a consumer item. (REF: Sect. 1.1.1.3—Domains, Subspecialties of Informatics)

23. **THE ANSWER IS A.** CDS interface issues are present in both data entry and output. A CDS integrated into an EMR is far more likely to be used than a stand-alone system requiring duplicate data entry. (REF: Sect. 2.1.3—Application of CDS)

24. **THE ANSWER IS B**. The Institute of Medicine has established a set of standards for guidelines to ensure validity, accuracy and reliability. They include the following metrics: (Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, Eds. Clinical practice guidelines we can trust. Institute of Medicine. 2011. National Academies Press, Washington, DC.)
    - Has an explicit description of development and funding processes that is publicly accessible
    - Follows a transparent process that minimizes bias, distortion, and conflicts of interest
    - Is developed by a multidisciplinary panel comprising clinicians; methodological experts; and representatives, including a patient or consumer, of populations expected to be affected by the guideline
    - Uses rigorous systematic evidence review and considers quality, quantity, and consistency of the aggregate of available evidence
    - Summarizes evidence (and evidentiary gaps) about potential benefits and harms relevant to each recommendation
    - Explains the parts that values, opinion, theory, and clinical experience play in deriving recommendations
    - Provides a rating of the level of confidence in the evidence underpinning each recommendation and a rating of the strength of each recommendation
    - Undergoes extensive external review that includes an open period for public comment
    - Has a mechanism for revision when new evidence becomes available

    (REF: Sect. 2.2.3—Clinical Guidelines)

25. **THE ANSWER IS C.** Of the primary determinants of health, biological factors are the hardest to change. Genetic engineering may someday enable the deactivation of the BRCA1 gene (a gene linked to development of breast cancer), but not today. The other choices represent social factors, and although they may be difficult to change, they are not currently impossible. (REF: Sect. 1.2.1—Determinants of Health)

26. **THE ANSWER IS B.** Process maps are a visual depiction of a process which easily shows which tasks depend on which. Tasks which do not depend on each other can potentially be run in parallel. Culling outliers from a dataset is a statistical process and probably not relevant to workflow analysis. When a new workflow is created, it may cause workers to expand their scope of practice. Similarly, workflow analysis often involves collecting paper forms, but neither of these processes enable parallelization. (REF: Sect. 2.3.1. Methods of Workflow Analysis)

27. **THE ANSWER IS C.** Hick's Law (or the Hick-Hyman Law) states that the time required to make a decision is logarithmically related to the number of choices available. If we decrease the number of menu options, we can expect to decrease the amount of time the uses spends deciding which option to pick. Distributed cognition is a theory which states that decisions are not made solely by the individual. Instead, they are

distributed across objects, individuals, artefacts, and tools in the environment. Fitt's law states that the time required to click a mouse on a screen item is related to the size of the item and the distance the mouse has to travel. Norman's theory of Action specifies seven items that must occur sequentially for an action to be performed: (1) Forming the goal; (2) Forming the intention; (3) Specifying an action; (4) Executing the action; (5) Perceiving the state of the world, (6) Interpreting the state of the world, (7) Evaluating the outcome (REF: Sect. 3.2.1 Models, Theories, and Practices of HCI)

28. **THE ANSWER IS D.** The critical path is the longest path from start to finish. This diagram has four paths:
    ACEG = 3 + 8 + 1 + 4 = 16
    ACFH = 3 + 8 + 6 + 4 = 21
    BDEG = 2 + 2 + 1 + 4 = 9
    BDFH = 2 + 2 + 6 + 4 = 14
    (REF: Sect. 4.4.4 Project Management Tools)

29. **THE ANSWER IS D.** Outcomes research is primarily concerned with outcomes that matter to patients. While the remained of the choices may be of interest to cardiologists or ecological researchers, the patient is most concerned with his mobility. LVEDV and ECG findings are disease-oriented endpoints, while ability to walk is a patient-oriented endpoint. (REF: Sect. 2.2.1—Evidence Sources)

30. **THE ANSWER IS C.** Store and forward is a common form of asynchronous telemedicine. Media files are stored on a local server and then forwarded to the consultant, who often reads the studies in batches. Real time communication and remote monitoring are forms of synchronous communication. (REF: Sect. 3.3.4—Telemedicine)

31. **THE ANSWER IS B.** Recall is the percentage of relevant documents which are retrieved. Of the 9 relevant documents (ABCDEFGHI), only 2 are relevant (AI), so recall = 2/7 = 22.2%. Note that you don't need to construct a 2 × 2 table in order to solve this problem. If you did, it should look like this:

	RELEVANT	NOT RELEVANT
Retrieved	A, I = 2	K, M, N, O, T, W = 6
Not retrieved	B, C, D, E, F, G, H = 7	J, L, P, Q, R, S, U, V, X, Y = 10

    R = 2/(7 + 2) = 22.2%
    (REF: Sect. 2.2.5—Information Retrieval)

32. **THE ANSWER IS D.** Workflow reengineering involves changing the way a company works in order to be more efficient. Revising a clinical guideline is analogous to workflow reengineering. Six-sigma is a quality improvement framework that seeks to reduce failure to very low levels (about 3 per million). Reduction in clinical staff and replacing paper forms with electronic equivalents both may be a part of workflow reengineering, but not always. (REF: Sect. 2.3.2 Principles of Workflow Re-engineering)

33. **THE ANSWER IS B.** The CCD is an HL7 standard which is a constraint on the Reference Information Model. It is designed to transfer health records between different systems. HCPCS is a code set for procedures and supplies that are not in the CPT. The Joint Commission is a quasi-governmental organization which inspects and certifies hospitals. (REF: Sect. 3.4.1—Standards Development)

34. **THE ANSWER IS A.** Defensive medicine is the practice of ordering low-yield tests in an attempt to decrease risk of future litigation. There are many other reasons why doc-

tors order tests that they expect to contribute little to the diagnostic process, such as choices C and D, but these are not defensive medicine. The fiduciary relationship would be best honored by acting in the client's best interest, which is usually at odds with defensive medicine. (REF: Sect. 1.2.6—Forces Shaping Healthcare Delivery)

35. **THE ANSWER IS D.** Knowing what information is needed and how to find it is known as information literacy. Computer competency is the ability to perform basic computer functions. A controlled vocabulary is a set of concepts in a particular domain. Informatics management is the process of collecting data, analyzing it and distributing the findings. (REF: Sect. 1.1.2—Key Informatics Concepts, Models, and Theories)

36. **THE ANSWER IS B.** Image compression may decrease the network overhead of sharing pictures, but the other choices more directly affect interoperability. Shared terminologies and common data definitions are more or less the same concept. Protocols are the mechanisms by which data is moved from one place to another. (REF: Sect. 3.4.2 Data Standards and Sharing)

37. **THE ANSWER IS D**. Research has shown that CPGs have the potential to reduce inappropriate practice variation, enhance translation of research into practice, and improve healthcare quality and safety. They may decrease the cost of care, but they may also increase the cost of care by recommending more interventions. (REF: Sect. 2.2.3—Clinical Guidelines)

38. **THE ANSWER IS C**. Clinical guidelines are recommendations only and do not include hard and fast rules for treating patients. (REF: Sect. 2.2.3—Clinical Guidelines)

39. **THE ANSWER IS B.** In a Standard Gamble, a patient is asked to choose between a certain time in state of illness vs. therapy with a known risk of cure or death. The standard gamble is defined as one minus the risk of death at the **point of indifference** (the point at which the patient cannot choose between treatment options). In a Time Tradeoff, a patient is asked to choose between some time in a state of illness vs. some time in a state of perfect health. When using a visual analog scale, patients are asked to rate different health states on a scale where 0 = death and 100 = perfect health. The quality-adjusted life-year (QALY) is a measure of the value of health outcomes. (REF: Sect. 2.1.2—Decision Science)

40. **THE ANSWER IS A.** Whenever possible, a clinical information system should be evaluated on the basis of clinically relevant outcomes, such as compliance with national guidelines or mortality. The other measures are important, but none are as valuable as a clinical improvement. (REF: Sect. 3.5.6—Clinical Information System Evaluation)

41. **THE ANSWER IS B.** Preventive maintenance (PM) is any activity designed to prevent failure of a system. Making backups, checking log files, ensuring drive capacity are all PM tasks. Disaster recovery and replacing a broken printer are corrective actions, not preventive. Upgrading monitors is a form of enhancement, not prevention. (REF: Sect. 3.5.5—Clinical Information System Maintenance)

42. **THE ANSWER IS D.** As medical records transitioned from paper to electronic formats, it became much easier to extract information from the chart for use in research activities. The other choices reflect clinical benefits. (REF: Sect. 1.1.1.6—Current and Future Informatics Challenges)

43. **THE ANSWER IS D.** A Service Level Agreement (SLA) is an agreement between a software vendor and consumer which describes the level of technical support to which the consumer is entitled. Effectively, this process shifts the risk of maintaining and sup-

porting the software from the consumer to the vendor. A Business Associate Agreement (BAA) is an agreement between a holder of protected health information and one of its business associates regarding the usage and dissemination of data. An End User Licensing Agreement (EULA) is an agreement between a software publisher and the end user, and most commonly exists to limit the user's ability to modify or resell the software and to disclaim responsibility from the publisher should the software malfunction. Open source software is distributed in an easily modifiable form, often for free. In general, open source software transfers all responsibilities from the publisher to the user, not the other way around. (REF: Sect. 3.5.1—Institutional Governance)

44. **THE ANSWER IS C.** Six-sigma is named because it seeks to minimize defects until they are six standard deviations from the mean. Although having zero defects would be ideal, C is a better answer because it is closer to 3.4 per million opportunities. The other choices are too high. (REF: Sect. 2.3.3 Quality Improvement)

45. **THE ANSWER IS B.** Accepting the current level of risk without attempting any other risk modification is called Risk Acceptance. Risk exploitation is an approach to positive risk where a risk manager does everything in his power to ensure that the risk occurs. Risk transference is when the risk is transferred to another entity, such as buying insurance. Finally, Risk Avoidance involves instituting systematic changes to ensure that the risk does not occur. In the case of cancer, this is not a valid response. (REF: Sect. 4.4.5 Project Management—Informatics Project Challenges)

46. **THE ANSWER IS A.** Integrated change control is a rigorous process to determine the need for changes in the scope of a project. It may involve a single individual or a committee or a change control board. Having a solid change process limits scope creep. Risk avoidance is a response to risk which seeks to avoid the risk entirely. The opposite of risk avoidance is risk exploitation, which seeks to ensure that the risk occurs. A run chart shows the output of a process over time. A sensitivity analysis relies on a mathematical model of a process. By changing input variables, one can predict how the process will turn out. (REF: Sect. 4.4.5 Project Management—Informatics Project Challenges)

47. **THE ANSWER IS D.** Adverse clinical events are the worst-case scenario for a poorly designed system. In general, the other choices are good outcomes. (REF: Sect. 3.2.2—HCI Evaluation)

48. **THE ANSWER IS D.** In an ontology the relationships between terms define those terms, and are therefore explicitly stated. Synonyms (aliases) are a type of relation and must be explicitly stated. Ontological relations are quite varied and are not limited to parent-child relationships. (REF: Sect. 3.4.6 Ontologies and Taxonomies)

49. **THE ANSWER IS C.** Recall is the percentage of relevant documents which are retrieved. In this case,
$R = 2/(1 + 2) = 66\%$ (REF: Sect. 2.2.5—Information Retrieval)

50. **THE ANSWER IS D.** The discount rate indicates the interest rate used in discounted cash flow analysis to determine the present value of future cash flows. After 1 year, the $100 would increase by 10% to $110. After 2 years, it would increase by another 10%, to $121. (REF: Sect. 4.5.5 Capital and Operating Budgeting)

51. **THE ANSWER IS C.** A researcher looking at secular (i.e. long term, non-cyclical) data trends does not need any access to live data. In fact, giving him access to live data causes two problems. Firstly, it will slow down the system for current patients and providers.

Second, if he inadvertently modifies live data, it could impugn the integrity of the whole system. (REF: Sect. 3.5.1—Institutional Governance)

52. **THE ANSWER IS C.** The question stem is describing black box testing where the tester has no knowledge of the inner workings of the software. As a consequence, testers generally do not have to have technical knowledge of the development platform. Static testing refers to looking at structural elements of the code itself, and therefore requires source code access. Unit tests typically involve testing small code fragments at the module or class level. While unit tests can be black box, they tend not to be, which makes C a better answer. (Ref: Sect. 3.5.4—Clinical Information System Testing)

53. **THE ANSWER IS C.** Metadata is data about the data, and may include information about when the document was created or by whom. This information may be useful to support more complex queries Corpus. The Corpus is the collection of documents being searched. An index allows for quick retrieval of information. Relevancy describes whether or not the document meets the information need. (REF: Sect. 2.2.5—Information Retrieval)

54. **THE ANSWER IS B.** The critical path of a project is the longest path from start to completion, which defines the minimum time required to complete the project. In this diagram, the critical path includes B and E. Tasks A, C and E can each be postponed without affecting the end of the project. (REF: Sect. 4.4.4 Project Management Tools)

55. **THE ANSWER IS A.** By limiting choices to one of four options, the implementer is using a controlled vocabulary. Both a taxonomy and an ontology have a hierarchical relationship among concepts, while a classification generally does not. Semantic encoding exists when the codes have meaning in relation to the concept being encoded. In this case, the numbers actually do have some correlation to the concepts. As the numbers get higher, the patient's limitations get more severe. However, this reflects ordinality rather than semantics, which makes choice A a better answer. (REF: Sect. 3.4.5 Nomenclatures, Vocabularies, and Terminologies)

56. **THE ANSWER IS C.** Early adopters and other volunteers are often selected from a user base to be "super users". They are given additional training and are enlisted to help train other users. In general, they are not given other technical responsibilities such as setting up interfaces, maintaining passwords or assisting with security review. In this context a superuser is not the same as the system administrator in a UNIX system who has superuser privileges. (REF: Sect. 3.5.3—Clinical Information System Implementation)

57. **THE ANSWER IS C.**
(Test taker's note: There is a lot of calculation required for this question, and I doubt you'd see anything this complicated on the boards. If done correctly without a calculator, this will probably take you 3–4 minutes.)

We are being asked to find the positive predictive value (PPV). First, we must construct our confusion matrix. Let's start with the 0.1 of the population with the disease. Since our sensitivity is 0.9, we know that the true positives should be 0.9×0.1, or 0.09. That leaves the false negatives as 0.001. Now, we calculate for the people without the disease. They make up 0.9 of the population and since the specificity is also 0.9, the number of true negatives is 0.81, leaving 0.09 false negatives

	TEST (+)	TEST (–)
Disease (+)	0.09	0.01
Disease (–)	0.09	0.81

Plugging into our equation,

$$\text{PPV} = TP/(TP+FP) = 0.09/(0.09+0.09) = 0.5$$

This could also be solved using Bayes' Theorem, where D is the likelihood of having the disease and T is the likelihood of a positive test. P(T|D) is the probability of having a positive test given the disease, or sensitivity. P(D) is the prevalence of disease. P(T) is the probability of having a positive test, including both true and false positives

$$P(D|T) = \frac{P(T|D)\cdot P(D)}{P(T)} = \frac{(0.9)(0.1)}{(0.09+0.09)} = 0.5$$

(REF: Sect. 2.1.2—Decision Science)

58. **THE ANSWER IS B.** The Leapfrog Group, founded by Fortune 500 companies with AHRQ support, was created in November 2000 in response to the 1999 Institute of Medicine report "To Err is Human". Among its many activities, it developed an evaluation tool to assess proper function of CDS in computerized physician order entry (CPOE) systems. (REF: Sect. 2.1.3—Application of CDS)

59. **THE ANSWER IS B.**

$$RRR = \frac{risk\ in\ control\ group - risk\ in\ study\ group}{risk\ in\ control\ group} = \frac{6/10 - 5/10}{6/10} = \frac{1/10}{6/10} = 17\%$$

(REF: Sect. 2.2.1—Evidence Sources)

60. **THE ANSWER IS B.** The DSM is a standard vocabulary for classifying mental disorders. (REF: Sect. 3.4.1—Standards Development)

61. **THE ANSWER IS D.** Negotiation only requires that the two parties involved come to an agreement. In mediation, a third party mediator helps both sides find a solution, but they must agree to it. In arbitration, a third party judge settles the argument. In litigation, the legal system decides the outcome. (REF: Sect. 4.1.3—Negotiation)

62. **THE ANSWER IS A.** Promoting or recruiting internal candidates is generally less expensive than external candidates. It can be used to recognize contributions of current staff and may improve morale. External candidates bring diversity and fresh insights into the organization. (REF: Sect. 4.2.1—Human Resources)

63. **THE ANSWER IS B.** Several concepts are important in maintaining a safe CDS. Usability testing will identify problems with user interface as well as CDS alerts that are inappropriate or difficult to use. The basis upon which the decisions are made (the medical knowledge repository) must be kept up-to-date with new findings and new recommendations. When errors do arise, a complete audit trail is beneficial for tracing errors and for debugging. Downtime procedures are not relevant to the CDS *per se*, but are important to have nonetheless, as people who are acclimated to a CDS tend to trust the system to catch their errors for them. (REF: Sect. 2.1.6—Quality and Safety Issues)

64. **THE ANSWER IS C.** Pre-coordinated items in a vocabulary are those that are included explicitly. Post-coordinated items are those that are created by the combination of pre-coordinated items. Codes, definitions and relationships are an intrinsic part of any vocabulary. (REF: Sect. 3.4.6 Ontologies and Taxonomies)

65. **THE ANSWER IS D.** This is a challenging question because it requires that you understand the difference between lexical and syntactic ambiguity. Lexical ambiguity results

when there is a single word with more than one meaning. An example of lexical ambiguity is that the word *bank* can refer to the land alongside a river or a business establishment which lends money. In syntactic ambiguity, the words are well-defined, but the sentence or phrase is ambiguous. An example of semantic ambiguity is: Olivia ate a salad with artichokes from New Zealand. Does this mean that the salad is from New Zealand? Are the artichokes from New Zealand? Both? (REF: Sect. 2.1.3—Application of CDS)

66. **THE ANSWER IS B.** A journal's impact factor is determined by comparing the number of articles it prints with the number times those articles are cited by other journals. While the other choices tend to be characteristic of high impact factor journals, B is the best choice. (REF: Sect. 1.1.3—Clinical Informatics Literature)

67. **THE ANSWER IS A.** Intrinsic motivations arise from within a person and tend to relate to personal feelings of success. Extrinsic motivators involve the outside world and are usually social, monetary or regulatory (REF: Sect. 4.1.6—Motivation)

68. **THE ANSWER IS A.** Of those listed, only a modern facility is a tangible resource. The remainder are intangible. REF: (Sect. 4.5.2—Environmental Scanning)

69. **THE ANSWER IS C.** The Net Present Value (NPV) is the difference between the present value of cash inflows and the present value of cash outflows. The Accounting rate of return is the total profits divided by investment. The average cost for a company to borrow money is the Weighted Average Cost of Capital, WACC. (REF: Sect. 4.5.5 Capital and Operating Budgeting)

70. **THE ANSWER IS D.** EHRs and order sets are only tools to assist a clinician in caring for patients. The ordering physician will be held liable for any bad outcome resulting from an order set, even if it is misconfigured. It is reasonable to assume that the software author, the hospital and the creator of the order set will bear *some* liability, but not as much as the ordering doctor. (REF: Sect. 2.1.5—Legal, Ethical and Regulatory Issues)

71. **THE ANSWER IS D.** The National Council for Prescription Drug Programs (NCPDP) is a standards development organization accredited by the American National Standards Institute (ANSI) for communications with outpatient pharmacies. Inpatient pharmacy orders are typically covered by Health Level Seven (HL7) messages. The X12 committee creates standards for electronic data interchange, and the X12N subcommittee is responsible for communications with insurers. (REF: Sect. 3.4.3 Transaction Standards)

72. **THE ANSWER IS B.** These are descriptions of innovativeness or eagerness to adopt new technology. (REF: Sect. 4.6.2—Change Theories)

73. **THE ANSWER IS B.** When the insurer requests information and it is returned by patient accounts, that represents a two-way conversation. The other choices are interactive, but none is truly bidirectional. For example, although the clinician need not agree with the clinical decision support system, he has no way of communicating with it. Similarly, although all research is informed by the medical literature, and researchers commonly write letters to the editors of their favorite journals, choice B is a better example of bidirectional communication. (REF: Sect. 1.2.3—The Flow of Information)

74. **THE ANSWER IS B.** Medicare Severity Diagnosis Related Groups (MSDRG) stratify patients by the severity of their disease and the expected length of time that they will remain under inpatient care. Each MSDRG is assigned a weight which determines hospital reimbursement as negotiated with individual payors. CPT is used to encode profes-

sional (i.e. physician) procedures. ICD-9 was used to record diagnoses until it was supplanted by ICD-10. The NDC is used to identify medication packages. (REF: Sect. 3.4.5 Nomenclatures, Vocabularies, and Terminologies)

75. **THE ANSWER IS D**. Interfacing is the process of setting up communication channels between information systems. In contrast, integration is when two or more systems use the same data store. In the case of two hospitals which would like to retain their respective EHRs, integration would be very difficult, if not impossible. Neither certification nor anonymization would help this process. (REF: Sect. 3.1.6. Technical Approaches that Enable Sharing Data)

76. **THE ANSWER IS A.** A mesh network connects each node to every other node. A simple point-to-point network connects two nodes to each other. (You might argue that in a two-node network, all nodes are connected to every other node, but the question specified that there were *multiple* nodes). A star network contains a central hub to which all nodes connect. A star of star networks is often called a snowflake. (REF: Sect. 3.1.3—Networks)

77. **THE ANSWER IS D.** TURF is a unified framework for EHR usability. Distributed Cognition is a theory that states that decisionmaking is not solely an individual activity, but distributed across objects, individuals, artefacts, and tools in the environment. GOMS is a cognitive model of human-computer interaction that seeks to measure complexity of tasks. A Learning Health System is an EHR which continuously incorporates new information to build a more robust and adaptive system. (REF: Sect. 3.2.3—Interface Design Standards and Design Principles)

78. **THE ANSWER IS D.** Tactical goals of project management involve making sure that a project runs within budget and schedule and otherwise meets the needs of the sponsors. Portfolio management is the process of picking which projects can be used to further the organization's long term strategy. (REF: Sect. 4.4.5 Project Management—Informatics Project Challenges)

79. **THE ANSWER IS D.** Interviews work well to obtain individual opinions, but are not as good in obtaining consensus. Group meetings require scheduling and skilled moderators to help alleviate complex power dynamics. (REF: Sect. 3.2.2—HCI Evaluation)

80. **THE ANSWER IS B.** In a prediction market, each member of the group is given a fixed amount of fake money with which to purchase ideas that they find most favorable. The idea with the most support wins. (REF: Sect. 4.2.3 Group Management Processes)

81. **THE ANSWER IS A.** Semantic interoperability refers to the ability of two systems to communicate using shared meanings. The other choices are unrelated to semantic interoperability. (REF: Sect. 3.5.5—Clinical Information System Maintenance)

82. **THE ANSWER IS A.** CQI, as its name suggests, involves continuously trying to improve systems so that defects can be eliminated. Value Stream Mapping (VSM) is the process of showing all the inputs, outputs and throughputs of a process in order to identify waste. VSM is a component of the LEAN methodology. Six-sigma is another quality paradigm, although it does not specify iterative improvement as much as CQI. (REF: Sect. 2.3.3 Quality Improvement)

83. **THE ANSWER IS A.** Effectiveness is the use of evidence to guide decisions. In this case, we are comparing a therapy which is 95% successful to one that is 98% successful. Efficiency is using limited resources wisely, such as when there are two competing therapies, but one is much more expensive. The scenario described represents a conflict

between Effectiveness and Efficiency. Timeliness refers to providing a responsive and agile system. Equity refers to providing equal care to all patients. Safety means reducing errors. Patient centeredness involves the patient in the decisionmaking process. (REF: Sect. 1.2.7 Institute of Medicine Quality Components)

84. **THE ANSWER IS A.** The Joint Commission, usually working with the Centers for Medicare and Medicaid Services (CMS) creates quality measures that are used to modify doctor and hospital behavior by adjusting reimbursement rewards. The state boards of medicine are responsible for issuing and rescinding medical licenses. Pharmaceutical companies often spend money trying to sway physicians to prescribe their drugs. (REF: Sect. 1.2.6—Forces Shaping Healthcare Delivery)

85. **THE ANSWER IS D.** This question tests a definition, but you should be able to figure out the answer from the available choices. The words compliance and conformity are most similar to the word affiliation. (REF: Sect. 4.6.2—Change Theories)

86. **THE ANSWER IS C.** Electronic mail addresses are considered uniquely identifying information. An age of 23 is does not identify a person (although an age of 90 or more would). Vital signs and medical history do not identify a person. However, if the person had an extremely rare disease, it could be an identifying factor. (REF: Sect. 3.1.6 Technical approaches that enable sharing data)

87. **THE ANSWER IS D.** Roger's Diffusion of Innovation theory describes how new ideas (innovations) spread throughout a community. The rate of adoption of an innovation is determined by relative advantage, compatibility, complexity, trialability and observability. (REF: Sect. 4.6.2—Change Theories)

88. **THE ANSWER IS C.** Data are observations collected directly from a patient or the environment, such as blood pressure or ambient temperature. Information refers to the analysis and processing of data into a relevant context—something which can be used to make decisions. All health information requires encryption. Raw data could include X-ray images but is mostly composed of objective measurements which tend to be numerical. (REF: Sect. 1.1.1.1—Definitions of Informatics)

89. **THE ANSWER IS A.** Accidental disclosure is the most common form of inappropriate disclosure of medical information. Intentional theft, either by hackers or by legitimate users of the system is quite rare. Choice C is wrong because it represents a permitted use of the medical record in the context of patient care. (REF: Sect. 1.1.5—Ethics and Professionalism)

90. **THE ANSWER IS D.** Technical safeguards are programming techniques to protect sensitive data, such as maintaining an audit log or using two factor authentication. Administrative safeguards are policies and procedures regarding data security. Physical safeguards are actual objects that block unauthorized access, such as locks on server room doors or privacy screens. (REF: Sect. 3.1.4—Security)

91. **THE ANSWER IS A.** The benefit of an ASP model is that the heavy computing is performed off-site by the vendor, so investment in a data center is not needed. However, since some of the computing requirements will be shared between client and server, printers, workstations and networks will require additional resources. (REF: Sect. 3.5.3—Clinical Information System Implementation)

92. **THE ANSWER IS B.** Metadata is information about data, such as its origin, meaning or context. The essence of interoperability is that both the sender and the receiver are speaking the same language. Shared data definition is the key to this process, and is usu-

ally transmitted as metadata. Although validating the origin of information, correcting errors and synchronizing timestamps are important, data definition is the MOST important of these items. (REF: Sect. 3.4.2 Data Standards and Sharing)

93. **THE ANSWER IS D.** Covered entities may not share identifiable patient information that is created, maintained, transmitted or received, even if it is relevant to a non-covered entity's workflow unless they sign a business associate agreement. (REF: Sect. 3.1.4—Security)

94. **THE ANSWER IS D.** This scenario represents a start-to-start dependency because none may *start* until the CEO *starts*. (REF: Sect. 4.4.3 Project Management Resource Allocation)

95. **THE ANSWER IS A.** It is the software developer's responsibility to act in good faith and to create software with as few errors as is reasonably possible. EULAs often attempt to shift risk from the developer to the user, and software is often provided AS IS with no warranties. That said, software is only a tool, and expert clinician judgement is always required. A SLA determines what level of technical support the institution can get. (REF: Sect. 2.1.5—Legal, Ethical and Regulatory Issues)

96. **THE ANSWER IS A.** Satisficing is the act of being satisfied with a satisfactory, if not ideal answer. It is known that more research could possibly find a better answer, but the decisionmaker is trying to be decisive. Making a choice on "gut feeling" without research is not satisficing. Multifocused decisionmakers may pursue multiple opportunities until one emerges as the best. Maximizers tend to perform extensive research prior to making a decision. (REF: Sect. 4.1.7—Decision Making)

97. **THE ANSWER IS D.** Surveys may not be detailed enough to capture a user's true feelings or complete opinions about the system. In-person interviews capture much more information, but are more costly and generally limit the number of respondents. (REF: Sect. 3.2.2—HCI Evaluation)

98. **THE ANSWER IS C.** There are several common sub-domains of bioinformatics. Clinical Informatics is the application of informatics to delivery of healthcare services. Clinical Research Informatics involves study of clinical trials and secondary research use of clinical data. Consumer Health Informatics analyzes information from the perspective of the health care consumer. Public Health Informatics is focused on the health of communities rather than individuals. Translational Bioinformatics involves the translation of voluminous data among multiple sources. (REF: Sect. 1.1.1.3—Domains, Subspecialties of Informatics)

99. **THE ANSWER IS D.** The SDLC generally includes an initiation phase followed by requirements, analysis, design (or acquisition), development, testing, implementation, maintenance and support, and feeds back into analysis. If the system is no longer valuable, there is a decommissioning or disposal phase. Payment is not usually part of the SDLC. (REF: Sect. 3.5.2—Clinical Information Needs Analysis)

100. **THE ANSWER IS D.** Permission systems in EHRs are generally set up according to particular roles, such as doctor, nurse, administrator, and so on. If one class of user is lacking permission, it is usually caused by an error in setting up the role permissions. Choice A is incorrect because hospital bylaws indicate that there is no distinction made between DO and MD physicians. Choice B is irrelevant. Choice C is wrong because at least some of the physicians have the correct order permissions.(REF: Sect. 3.5.1—Institutional Governance)

101. **THE ANSWER IS D.** Just over half of clinical research in the US is sponsored by industry, such as drug and medical device manufacturers. The remained is funded by public sources, such as the NIH. Academia typically receives funding for research but funds only a small amount itself. Charity, in the form of private grants, makes the smallest contribution. (REF: Sect. 1.2.2.3—Clinical Research)
102. **THE ANSWER IS B.** Telemedicine providers are required to maintain licenses in each state or province in which patients may be found, regardless of what location they are in when the service is provided. The IMLC attempted to enact a rule that would ease this restriction. Unfortunately the act never passed. (REF: Sect. 3.3.4—Telemedicine)

103. **THE ANSWER IS B.** DICOM files are binary encoded and are not easily readable without a dedicated parsing program. The CCD is a constraint on the Reference Information Model (RIM) and is a type of HL7 V3 document. These are encoded in extensible markup language (XML), which is generally human readable. In addition, the CCD is constrained to specifically have a human-readable text component. By specification, FHIR also should have a human readable component. (REF: Sect. 3.4.4—Messaging Standards)

104. **THE ANSWER IS A.** Despite the fancy language, a corrective action is something that fixes a known problem. This is distinguished from a preventive action, which is something that ensures the *future* performance of the project work is aligned with the project management plan. Integrated change control is a process where the scope of the work is changed from what was originally planned. Project acquisition involves the implementation and close-out of a project. (REF: Sect. 4.4.5 Project Management—Informatics Project Challenges)

105. **THE ANSWER IS C.** Physician licensure is under the control of state medical boards. Board exams are administered by one or more of the member boards of the American Board of Medical Specialties. Permission to begin clinical trials on a new drug is the purview of the Federal Drug Administration. Hospital accreditation is usually performed by private companies, such as the Joint Commission, but can also be done by state agencies. However, since it is *normally* done by private agencies, choice C is a better answer. (REF: Sect. 1.1.6—Legal and Regulatory Issues)

106. **THE ANSWER IS C.** Clinical decision support should be a way to reduce physicians' cognitive burden. Although it is often characterized as pop-up alerts which interrupt workflow, this is not the intention. Infobuttons are links embedded in an EHR which refer to external websites. (REF: Sect. 2.1.3—Application of CDS)

107. **THE ANSWER IS D.** Selecting a testing methodology will never be a one-size-fits-all proposition. It will depend on the organization's goals and constraints as well as user accessibility, and experience of the design team. Role-playing and cognitive walk-throughs may be used, but not always. Security concerns may be important, but are only part of the decision for picking a methodology. In general, testers should not be developers of the intended system, as they are likely to bring biases and training to the testing suite. (REF: Sect. 3.2.2—HCI Evaluation)

108. **THE ANSWER IS C.** Normalized databases are designed to have as little redundancy as possible so that each database row refers to a single concept (atom). Compared to denormalized databases, they tend to take up less space on disk and allow for easier writes (assuming the write only involves a single table). They may contain indexes, but this is not a defining feature of denormalization. They are less prone to data anomalies because they have less redundant information. Denormalization is often used to optimize

read performance, and normalized tables tend to be slower because the database has to spend time matching keys from different tables. (REF: Sect. 3.1.1—Computer Systems)

109. **THE ANSWER IS C.** Gerteis listed six dimensions of patient-centered care: Respect for values; coordination of care; education and communication; comfort; emotional support; involvement of friends and family. Effectiveness refers to selecting treatments based on best available evidence. Efficiency is getting the most reward for the health-care dollar. Safety means reducing errors. (REF: Sect. 1.2.7 Institute of Medicine Quality Components)

110. **THE ANSWER IS B.** Patients with unusual or conflicting diagnoses pose a challenge to human physicians and even more to computers. Errors may occur when users have "alert fatigue" or when the order entry system is far away from the bedside, but that would not cause the CDS to give wrong information. When the CDS requires structured data input, users may attempt to put misleading information into the CDS, but does not directly affect the integrity of the CDS. (REF: Sect. 2.1.6—Quality and Safety Issues)

111. **THE ANSWER IS A.** A case series is a published report of similar patient presentations, usually less than 10. When it is only a single patient, it is a case report. An editorial is a published opinion by a member of a journal's editorial staff. It rarely presents new information. A method paper (also called an application paper) describes a novel technique or procedure. Original research involves asking a study question and using statistical methods to analyze results. (REF: Sect. 2.2.1—Evidence Sources)

112. **THE ANSWER IS A.** Before teams can work together, the goals of the team have to be known. After that, the rules of operation are described and individual roles are clarified. (REF: Sect. 4.2.2—Team Productivity)

113. **THE ANSWER IS B.** Waterfall is one of the oldest methods of software development, and it is modeled after manufacturing design. Its five steps include requirement (defining the project requirements), design (creating the software architecture) implementation (writing the code), verification (debugging), and maintenance. The first two steps in waterfall consume nearly 50% of resources. The rationale of waterfall is that a few hours of careful planning can save days or weeks down the line. One of the most important tenets of waterfall is that steps only go forward, and one can not progress to the next step until the previous step is finished. Changing project requirements in the middle of a project is avoided at all costs. It is sometimes called a top-down process because it starts with planning and ends with implementation. In the rapid prototyping approach, the developer creates a user interface and later implements the business logic. This is sometimes called a "bottom-up" process. (REF: Sect. 3.1.1—Computer Systems)

114. **THE ANSWER IS B.** Concept orientation means that concepts have one meaning ("nonvagueness") and no more than one meaning ("nonambiguity"). Similarly, a given meaning may correspond to no more than one concept ("nonredundancy"). Versioning refers to maintaining explicit versions of an ontology so that changes to the ontology do not create discrepancies between communicators. (REF: Sect. 3.4.6 Ontologies and Taxonomies)

115. **THE ANSWER IS B.** Public health experts are not legislators or regulators, and are not involved in creating laws. They may, however advise government officials on how to control illness. They are commonly involved in syndromic surveillance as well as public education programs. (REF: Sect. 1.2.2.2—Public Health)

116. **THE ANSWER IS B.** The earned value is the estimate of what the current work is worth. The amount of money spent on the project is the actual cost. The amount of value that is expected to be done at this point in time is called the planned value. If the earned value is greater than the actual cost, the project is under budget and has a positive cost variance. If the earned value is greater than the planned value it is called positive schedule variance, and the project is ahead of schedule. Choice B is expresses this situation. (REF: Sect. 4.4.3 Project Management Resource Allocation)

117. **THE ANSWER IS A.** A champion is a respected member of a group in which a change is desired. In the informatics context, this term is mostly used in conjunction with a physician champion, a member of the medical staff who is passionate about embracing technological or operational changes. Developers and designers create products. Officers are leaders and decisionmakers in an organization. They are often entrusted to bind the organization's resources to specific projects. (REF: Sect. 1.1.1.4—Careers in Informatics)

118. **THE ANSWER IS A.** In a mesh network, each node is connected to every other node. If a single node or link fails, all the remaining nodes and links remain active. In a point-to-point network, if a single link or node goes down, the network is effectively divided in half. In a star network, if the central hub fails, there is no further communication. A Snowflake is a star of star networks and has the same susceptibility. (REF: Sect. 3.1.3—Networks)

119. **THE ANSWER IS B.** Meta-analyses often use odds ratio (OR) for discrete variables and mean difference (MD) or standardized mean difference (SMD) for continuous variables. An odds ratio of >1 generally indicates a treatment benefit. If the confidence interval (CI) does not cross the OR = 1 line, the results are statistically significant. (REF: Sect. 2.2.3—Clinical Guidelines)

120. **THE ANSWER IS A.** There are at least four problems which persist in even the best of medical record systems: (1) the need for standards in medical terminology; (2) concern about privacy, confidentiality and security; (3) many physicians remain resistant to using an EHR, and most will claim that they can document and order tests much more quickly on paper; and (4) interoperability between disparate systems is still quite difficult. Audit trails, however, are much more reliable. (REF: Sect. 1.1.1.6—Current and Future Informatics Challenges)

121. **THE ANSWER IS B.** Environmental scanning, or SWOT analysis seeks to identify Strengths, Weaknesses, Opportunities and Threats. The internal scan includes the strengths and weaknesses while the external scan includes the opportunities and threats. A company's resources may be tangible, such as financial, physical or technological resources. They may also be intangible, such as human resources or reputations. Highly skilled workers would be an intangible resource and therefore be considered one of the company's strengths. The external scan (sometimes called PESTEL analysis) identifies political, economic, social, technological, environmental and legal factors which may impact the organization. (REF: Sect. 4.5.2—Environmental Scanning)

122. **THE ANSWER IS A.** The five rights of CDS refers to a framework when planning or implementing CDS interventions, which are (1) The right information; (2) To the right person; (3) In the right format; (4) Through the right channel; (5) At the right time. The other options are irrelevant. Incidentally, it would be difficult to construct a star with 5 right angles. (REF: Sect. 2.1.3—Application of CDS)

123. **THE ANSWER IS C.** This question is tricky because it expects you to know the rate at which things are adopted—not how many are in each category. The S-shaped curve is sometimes called a sigmoid curve. (REF: Sect. 4.6.2—Change Theories)

124. **THE ANSWER IS D.** A systematic review involves employing a rigorous search strategy to identify sources of information relevant to a clinical question. When data from those studies are pooled into a single data table, the result is a meta-analysis. A randomized, controlled trial is a type of original research where participants are randomized into a study arm and a control arm and analyzed for differences. A chart review generally involves reviewing patient records for research or quality improvement. (REF: Sect. 2.2.1—Evidence Sources)

125. **THE ANSWER IS D.** The organizational chart shows staff members who report to project managers who report directly to the chief executive. This is a project organizational chart. The most common type of organizational chart is the functional organizational chart where workers are arranged by function instead of their role in a particular project. A matrix organizational chart is a hybrid between project and functional because each worker reports to two people, a functional leader as well as a project manager. A geographical organizational chart groups workers by the region they serve. (REF: Sect. 4.4.1 Project Management Basics)

126. **THE ANSWER IS D.** McClelland's acquired needs theory states that an individual's specific needs are acquired over time and shaped by personal life experiences. Herzberg's Motivation-Hygiene theory describes hygiene factors (required for sustenance) and motivation factors (useful for inspiration). Maslow's hierarchy of needs categorizes needs from physical survival, safety, security, followed by psychological needs and then self-fulfillment. Lewin's Field Theory states that an individual's behavior is a function of one's own characteristics as well as the group. (REF: Sect. 4.1.6—Motivation)

127. **THE ANSWER IS D.** RxNorm is a normalized database of prescribable medications and can be used as a crosswalk between different databases. (REF: Sect. 3.4.1—Standards Development)

128. **THE ANSWER IS B.** The purpose of regression testing is to make sure that upgrades in the software do not break any other modules or components of the program. Installation testing ensures that the program runs in the expected environment. Unit testing involves supplying test data to small sections of code to make sure that they provide correct results. White-box testing refers to testing software when the source code is known. It is distinguished from Black-box testing where the software internals are unknown to the tester. (Ref: Sect. 3.5.4—Clinical Information System Testing)

129. **THE ANSWER IS A.** This question tests to see if you are passingly familiar with PRECEDE/PROCEED. It is one of the few discrete items mentioned in the Core Content article, so you should probably be familiar with it. (REF: Sect. 4.6.2—Change Theories)

130. **THE ANSWER IS D.** Assemblers translate assembly language into machine code. A compiler translates higher level languages (such as FORTRAN) into machine code. An interpreter is required for all interpreted languages, such as BASIC. Neither compilers nor assemblers are concerned with the cosmetic appearance of source code. (REF: Sect. 3.1.1—Computer Systems)

131. **THE ANSWER IS C.** Subgroup analysis involves selecting certain patients from the original population with a particular trait to see if findings vary considerably for that

group. A post-hoc analysis means that they decided to investigate the subgroup after the initial study planning was completed. An ecological study examines geographical distributions of health-related phenomena. Hypothesis generation is common to all research and involves creating predictions about the natural world. A surrogate marker is a readily visible trait which is measured because the actual measure would be too difficult to capture. (REF: Sect. 2.2.2 Evidence Grading)

132. **THE ANSWER IS D.** A firewall is a node that sits between two networks and decides which communications may pass through. A virtual private network is a system where a computer appears to be a node on a remote network. This is accomplished by transmitting encrypted packets over a public network. A virtual machine is an instance of an operating system running on a time-shared computer. A remote desktop is a technique of rerouting the input and output devices of one computer onto another. (REF: Sect. 3.1.4—Security)

133. **THE ANSWER IS B.** Denormalization is the intentional duplication of data to improve database performance. This performance comes at a cost. Denormalized databases are at risk for insertion, deletion and update anomalies. A database join is the process by which two tables are linked by a common identifier. A query is a request from a database for some particular information. (REF: Sect. 3.1.1—Computer Systems)

134. **THE ANSWER IS C.** In Test-Driven Development (TDD), the programmer creates numerous automated tests which must pass before any code can be incorporated into a project. Rapid application development involves creating a user interface or prototype first and then creating an implementation. Scrum and Xtreme Programming are forms of Agile programming which involves daily meetings with customers to ensure that the product will meet their needs. (REF: Sect. 3.1.1—Computer Systems)

135. **THE ANSWER IS C.** The Reference Information Model (RIM) is the basis of Health Level Seven (HL7) version 3. In addition to transmitting information, it requires transmission of metadata which externally defines the meaning of that information. For example, instead of simply transmitting a laboratory result, the RIM requires the sender to refer to a data dictionary which explains what that finding means. The goal of this process is to ensure that two computers can transmit information with shared meaning. Although some parts of the RIM do improve human readability, this is not always the case, and choice C is a better answer. Patient outcomes and timely reimbursement are potential benefits, but are not required by RIM. (REF: Sect. 3.4.7 Interoperability Standards)

136. **THE ANSWER IS A.** A transaction which is designed to be indivisible is called atomic. If part of the transaction succeeded and part failed, it would result in an incorrect database state. Consider the case where money is transferred from one account to another. One account must be credited while the other must be debited. If only one of these updates occurs, the accounts will be incorrect. Consistency means that the database is always in a valid state. Isolation means that two transactions run simultaneously will not interfere with each other. Durability means that the persistent data store will always contain up-to-date information. (REF: Sect. 3.1.2—Architecture)

137. **THE ANSWER IS A.** Disparate impact means that certain classes of people will be over-represented in the recruitment and selection process. If Mandarin is required as per the job specification, it is likely that there will be more people of Asian extraction on the staff. Disparate treatment, or discrimination, is the deliberate maltreatment of a

particular group of people, and is illegal. Selection is the process of picking employees from a group that has been recruited. Selection bias refers the systematic selection of particular subjects in a clinical trial. (REF: Sect. 4.2.1—Human Resources)

138. **THE ANSWER IS A.** According to PMBOK, a stakeholder is an individual, group, or organization who may affect, be affected by or perceive itself to be affected by a decision, activity, or outcome of a project. Managing stakeholders proactively is an important knowledge area. Hospital employees who will use the system are obvious stakeholders. Regulatory agencies are also considered stakeholders because their approval is required for completion of the project. A member of the medical staff, even though he is not an employee and not in favor of the EMR project is also considered a stakeholder because the project directly affects him. He is known as a negative stakeholder. On the other hand, competitors are not negative stakeholders because the project does not have to meet their requirements and they do not have sway in the project's evolution. (REF: Sect. 4.4.1 Project Management Basics)

139. **THE ANSWER IS B.** Horizontal integration involves creating a new system called the enterprise service bus, or simply bus. This platform allows communication among all components connected to it. Each component must have an interface to the bus, but does not necessarily have to have an interface to each other. Unfortunately, this system is vulnerable because a failure in the bus means that no two components can communicate. In a star topology, each system is connected to every other system. In a vertical system integration, similar systems are grouped together. (REF: Sect. 3.1.1—Computer Systems)

140. **THE ANSWER IS B.**

$$NNH = \frac{1}{risk\ in\ study\ group - risk\ in\ control\ group}$$

$$= \frac{1}{20/10000 - 10/10000} = \frac{1}{10/10000} = 1000$$

(REF: Sect. 2.2.1—Evidence Sources)

141. **THE ANSWER IS B.** A circuit switching network has a finite number of circuits which are created and broken when two nodes wish to communicate. When the circuit is in use, it can not be accessed by any other nodes. Historically, this was created when an operator inserted a jack into a receptacle, but is now accomplished automatically with a switch. Choices A and D describe a shared network, such as VOIP or cell phone spectra. (REF: Sect. 3.1.3—Networks)

142. **THE ANSWER IS C.** Referential integrity requires that whenever one database column refers to another (such as in a primary key—foreign key relationship), the key actually exists in the primary table. Logical integrity means that the data makes sense. Domain integrity applies when the data is restricted to a predefined set of values (e.g. a controlled vocabulary). Table integrity is a red herring. (REF: Sect. 3.1.5.1—Integrity)

143. **THE ANSWER IS C.** FHIR is characterized by common web standards and is intended to be easy to implement. (REF: Sect. 3.4.1—Standards Development)

144. **THE ANSWER IS B.** There are several types of loops which are used to repeat code segments. Some of the common names for loops are for/next, while/do, do/loop, repeat/until and others. A loop which continues forever is called an infinite loop. Syntax is the grammatical rules that govern now source code is written. An if/then/else block is a conditional, but is only executed once. Recursion is the process by which a function calls itself repeatedly to find an answer. (REF: Sect. 3.1.1—Computer Systems)

145. **THE ANSWER IS A.** Fallout refers to the proportion of non-relevant documents which are retrieved, or the false positive rate. It is equal to 1-specificity. Precision is the proportion of retrieved documents which are relevant, while recall is the proportion of relevant documents which are retrieved. (REF: Sect. 2.2.5—Information Retrieval)

146. **THE ANSWER IS A.** The typical steps in a Clinical Practice Guideline algorithm include the following:
- Action—perform a specific action
- Conditional—carry out an action (or actions) based on defined criteria
- Branch—direct flow to one or more additional steps
- Synchronization—converge paths back from branches to a common outcome/end point

(REF: Sect. 2.2.3—Clinical Guidelines)

147. **THE ANSWER IS D.** Mandatory safeguards are those that are always required. Addressable safeguards are those that may be met with a number of different alternatives based on the needs or capabilities of the covered entity. Meaningful use offers some menu choices (e.g. complete 5 of 8 of the requirements) but HIPAA does not. The location of the entity is not relevant to the HIPAA standard. (REF: Sect. 3.1.4—Security)

148. **THE ANSWER IS C.** Job costing is the process of assigning manufacturing costs to an individual product or service. Trend analysis or forecasting is the process of reviewing costs searching for anomalies. Margin analysis examines the profits made from various products and services. A pro forma sales budget estimates the revenue from goods and services for the coming year. (REF: Sect. 4.5.6—Principles of Managerial Accounting)

149. **THE ANSWER IS D.** Data warehouses are optimized for online analytic processing, and often contain data denormalized into multidimensional "cubes". Warehouses usually do not have real-time data, but rather rely on snapshots of live data. Both data warehouses and regular databases may use any kind of storage media. A data mart is a section of a data warehouse which contains information related to a particular line of service or organizational unit. (REF: Sect. 3.1.2—Architecture)

150. **THE ANSWER IS A.** The Health Information Technology for Economic and Clinical Health (HITECH) act which is a component of ARRA introduced rewards for eligible providers who were able to achieve meaningful use of electronic health records. HIPAA provides for data privacy and security. PPACA created health insurance exchanges, expanded medicaid and generally aimed to get affordable health insurance for all Americans. FDASIA expanded the role of the Food and Drug Administration to collect fees from industry, spur innovation and increase the safety of the drug supply chain. (REF: Sect. 1.1.6—Legal and Regulatory Issues)

151. **THE ANSWER IS D.** LOINC is a vocabulary of codes used to represent laboratory tests. CPT is a set of procedures, developed by the American Medical Association. (REF: Sect. 3.4.1—Standards Development)

152. **THE ANSWER IS D.** External representations are an example of external cognition, which is using external elements to help us make decisions. These external elements must be abstractions of the data at hand and much change its presentation in some way. It does not include new data. Working with other providers constitutes obtaining new

information. The other options are all abstractions of the original data. (REF: Sect. 3.2.1 Models, Theories, and Practices of HCI)

153. **THE ANSWER IS C.** In most states, minors are allowed to consent for treatment of pregnancy, sexually transmitted disease and mental health problems. The rationale is that if these services required parental consent, children would either be denied services or would seek unsafe alternatives. As a result, the PHI that is generated from these encounters remains protected and parents should not have access to it. Choice A is wrong because there is no evidence that she is emancipated. Choice B is wrong because it fails to take into account the fact that she is receiving services for a condition where minors are allowed to consent by themselves. Choice D is wrong because even though PHI is routinely transmitted to the payor, the insurer is the payor, not the mother. (REF: Sect. 1.1.5—Ethics and Professionalism)

154. **THE ANSWER IS D.** Syndromic surveillance is the systematic monitoring of health related data to inform public health. It often includes symptomatic data (fever, chills, neck stiffness) which precede definitive tests (e.g. blood cultures showing N. meningitidis) Insurance utilization data and physician referral patterns are unlikely to identify an emerging infection. (REF: Sect. 2.1.7—Supporting Decisions for Populations)

155. **THE ANSWER IS B.** CIGS are most effective when they are incorporated into the clinical workflow (as opposed to systems which require duplicate data entry). Incorporating physician preferences if a valuable add-on, but is not as good an answer as B. Choices C and D are not related. (REF: Sect. 2.1.3—Application of CDS)

156. **THE ANSWER IS B.** Authoritarian managers rule by fiat and are unconcerned with the opinions of their workers, which represents choice B. Choices A, C and D represent the team leader, country club and impoverished leaders, respectively. (REF: Sect. 4.1.1 Dimensions of Effective Leadership)

157. **THE ANSWER IS B.** An unsigned integer allows storage of whole numbers between 0 and one less than the power of two correlating to the number of storage bits. An 8-bit unsigned integer can contain numbers from 0 to $2^8 - 1$, or 0 to 255. Increasing the number of storage bits increases the maximum allowed value. In a signed integer, increasing the storage bits increases the maximum and decreases the minimum allowable values. Since integers can only store whole numbers, the precision is always 1, and there are no exponents. (REF: Sect. 3.1.5—Data)

158. **THE ANSWER IS D.** Tailoring is the process of modifying a clinical information system to better suit the needs of the client. Since many stakeholders will want different things out of an information system, there must be a change control process in place to ensure that the work is prioritized according to the mission and vision of the organization. Data Quality Management involves ensuring that clinical data is accurate and appropriate for use. Preventive maintenance checks for problems before they occur. Downtime procedures are followed when an information system is not functioning normally. (REF: Sect. 3.5.5—Clinical Information System Maintenance)

159. **THE ANSWER IS D.** Using discounted cash flow analysis, the present value of cash is discounted at the discount rate. The future value of cash remains constant while the present value decreases. (REF: Sect. 4.5.5 Capital and Operating Budgeting)

160. **THE ANSWER IS D.** Systems should be evaluated by users in their own settings whenever possible. Certain circumstances, such as sensitive information may mandate testing in a laboratory. (REF: Sect. 3.2.2—HCI Evaluation)

161. **THE ANSWER IS A.** There are many ways to view the ideological differences between leaders and managers. Perhaps the most telling is that leaders have far-reaching vision, tend to be charismatic, and people admire them and just want to follow them. Although they often rise to positions of responsibility, they do not necessarily hold a high office in the organization. They focus on other people and appeal to their passions and dreams. Managers, on the other hand, hold specific offices in the organization and subordinates report directly to them. The relationship is often described as "transactional" in the sense that managers define the expected work product and employees receive a salary for completing it. (REF: Sect. 4.1.1 Dimensions of Effective Leadership)

162. **THE ANSWER IS D.** In a competitive marketplace, manufacturers will vie for customers by offering better prices. This process falls down in the not-unusual case where a particular drug is out of patent and is being manufactured by a single generic manufacturer. Discount formularies list almost exclusively generic drugs. The Food and Drug Administration ensures that generic drugs adhere to the same quality standards as brand-name drugs. Generic manufacturers should be just as efficient as brand name manufacturers, sometimes more so. (REF: Sect. 1.2.6—Forces Shaping Healthcare Delivery)

163. **THE ANSWER IS B.** In general, quantitative analysis is always preferred because it is objective and repeatable and can be subject to statistical analysis. When the population is too small for statistics, qualitative analysis may be used. The other options are not relevant to the distinction between qualitative and quantitative analysis. (REF: Sect. 3.5.6—Clinical Information System Evaluation)

164. **THE ANSWER IS A.** HL7 V2 was developed many years ago, and different vendors have created fields and used them in different ways. Since fields are essentially appended from one onto the next, it has been convenient for various implementers to add fields in arbitrary order to the existing standard. HL7 V2 does not include metadata or references to metadata. Parsing V2 messages requires knowledge of the implementation standard. V2 is still the most common messaging protocol in the US, despite introduction of V3 and the Reference Information Model. V2 does enable binary encoding, and there is no fixed limit to transmission size. (REF: Sect. 3.4.4—Messaging Standards)

165. **THE ANSWER IS B.** Unstructured meetings tend to require less administrative overhead and are therefore less costly. It is assumed that leaders are always allowed to voice their opinions. Group management processes, especially those that allow anonymous input, allow people lower on the hierarchy to voice their opinions as well. (REF: Sect. 4.2.3 Group Management Processes)

166. **THE ANSWER IS D.** Norman's theory of Action specifies a series of seven parts of an action: (1) Forming the goal; (2) Forming the intention; (3) Specifying an action; (4) Executing the action; (5) Perceiving the state of the world, (6) Interpreting the state of the world, (7) Evaluating the outcome. (REF: Sect. 3.2.1 Models, Theories, and Practices of HCI)

167. **THE ANSWER IS A.** Clinical informatics involves all areas of clinical and epidemiological research with a focus on analyzing studies that are meaningful to clinical scenarios. It then aims to bring that knowledge to bear when the patient and provider have an opportunity to use it. The other choices are areas where some informaticians will be involved, but none represent the overarching goals of informatics. (REF: Sect. 1.1.1.1—Definitions of Informatics)

168. **THE ANSWER IS D.** A corporate culture is the values and behaviors that describe the psychological environment of a company. Although some of this information is contained in the policy and procedure manual, much of it is unwritten and must be obtained by speaking to employees. However, of the choices listed, the policy manual is the best option. (REF: Sect. 4.6.1 Assessment of Corporate Culture)

169. **THE ANSWER IS B.** State licensing boards are regulatory bodies that determine who may practice medicine in a given state. Choices A and C are poorly defined in this context. Nurse anesthetists are supervised by anesthesiologists in their practice. Another term to describe this relationship could be collaborative. (REF: Sect. 1.2.2.1—Health Care Delivery)

170. **THE ANSWER IS D.** The weight of research is designed to show that CDS can alter decisions and actions. Most studies focus on changes in behavior, not on patient outcomes. (REF: Sect. 2.1.3—Application of CDS)

171. **THE ANSWER IS B.** Case control studies are retrospective and, of the choices offered, subject to the most bias. Choices A and D represent very good sources of evidence. A cohort study, even if it were retrospective, is ranked more highly than a case-control study. (REF: Sect. 2.2.2 Evidence Grading)

172. **THE ANSWER IS B.** Precision is the percentage of retrieved documents which are relevant. In our case, 8 documents were retrieved, of which 2 were relevant. Precision = 2/8 = 25%. Note that you do not need to create a 2 × 2 table to solve this problem, but if you did, it should look like this:

	RELEVANT	NOT RELEVANT
Retrieved	A, I = 2	K, M, N, O, T, W = 6
Not retrieved	B, C, D, E, F, G, H = 7	J, L, P, Q, R, S, U, V, X, Y = 10

P = 2/(6 + 2) = 25%
(REF: Sect. 2.2.5—Information Retrieval)

173. **THE ANSWER IS A.** The Health Information Technology for Economic and Clinical Health Act (HITECH) was enacted under Title XIII of the American Recovery and Reinvestment Act of 2009. The HITECH Act set meaningful use of interoperable EHR adoption in the health care system as a critical national goal and incentivized EHR adoption. (REF: Sect. 1.1.4—International Medical Informatics)

174. **THE ANSWER IS B.** SNOMED is an extensive vocabulary which includes anatomy, disease, findings, procedures, organisms, substances and many other terms. The ICD contains diagnosis codes and some external causes of disease as well. (REF: Sect. 3.4.1—Standards Development)

175. **THE ANSWER IS D.** In the DIKW framework, data are observations; information is data in context; knowledge is analysis of how and why; wisdom is the application of knowledge to the real world, such as an ethical consideration. (REF: Sect. 1.1.2—Key Informatics Concepts, Models, and Theories)

176. **THE ANSWER IS B.** HL7 V2 is sometimes called "pipehat" because it uses vertical bars (pipes) and carets (hats) as delimiters. The MSH segment defines what characters are used as delimiters, but pipes and hats are by far the most common. (REF: Sect. 3.4.4—Messaging Standards)

177. **THE ANSWER IS B.** The ICD has a long history indeed. The DSM was developed by the American Psychiatric Association for classifying mental disorders. The Nuremberg Code describes ethics for medical research. (REF: Sect. 3.4.1—Standards Development)

178. **THE ANSWER IS D.** CPT includes various components of the RVU, including professional liability insurance (PLI), practice expense (PE) as well as work. Work is calculated from the amount of skill and time required for the procedure. The geographical location is often used as part of the calculation in determining reimbursement, but not in calculating the RVU. (REF: Sect. 3.4.5 Nomenclatures, Vocabularies, and Terminologies)

179. **THE ANSWER IS D.** Trust among team members is the most important precondition for effective collaboration. Diversity of backgrounds makes teams more capable to tackle complex problems. Individual dominance can ruin collaborative efforts. Training is must less important for effective collaboration than a willingness to work together. (REF: Sect. 4.1.5—Collaboration)

180. **THE ANSWER IS D.** Value bias is the tendency to interpret data in a way that supports a decision that is very valuable or highly desired. Anchoring Bias tends to interpret information to support a previously made conclusion. Similarly, confirmation bias tends to confirm a conclusion previously made. "Blois" decision making is a model of decision making that results in adjusting conclusions using collected data over an iterative process. This ultimately leads to refining and shortening the list of possibilities and ultimately a more precise conclusion. (REF: Sect. 2.1.1—The Nature and Cognitive Aspects of Decision Making)

181. **THE ANSWER IS A.** Logical integrity means that the data is reasonable and appropriate. A sanity check is a quick-and-dirty evaluation of data to make sure that it is reasonable for our purposes. Restricting database access is a security precaution. Entity integrity is when every table has a primary key. Making regular backups is useful in data recovery, but does not enhance integrity. (REF: Sect. 3.1.5.1—Integrity)

182. **THE ANSWER IS C.** The probability/impact chart stratifies risks based on their impact and their probability of occurring. High-impact, high-probability risks have the highest priority. A responsibility activity matrix specifies which personnel are responsible for which tasks and to what degree. This type of chart is also called a RACI chart which is a mnemonic for the various levels of responsibility: Responsible, Accountable, Consult, Inform. A Monte Carlo simulation is a statistical method for assessing the risk of a whole project when the component risks are known. A control chart is a graphical depiction of the output of a process which includes upper and lower bounds of acceptable values. (REF: Sect. 4.4.5 Project Management—Informatics project challenges)

183. **THE ANSWER IS C.** In the Bayesian model, a clinician may calculate the probability of a condition based on the prevalence or pretest probability of the condition and other related events, such as diagnostic test results. In the additive model, certain inputs add to or subtract from the probability of a certain diagnosis. Likewise, in the Algorithmic and Blois model, pretest probability does not influence the weighting of inputs and diagnostic testing. (REF: Sect. 2.1.1—The Nature and Cognitive Aspects of Decision Making)

184. **THE ANSWER IS B.** Drill-down expands a category into smaller categories, such as breaking national data into regional data or state data. Roll-up is the reverse process

and involves combining sections of data into a larger category. Pivot involves changing the axes of the display. Dicing refers to holding two or more dimensions constant. (REF: Sect. 3.1.2—Architecture)

185. **THE ANSWER IS D.** This is a simple definition, but even if you didn't know the answer, you could probably eliminate one or two choices in order to make an educated guess. (REF: Sect. 4.6.2—Change Theories)

186. **THE ANSWER IS D.** CDS requires physician cooperation and ongoing resources and provisions. Even if a CDS were perfectly implemented at go-live, medical knowledge continuously changes and demands ongoing resources to maintain. (REF: Sect. 2.1.3—Application of CDS)

187. **THE ANSWER IS B.** A database schema defines the characteristics of all the columns in a database. In may include constraints to prohibit data that is inaccurate. It may also include relationships between tables to identify how tables can be joined when needed. Indivisible rows of information are the cornerstone of normalized data. Having a schema does not ensure that the data are normalized. Many databases are intentionally denormalized to improve performance. Most databases store rows on disk based on availability of disk space at the time that information is created. It is not usually specified by the schema. (REF: Sect. 3.1.1—Computer Systems)

188. **THE ANSWER IS C.** Vision statements tend to aspirational and describe how the company would like to see the world. They are terse and rarely include specifics. Choice A is more specific and could be a mission statement. Choice B is more specific still and could be a goal. Choice D is even more goal oriented and could be a goal or objective or an action. (REF: Sect. 4.5.1—Establishing Mission and Objectives)

189. **THE ANSWER IS A.** X12N is the subcommittee involved in established standards for communication with insurers. ANSI is the body that accredits standards developers. NEMA holds the copyright to DICOM, Digital Imaging and Communications in Medicine. The FDA does not develop standards. (REF: Sect. 3.4.3 Transaction Standards)

190. **THE ANSWER IS D.** Scope is the sum of all deliverables for a project. A milestone is a timeline feature where some fraction of the work is completed. A program is a group of similar projects. An activity is a distinct portion of work performed as part of a project. (REF: Sect. 4.4.1 Project Management Basics)

191. **THE ANSWER IS C.** The F-score (also known as the F-measure or the F1 score) is the harmonic mean between the precision and recall. Note that even if you did not know the formula for harmonic mean, you can get this question by recognizing that there is only one answer choice between 0.4 and 0.6.

$$F_1 = 2 \cdot \frac{precision \cdot recall}{precision + recall} = 2 \cdot \frac{0.4^{*}\,0.6}{0.4 + 0.6} = 0.48$$

(REF: Sect. 2.2.5—Information Retrieval)

192. **THE ANSWER IS A.** The IPPS pays hospitals based on the Diagnosis Related Group (DRG). Physicians are not paid via the IPPS. The DRG is determined primarily by the diagnosis itself, not based on the number of services that are actually provided or days the patient spends in the hospital. (REF: Sect. 1.2.5—Health Economics and Financing)

193. **THE ANSWER IS D.** According to McClelland's theory, there are three classes of needs: need for achievement—a strong need to excel by setting and accomplishing challenging goals; need for affiliation—an individual's need to belong to a group, be liked by the group, and be accepted by others; need for power—the need to be strongly influential, lead, and make a lasting impact on others. (REF: Sect. 4.1.6—Motivation)

194. **THE ANSWER IS A.** This is a description of a case-control study. The investigator has tried to match cases with controls to provide more meaningful statistical comparison. A cross-sectional study is a "moment in time" study of a population. A prospective cohort study is similar to a case-control study, but differs in two significant ways. A case-control study is retrospective while a cohort study could be prospective or retrospective. A cohort study identifies people with a risk and seeks to find if they have an outcome. A case-control study identifies patients with a disease and seeks to find risks. (REF: Sect. 2.2.1—Evidence Sources)

195. **THE ANSWER IS A.** The Reference Information Model (RIM) is a structure which allows transmission of information along with references to data dictionaries that define that information. Since different types of communications have different requirements, various *constraints* have been defined. One of the best known constraints on the RIM is the Continuity of Care Document which is a requirement for Meaningful Use. The other choices are very wrong. Hopefully, you didn't pick them. XML is a markup language which is used to express classes of the RIM. SNOMED is a controlled vocabulary which is a heavily referenced data dictionary in the RIM. HL7 V2 is the predecessor to V3, and predates the RIM. By the way, I'm kidding about the other choices. I put them in to trick you. It's OK if you picked them. (REF: Sect. 3.4.7 Interoperability Standards)

196. **THE ANSWER IS D.** Choice D represents a patient-oriented outcome, and would be given SORT class A or B depending on the quality of the study. Choice C gives a disease-oriented outcome and is class C. Choices A and B are also class C. NOTE that you really don't have to know the SORT criteria to answer this question, as long as you know that clinical evidence is better than consensus and that patient-oriented outcomes are better than disease oriented outcomes. (REF: Sect. 2.2.2 Evidence Grading)

197. **THE ANSWER IS D.** The hallmark of the situational leadership model is that the degree of supervision roughly correlates to the degree of maturity (performance readiness) of the subordinate. Choice A is specifically wrong because it encourages delegation in most groups instead of just the most mature. Choice B is an example of the trait theory, or the Great Man theory. Situational Awareness is not part of the Situational Leadership Model, and was just thrown in as a foil. It refers to the ability to remain aware of one's surroundings while working on a task. (REF: Sect. 4.1.1 Dimensions of Effective Leadership)

198. **THE ANSWER IS C.** In a fee for service model, physicians are paid for the services they provide. More services translates into more revenue. Capitation, the model used by accountable care organizations, involves paying a fixed price for each patient insured, so increasing services does not result in more revenue. The IPPS is similar to capitation in that it assigns a particular value to each hospital admission, grouped by diagnosis, not by length of stay or services provided. Notably, IPPS pays hospitals, not doctors. (REF: Sect. 1.2.5—Health Economics and Financing)

199. **THE ANSWER IS C.** Representation Bias is the tendency to overestimate unusual diseases or conditions due to matching pieces of the typical picture of that disease. Anchoring Bias is the tendency to rely too heavily, or "anchor", on one trait or piece of

information when making decisions (usually the first piece of information acquired on that subject). This usually leads to a failure to adjust the probability of a disease based on new information. Value based bias is the tendency to over or under estimate the probability of an outcome based on the perceived value associated with that outcome. Belief bias is the tendency to judge the strength of arguments based on the plausibility of their conclusion rather than how strongly the evidence supports that conclusion. (REF: Sect. 2.1.1—The Nature and Cognitive Aspects of Decision Making)

200. **THE ANSWER IS B.** In the Delphi method, a group leader sends open-ended questions to all participants. Their responses are collected anonymously and then collated and sent back to the group for refinement. After several cycles, an answer is found. The participants never actually meet face-to-face. Consensus Mapping is a complicated procedure where group members meet in small and larger groups in order to determine consensus. In Nominal Groups, each member writes their idea on a slip of paper, which is then discussed in a round-robin format. Groupthink is the tendency for members of a group to surrender their individual ideas to the group. (REF: Sect. 4.2.3 Group Management Processes)

201. **THE ANSWER IS C.** Choice C represents the win-win situation where the parties desire a mutually beneficial solution. This is called Problem Solving by Pruitt, Integrating by Rahim and Collaborating by Thomas. The other choices represent lesser options. If Compromising had been a choice, that would also have been correct. (REF: Sect. 4.1.4 Conflict Management)

202. **THE ANSWER IS A.** Technological developments in the United States continue to facilitate the use of CDS. There has been an increased purchase and use of EHR systems primarily as a result of governmental funding and policy initiatives. Stabilization in technology has also added to CDS adoption, but finances are a better option. Physicians and patients are rarely part of the decisionmaking process in terms of implementing CDS. (REF: Sect. 2.1.3—Application of CDS)

203. **THE ANSWER IS C.** External validity refers to the ability to extrapolate findings from the study population to the general population. If the populations differ in significant ways, the results may not translate well. Choice A describes a lack of precision introduced by an inaccurate measurement device. Choice B describes a systematic bias because the machine always reports high, which is consistent with a lack of internal validity. Choice D is irrelevant. Observational studies do not have blinding. (REF: Sect. 2.2.2 Evidence Grading)

204. **THE ANSWER IS A.** Choice A reflects indirectness. There is no study comparing A to B directly, only to a placebo intermediate. Choice B describes a dose-response curve which strengthens the evidence. Choice C describes an opportunity for attrition bias (or transfer bias). However, the evidence shows effect in the opposite direction, making it more credible. Choice D is an example of an all-or-none effect which also strengthens the evidence. Again, to answer this question, you don't need to know the GRADE criteria, only that overcoming bias, finding a dose-response curve or an all-or-none finding strengthens a claim while indirectness weakens it. (REF: Sect. 2.2.2 Evidence Grading)

205. **THE ANSWER IS C.** In 2009, the American Medical Informatics Association published two key papers that introduced a clinical subspecialty for informatics physicians. During the coming years, AMIA leadership petitioned the Accreditation Council for Graduate Medical Education (ACGME), American Board of Medical Specialties (ABMS) and the American Board of Preventive Medicine (ABPM) and American

Board of Pathology (ABP) to establish a board exam as well as accreditation standards for fellowships in clinical informatics. See Clinical Informatics: Emergence of a New Profession in Finnel and Dixon's Clinical Informatics and Study Guide for a first-hand narrative of the story by Ted Shortliffe. (REF: Sect. 1.1.1.5—Professional Organizations)

206. **THE ANSWER IS B.** Publication bias refers to the fact the journals are much more likely to accept manuscripts which are interesting to its readers. Negative studies (i.e. those that fail to demonstrate some novelty) are less likely to be published. Peer review is the process where subject experts evaluate a manuscript before publication. Selection bias refers to the systematic recruitment of subjects with characteristics that may generate inappropriate results. I made up Rejection bias. (REF: Sect. 2.2.1—Evidence Sources)

207. **THE ANSWER IS D.** Since the 95% confidence interval contains the null value of ARR = 0, we know that the findings are not significant at the p = 0.05 level. The remainder of the calculations are incorrect. This question is one example of where it really makes a difference if you read all the choices before beginning calculations! (REF: Sect. 2.2.1—Evidence Sources)

208. **THE ANSWER IS C.** Indexes allow rapid searching for keywords and can speed queries by several orders of magnitude compared to linear search. Recall and Fallout are measures that reflect the accuracy of the query, but not its speed. Tokenization is the process of breaking documents into searchable items. Tokenization must be done before items are placed into an index. (REF: Sect. 2.2.5—Information Retrieval)

209. **THE ANSWER IS A.** The Negative Predictive Value of a test is defined as the number of true negatives divided by the total number of negative tests i.e. NPV = TN/(TN + FN). For any given specificity of a test, the larger the percentage of tested patients who have the disease, the more likely there will be false negatives, thus making the NPV lower. (REF: Sect. 2.1.2 - Decision Science)

210. **THE ANSWER IS A.** Remote monitoring of ICU patients is a common application of telemedicine technology. PACS requires higher bandwidth than can be provided by telephone (voice only) service. Poison control centers normally use voice-only communications. Telepresence refers to simulating the remote environment locally. Video conferencing is rarely needed for scheduling

211. **THE ANSWER IS A.** According to the report, expanding information technology is one way to cross the quality chasm. It should be no surprise that that is one of the reasons why this report is required reading for the clinical informatics boards. The other options are all mentioned in the report, but are not as prominent or over-arching as expanding technology. (REF: Sect. 1.2.7 Institute of Medicine Quality Components)

212. **THE ANSWER IS A.** By appealing to an outside authority, the negotiator effectively stops the negotiation by saying that he is unable to commit to a resolution at that time. The other choices often result in a quicker negotiation. (REF: Sect. 4.1.3—Negotiation)

213. **THE ANSWER IS C.** The p-value indicates the likelihood that the results could be entirely due to chance. It does not take bias or measurement inaccuracy into account. (REF: Sect. 2.2.1—Evidence Sources)

214. **THE ANSWER IS D.** The reason why systematic reviews and meta-analyses are so powerful is that they can reduce the risk of bias introduced by individual studies. While the remaining answers are essentially true, they do not address the issue of bias which is the most important in grading of evidence. Choice A points out the greatest weak-

ness of basic science research. Since it doesn't take into account human behavior, it can't reliably predict outcomes. Choice B fails to account for the fact that an individual observer is much MORE likely to have bias than a group of observers. Choice C is true, but we are talking about grading of evidence, and expert opinion is not evidence. (REF: Sect. 2.2.2 Evidence Grading)

215. **THE ANSWER IS B.** As computers are unable to lie, they have no choice but to be honest. Choices A and D are wrong because the majority of EHR's do not prevent misdiagnosis and very few of them are capable of the fine-grained access control described. Consider the case of a 17-year old girl who wishes to hide her pregnancy from her parents, but wants them to be able to see the rest of her medical records unimpeded. Choice C is wrong because poorer people do not have the same access to internet as richer people (e.g. the "digital divide") (REF: Sect. 1.1.5—Ethics and Professionalism)

216. **THE ANSWER IS B.** Responsibility is being accountable for something. Authority is the power to make decisions and issue orders. When the board of directors asks for something, they are extending responsibility; when they restrict the budget, they are taking authority. (REF: Sect. 4.1.2—Governance)

217. **THE ANSWER IS D.** Sensitivity analysis is an analysis method that is used to identify how much variations in the input values for a given variable will impact the results for a mathematical model. A run chart graphs the output of a process over time. A control chart is similar to a run chart but also includes upper and lower bounds. Monte Carlo analysis is an iterative process where the risk of a project can be calculated from the combination of its component risks. (REF: Sect. 4.4.5 Project Management—Informatics Project Challenges)

218. **THE ANSWER IS B.**

$$HR = \frac{risk\ in\ study\ group}{risk\ in\ control\ group} = 8 = \frac{n/90}{15/900} \Rightarrow n = \frac{8 \cdot 15 \cdot 90}{900} = 12$$

(REF: Sect. 2.2.1—Evidence Sources)

219. **THE ANSWER IS C**. Governance is a method to provide consistency and transparency within an organization. As a result, workers have a predictable and stable environment. This does not necessarily guarantee profits or reward jobs well done. Organizational governance is unrelated to municipal government. (REF: Sect. 4.1.2—Governance)

220. **THE ANSWER IS C.** Strategy formulation is a creative, theoretical entrepreneurial activity involving a few top executives while implementation is a productive, rational, action-oriented, administrative task and may involve the whole organization. (REF: Sect. 4.5.4—Action Planning and Strategy Implementation)

221. **THE ANSWER IS A.** Depreciation is an accounting method of allocating the cost of a tangible asset over its useful life. The direct materials budget is part of the operating budget for purchasing raw materials. An MRI machine is expected to last more than 1 year, and would therefore be on the capital budget, and not an operating expense. A mortgage is a many-year loan used to buy large items, usually real estate. (REF: Sect. 4.5.5 Capital and Operating Budgeting)

222. **THE ANSWER IS A.** When the results of a study are dichotomous and dramatic, it is often termed an all-or-none study. This particular study could also be called a case series or perhaps even a method paper, but these were not among the options. Ethics violations arise when patients are subjected to substandard care. In this case, there is no available cure or treatment for macular degeneration, so as long as patients consented to treatment, there are no ethical problems. Ecological studies involve studying at least one variable at the population level. (REF: Sect. 2.2.1—Evidence Sources)

223. **THE ANSWER IS B.** DICOM is a set of protocols and file formats used for transfer of medical images. Ethernet Cat-6 is a cabling specification to support gigabit transmission speeds. The W3C helps define standards for the world wide web. (REF: Sect. 3.4.1—Standards Development)

224. **THE ANSWER IS D.** Instituting a significant change for a small part of the population would not be as effective as initiating a modest change for the majority of the population. In this question, choice A reflects making a big change for few people, while choice D would make a modest change for many people. Choice C is actually very similar to choice A in that it would make a big difference to very few people. Choice B offers a modest benefit to a small population. (REF: Sect. 1.2.1—Determinants of Health)

225. **THE ANSWER IS B.** A strategy is the means by which an organization sets out to achieve its goals. A resource is a tangible or intangible aspect of the organization which can be used for this task. A value chain is a set of activities that an organization performs in order to deliver a product or service. Vision is the ideal that the organization pursues. (REF: Sect. 4.5.3—Strategy Formulation)

226. **THE ANSWER IS D.** The SQL UPDATE command is used to modify an existing table. In this case, we want to change the Last_Name field of the record with id = 3 to 'Mankowitz'. Choice C will update **all** records to have Last_Name 'Mankowitz'. Choice B will delete a record from the table. The ALTER TABLE command is used to modify the schema. As written, this command will generate a syntax error. (REF: Sect. 3.1.5—Data)

227. **THE ANSWER IS A.** The peer-review process means that experts in the field of study review manuscripts before they are published. It is a hallmark of respected journals. The other choices are all false. (REF: Sect. 1.1.3—Clinical Informatics Literature)

228. **THE ANSWER IS B.** Only licensed surgeons may perform complex surgical operations. Physician assistants are allowed to assist in these operations as long as they are supervised by a physician. Nurse practitioners are allowed to perform some invasive procedures without supervision (depending on the state). Any provider of medical care may be sued for malpractice. All providers are required to complete some degree of continuing education. Many non-physician providers possess doctoral degrees. (REF: Sect. 1.2.2.4—Education of Health Professionals)

229. **THE ANSWER IS A.** A manager makes a make-or-buy decision when he decides whether goods or services should be made by the organization, or bought from an outside party. This decision is usually based on cost and availability of resources (such as staff expertise). It does not take into account other market forces, such as a competitor's market share. (REF: Sect. 4.4.2 Project Management—Identifying Resources)

230. **THE ANSWER IS B.** The reduction of waste (non-value-added processes) is the hallmark of the LEAN methodology. Delphi is a method of obtaining group consensus. Plan-Do-Study-Act (PDSA) is the most common method of quality improvement. Six-

sigma seeks to improve processes until defects are so rare that they represent six standard deviations from the mean. (REF: Sect. 2.3.3 Quality Improvement)

231. **THE ANSWER IS A.** The BlueButton Initiative was one of the first attempts to allow patients to download their medical information. It was developed at the Veterans Affairs hospitals for use in their EHR, called VistA. The CCD is a standard developed by HL7 and is a constrain on the RIM. It became popular when it was included in the Meaningful Use criteria. (REF: Sect. 3.4.1—Standards Development)

232. **THE ANSWER IS C.** Hospitals, like other service industries, spend most of their capital on labor costs, so minimizing those costs increases revenues. Product innovation and customer loyalty may be important goals, but are not HRM tasks. Decreasing revenues is not an objective. (REF: Sect. 4.2.1—Human Resources)

233. **THE ANSWER IS B.** As time goes on, bugs become easier to find, but harder to fix because of the numerous moving parts. Warranties are sometimes, but not always provided with software, and tend to have limited support options. Testing a running system is a form of dynamic testing. Static testing involves reviewing source code. By definition, implementation means a running system, which makes static testing a poor answer. (Ref: Sect. 3.5.4—Clinical Information System Testing)

234. **THE ANSWER IS D.** A service which can be provided on a large scale is not valuable, rare, inimitable or specific to the organization. The other choices all contain an aspect which makes the product hard to replicate. (REF: Sect. 4.5.3—Strategy Formulation)

235. **THE ANSWER IS C.** Criteria for de-identification are based on how hard it would be to re-identify a patient based on bits of data. Since dates of birth are often found in public records, it is much more susceptible to re-identification than, say, account numbers which are only found in patient records and hospital information systems. While choices B and D are true, they are not relevant to this question. (REF: Sect. 3.1.6 Technical Approaches that Enable Sharing Data)

236. **THE ANSWER IS C.** Of the three requests listed, the RFQ is the most basic, and is used when the nature of the product is already known and the purchaser is simply negotiating price. An RFP is a formal document which explains, in detail, an organization's needs and typically includes a thorough response from a vendor. An RFI is a shorter, less formal document of the same nature. The SDLC is a systematic method of designing and building systems. (REF: Sect. 3.5.2—Clinical Information Needs Analysis)

237. **THE ANSWER IS B.** This question tests a simple definition, but even if you did not know the answer, you should be able eliminate some choices. (REF: Sect. 4.6.2—Change Theories)

238. **THE ANSWER IS D.** Heuristics allow people to solve problems and make judgments quickly and efficiently, but they are also prone to errors. Cognitive bias often results from heuristics and can lead to systematic deviations from a standard of rationality or good judgment. Decision support tools are designed to optimize results by providing additional information or alerting a clinician to the need for additional information. Likewise, Bayes Theorem is designed to optimize decision making. It does this by taking into account the pretest probability of a condition, while interpreting the results of testing. (REF: Sect. 2.1.1—The Nature and Cognitive Aspects of Decision Making)

239. **THE ANSWER IS D.** This is a confusing question, but it illustrates some points about nonsemantic concept identifiers. First of all, semantic concept identifiers can help the

reader understand a concept's place in the hierarchy. For example, ICD-10 is a hierarchical terminology. The code W21 corresponds to being hit by a ball. The code W21.01 corresponds to being struck by a football. W21.02 is a soccer ball. W21.03 is a baseball. Suppose we wanted to extend the hierarchy to include all kinds of sports injuries, including being hit by a jai-alai ball or a medicine ball. At some point, we'd either run out of numbers or we'd have to change the coding system. This is why choice B is a good argument. Now suppose we decide that we want to group all football injuries together, such as being tackled, which is Y93.61. Unfortunately, this code is found in a completely different hierarchy and can't be found within the W21 group, which is why C is a good reason. Similarly, choice A explains the next step in this argument. Suppose we *did* reclassify all football injuries into the same heading. As long as we respect concept permanence (concepts can not be deleted), we would now have an orphan code of Y93.61. Finally, we are left with choice D. At one point, when computing power was relatively expensive, using integer codes was much more efficient. With modern systems, the difference is less important. Although D is a *reasonable* choice, it is the weakest argument among those listed. (REF: Sect. 3.4.6 Ontologies and Taxonomies)

240. **THE ANSWER IS D.** Using the formula for the positive predictive value,
PPV = TP/(TP + FP)
19/(19 + 1) = 95%
(REF: Sect. 2.1.2—Decision Science)

241. **THE ANSWER IS C.** There are many approaches to managing change, but all include the formation of a group of leaders to spearhead the mission. Effective change requires buy-in from all stakeholders. If rank and file employees are unaware of the ultimate goals of the change, they are less likely support the process. Similarly, if employees are not empowered to make decisions, the entire process will slow down whenever it encounters a new variable. Short term wins should be in line with the corporate vision, but should not be used to define the vision. The vision should already be in place before short term wins are achieved. (REF: Sect. 4.6.3 Change Management Strategies)

242. **THE ANSWER IS A.** Operational expenses (opex) are usually funded with cash flow. Capital budgets are funded with retained earnings, debt or equity. (REF: Sect. 4.5.5 Capital and operating budgeting)

243. **THE ANSWER IS B.** The OSI model contains seven layers. The lowest layer is the physical layer, such as network cabling. The highest level is the application level. In the middle are levels for networking, authentication, session management, presentation and other technologies. (REF: Sect. 3.1.3—Networks)

244. **THE ANSWER IS D.** The project charter is the output from the initiating phase of integration management. Note that it is not necessary to know that we are talking about integration management, because the only other activity in the initiating phase is identification of stakeholders. HR Planning and the creation of the project team is done in the HR knowledge area. Both procurements and creating the team are part of the execution phase. (REF: Sect. 4.4.1 Project Management Basics)

245. **THE ANSWER IS B.** A/B testing presents users with two alternatives and measures their acceptance. It can be done on a large scale (such as with web sites) or a smaller scale with individual interviews. (REF: Sect. 3.2.2—HCI Evaluation)

246. **THE ANSWER IS A.** The distinction between conflict management and conflict resolution is that conflict management seeks to preserve the positive aspects of conflict while conflict resolution seeks to remove the conflict entirely. The other choices are all

true, but do not reflect the difference between resolution and management. (REF: Sect. 4.1.4 Conflict Management)

247. **THE ANSWER IS D.** Keystroke-Level Model is a type of HCI analysis that focuses on how the keyboard and mouse are utilized. Mental preparation is considered part of the action. Sketching would not be included in this kind of analysis. (REF: Sect. 3.2.1 Models, Theories, and Practices of HCI)

248. **THE ANSWER IS C.** In a double-blind study, neither the investigator nor the subject knows which study arm they are in. The other choices may represent also represent methodological flaws. (REF: Sect. 2.2.1—Evidence Sources)

249. **THE ANSWER IS D.** A method paper (also called an application paper) describes a novel technique or procedure. Choices A and C represent case reports. Choice B is probably original research. (REF: Sect. 2.2.1—Evidence Sources)

250. **THE ANSWER IS A.** CDS has shown benefits in diagnosis, treatment guidelines, clinical pathway adherence. Unfortunately, data on patient outcomes, physician efficiency and errors in data entry are lacking. (REF: Sect. 2.1.3—Application of CDS)

251. **THE ANSWER IS C.** An outcome measure describes a real-world patient benefit. Using an appropriate drug-drug interaction checker, maintaining an accurate active medication list would be expected to reduce the number of drug-drug interactions. Choice B is a process measure, not an outcome measure. Choices A and D are possible benefits of maintaining an active medication list, but are not as good as choice C. (REF: Sect. 2.3.3 Quality Improvement)

252. **THE ANSWER IS A.** A milestone is a zero-length task meant to signify completion of some part of a project. Slack (or float) is the degree to which a task can be delayed without delaying the end of the project. A summary task is an overarching structure that includes other tasks. In this diagram, the line that reads "Project 15" is a summary task. A start-start dependency describes the situation where one task can not start until another one starts. (REF: Sect. 4.4.4 Project Management Tools)

253. **THE ANSWER IS D.** Distributive bargaining is encountered when there is a fixed amount of resources that must be split among all parties, such as when buyer and seller haggle over a price. Choice A involves litigation, which is not a form of negotiation or alternative dispute resolution. Choice B and C are much more likely to be examples of integrative bargaining. (REF: Sect. 4.1.3—Negotiation)

254. **THE ANSWER IS D.** Real time communication, such as interactive video, is a form of synchronous communication. This is distinguished from asynchronous communication where the sender and receiver may not be utilizing the system at the same time. Remote monitoring is usually synchronous, where the remote provider is able to view a live stream of monitoring equipment. Store-and-forward is an asynchronous technique where the data file is stored on a server and forwarded to another server to provide care. (REF: Sect. 3.3.4—Telemedicine)

255. **THE ANSWER IS A.** Sensitivity is the probability that a test will be positive in a patient with the disease. Similarly, Specificity is the probability that a test will be negative in patients without the disease. Positive Predictive Value and Negative predictive value measure the likelihood a patient will have a disease (or not) given a positive or negative test. (REF: Sect. 2.1.2—Decision Science)

256. **THE ANSWER IS D.** This represents a finish-to-finish dependency. Task B can not be finished until task A is finished. The easy way to remember this is that the arrowhead determines the task that is constrained. The location of the arrow determines if the dependency applies to the finish or the start. In our case, the network update finish is constrained by the finish of the rewiring project. Choices A and C are essentially the same. Choice B represents a finish-to-start dependency. (REF: Sect. 4.4.3 Project Management Resource Allocation)

257. **THE ANSWER IS A.** Data stewardship includes many processes, including those that ensure that the right data is stored in the right place in the database so that users can get to it easily. The stem provides an example of data which is not being stored in the appropriate field, which may hinder future access. Correcting this behavior is an example of data stewardship. Referential Integrity is a characteristic of a database that indicates that all rows which refer to other rows in other tables are valid. Usability refers to the ease with which a user interacts with a system. Syntax is the collection of grammatical rules that defines a well-formed statement in a given language. (REF: Sect. 3.5.5—Clinical Information System Maintenance)

258. **THE ANSWER IS A.** ICD-10 supplanted ICD-9 as the most commonly used method of encoding diagnoses in 2016. Both versions are hierarchical and include codes for external causes (e.g. V-codes in ICD-9). ICD-10 allows for greater specificity by including codes for laterality and visit type. (REF: Sect. 3.4.5 Nomenclatures, Vocabularies, and Terminologies)

259. **THE ANSWER IS D.** Telepresence, which is the simulation of a remote environment, requires immediate feedback to be successful. Messaging, and to a lesser extent, telephone can tolerate latency much better. Remote monitoring tends to have less bandwidth requirement than telepresence

260. **THE ANSWER IS C.** User centered design should consider user goals, motivations, and environment throughout the design and development phases. Relying solely on market research or organizational benchmarks will not yield enough useful information. Design should be optimized for all users, not just patients. (REF: Sect. 3.2.2—HCI Evaluation)

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