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Foreword

William F. Rayburn, MD, MBA
Consulting Editor

The discipline of obstetrics and gynecology has a long tradition of leadership in quality assessment and accompanying patient safety. The quest for patient safety is an ongoing, continuously refined process, incorporating information sharing and collaboration into daily practice. Quality improvement efforts have shifted from a punitive approach to an educational process to assist all providers.

This issue of the *Obstetrics and Gynecology Clinics of North America*, edited by Paul Gluck, MD, brings together leading advocates for improving patient safety in general, and in obstetrics and gynecology specifically, to increase our understanding and to suggest solutions. Practical suggestions are offered to reduce errors in the office, during surgery, and in labor and delivery. Depending on the setting and type of practice, certain solutions mentioned in these articles can be implemented rapidly while others require incremental change.

Efforts to improve quality and safety are more likely to achieve consensus if changes come from within the departments. These changes include working collaboratively in teams, improving communication, and increasing utilization of information technology. As described in this issue, examples of ways to reduce errors include (1) using electronic medical records and e-prescribing, (2) working collaboratively in multidisciplinary teams, and (3) using high-fidelity simulations for learning and for assessing competence and credentialing. Disclosing any medical error, especially to an injured patient or to a grieving relative, is one of the most difficult but most important tasks.

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Most medical errors should be handled in a nonpunitive environment to improve reporting and to gain an understanding of the breadth of problems in health care systems. To improve patient safety, physicians should disclose errors and near misses openly and encourage their colleagues to do the same. This openness will promote and increase error reporting, identify potentially hidden problems, and motivate providers to find and resolve system problems.

Involving patients in decisions about their own medical care is good for their health, not only because it is a protection against treatment that patients might consider harmful, but because it contributes positively to their well-being. Patients are to be encouraged to ask questions about medical procedures, the medications they are taking, and any other aspect of their care. Patient education materials developed by the America College of Obstetricians and Gynecologists and other organizations are available.

This issue describes in detail the steps necessary to develop a program to monitor the quality of care in a typical department of obstetrics and gynecology. Emphasizing compassion, communication, and patient-focused care will aid in creating a culture of excellence.

I thank the authors for their timely contributions to this important topic of interest to all of our readers.

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Preface

Paul A. Gluck, MD
Guest Editor

> Medicine used to be simple, ineffective and relatively safe. Now it is complex, effective and potentially dangerous.
>
> —Cyril Chantler

Lewis Thomas, in his semi-autobiographical book *The Youngest Science: Notes of a Medicine-Watcher*, reminisced about his father, an internist in the early twentieth century who would sit by his patient, holding his hand while nature affected the cure. There was little else he could offer. Now, after almost 100 years, we have crossed vast frontiers in medicine, from hormones to the immune system to unlocking the promise of genomics. We have relegated diseases such as erythroblastosis to the history books and transformed AIDS from a death sentence to a chronic illness. Yet each new treatment modality brings with it more complexity and greater risk for medical error. According to Robert Wachter and Kaveh Shojania, in their book *Internal Bleeding,* deaths from medical errors are the collateral damage of our war on disease. Many more patients are dying not from their underlying illness but from well-intentioned but erroneously applied treatment.

Medical errors can now be counted among the leading causes of death along with cancer, heart disease, and accidents. We must approach this epidemic of errors with education, research, and system changes. This issue of the *Obstetrics and Gynecology Clinics of North America* brings together some of the leading advocates for improving patient safety in general and in obstetrics and gynecology specifically to increase our understanding and suggest solutions.

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Lucian Leape was one of the first to raise the alarm about the unacceptably high number of patients who are harmed and even die as a result of medical errors. Not surprisingly, his warnings were met with denial by providers who questioned everything from the methodology to the significance of his findings. Now, some 16 years later, most physicians believe that Leape's original numbers regarding deaths from medical error are underestimates. From his unique perspective, Leape looks back on his 20-year journey working to improve patient safety.

I next discuss error theory as applied to medicine. Understanding the cause of disease will lead to better diagnosis and treatment. Through an understanding of why mistakes happen, we can better prevent errors and help mitigate the harmful effects of those that still occur.

Translating theory into practice, Paul Stumpf, past chair of the American College of Obstetricians and Gynecologists' Patient Safety and Quality Improvement Committee, provides practical suggestions that can be rapidly implemented to reduce errors in the office, in surgery, and in labor and delivery.

Medication errors account for the largest number of errors in health care. Over the years, the group at Brigham and Women's Hospital has led the way in determining the scope of this problem. Carol Keohane and David Bates put this problem into perspective and outline strategies to improve medication safety in the hospital and ambulatory settings.

When patients suffer harm or die as a result of medical errors, it is our ethical and moral obligation to provide a truthful and compassionate explanation as well as an apology if appropriate. Yet disclosing medical error to an injured patient or a grieving relative is one of the most difficult tasks any of us will face. Patrice Weiss, who trained at the Bayer Institute for Healthcare Communication, outlines a practical approach for disclosing adverse outcomes.

Compared with other industries, health care spends the smallest percentage for information technology. Yet electronic health records and e-prescriptions hold the promise of improving safety, increasing efficiencies, and reducing costs. Caitlin Cusack lays out the promises as well as the pitfalls for those moving toward implementation of a robust, fully integrated electronic health record.

Working collaboratively in multidisciplinary teams has significantly transformed other high-risk industries. Teamwork has the potential to improve efficiency, reduce risks, and increase patient and provider satisfaction. Peter Nielsen and Susan Mann discuss team training principles and the impact they have on reducing adverse outcomes in labor and delivery.

With improved technology, high-fidelity simulations are becoming a valuable tool for perfecting technical skills and practicing team behaviors in medical emergencies. Roxanne Gardner and Dan Raemer, leaders in this field from the Center for Medical Simulation, outline the remarkable technical advances in the field. Simulation is being incorporated into

training programs and postgraduate education, not only for learning but also for assessment of competence and credentialing.

Looking beyond the individual practitioner and at the systems of care, Joseph Gambone and Robert Reiter discuss the critical elements needed for a successful, sustainable departmental quality improvement program. Efforts to improve quality and safety will be much more likely to achieve consensus if changes come from within the department as opposed to regulations from outside.

Finally, Abraham Lichtmaker reviews the work of the Voluntary Review for Quality of Care Program of the American College of Obstetricians and Gynecologists. This unique consultative service has reviewed 236 obstetrics and gynecology departments from a diverse cohort of institutions. The problems encountered in these hospitals were surprisingly similar. Suggested solutions may be helpful to other institutions encountering similar problems.

Progress is achieved both through incremental steps and giant strides. The contributors to this issue hope that readers will be able to rapidly adopt some incremental changes to improve patient safety in any setting and in any type of practice. Beyond that, we hope that readers will see the value of addressing some of the long-term, transformational changes in health care systems that will result in quantum improvements in patient safety. Examples of these changes include collaborative teamwork, improved communication, and increased use of health information technology. Only through these and other changes can we substantially reduce the number of patients harmed by well-intentioned providers who struggle every day to care for patients in a flawed medical system.

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Scope of Problem and History of Patient Safety

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Scope

How much of a problem is patient safety? The unsettling fact is that no one knows. What we "know" depends on how we gather information, on how and who determines that a patient has been injured by an error or other lapse in care. However, because we have traditionally punished people for making errors, caregivers, not surprisingly, often do not report errors they can hide. Add to that the fact that many errors are not recognized, even when they cause harm, and it is clear that obtaining a reliable estimate of errors is difficult.

According to the National Academy of Sciences' Institute of Medicine (IOM), the definition of safety is "freedom from accidental injury," not freedom from errors [1]. (Our safest industry, commercial aviation, still has many errors, but few crashes.) Thus, many experts believe that it is more feasible and productive to focus on the number of injuries that occur, not the errors. However, even counting injuries proves to be a challenge. For example, the estimates of the annual number of preventable adverse events (AE) suffered by hospitalized patients in the United States vary by an order of magnitude of 1.3 million [2] to 15 million [3].

Some of this discrepancy is definitional. That is, the Medical Practice Study (MPS) measured only "disabling" injuries: those prolonging hospital stay or resulting in a disability at discharge (including death). The Institute for Healthcare Improvement (IHI) attempts to identify all injuries suffered by hospitalized patients, including, for example, nausea and vomiting resulting from a medication dosage error.

An even greater cause of discrepancies is the method used to collect data on adverse events. Traditionally, we have relied on voluntary reporting. But

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studies have shown that the vast majority of events are not reported [4]. As a result, modern studies usually rely on collecting data from record review (itself fraught with errors), analysis of laboratory data, and investigation or observation. Costs of data collection increase accordingly. But no method yet devised has been shown to identify all adverse events, much less errors. There is no "gold standard" to follow in this area of investigation.

Modern counting began with the MPS findings from record reviews that 3.7% of hospitalized patients suffered AEs, two thirds of which were preventable and 14% of which were fatal [5,6]. When extrapolated to the country as a whole by the IOM in 1999, the resulting estimate of 98,000 preventable deaths was greeted with skepticism by many physicians and spawned a burst of rebuttals. The MPS study was subsequently replicated in seven other countries with comparable health care training and standards (Australia, New Zealand, the United Kingdom, Denmark, France, the Netherlands, and Canada) [7,8], with injury rates ranging from 7.5% to 15%. The international consensus now is that approximately 10% of hospitalized patients experience a treatment-caused injury and at least half of these are preventable.

When specific types of AE are investigated, the figures are stunning. Adverse drug events (ADE) have been studied the most extensively. An early study of ADE found that 6.5% of hospitalized patients had an injury related to use of a medication, of which 28% were preventable [9]. In nursing homes, the ADE rate is 227 per 1,000 resident-years [10]. A study of ADE in office practice revealed a rate of 25% [11]. Based on these and other studies, the IOM estimates that 1.5 million patients in the United States experience an adverse drug event each year [12].

The problem of hospital-acquired infections has recently received increased public scrutiny, particularly the incidence of antibiotic-resistant infections. The Centers for Disease Control and Prevention (CDC) estimates that each year 1.7 million hospitalized patients acquire an infection, of which 126,000 are caused by resistant staphylococci, and 99,000 are fatal [13]. Most are preventable with current best practices and, indeed, there have been some stunning successes in prevention of central line infections and ventilator-associated pneumonia.

In obstetrics, Mann and colleagues [14,15] found that team training in labor and delivery substantially reduced the complications salient to delivery. About half of the AEs in patients in the MPS were associated with a surgical operation [6]. Subsequent studies suggest as many as 3.5 million patients suffer a postoperative AE.

Recently, the IHI reported the results of the use of its "trigger tool" to identify AE. These are indicators (such as a high international normalized ratio or the use of naloxone) that suggest a mishap. The record is then reviewed to determine if an injury has in fact occurred. Data from a number of hospitals using the trigger tool show that 40% of patients, or 15 million Americans per year, have an adverse event while hospitalized [16].

History

The beginnings

It is probably fair to say that the modern patient safety movement began with the publication of the results of the Harvard Medical Practice Study in the New England Journal of Medicine in February, 1991 [5,6]. The study examined a random sample of medical records of 30,000 patients hospitalized in acute care hospitals in New York State in 1984. Although the impetus for the study was the contemporary medical malpractice crisis, the investigators expanded the focus to obtain a population-based estimate of the extent of all medical injury, its preventability, and its consequences, both in human terms and economically.

The MPS found that 3.7% of hospitalized patients suffered an adverse event, defined as an injury caused by medical treatment (in contrast to complications of disease), which either delayed discharge or caused a measurable disability. Of these injuries, 14% were fatal.

In more than two-thirds (69%) of adverse events identified in the MPS, errors or other failures in treatment were identified that led physicians who reviewed the records to conclude they were preventable, and nearly half of those (1% of patients) were judged to meet the definition of negligence: failure to meet the standard of care. About one-half of adverse events occurred in surgical patients, and nearly one in five were related to use or misuse of medications.

Interviews with patients or next of kin 5 years after injury identified the long-term consequences of these injuries, from which the economic burden of medical injury was calculated. It was estimated that the total cost of adverse events suffered by patients in New York was approximately $4 billion (in 1989 dollars), of which one-fourth was out-of-pocket expense [17]. Fewer than 2% of patients with presumed negligent injuries ever filed a suit.

Although the study was published in the New England Journal of Medicine and ran as a front-page article in the *New York Times*, the findings were essentially ignored. The state medical society rejoiced in the finding that negligence accounted for injuries to "only" 1% of patients. Based on the findings of the study, the investigators made a single recommendation: that the State of New York implement a no-fault compensation plan for medical injuries. The Health Commissioner agreed and proposed legislation, but his subsequent serious illness and a fiscal downturn led to it being ignored.

Early days

The finding that a substantial majority of adverse events was caused by errors led to a search for methods to reduce errors and, thus, to the discovery of lessons from cognitive psychology and human factors engineering. These insights, the most important of which is that errors can be reduced

by redesigning systems, led to dramatic reductions in accidents and injuries in other hazardous industries, such as aviation and nuclear power. Many of these concepts seemed applicable in health care as well [18].

1995 was a pivotal year for patient safety. It began with a series of egregious events that put the issue of medical errors on the front pages of papers across the country: amputation of the wrong leg, removal of the wrong breast, operation on the wrong side of the brain. Perhaps the most gripping was the death of a health reporter in Boston from a fourfold overdose of chemotherapy. The public wanted to know: What was medicine going to do about it?

By summer, the first studies appeared, applying the systems analysis approach in health care [9,19]. The American Medical Association (AMA), prodded by its legal counsel, Martin Hatlie, decided to establish a foundation of stakeholders to promote patient safety, while the new head of the Veteran's Health Administration (VA), Ken Kizer, decided to make safety a system priority.

In 1996, the AMA and the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) joined the American Association for the Advancement of Science and the Annenberg Foundation to host the first multidisciplinary conference on medical errors at the Annenberg Center in California. At this meeting, the AMA announced the formation of the National Patient Safety Foundation, and the JCAHO announced that it was making its reporting system nonpunitive. But the memorable events of the conference were Diane Vaughan's recounting of events leading to the *Challenger* disaster and Martin Memorial Hospital's presentation of full and open disclosure of a fatal medication error in a child.

Over the next several years, more evidence appeared on the efficacy of systems changes, largely in the medication system: use of computerized physician order entry [20], use of bar coding to prevent medication administration errors [21], having a pharmacist participate in rounds in the intensive care unit [22], and the role of simulation [23,24]. Studies examined the costs of adverse drug events [25,26] and the effect of sleep deprivation [27,28]. Replication of the Medical Practice Study in Australia produced a rude shock: an adverse event rate of 13%, three times that found in the MPS [7]. Meanwhile, the IHI began to train multidisciplinary hospital teams how to change systems and implement new safe practices in a series of collaborations [29,30].

The IOM report

Still, patient safety was not a major concern for most hospitals or doctors, nor for the public, until November of 1999 when the IOM released its report, "To Err is Human" [1]. Extrapolating from the MPS study of a decade earlier, and a later study in Colorado and Utah, the IOM proclaimed that medical errors caused 44,000 to 98,000 of preventable deaths

a year. That figure grabbed the headlines. All of the major television networks led with the story that night. But the IOM had a second message that also got through: that the cause of these errors was not calloused or careless doctors and nurses, but defective systems. Fix those systems, said the IOM, and we can reduce preventable injuries by 90%: the federal government should launch a major national effort.

Overnight, public and professional awareness of the seriousness of the medical error problem spread from hundreds to millions. President Clinton appointed an intergovernmental task force to review the report and make recommendations for federal action.

The IOM report had three important effects. First, it ended the period of denial, during which increasing evidence from research and the entreaties of the small group of safety investigators were ignored. No longer could hospitals or doctors, administrators, regulators, or payers ignore the problem.

Second, it brought a number of stakeholders into action. The first was Congress, which in 2001 appropriated $50 million annually to the Agency for Healthcare Research and Quality (AHRQ) for patient safety research. Although merely one-fifth of 1% of the $28 billion budget for the National Institute for Health, that funding helped enlist hundreds of new investigators into patient safety research. Research in error prevention and patient safety became a legitimate academic pursuit. Unfortunately, in 2004, after only 3 years of support, Congress required the AHRQ to devote those funds toward studies of information technology, in effect cutting off funding for other safety initiatives. Congress also gave the AHRQ the lead as the federal agency responsible for patient safety research and education, and the AHRQ established a Center for Quality Improvement and Safety, which has become the leader in educating, training, convening agenda-setting workshops, disseminating safety information, developing measures, and facilitating the setting of standards in the United States.

The third major effect of the IOM report was to motivate hospitals to make the changes in practice needed to make health care safe. Some hospitals had already responded to recommendations for medication safety from regional coalitions or the American Hospital Association, and many had sent teams to IHI programs to learn rapid cycle improvement and the application of human factors principles in the effort to redesign their processes. These efforts now took on new life.

Since the IOM report

The Veteran's Health Administration, having already established a VA National Center for Patient Safety in 1998 headed by former astronaut and physician, James Bagian, established four patient safety research centers [31,32] and implemented nonpunitive reporting, use of computerized order entry systems, and bar coding, in addition to team training and other initiatives.

The Centers for Medicare & Medicaid Services and the CDC joined with over 20 surgical organizations in a new program to reduce surgical complications [33], and many other specialty societies have incorporated safety topics into their meetings, education, and research.

A host of nongovernmental organizations have made safety a priority. Under the forceful direction of Kenneth Kizer (who previously led the reorganization of the VA health system and initiated its safety program), the National Quality Forum (NQF) was established as a public-private partnership to develop and approve measures of quality of care. Broadly representing many stakeholders (providers, purchasers, and consumers), the NQF developed a consensus process that has generated standards for mandatory reporting [34] and created a list of 30 high-impact evidence-based safe practices ready for implementation by hospitals [35]. The NQF has also developed standards for nursing care and a standard taxonomy for medical error.

The JCAHO has been one of the most effective instruments of change for safety, first by changing to unannounced accreditation audits and more recently by requiring hospitals to implement new safe practices [36]. Following the publication by the NQF of a list of 30 evidence-based safe practices ready for implementation, the JCAHO in 2003 required hospitals to implement 11 of these practices, known as National Patient Safety Goals (NPSG), and has added to the list each year since. Currently, there are 23 NPSG. Each of these goals is explicit, evidence based, easily understood, and measurable.

The National Patient Safety Foundation, established and funded by the AMA with additional support from CNA Pro-National Insurance, 3M, and Schering Plough, but now independent, has been a strong advocate for patient safety, funds safety research, and has convened many regional and national conferences to inform, motivate, and instruct safety leaders.

The Accreditation Council on Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS) are engaged in a massive effort to define competencies in each specialty, both for residency training and for continuing evaluation of practicing physicians [37]. Their six domains of competence, which include safe practices and systems analysis, have been widely accepted, and the various specialty boards are now developing assessment measures for use in continuing "maintenance of certification."

In 2003, all residency-training programs implemented new residency training work-hour limitations promulgated by the ACGME. Unfortunately, the ACGME stopped short of addressing the most important cause of fatigue: sleep deprivation resulting from extended duty shifts. Recent studies have provided specific evidence of the pernicious effect of sleep deprivation on resident performance [38].

The IHI has been the most powerful force behind changes for safety. Beginning in 1996, well before the IOM report, the IHI began to help hospitals redesign their systems for safety through collaborations focused on

medication safety, intensive care, cardiac care, and other treatments. In the ensuing decade, they have spawned demonstration projects, developed system changes and measures (such as the ''trigger tool''), and trained thousands of doctors, nurses, pharmacists, and administrators in the implementation of safe practices.

The American Hospital Association (AHA) disseminated to all hospitals a set of recommended medication safety practices, tools for systems analysis of medication systems, survey instruments, and safety leadership recommendations for hospital CEOs.

Regional coalitions have sprung up across the country to facilitate stakeholders working together to set goals, collect data, disseminate information, and provide education and training to improve safety [39]. For example, the list of medication safety practices for hospitals disseminated in 1999 by the Massachusetts Coalition for the Prevention of Medical Errors was later adopted by the AHA.

In addition to the VA, several large integrated health care systems, notably Kaiser-Permanente and Ascension [40], have been leaders in implementing new safe policies and practices. Many hospitals have made changes in their medications systems in response to programs initiated by these groups [41–43]. Kaiser has led the way in team training, adapting lessons from aviation crew resource management to health care. Other institutions have followed.

Virtually every hospital now has some sort of a safety program as required by JCAHO, and many are trying to create a nonpunitive environment that encourages workers to report errors and to identify systems failures. Many have added executive ''walk rounds,'' where hospital leaders visit care units to solicit safety concerns of nurses and others, and then work to address them through systems changes [44]. Several large health care systems (eg, Health Corporation of America HCA, Premier, Voluntary Hospital Association VHA, and Allina) have recommended various safe practices (mostly in the medication realm) to all of their member hospitals.

Purchasers and payers have entered the arena, particularly the ''Leapfrog Group,'' the insurance purchasing coalition of major American corporations. Leapfrog has strongly encouraged hospital adoption of a number of safer practices, including computerized physician order entry systems, proper staffing of intensive care units, and the concentration of highly technical surgery services in high-volume centers. The most recent ''Leap'' focuses on implementation of the National Quality Forum's Safe Practices.

Patients have become much more involved in their own care and decision-making [45]. This has occurred in response to entreaties by aggrieved individuals, as well as those by consumer advocacy groups. A variety of national and regional organizations, such as the National Patient Safety Foundation and the AHA, state and regional coalitions, and the AHRQ, have published tips for safety for consumers, and have encouraged hospital full disclosure programs and patient partnering. The movement toward full

and honest disclosure has gained momentum in the past few years as more hospitals make a commitment to increased transparency and apology [46].

The focus on patient safety has spread around the world, spurred by the founding in 2003 of the World Alliance for Patient Safety under the World Health Organization [47]. International campaigns in infection control, particularly hand hygiene and safe surgery, have stimulated changes in health care in countries as diverse as Ghana and Spain.

Most importantly, thousands of devoted nurses, doctors, therapists, and pharmacists have become much more alert to safety, moving beyond the initial blame and denial. These health care professionals are making many changes, streamlining medication processes, working together to eliminate infections, and improving teamwork, not primarily in response to mandates, but to improve the quality of care for their patients.

That work is finally paying off. Although many hospitals have reported isolated successes over the past 5 years following introduction of specific systems changes, such as reduction of hypoglycemic episodes [48], adverse drug events [49,50], and wound infections (Whittington J, personal communication, 2005), larger scale improvement is a recent phenomenon. In 2005, the ''Keystone'' project in Michigan reported that 68 hospitals were able to completely eliminate both blood stream infections associated with central venous catheters and ventilator-associated pneumonias for more than 6 months [51]. The resulting savings: 1,578 lives and $165 million.

Even more impressive was the report of the IHI's ''100,000 Lives'' campaign, in which 3,100 hospitals signed on to implement one or more of six proven safe practices, with the goal of preventing deaths from adverse events in 100,000 patients over a 2-year period, ending in June, 2006. The actual result: a reduction in mortality of 122,000 patients, much of it attributable to the new practices [52].

Patient safety has finally ''arrived.'' Every hospital now has a patient safety officer and many have implemented meaningful changes in policy and practice that are reducing errors and injuries to patients. Creating a safe environment in our incredibly complex health care system requires a major culture change. As such, it will be frustratingly slow and halting. But that change is occurring and beginning to show results. The possibility of injury-free care no longer seems inconceivable.

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Medical Error Theory

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In attempting to improve safety and quality in health care, it is imperative to reduce patient harm and death from preventable adverse events. To achieve this goal, we must understand why these errors happen and how they lead to patient harm. Only then can we devise solutions that will address the root cause of errors and improve patient safety. First we must minimize mistakes and second, prevent those mistakes that still occur from causing harm.

There are four factors in health care contributing to medical errors that can lead to patient harm: (1) human fallibility, (2) complexity, (3) system deficiencies, and (4) vulnerability of defensive barriers. All of these factors must be addressed to significantly improve patient safety [1].

Human fallibility

As indicated by the title of the landmark Institute of Medicine report: "To Err is Human," mistakes are part of the human condition [2]. They cannot be prevented by trying harder. There needs to be system changes to make it difficult to do the wrong thing and easy to do the right thing by hardwiring forcing functions into medical systems and providing information at the point of care [3].

Forcing functions

Forcing functions are physical or process constraints that make errors difficult if not impossible and make the correct action the default mode.

An example of a physical forcing function is the development of noncompatible connections for gas lines. In the past, the couplings connecting the various gases to the anesthesia machine were universal. The oxygen could be connected to the nitrous oxide port and vice versa. This misconnection

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accounted for many deaths annually. To prevent this error, the Pin Insertion Safety System, a noncompatible connection system, was developed. The oxygen connector now only fits into the oxygen port of the anesthesia machine while the nitrous oxide connector will only fit in its proper location.

Forcing functions can also take the form of a process constraint. Previously, concentrated solutions of KCl were kept in patient care areas to be added to intravenous solutions when needed. Patients died as a result of excess KCl either added to intravenous solutions or being directly injected. To prevent these errors, it has been recommended by The Joint Commission that concentrated KCl be removed from all patient care areas [4]. All IV solutions should be prepared in the pharmacy thus significantly reducing the risk of inadvertent overdoses of KCl.

Reminders at the point of care

The sequence of steps in a complex process, especially if the practitioner uses the process infrequently, is particularly prone to error. Keeping a checklist, similar to a cockpit flight crew, will help ensure that the steps are performed in the proper sequence and that no steps are omitted. One such example is the ThermaChoice Endometrial Ablation System (Gynecare). There is a checklist attached to the machine that lists the sequence for the nurse to properly attach the connections. The machine itself prompts the physician on the order of the therapeutic steps and monitors the successful completion of one step before proceeding to the next. These reminders help ensure that this complex procedure is performed properly and thereby reducing patient harm.

Complexity

According to Kizer [5], former head of the Veterans Affairs Health System and former President of the National Quality Forum, modern health care is the most complex activity ever undertaken by human beings. He then specified the various dimensions of care to support his assertions. Health care involves:

1. Highly complicated technologies
2. A panoply of powerful drugs
3. Widely differing professional backgrounds of providers
4. Unclear lines of authority
5. Highly variable physical settings
6. Unique combinations of diverse patients
7. Communication barriers
8. Care processes that widely vary
9. A time-pressured environment

Similarly, Dain [6] asserts that some types of errors are inevitable because system complexity leads to multiple and unexpected interactions.

Given this degree of complexity, one strategy to reduce the risk of error is to simplify and standardize care processes. One particularly complex process prone to error is inpatient medication use (see the article by Keohane and Bates in this issue) (Table 1) [7]. The major steps in this process are prescribing, transcribing, dispensing, administration, and monitoring. Each of these major steps has several components, all potential sources of error. This system is complex and disjointed. A strategy to improve medication safety would therefore include simplifying and standardizing the process by using tools such as electronic prescribing and clinical information at the point of care [8].

System deficiencies

The health care system, as we know it, can be divided into two major components (Fig. 1) [9]. At the sharp end of care are practitioners and providers who interact directly with the patient, such as physicians, nurses, and therapists. Supporting those practitioners at the sharp end is a large infrastructure without which health care would not happen. The blunt end of care includes administration, physical facilities, payers, pharmaceutical industry, regulatory agencies, and government.

In this context, there are two types of errors that can occur in health care (Fig. 2). First are active errors. These occur at the sharp end of care with immediate effects and are generally unpredictable and unpreventable. An example of sharp end error would be inadvertent bladder injury during a hysterectomy for endometriosis with multiple adhesions. There is no ''system'' that would prevent this injury. With good surgical technique this type of injury should be infrequent but can still happen.

On the other hand, latent errors are system deficiencies hidden in the blunt end of care. Providers work around these hazards that seldom cause patient harm, until the wrong set of circumstances occur. These unsafe

Table 1
Inpatient medication system

Prescribe ⟶	Transcribe ⟶	Dispensing ⟶	Administer ⟶	Monitor
Clinical decision	Receive order	Data entry	Receive from pharmacy	Assess therapy effect
Choose drug	Verify correct	Prepare, mix, compound	Prepare to administer	Assess side effects
Determine dose	Check allergy	Check Accuracy	Verify order and allergy	Review labs
Med record document		Check allergy	Administer drug	Treat side effects
Order		Dispense to unit	Document in MAR	Document

Abbreviation: MAR, medication administration record.

Adapted from Aspden P, Wolcott J, Bootman, JL, et al. Preventing medication errors. Washington, DC: The National Academies Press; 2006. p. 60; with permission.

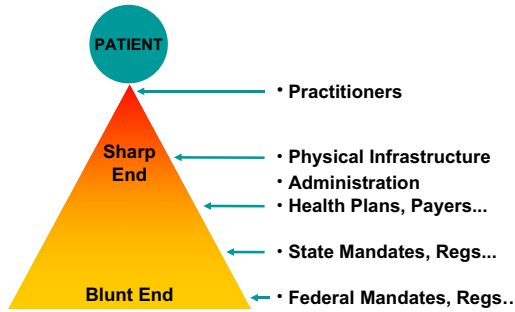

Fig. 1. Components of health systems.

conditions can then result in patient injury. An example of a blunt end error is the nursing shortage resulting in understaffing. In many hospitals across the country, nurses deal with this shortage daily, providing excellent care under difficult conditions. Despite these efforts, understaffing creates a potential hazard that increases the risk for significant complications including death [10–13]. Other examples of latent errors include problems with credentialing, peer review, engineering defects, and paging and telephone systems.

To make health care safer, however, everyone must identify these hazards even if no patient has been harmed yet. Once identified, the hazard should be corrected or brought to someone else's attention, who is better able to address the solution. These potential dangers must be identified and eliminated before patients are harmed.

Defensive barriers

Because of human fallibility, errors occur frequently as shown by observational studies both in aviation [14] and health care [15]. In high-reliability organizations, operational barriers have been installed to reduce the risk

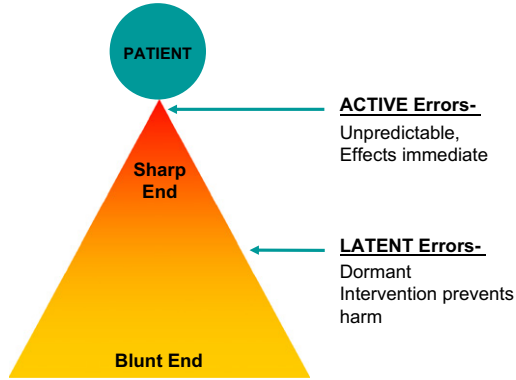

Fig. 2. Types of errors in health systems.

that these errors will result in accidents or injury. These defensive barriers in health care may take the form of physical constraints (such as incompatible connectors) or procedural constraints (such as information technology with decision support at the point of care) all designed for one purpose: to intercept errors before patients suffer harm.

This approach to health care safety has been conceptualized by the English psychologist, Reason [16], as the Swiss cheese theory of error (Fig. 3). No defensive barrier is perfect; each has inherent vulnerabilities that, under the wrong set of circumstances, can be pierced by the "trajectory" of the error. Complex medical processes will often have multiple "layers" of these defensive barriers. When the potential defects in each of these barriers align in just the wrong way, the error will not be deflected and patient injury or death will result.

The following clinical scenario illustrates this concept [1].

A penicillin-allergic patient is admitted to the hospital at 2 AM in obvious need of antibiotics. The nurse caring for her is working a double shift, now beginning her 12th hour of work. She is fatigued and overworked already caring for seven other patients, one of them also just admitted. After contacting the attending physician for admitting orders and absent the allergic history, she is given a verbal order for amoxicillin. This order created a hazard for this patient that potentially could result in harm. The nurse is the first barrier that could have intercepted the hazard and prevent harm, but absent the allergic history, the order is transcribed and sent to the pharmacy. Working that night is a pharmacy intern. Medication should not be dispensed absent an allergic history, but because of his inexperience the amoxicillin is sent to the floor. The hazard has now pierced another defensive barrier. Back on the patient care unit, the admitting nurse, behind on her

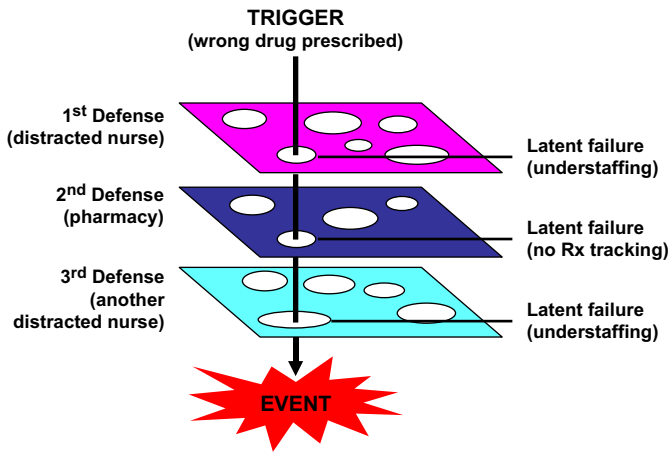

Fig. 3. Swiss cheese theory. (*Adapted from* Reason J. Human error: models and management. BMJ 2000:320:768–70; with permission.)

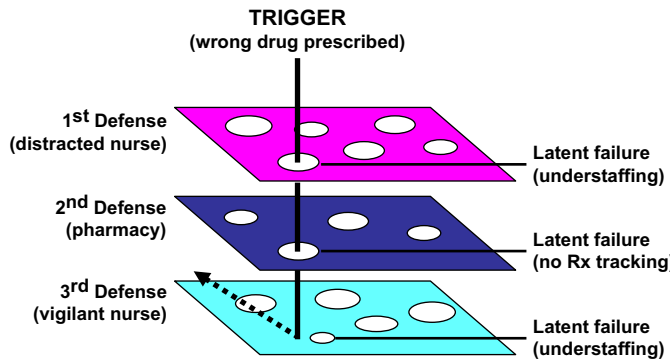

Fig. 4. Defensive barriers. (*Adapted from* Reason J. Human error: models and management. BMJ 2000:320:768–70; with permission.)

duties requests that her *coworker* administer the intravenous amoxicillin. The second nurse readily agrees, assumes that her colleague has already checked the allergic history and begins the antibiotic infusion. The patient then develops an anaphylactic reaction. In this case the hazard created by the physician's order has pierced three potential defensive barriers where it could have been intercepted and patient harm could have been prevented.

Given this construct, patient safety can be improved by either interposing another piece of "Swiss cheese" between the hazard and the potential injury or by examining each individual defensive barrier and making the holes smaller to reduce or eliminate potential vulnerabilities (Fig. 4).

Summary

Similar to other high-risk industries, clinical medicine is a complex, often fragmented system that is susceptible to error with potentially catastrophic results for the patients.

To improve patient safety and reduce the risk from harm we must accept that some errors are inevitable during the delivery of health care. Strategies must be developed to minimize these occurrences through forcing functions, reminders at the point of care for the individuals and reduction of complexity for the organizations. Everyone working within health care must be alert to identify and eliminate latent errors within the organizational infrastructure. Finally, defensive barriers within our care process must be examined to reduce, if not totally eliminate, vulnerabilities to intercept hazards from causing patient harm. Only in this way can health care fulfill its potential and significantly reduce if not eliminate iatrogenic harm.

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Practical Solutions to Improve Safety in the Obstetrics/Gynecology Office Setting and in the Operating Room

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Most of the attention of the patient safety movement has been focused on hospitalized patients, and perhaps rightly so, with estimates ranging from 44,000 [1] to 195,000 [2] deaths per year attributable to medical errors occurring in the approximately 34.7 million in-patients (excluding newborn infants) discharged from nonfederal short-stay hospitals in the United States [3]. However, patient encounters outside of hospitalization occur 35 times more commonly than in the hospital, with an estimated 1.2 billion visits to physicians' offices, emergency departments, and out-patient departments in the United States during 2005, representing an increase of about 36% in the last decade [4]. Of those 1.2 billion encounters, 82.4% occurred in primary care offices, surgical specialty offices, and medical specialty offices [4], in which there is little, if any, external oversight of the environment of care or the policies in place to safeguard patient safety. In fact, physician offices are the most frequently used sites for providing health care, including the delivery of primary and specialty care [5]. Thus, even with little hard evidence available regarding outcomes, it seems reasonable to explore strategies that will likely to enhance patient safety overall in the office setting.

Within the hospital, errors in the surgical environment can result in catastrophic consequences for patients, surgeons, and institutions. There is little published data, and there are few tools available, to demonstrate that patient safety interventions have had the desired effect on outcomes; however, given the very serious negative consequences, it may be prudent to take steps that may enhance safety even without published evidence of improvement [6]. This article suggests practical steps that may be considered

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for implementation in both the office and the operating room, with the aim of improving patient safety in women's health care.

Office setting

There is increasing recognition that clinical patient care in the ambulatory arena is subject to a different pattern of risks to patient safety than that found in the hospital environment [7]. For example, errors resulting from missed diagnosis appear to be much more common in office practice than in the hospital, at least based on data from closed malpractice claims [8]. As another example, of the four types of medication errors— prescribing (physician ordering), transcription and verification errors, pharmacy dispensing and delivery errors, and administration (nurse-to-patient) errors—medication administration errors are common in the hospital [9] but would be uncommon in office practice. For that reason, patient safety techniques developed and validated for in-patient care may need to be adapted and re-examined for the out-patient setting.

Medication errors

A recent systematic review of preventable adverse drug events (ADEs) in ambulatory care suggests that ADEs in ambulatory care are common (14.9 per 1,000 person-months), many are preventable (preventability rate 21%), and of those, many (45.4%) are caused by inadequate monitoring and may result in hospitalization (4.5 per 1,000 person-months) [10]. For written prescriptions, prudence dictates clear handwriting, clearly distinguishing between look-alike or sound-alike drugs, and avoiding use of abbreviations that can be misinterpreted. Electronic systems for generating and transmitting prescriptions, such as computerized physician order entry, have been shown to reduce drug errors in certain settings [11], and electronic medical record (EMR) systems to facilitate monitoring and tracking are available for use in medical offices.

In 2006, only 29% of office-based physicians reported using full or partial EMR systems. Although this represents a 22% increase over usage in 2005 and a 60% increase since 2001, when the National Ambulatory Medical Care Survey began monitoring this technology, only 9% of office-based medical practices and 12% of physicians within these practices had an EMR system with the minimal four features of a comprehensive system (computerized orders for prescriptions, computerized orders for tests, access to laboratory or imaging test results, and clinical notes), a level unchanged since 2005 [12]. This is unfortunate because it is estimated that almost half of all medication errors may be associated with the prescriber lacking pertinent information about the patient or medication at the time of prescribing, a deficiency that might be ameliorated by clinical decision support programs [13]. Clinical decision support systems can give the prescriber access to

timely clinical information, including patient characteristics (such as drug allergies), recent clinical data (such as weight or blood pressure), recent laboratory results (such as liver or kidney function tests), and relevant information about the medication's indications, contraindications, possible drug interactions, and dosage considerations, all of which may reduce the risk of prescribing errors.

All prescriptions, written or electronic, should include detailed instructions to the patient for using the medication, with the aim of reducing the risk of dispensing or administration errors. Electronic prescribing systems will help reduce these risks by providing the proper instructions when the prescription is entered, filled, or dispensed. Dispensing errors are estimated to occur in about 2% of the 3 billion prescriptions filled in United States pharmacies annually, an impact of up to 60 million dispensing errors each year [14]. When patients are given clear information about the prescribed medication and its proper use at the time the prescription is written and dispensed, they are empowered as partners in their own patient safety, equipped to recognize problems if a prescribing or dispensing error occurs.

Tracking errors

Patient visits to a medical office frequently generate orders for clinical laboratory or imaging tests, referrals to consulting professionals, communication of test and consultation results to the patient, and reminders for appropriate follow-up, all of which need to be tracked to reduce the risk that necessary communications will be missed. The American College of Obstetricians and Gynecologists (ACOG) has recommended that an effective and reliable tracking system "is a necessity for obstetric and gynecologic care in all practice settings" [15]. If a patient fails to obtain ordered tests or consultation, or if results of testing or consultation are missed by the requesting physician, delayed or missed diagnosis may occur, potentially resulting in injury to patients and liability for physicians. Even though the principles of autonomy dictate that patients participate in responsibility for their medical care, it is generally considered within physician responsibility to confirm patient compliance with recommended testing or treatment, to properly interpret test results and treatment outcomes in a timely fashion, and to communicate to patients the implications of those results and recommendations for follow-up [16].

Historically, most medical office tracking systems have been manual, using log books, card files, file folders, and the like; but electronic systems, especially those integrated with a comprehensive electronic health record, will offer certain advantages in reliability and automatic generation of correspondence. Whatever system is used, a key element is to ensure that data are entered and recorded in an organized and timely fashion when tests or consultations are ordered, results received, and patients notified. It may also be helpful to document when clear instructions are given to the patient

regarding the nature of the test or consultation being ordered, the clinical importance of obtaining the results, and the recommendations for follow-up, including the modality used to inform the patient.

ACOG recommends the following items be included in tracking system entries: date ordered; patient name and identifying number; type of test, procedure, consult, or referral; date of results; follow-up required; and evaluation completed and patient notified [15]. An effective tracking system can be used to remind patients about obtaining recommended screening tests, including specific advice as to how they can go about arranging the recommended testing. For example, a mail reminder system has been shown to produce a 40% increase in patient compliance with Pap smear recommendations (although there was no effect on mammogram compliance) [17]. Physicians should avoid the system of follow-up, often referred to as the "no news is good news" approach, in which patients are told that they will only be contacted if test results are abnormal [15]. It is preferable to instruct patients to contact the office if they have not received the results, normal or abnormal, within a reasonable time frame. This approach will decrease the risk that a critical result will be missed or delayed. In this manner, the patient will become a more active partner in avoiding errors in tracking.

Prenatal testing represents a risk of tracking error unique to the obstetrics office. The number and complexity of the tests that are recommended, explained, and tracked, the fact that testing is done on both the pregnant woman and her fetus, the relative urgency in dealing with test results, and the need to communicate the out-patient prenatal findings with the in-patient maternity suite, are special challenges to patient safety. An effective tracking system in an obstetrics office should have safeguards in place to accommodate these special circumstances and concerns. An efficient tracking system that interfaces with a comprehensive electronic health record that can be accessed by the office obstetrician and the maternity suite will be useful in addressing some of these issues.

In the office setting, a particular area of jeopardy is the need to track patient phone calls, patient encounters outside the office such as in the emergency room, results of tests ordered outside the usual office routine, and results that arrive long after a patient encounter [15,16]. For that reason, tracking and reminder systems should include mechanisms for recording information related to telephone calls and for timely communication with office staff, outside laboratories, radiology services, nurses, and covering physicians to facilitate follow-up of clinical issues arising outside of patient visits.

Within hospitals, ineffective communication between health care providers was the root cause of 66% of all reported sentinel events from 1995 to 2004, and 85% of sentinel events related to maternal death and injury in 2005, according to the Joint Commission [18]. It seems reasonable to assume the opportunity for error is similar or greater in the ambulatory setting. Free-standing laboratories and imaging services should inform

physicians of critical results in a fashion similar to that used for hospitalized patients [19]. Specifically, threshold findings should be established for imaging findings and laboratory results, beyond which the ordering physician will be contacted expeditiously because of the possibility of a problem. The date, time, mode of contact, and content of the communication should be recorded by the imaging center or laboratory. The practice where the order originated should record the date, time, mode of contact, and content of the communication, together with a statement of the interpretation of the reported data and the treatment plan.

Stress and fatigue

Britain's Health and Safety Laboratory has said "Disrupted sleep patterns and inadequate sleep can result in fatigue and reduced levels of cognitive performance thus increasing the risk of an accident… (H)uman error arising from fatigue may have catastrophic results in safety critical environments" [20]. The United States National Traffic Safety Administration reports sleepy drivers are responsible for at least 100,000 automobile accidents, resulting in 40,000 injuries and 1,500 deaths annually in the United States [21], demonstrating that sleep deprivation increases errors in performing even simple, familiar tasks. As a result, individuals in vulnerable occupations, including airline crews and air traffic controllers, truck drivers, and power plant personnel have strict limitations on their working hours. The Accreditation Council on Graduate Medical Education restricts work hours of physicians in residency to decrease the chance of sleep deprivation and fatigue that might cause medical errors [22,23], but no legal restrictions have yet been imposed on the work hours of practicing physicians. The increased threat of professional liability, economic pressures to see more patients per unit time and to order fewer tests, and the increasing burdens of paperwork and documentation can result in more potential errors, especially in physicians already fatigued. Yet obstetrics and gynecology practice, by its very nature, is prone to demanding long hours on duty or on call, followed by routine, scheduled, busy office hours or surgery, often without the opportunity for rest or relief. Because of the absence of regulations or daily oversight, and the possible difficulty and expense in arranging back-up coverage, physicians in free-standing office practices must be particularly vigilant against the potential risks of sleep deprivation, stress, and fatigue on safe provision of care. If feasible, physicians should schedule reduced duty hours following a night on call.

A culture of patient safety in office practice of women's health care

Increasing awareness of patient safety concerns and the benefits of implementing patient safety techniques into women's health care have recently been championed by Gluck and others [24–28]. Based on data from

ACOG's Voluntary Review of Quality of Care, it has been shown that some general concepts in patient safety, such as the impact of system problems over individual behavior, are applicable to in-patient women's health care [29,30]. It is worthwhile to consider extending these concepts to women's health care office practice as well. Physicians are in a position to foster the culture of patient safety into their practice by discussing patient safety aspects of care with their office staff, with plan administrators, and with residents and medical students rotating in their offices. Physicians have a special opportunity to create and support patient safety protocols and guidelines in their practice to avoid medication and tracking errors, monitor medical errors and near misses in their office, and foster effective communication among all members of their health care team to help reduce their risk of medical error. Some practical resources in implementing the culture of patient safety include ACOG (http://www.acog.org), the National Patient Safety Foundation (http://www.npsf.org), and the National Center for Patient Safety of the Veterans Health Administration (http://www.patientsafety.gov).

Surgical environment

At times it may seem as though women's health care has become a less surgical specialty than it may have been in the past. The risks of surgical error in this specialty may have increased with the increase in caesarean sections and minimally-invasive surgery, including robot-assisted laparoscopy, and the pressures for shorter lengths-of-stay post operatively, as well as more out-patient surgery. More than 70 million in-patient and out-patient surgeries are performed each year in the United States [31]. About half of all adverse events (AEs) in hospitals were associated with a surgical procedure, 14% of AEs in hospitals are caused by wound infections, and 13% result from surgical complications [32]. Moreover, surgical complications are the cause for 22% of preventable patient deaths in hospital [33]. Between 1997 and 2003, the number of cesarean sections performed in the United States increased by 46% (while the number of episiotomies decreased by 35%, and forceps procedures decreased by more than 27%) [34]. It is estimated that 36,600 robotic procedures were performed in 2005, up nearly 50% from 2004, and more than 70,000 procedures in 2006 [35]. Incorporating new patterns of surgical practice and new surgical technologies may add new risks for surgical error in women's health care, in addition to those associated with routine surgery.

Retained foreign objects

Retained foreign bodies, such as sponges and surgical instruments, represent a class of medical error peculiar to the surgical environment that has

not yet been well studied [36]. A recent case controlled analysis reviewed medical records with ICD-9 code 998.4 (unintentional foreign object remaining in the body during surgery) and risk management incident reports of retained foreign objects from 1996 to 2005. Of 30 instances of retained foreign objects, 52% involved sponges and 43% instruments, with the abdominal cavity most commonly involved (46%), followed by the thoracic cavity (23%); no body cavity was uninvolved. Although there was no mortality, 8 patients were readmitted to hospital (30%) and 25 had a reoperation (83%). Multivariate analysis suggests that factors associated with a significantly higher risk of retained foreign objects were the total number of major procedures performed at the same surgery (odds ratio or OR = 1.6; 95% confidence interval or CI = 1.1–2.3; $P = .008$) and an incorrect count (OR = 16.2; 95% CI = 1.3–197.8; $P = .02$) [36].

An earlier report based on all claims or incident reports of a retained surgical sponge or instrument filed between 1985 and 2001 with a large malpractice insurer suggested the risk of retained foreign body after surgery significantly increases in emergencies, with unplanned changes in procedure, and with higher body-mass index [37]. A case series from Asia also found retained sponges more common in obese patients and after emergency surgery, and suggested increased preoperative awareness of these risk factors, as routine use of radio-opaque sponges and mandatory sponge counts have not eliminated the problem [38]. Based on the incidence found in case series, there may be 1,500 cases of surgical retained foreign objects annually in the United States, and beyond the patient injury involved, leaving a sponge or instrument in a patient is generally considered indefensible, so a ''correct sponge count'' does not exonerate the surgeon [39]. Although retained sponges in the vagina are clinically recognized as a risk factor in both obstetric and gynecologic surgery, a PubMed search failed to retrieve any recent information about the frequency of or risk factors for this problem.

Surgical fires

Fires that occur on or in a surgical patient are rare but may have devastating consequences. The Joint Commission estimates that there are approximately 100 surgical fires each year in the United States, resulting in up to 20 serious injuries and one or two patient deaths annually [40]. The surgical environment routinely contains all three elements necessary to start or support fires: namely, oxidizers like supplies of oxygen gas; ignition sources, such as electrocautery instruments, fiberoptic light cables and lasers; and flammable fuel, such as surgical drapes, alcohol-based prepping agents, and certain anesthetic gases. Because these elements cannot realistically be eliminated, all members of the surgical team must be alert to the risk and practiced at recognizing and suppressing a fire at the earliest possible stages. Electrosurgical equipment (68%) and lasers (13%) were the most common

ignition sources. Fires most commonly occur in the patient's airway (34%) and head or face (28%), and an oxygen-enriched atmosphere was a contributing factor in 74% of all cases [41]. To help prevent surgical fires, the Joint Commission recommends training all surgical staff members to control ignition sources by following laser and electrosurgical safety practices, to allow potentially flammable fumes to disperse after preoperative preparation, to minimize oxygen concentration under surgical drapes, to respond rapidly and effectively to any fire in the operating room, and to report all incidents of surgical fires for root cause analysis [40].

Medication errors

Prophylactic antibiotics have demonstrated effectiveness in reducing surgical morbidity in women's health care, so failure to use these agents when appropriate is a medication error. Errors in using prophylactic antibiotics include inappropriate choice of agent, ineffective start of administration, and incorrect duration of exposure. An appropriate prophylactic antibiotic must be relatively safe (low toxicity and established safety record in practice), infrequently used for treating serious infections, effective against microorganisms most likely to cause surgical infections, capable of reaching and maintaining clinically useful concentrations in target tissues during the operation, and given only for the duration of exposure shown to be clinically useful [42].

It is estimated that 40% to 60% of surgical site infections are preventable with appropriate use of prophylactic antibiotics. The Institute for Health care Improvement (IHI) estimates that overuse, under use, improper timing, and misuse of antibiotics occurs in 25% to 50% of operations in the United States [43]. Appropriate use of prophylactic antibiotics to prevent surgical infections is endorsed by ACOG [44], the Joint Commission, the National Quality Forum, and the Center for Medicare and Medicaid Services. The IHI suggests the following changes for improvement:

- Designate responsibility and accountability for preoperative prophylactic antibiotic administration (eg, preoperative nurse, circulating nurse, anesthesiologist) connected to key point in process.
- Standardize the administration process to occur with commonly performed activity within 1 hour before incision.
- Through the use of antibiotic standing orders specific to surgical site, administer prophylactic antibiotics according to guidelines based on local consensus.
- Make agreed upon antibiotics available in the operating room.
- Standardize the delivery process to ensure timely delivery of preoperative antibiotics to the holding area.
- Provide a visible reminder or checklist to give antibiotics on each case (eg, brightly colored sticker).

Ensure systematic documentation of antibiotic administration on every patient chart (paper or electronic).

Develop a system where the antibiotic is hanging at head of patient's bed ready for administration.

Design protocols to deliver antibiotics to the operating room with the patient.

Educate the operating room staff regarding the importance and reasoning of antibiotic timing, selection, and duration.

Provide feedback on prophylaxis compliance and infection data monthly.

Involve pharmacy staff to ensure that timing, selection, and duration are maintained.

Institute a computerized physician order entry system with procedure-specific fields for antibiotic selection, timing, and duration.

Improve screening for allergies to beta lactam antibiotics to eliminate false positives.

Consider weight-based antibiotic dosing (higher dose for larger patients).

Redose for longer surgeries (eg, after 3 hours for short half-life cephalosporin) [43].

The IHI also points out that "inappropriate use of broad spectrum antibiotics or prolonged courses of prophylactic antibiotics puts all patients at even greater health risks due to the development of antibiotic-resistant pathogens" [43].

For gynecologic surgery, ACOG has published the following recommendations:

Patients undergoing abdominal or vaginal hysterectomy should receive single-dose antimicrobial prophylaxis.

Pelvic inflammatory disease complicating intrauterine device insertion is uncommon. The cost-effectiveness of screening for gonorrhea and chlamydia before insertion is unclear; in women screened and found to be negative, prophylactic antibiotics appear to provide no benefit.

Antibiotic prophylaxis is indicated for suction curettage abortion.

Appropriate prophylaxis for women undergoing surgery that may involve the bowel includes a mechanical bowel preparation without oral antibiotics and the use of a broad-spectrum parenteral antibiotic, given immediately preoperatively.

Antibiotic prophylaxis is not recommended in patients undergoing diagnostic laparoscopy.

In patients with no history of pelvic infection, hysterosalpingogram (HSG) can be performed without prophylactic antibiotics. If HSG demonstrates dilated fallopian tubes, antibiotic prophylaxis should be given to reduce the incidence of post-HSG pelvic inflammatory disease.

Routine antibiotic prophylaxis is not recommended in patients undergoing hysteroscopic surgery.

Cephalosporin antibiotics may be used for antimicrobial prophylaxis in women with a history of penicillin allergy not manifested by an immediate hypersensitivity reaction.

Patients found to have preoperative bacterial vaginosis should be treated before surgery.

Antibiotic prophylaxis is not recommended in patients undergoing exploratory laparotomy.

Use of antibiotic prophylaxis with saline infusion ultrasonography should be based on clinical considerations, including individual risk factors.

Patients with high- and moderate-risk structural cardiac defects undergoing certain surgical procedures may benefit from endocarditis antimicrobial prophylaxis.

Patients with a history of anaphylactic reaction to penicillin should not receive cephalosporins.

Pretest screening for bacteriuria or urinary tract infection by urine culture or urinalysis, or both, is recommended in women undergoing urodynamic testing. Those with positive results should be given antibiotic treatment.

For obstetric procedures, ACOG has published the following recommendations:

All high-risk patients undergoing cesarean delivery should be given antibiotic prophylaxis.

For prophylaxis with cesarean delivery, narrow-spectrum antibiotics, such as a first-generation cephalosporin, should be used.

Antibiotic prophylaxis may be considered for patients with premature rupture of membranes, particularly in cases of extreme prematurity, to prolong the latency period between membrane rupture and delivery.

Evidence is insufficient to recommend perioperative antibiotic prophylaxis at the time of prophylactic or emergency cervical cerclage.

Prophylaxis for bacterial endocarditis is optional in patients with the following cardiac conditions who are undergoing uncomplicated obstetric delivery: prosthetic cardiac valves, prior bacterial endocarditis, complex cyanotic congenital cardiac malformations, and surgically constructed systemic pulmonary shunts or conduits.

Patients with the above cardiac conditions who are undergoing obstetric delivery complicated by intra-amniotic infection should receive prophylaxis.

Although the evidence is inconclusive, for low-risk patients undergoing cesarean delivery, use of prophylactic antibiotics is recommended.

Venous thromboembolism

Surgery increases the risk of deep vein thrombosis (DVT) and pulmonary embolism, and prophylaxis has been shown to mitigate the increased risk [45]. For this reason, failure to use accepted surgical thromoprophylaxis may constitute another class of surgical error in patient safety. Geerts and associates have published a thorough review of the thromboembolism and its prevention, including gynecologic surgery [46].

It is reported that without effective thromboprophylaxis, major gynecologic surgery is associated with a prevalence of DVT ranging from 15% to 40% [45]. ACOG recommends preoperative classification of patients into low, medium, high, and highest risk groups before gynecologic procedures. For all but the low risk group (surgery lasting less than 30 minutes in patients younger than 40 years with no additional risk factors), various regimens for use of graded compression stockings, intermittent pneumatic compression devices, low-dose unfractionated heparin, or low molecular weight heparin are recommended. A combined regimen of medical and mechanical prophylaxis may improve efficacy, especially in the patients at highest risk for venous thromboembolism [45]. A detailed discussion of the various available protocols is beyond the scope of the current review. Suffice it to say that early postoperative ambulation is advisable whenever possible, and some recognized regimen of thromboprophylaxis is strongly encouraged in all patients above low risk.

Universal protocol

''Wrong-site surgery'' refers to any surgical procedure performed on the wrong patient, wrong body part, wrong side of the body, or at the wrong level or part of the operative field or of the correctly identified anatomic site. According to the Joint Commission, multiple surgeons involved in one surgical case, multiple procedures during a single surgical session, unusual time pressures to start or finish the operation, and a patient's unusual physical characteristics, such as morbid obesity or physical deformity, may increase the risk of wrong-site surgery. To address this problem, the Joint Commission published the ''Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery'' in 2003 [47].

The universal protocol, endorsed by many organizations including ACOG, requires three levels of activity before beginning any surgical procedure: a preoperative verification process, unambiguous identification and marking of the operative site, and a final ''time out'' check just before starting the operation. In the preoperative verification process, the members of the surgical team confirm that all relevant documents and studies are available and have been reviewed, and verified to be consistent with each other, with the patient's expectations, and with the team's understanding of the intended patient, procedure, and operative site. Any missing information

or discrepancies must be resolved before surgery begins. The intended operative site is then unambiguously identified by the health care team, including the patient (if possible), and the site of incision or insertion are marked if laterality, multiple structures, or multiple levels are involved. A final "time out" is called just before starting the procedure for a final verification of the correct patient, procedure, and site. Although all members of the surgical team share in the responsibility, it is desirable to involve the patient (or the patient's designee) as much as possible in this process, because the patient has the greatest stake in avoiding errors and achieving a successful outcome. Failed communication between the surgeon or surgeons, the other members of the health care team, and the patient may increase the risk of error. Thorough communication may be facilitated by using a predetermined checklist to ensure that all necessary elements have been covered before the operation begins. To minimize risks to patient safety in the operating room, all members of the surgical team should be encouraged and expected to point out any possible error without fear of ridicule, reprimand, or retaliation.

New surgical technologies and procedures

As new techniques and new equipment are introduced in the operating room, the potential for surgical error may increase. New equipment should be inspected and certified by the institution's medical engineering department, if appropriate, to be sure it is functioning properly before the equipment is used clinically. All informational material, such as user's manuals, warnings, checklists, or operating instructions provided by the manufacturer of the equipment, should be carefully reviewed in advance by anyone scheduled to use the equipment. All members of the surgical team must be familiar with the new equipment as appropriate to the extent of their involvement, including all safety features, warning mechanisms, and alarms on the device. Informational stickers attached to the device or plastic cards summarizing instructions for proper use may be helpful, and all necessary adaptors, attachments, and supplies should be in the room or readily available before beginning surgery. To ensure the safety of all concerned, any recommended protective devices, such as eye shields or special draping material, should be employed. Institutional leaders are responsible for determining specific requirements for granting privileges for the use of new techniques or equipment. Whenever possible, a surgeon who is incorporating a new surgical technique should be assisted or supervised by a more experienced colleague until full competency is achieved. If a technique is so innovative that no other surgeon at the site has more experience, the surgeon involved should have already documented skills and experience in related surgical procedures, and extra support staff or surgical backup should be available in case difficulties arise. Nonmedical, noncredentialed individuals, such as industry representatives, should not be relied upon or allowed to perform the actual surgery, and should be excluded from the operating

room if their presence would present a distraction or discomfort for any member of the essential operating room team [48].

Teaching and distractions

Surgical education is a necessary and appropriate activity in the operating room, but deserves special attention to protect patient safety. All trainees, such as obstetric-gynecologic residents, surgical residents, anesthesiology residents, medical students, nursing students, and operating room technician students, must be meticulously supervised and assisted when participating in surgery. Trainees and their supervisors should be alert, well rested, and well prepared in advance for the surgical procedure being performed, and because patient safety depends on effective communication, trainees should be clear about their appropriate role in the case and familiar with the pertinent terminology in advance. The use of simulators may be helpful to prepare trainees for their clinical activities well before actual surgery on a patient. Uninvolved observers in the operating room may be a source of distraction to the surgical team. Similarly, beepers, radios, telephone calls, and other potential distractions in the surgical environment should be kept to a minimum, especially during critical stages of the operation, and nonessential conversation should be postponed until the operation is completed. The time pressures and chaotic circumstances of some emergency situations may distract the surgical team from routine patient safety protocols, and may be associated with increased risk of error, especially if the surgical team is stressed and fatigued already. Although no work hour restrictions have yet been imposed on practicing physicians, all members of the surgical team, especially the lead surgeon, should be alert and well rested for any major surgical procedure.

Medication errors in the operating room

The Joint Commission has suggested that safe medication practices in the operating room should include standardized procedures for: verifying medication labels; delivering medications to the operating room (OR); properly labeling all medications on and off the sterile field; confirming labeled medication in the OR; purposefully communicating medication, strength, and dosage as the medication is passed to the clinician who will administer it; establishing dose limits; monitoring patients for adverse medication reactions; and verifying that all OR medications are labeled at all times [49].

In the operating room, medication orders often are given verbally rather than in writing, making such orders particularly vulnerable to misinterpretation or misapplication. The possibility of error in prescribing, administering, or monitoring medications may be increased by stress or confusion associated with urgent situations during surgery. Protocols should be developed and implemented for administering commonly used medications during surgery. The risk of errors because of misunderstanding may be

reduced by timely and effective communication between the surgical and anesthesia teams during the entire operation. All verbal orders should be written down and read back.

Obstetric surgery

Obstetric surgery and nonobstetric surgery for pregnant women present special patient safety issues. Similar to other surgery, emergency situations, unusual time pressures to start or finish the operation, unplanned changes in procedure, higher body-mass index, and a patient's unusual physical characteristics, may increase the risk of surgical error in obstetrics. Yet obstetric surgery is often, by its very nature, unplanned and urgent. The changing anatomic and physiologic conditions of pregnancy add another level of complexity. The course of an obstetric surgical procedure is fluid and highly dependent on the changing condition of two patients: the pregnant mother and her unborn child. For these reasons, obstetric surgery deserves particular attention to following established safety guidelines and protocols, despite the tendency to bypass them in emergencies. Extra attention is appropriate to effect timely and efficient communication among the obstetrics team, nursing staff, anesthesia specialists, and pediatricians. The presence of adequate personnel to care for both mother and baby must be arranged in advance, if possible. Obstetric surgery may involve certain high-risk medications, such as oxytocin, methergotamine, and magnesium sulfate that require special precautions.

Ambulatory and office surgery facilities

Although the number of surgeries performed in the United States is increasing overall, the proportion done in hospital is decreasing while the proportion done in freestanding clinics and physician's offices is increasing. Of over 32 million surgical procedures in 2006, only about 25% were in-patient procedures; the remaining surgeries were performed in freestanding facilities, physician's offices, or in hospital out-patient facilities [50]. Although patient selection tends to favor low risk patients for out-patient surgical procedures, many of the same safety considerations for in-patient surgery also apply to out-patient surgical services. In addition, there may be the added risks associated with less organizational oversight of ambulatory facilities, particularly office surgery units, and the introduction of novel or nontraditional procedures for gynecologists, such as liposuction. In one review of all adverse incident reports to the Florida Board of Medicine for a 2-year period, the of rate adverse incidents in office surgery was 66 per 100,000 procedures, and in ambulatory surgery centers, 5.3 adverse incidents per 100,000 procedures. For office surgery, the death rate was 9.2 deaths per 100,000 procedures, while in ambulatory surgery centers, the death rate was 0.78 deaths per 100,000 procedures: a 10-fold increased risk of adverse incidents and death in the office setting [51]. Physicians

who perform surgery in physicians' offices, freestanding surgical facilities, or "surgi-centers" should take special care to ensure adequate availability and training of personnel, appropriately maintained equipment and instruments, and protocols for emergency transport.

Summary

The impact of medical error in office practice has been less well studied than in the hospital environment, but appears to present a significant potential risk to patient safety. Some principles and solutions appropriate to patient safety in the hospital may apply to office practice, while others may not; therefore it is particularly important for individual practices to examine their own procedures and outcomes and evaluate possible steps for improvement and the outcome of those initiatives.

Some aspects of patient care unique to the surgical environment may involve infrequent but potentially serious risks to patient safety, and nontraditional surgical venues may be associated with particular opportunity for vigilance. Certain steps toward improvement in both office practice and the surgical environment appear reasonable, even in the absence of documented evidence of positive impact. The individual practitioner is challenged to adopt and adapt patient safety activities according to local circumstances, needs, and resources.

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Medication Safety

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Since the 1999 landmark report by the Institute of Medicine, ''To Err is Human,'' increasing attention has been directed toward patient safety in the United States, and in fact world wide. This report estimated that approximately 44,000 to 98,000 patients die annually as a result of errors in the care received, and that more than a million patients are injured annually [1]. While the exact number of deaths is uncertain and remains controversial, with strong arguments being made that the true figure is lower [2], other recent reports have suggested that the actual figure might be even higher. For example, a 2004 report by Health Grades Incorporated, which evaluated 37 million patient records, estimated that between the years 2000 and 2002 as many as 195,000 people in the United States died as a result of potentially avoidable medical errors [3].

Medication errors occur in all clinical domains, affecting all patient populations from the tiny neonate to the frail elderly. In recent years, research has focused not only on the incidence of these errors but also on the circumstances and conditions leading to their occurrence. One of the first large studies to systematically examine the incidence of harm in the in-patient setting was the Harvard Medical Practice Study, published in 1991. In that study, which reported an adverse event rate of 3.7%, investigators found that medication errors were one of the most common causes of harm, causing 19.4% of the adverse events [4].

In 1995, the Adverse Drug Event (ADE) Prevention Study further assessed the incidence and preventability of both adverse drug events and potential adverse drug events in an effort to develop prevention strategies [5]. In two large academic centers, the adverse drug event rate was 6.5 per

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100 admissions, and 28% of the ADEs were determined to be preventable. In addition, for every preventable ADE, investigators found nearly three times as many potential ADEs or near-misses [5].

The epidemiology of medication errors has also been examined in the outpatient setting. The Improving Medication Prescribing Study by Gandhi and colleagues [6] studied four primary care practices to determine the rate of adverse drug events. Investigators found that 25% of patients suffered an adverse drug event, of which 13% were classified as serious. Of the ADEs, 11% were considered preventable and 28% were categorized as ameliorable.

Since this research conducted in the 1990s, there has been an increased focus in the United States at addressing actual and potential harm associated with medication use. The general public is also concerned. A national survey conducted by the American Society of Health-System Pharmacists in 2002 noted that 85% of Americans are concerned about at least one medication related issue. Among concerns expressed by respondents were: concern about being given the wrong medication, being given two or more medications that may interact in a negative way, concern over the cost of prescriptions, and worry over potential harmful side effects [7]. Medication safety research has shown that these concerns are valid and worrisome.

In 2005, at the request of the Center for Medicare and Medicaid Services, the Institute of Medicine (IOM) commissioned a group of scientific leaders to study the prevalence of medication errors and develop a national agenda aimed at reducing their occurrence. This report, ''Preventing Medication Errors,'' underscored the alarming rates of adverse drug events in various clinical settings. Among the key findings was the estimate of as many as 450,000 preventable ADEs per year. ADE rates among the elderly and those residing in long-term settings are also worrisome, with estimates reaching 800,000 ADEs per year. Because these studies did not account for errors of omission in their analysis, when a drug should have been prescribed for a particular patient condition but was not, the Committee felt these figures are likely underestimated. Based on review of scientific evidence to date, the Committee concluded that at least 1.5 million preventable ADEs occur each year in the United States in all settings combined. Medication errors—most of which have little or no potential for harm—are ubiquitous; the Committee estimated that the rate of errors in hospitalized patients is approximately one medication error per patient per day [8].

This IOM Committee also examined the costs associated with medication errors. The average increase to a patient's length of stay because of this complication is 4.6 days, with additional hospitalization costs of $5,857 [9]. Adjusting for the 2006 increase in expenditures, researchers estimate the additional hospitalization costs at $8,750. Using a conservative estimate of 400,000 preventable ADEs in hospitalized patients per year, this translates to a national burden of approximately $3.5 billion [8].

Defining medication errors and the medication use process

There are many factors that contribute to the complexity of the medication use process. When a medication error happens, it is often multifaceted in nature and can involve a combination of human factors and systems issues.

Researchers studying the epidemiology and prevention of medication errors have developed a standard nomenclature for defining medication errors and adverse drug events, and for classifying the impact in terms of degree of harm associated with these events [10]. The Committee on Data Standards for Patient Safety defines an error as "the failure of a planned action to be completed as intended (ie, error of execution) or the use of a wrong plan to achieve an aim (error of planning). An error may be an act of commission or an act of omission" [8].

Upon review of the of the Patient Safety report, by the Committee on Data Standards, the Committee on Identifying and Preventing Medication Errors adopted the following definitions [8]. A medication error was defined as any error occurring in the medication-use process [11]. Examples include wrong dosage prescribed, wrong dosage administered, or failure to give (by provider) or take (by patient) a medication. An ADE was defined as any injury caused by a medication [5]. The Committee on Data Standards states that "an adverse event results in unintended harm by the patient by an act of commission or omission rather than by the underlying disease or condition of the patient" [8]. Adverse drug events can be further classified based on preventability of the event. A preventable ADE is an injury caused by a medication that is caused by an error in the medication use process. An example of a preventable ADE would be if a patient develops an anaphylactic reaction to an antibiotic to which he or she is known to be allergic. A nonpreventable ADE, often referred to as an adverse drug reaction or ADR, is not the result of an error. An example of a nonpreventable ADE would be if a patient is prescribed amoxicillin for an ear infection and subsequently develops diarrhea during the course of treatment. In this case, assuming the medication is prescribed appropriately, there is no error associated with the event as diarrhea is a known side effect of this medication and thus, most likely the cause of the reaction. Some nonpreventable adverse drug events can be ameliorated if communicated to and acted upon by a patient's provider; an example would be a patient who develops a cough related to an angiotensin-converting enzyme inhibitor, which is treated promptly. While the ADE would not have been preventable, it would be considered ameliorable if it persisted for a long period of time (eg, 3 months). A potential ADE or near miss is a medication error that has the potential to cause harm but does not, either because it is intercepted or as the result of luck. An example of a near miss or potential ADE would be a pharmacist identifying and subsequently intercepting a tenfold overdose of morphine prescribed for a neonate. Fig. 1 further illustrates the relationship between medication errors, adverse drug events, and potential adverse drug events.

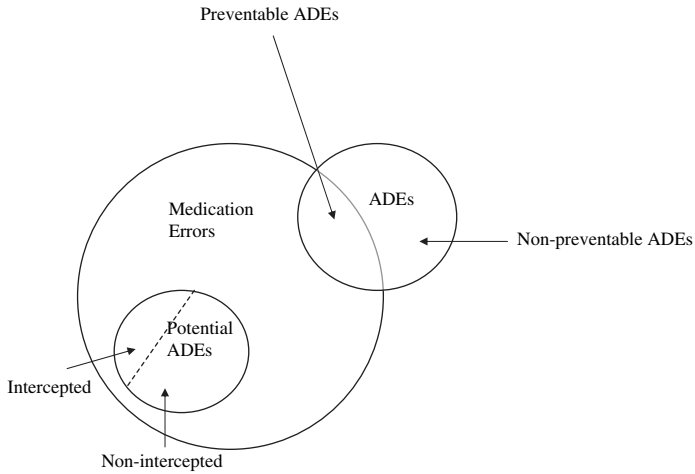

Fig. 1. Relationship between medication errors and adverse drug events. The preventable ADEs (errors resulting in patient harm) and the nonintercepted potential ADEs (errors that had the potential to cause harm and reached the patient) make up the serious medication errors. Patient safety efforts and prevention strategies focus on the serious medication errors. (*Adapted from* Bates DW, Boyle DL, Vander Vliet MB, et al. Relationship between medication errors and adverse drug events. J Gen Intern Med 1995;10:199–205; with permission.)

Assessing the stage at which a medication error occurs is important in the process of identifying and developing prevention strategies to mitigate their prevalence. As previously mentioned, a medication error can occur at any stage in the medication use process, including prescribing, transcribing, dispensing, administering, or monitoring. In the ADE Prevention study, which was performed in the in-patient setting, investigators reported the following distribution of errors among 264 preventable events [5]: the primary error associated in 49% of cases reviewed occurred at the ordering stage, 26% of errors occurred during administration, 11% occurred at the transcription stage, and 14% occurred during the dispensing process. The investigators concluded that error reduction strategies should be aimed particularly at stages where the greatest risk exists: in this instance, prescribing and administration. Subsequent studies assessed interventions aimed at these stages [12].

Although only a small minority of medication errors actually result in patient harm, the rate of incidence and frequency of those that do remain a major concern. In the above referenced study, among cases that were classified as life-threatening or serious, 42%, were preventable [5].

Medication safety in obstetrics

Specialty areas, such as obstetrics, present specific challenges with respect to medication safety, although the issues in gynecology parallel those in

many other surgical domains. In obstetrics, the frequent and often rapid transitions to and from various clinical areas within an obstetric unit require additional vigilance when administering and monitoring a patient's response to medications. In traditionally modeled units, patients are often admitted to labor and delivery, but then depending on the patient's clinical status, there is often a transition in the care environment and care may later be rendered in the operating room, obstetric recovery area, and postpartum unit. The only study that the authors are aware of, involving primary data collection that evaluated the frequency of ADEs in obstetrics, found relatively low rates of ADEs when compared with those found in medical and surgical units, in part because relatively few medications were used [11]. Nonetheless, data from spontaneous reporting have identified many serious events. Thus, the obstetrics setting still represents an environment with substantial risk when it comes to medication safety, and prescribing in the outpatient setting is clearly more complicated because of the concerns about adverse drug effects on the fetus.

According to data submitted to the United States Pharmacopoeia MedMarx program, 3,800 medication errors were reported in obstetric areas between 1998 and 2002. The MedMarx program is a voluntary, national, internet-accessible database that enables hospitals and health care systems to track and trend adverse drug reactions and medication errors [13].

The distribution of errors in cases reported found the greatest percentage of medication errors occurring in the labor and delivery area (49%). Approximately 41% of errors occurred in maternity units, while 10% occurred in obstetric recovery areas. Similar to data seen in other medication error studies, the majority of these errors did reach the patient but no harm ensued. The MedMarx analysis also revealed that among the medication errors that did result in patient harm, the highest proportion occurred in labor and delivery (5%), compared with 1.9% in the obstetric recovery area and 1.6% in maternity units. In the labor and delivery setting, the types of errors most common were errors of omission and administration of improper dose or quantity. The drugs most associated with these errors were cefazolin, ampicillin, magnesium sulfate, oxytocin, insulin, and penicillin G. In particular, magnesium sulfate, oxytocin, and insulin are known to be high-alert medications associated with a high frequency of serious adverse effects [13].

This analysis also noted recurring practice issues including misprogramming of infusion pumps, misconnected or disconnected intravenous tubing, erroneous administration of peripheral intravenous medications through epidural catheters, unavailable drug allergy information, and incomplete communication and documentation [13]. Among the contributing factors identified, nurse distractions and workload increases were most common. The labor and delivery setting represents a dynamic environment where fluctuating census often necessitates constant shifting of workload assignments based on the acuity of the patient and the intensity of care needed. Reasons

such as inexperienced staff, inadequate staffing, cross coverage, emergent clinical situations, and flawed dispensing systems were all contributing factors associated with medication errors [14].

As this examination demonstrates, errors in the medication use process are often the result of a combination of human factors and system issues. Failure in process design, task design, and equipment design are the three most common causes identified in system breakdowns [15]. In an analysis of ADEs and near misses by Leape and colleagues [16], investigators found over half of the errors were the result of system failures.

The following case studies are examples of serious medication errors that have occurred in labor and delivery settings.

In June 2006, an 18-year-old gravida died after receiving an overdose of magnesium sulfate that was prescribed for preterm labor tocolysis. Investigation into the error revealed that the patient was given a 16-g bolus of magnesium sulfate instead of the prescribed 4-g bolus. The intravenous (IV) solution contained 40 g of magnesium sulfate rather than an IV piggyback solution of 4 g. This administration error was attributed to a mathematic miscalculation [17]. The Institute of Safe Medication Practices notes that there were at least 52 prior cases of magnesium sulfate overdose reported before this death in Florida. Seven of these errors resulted in maternal deaths, and two women remain in a persistent vegetative state [14]. Because of the risk of serious harm associated with errors involving this medication, magnesium sulfate is now on the Institute of Safe Medication Practices ''List of High-Alert Medications.''

In Wisconsin, a perinatal nurse accidentally administered a bag of epidural analgesia intravenously, containing a combination of bupivacaine and fentanyl instead of the prescribed penicillin. This 16-year-old laboring patient died as a result of poisoning by the intravenous anesthetic. The nurse, with 16 years of experience, was charged with criminal neglect for ''failing to provide adequate medical care, creating a significant danger and causing great bodily harm'' [18]. The complaint asserted that the nurse did not follow the ''five rights'' of medication administration, failed to use an available bedside bar-code scanner, and did not read the label on the medication. The nurse faced a threat of 6 years in jail and a $25,000 fine [14]. In response to this indictment, the Wisconsin Nurses Association issued a statement opposing the pursuit of criminal prosecution of the nurse for an unintentional medical error. This position was supported by the Institute for Safe Medication Practice, the Wisconsin Medical Society, and the Wisconsin Hospital Association [18].

Investigation into the above incident revealed that the experienced nurse had worked two consecutive 8-hour shifts the day before the incident, with the latter shift ending at midnight. She then made arrangements to sleep at the hospital because she was scheduled to return to work the next morning for the 7 AM shift. The error occurred during this following day shift. The RN involved in this case had her license suspended for 9 months. Practice

limitations were also imposed, including restricting work hours to no more than 12 hours in any 24 consecutive hours and not working more than 60 hours in any 7 consecutive days. (However, no similar system-wide restrictions in work hours were implemented by the hospital) [18].

Recent studies have demonstrated the impact of fatigue on patient care [19]. The Accreditation Council on Graduate Medical Education has since enacted regulations reducing the allowable working hours for residents and interns to 80 hours per week, although the basic research suggests that this limitation does not address the core underlying issue, which is extended duty shifts [19]. Nurse researchers at the University of Pennsylvania have also demonstrated that nurses who work long hours and are sleep deprived place themselves and their patients at risk for injury [20,21]. Regulations need to be drafted to protect nurses from the risks of extended work hours [21]. In their report, ''Keeping patients safe: transforming the work environment of nurses,'' the Institute of Medicine recommended limiting nursing work hours to 60 per week [22].

This case also illustrates the effects of an equipment design failure. In this case, the nurse connected an epidural catheter to a syringe filled with medication prepared for intravenous use. A forcing function design similar to that used with nitrous oxide and oxygen connections could have prevented this error. The connection between the IV syringe and the epidural catheter could have been incompatible, preventing misconnections similar to what is now standard for gas line connections [15]. Furthermore, while bar-coding was in place at the institution, there were still many potential issues, and it was not being used in all cases.

Medication safety in the ambulatory setting

Medication errors are also common in the ambulatory setting. The study by Gandhi and colleagues [6], revealed a preventable ADE rate of three per 100 patients studied. In a study of ADEs among elderly patients in ambulatory care settings, researchers identified 421 preventable ADEs, of which medication errors occurred in the prescribing stage in over half of the cases identified (246 out of 421) [8,23].

The National Center for Health Statistics (2004) reported that clinicians wrote more than 1.6 billion prescriptions in 2004. This equates to 5.4 prescriptions per United States resident. Seven out of 10 office visits result in a written prescription [24]. Although there are a variety of medications administered in the ambulatory setting, few safeguards exist to prevent errors.

Unlike the inpatient setting, medication orders are not routinely reviewed in an electronic system or in paper form by either pharmacists or nurses before dispensing and administration. For in-patient medication administrations, a nurse must follow a standard protocol verifying the patient's identity, the correct drug name, dose, route, and time. In the office setting, a medication is usually ordered by the clinician and retrieved from an onsite

stock area by the clinician or other medical staff personnel and subsequently administered to the patient. Although efficient, this process lacks the necessary safeguards to prevent medication errors from occurring. Ambulatory practices often lack policies for the administration of high hazard drugs. (ie, double checks for insulin) or read back of verbal orders [24].

Suggestions for improving medication safety in the office setting include use of prescribing writing aids to help ensure that prescriptions are accurate and complete, electronic prescribing that include standardized fields to prevent the use of unsafe abbreviations, medication-related computer alerts and warnings, evidence-based guidelines and standardized protocols, educational programs for physicians in training, and point-of-care reference material [8]. Routine monitoring of medication-related supplies and elimination of samples are also helpful for improving the safety of the medication environment in the ambulatory setting.

Provider strategies for improving medication safety

Providers should take an active role in maintaining safe medication practices. There are several steps they can to do to improve the medication use process. For example, they can verify the patient's current medication list for appropriateness at each encounter, to ensure that this list is accurate and up to date, particularly during times of transition. They can educate their patients about their medication regimen, understanding that patients need different kinds of information at different times and for different purposes. Providers should also take time to instruct patients on when and how to take medications and discuss potential side effects and drug-drug interactions. Partnering with patients and engaging them in the medication use process can also serve as an additional layer of safety in the ambulatory care area [24].

When prescribing, providers should seek to avoid missing any essential components of a medication order. Complete, legible medication orders should contain the following components: name of drug, dose, route, frequency of administration, reason or conditions for which the medication should be administered, and the patient's weight and age (when relevant to dosing, as with elderly patients). Verbal communication of prescriptions or medication orders should be limited to urgent situations where immediate written or electronic communication is not possible. It is important for health care organizations to develop policies explaining situations when it is acceptable to use verbal orders, as well as defining limitations for their use. Establishing guidelines for clear and effective communication and documentation of verbal orders is also important [25,26].

Medication reconciliation

Medication reconciliation involves obtaining a complete and accurate list of medications a patient is taking at each new encounter, and comparing this

to the active medication list present in the patient's ambulatory medical record. This process of reconciliation aims to prevent errors of transcription, omission, duplicate therapy, and potential drug-drug and drug-disease interactions [8]. This process is particularly important during transitions, when a patient's vulnerability to medication errors increases. In a study by Moore and colleagues [27], investigators reviewed the in-patient and out-patient medical records of 86 patients at 2 months after discharge and noted that 42% of in-patients had at least one medication continuity error. In this study, a medication continuity error was defined as a discharge medication that was documented in the hospital chart, but not in the medication list of the first post-discharge primary care provider visit. Investigators also note that the 42% rate of medication continuity errors identified in this study is similar to studies of patient nonadherence with intended discharge medications. The study investigators concluded that the primary care providers in this study may be documenting what the patient reports they are currently taking, while being unaware that the current medication regimen is different from the intended discharge plan [27].

Partnering with patients to improve medication safety

Establishing and maintaining a strong provider-patient partnership represents a key to reducing medication error rates [8]. The Institute of Medicine report advises consumers to maintain a current list of both prescription and nonprescription drugs, and other natural products such as vitamins or minerals they are currently taking, and present and review this list with their provider at every visit [8]. Engaging patients in their care improves compliance, satisfaction, and reduces error. Communication between the provider and patient is paramount to safe medication practices. Providers should never assume that information is shared among different providers. Education is also centrally important and can be provided in a variety of concurrent formats: oral, written, and video. Patients should be provided with written information, as well as verbal instructions, about medications prescribed. An additional layer of safety involves including family members who will assist in the patient's care in these discussions and review.

Information technology strategies for improving medication safety

Advances in information technology are rapidly becoming one of the most effective strategies for reducing medication errors and thus improving the quality of patient care. In recent years, computerized tools have been developed to assist clinicians in a number of ways, including improving communication, making knowledge more readily accessible, providing key elements of information as well as decision support at the point of care, assisting with drug dose calculations, performing checks in real time, and

assisting with monitoring the patients response to drugs and other therapies [28].

One of the major problems in current medication systems is the inability to access pertinent patient and drug information at the time when it is needed most, at the point of care [16]. In 1995, Leape and colleagues [16] performed an analysis of system failures that lead to errors causing ADEs and potential ADEs. In this study, investigators found 16 major system failures as the underlying cause among the 264 preventable ADEs and potential ADEs. Twenty-nine percent of medication errors were attributed to failures in disseminating drug information to providers. In addition, inadequate availability of patient information, including important laboratory results, was associated with18% of errors.

Computerized physician order entry

Computerized physician order entry (CPOE) is one prevention strategy with strong evidence base support for its effectiveness [29], and it has been endorsed by many, including the federal government's Quality Interagency Coordination Task Force, the Institute of Medicine, and major stakeholders including the Leapfrog Group, as a key intervention for reducing medication error rates and improving medication safety [15]. Basic CPOE involves electronic entry of a medication order. Basic electronic prescribing eliminates errors created by illegible handwriting. Fig. 2 illustrates an example of this in the gynecologic setting. CPOE with decision support streamlines and structures the prescribing process by allowing clinicians to choose medication dosing from programmed drop down menus, thus improving

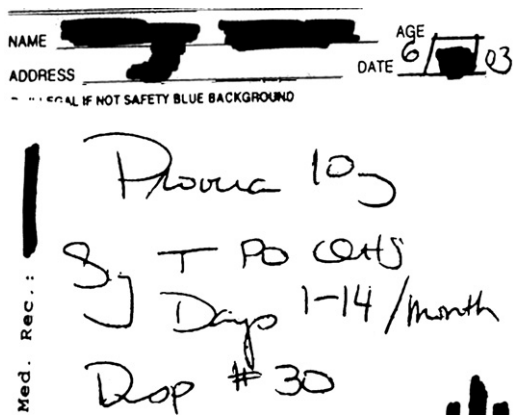

Fig. 2. Prescription illustrating the dangers of poor handwriting. The medication to be dispensed was misinterpreted by the pharmacy and dispensed as Prozac (Eli Lilly and Company, Indianapolis, IN), instead of the intended Provera, (Pfizer Inc., New York, NY), which has a similarly spelled trade name.

accuracy. Use of this technology aids in decreasing transcription and ensures completeness of the medication order. Decision support features embedded in this technology allow providers access to relevant patient laboratory data, as well as specific drug guidelines and guided dose algorithms (see Fig. 3 for an example of this decision support tool). An additional benefit of computerized order entry is the ability to perform important safety checks, such as drug-allergy, drug-drug, drug-laboratory, and drug-patient characteristics.

While CPOE appears beneficial in the aggregate, there has been much recent discussion related to the unintended consequences [30,31], which can be substantial. The IOM Committee reviewed the results of ten investigational studies that evaluated the effectiveness of CPOE with decision support capabilities. In their report, the IOM concluded that all ten studies showed a statistically significant reduction in medication errors. The report notes that medication error rates were reduced between 13% and 86%, and preventable adverse drug events decreased by a rate of 17% to 62% [8]. The IOM did acknowledge that the adoption of computerized systems can themselves introduce errors, and in some instances even contribute to worse outcomes. However, these consequences

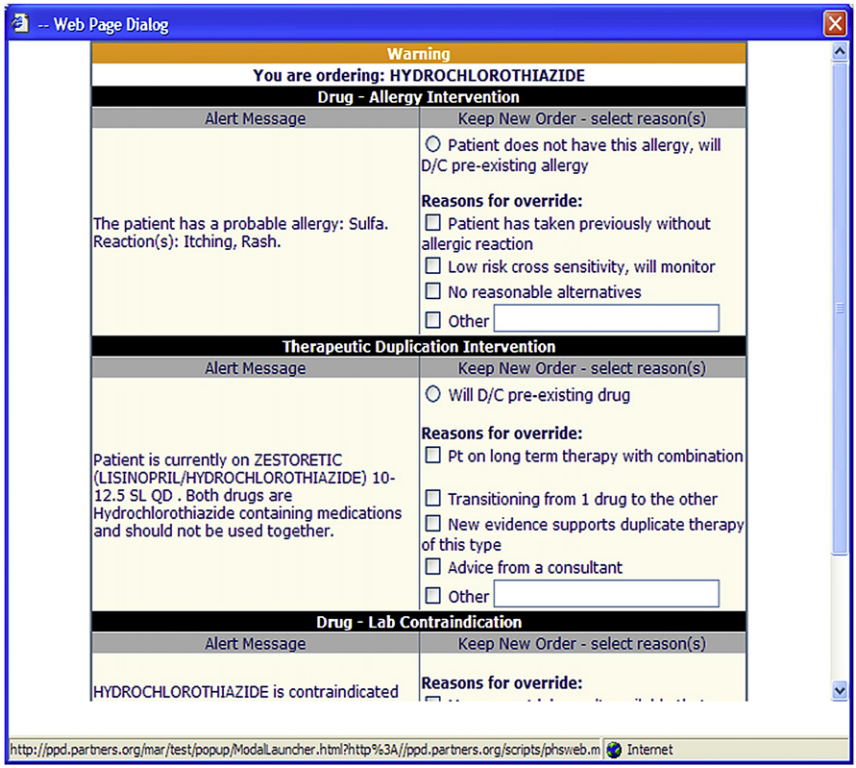

Fig. 3. Example of advance decision support alerts within computerized provider order entry.

tend to occur when flaws exist in the planning and implementation process [8]. Thorough planning, redesign of the health care delivery process that includes careful integration of the technology with existing hospital systems, continuous monitoring of problems that arise during and after implementation, and immediate response to these issues are all key factors in the effectiveness this technology has as a patient safety intervention.

Bar-coding

Barcode technology with an electronic medication administration record (eMAR) is another major advance recently introduced to improve medication safety. Benefits of this technology are that it allows for matching of medication orders with drug products, provides verification of drugs at the dispensing and administration stages, and automates the "five rights" of medication administration: verifying the who/what/when/dose/route. Bar-coding streamlines workflow by updating the eMAR immediately, ensuring accuracy and saving time that would otherwise be spent documenting the administration on a paper medication administration record. Several research efforts are underway to evaluate and validate the effectiveness of this technology on reducing medication errors and ADEs and assessing the impact on clinician workflow. Early studies suggest that there will be benefits at the dispensing and administration stages, as well as from a cost perspective. One study has shown that before barcode medication administration (BCMA) implementation, nurses spent 26.5% of their time on medication administration. After BCMA implementation, this proportion remained statistically unchanged at 24.5% [32]. In a recent study by Maviglia and colleagues [33], researchers performed a cost benefit analysis of a BCMA system in a large academic institution. Investigators found that the major cost benefit was achieved through the decrease of dispensing errors leading to ADEs (517 events). This decrease translated into an annual cost savings of $2.20 million. The study's investigators also reported that the break-even point for the hospital's investment of $2.24 million occurred within 1 year of when bar-coding became fully operational.

In September of 2006, three preterm infants in an Indiana hospital died as a result of lethal overdoses of intravenous heparin. The error was the result of a pharmacy technician accidentally stocking the drawer in the nursery with the adult dosage of the heparin. Fig. 4 shows that the doses for adults and infants were similarly packaged, contributing to the error. The use of barcode scanning at the dispensing and administration stages might have prevented these errors.

Smart pumps

Medications delivered by intravenous infusion are of vital importance in the care of hospitalized patients, and are quite important in the care of

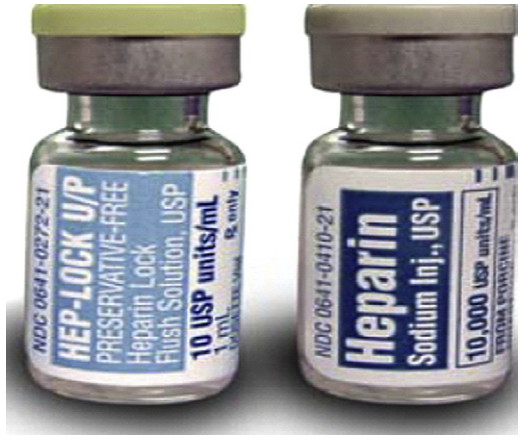

Fig. 4. Similar vials of heparin involved in fatal dispensing error in neonatal setting.

obstetric and gynecologic patients. Often intravenous infusions involve potent drugs, such as oxytocin and magnesium sulfate, with narrow safety margins that require frequent dose adjusting to respond to a patient's clinical condition [34]. Although barcode technology can verify the right drug for the right patient, these technologies lack safety features to ensure accurate programming of drug delivery by intravenous route. Smart infusion systems have been developed to assist in averting IV medication errors at the point of care. The role of ''smart'' technology is to remember the rules that apply (eg, dosing limits and clinical advisories) by incorporating them into the safety software. The following case illustrates an intercepted error at this level of medication administration: A patient was ordered for a heparin bolus dose of 4,000 units, followed by an infusion of 890 units per hour. The nurse administered the 4,000-unit bolus dose appropriately; however the nurse misinterpreted the order and programmed the infusion device to deliver 4,000 units per hour instead of 890 units per hour. The medication was being administered through an infusion device, which had the smart technology software, and subsequently the smart pump alerted nurse that the dose exceeded maximum limits defined in drug library, thus intercepting the error before administration.

Electronic prescribing in the ambulatory setting

Electronic prescribing involves writing an outpatient prescription with the use of a computer. Basic electronic prescribing systems ensure prescription completeness (avoiding errors of omission) and allow for printed copies of prescriptions (avoiding legibility issues). Advanced electronic prescribing systems incorporate decision support tools into the prescribing process. One important benefit is that e-prescribing systems are often integrated into

electronic health records, thus making patients' active medications more readily accessible to clinicians. Electronic submission of prescriptions directly into the pharmacy system is ideal, but not all pharmacies have this capability yet. Upon receipt of electronic submission (often by fax), many pharmacies still manually enter the prescribing information into their systems [35]. Because of the known benefits of e-prescribing, the IOM Committee on Prevention of Medication recommends that by 2010 all prescribers and pharmacies use e-prescribing.

Barriers to adoption

Although advances in health information technology are showing tremendous promise in mitigating and averting serious medication errors, there are many barriers that have impeded their widespread adoption. Among these are financial barriers. Physicians are typically rewarded for excellent billing capabilities, not improvements in clinical care. Most applications are commercially funded, making customization and integration into existing clinical systems more challenging. While national standards exist for most types of clinical data, many are not yet in wide use. Among the cultural barriers that inhibit implementation efforts are lack of physician comfort with adopting new technology, desire to maintain the status quo, lack of recognition, and understanding and concerns about privacy and security [36]. Furthermore, any changes that the physicians regard as increasing work instead of reducing work is certain to be met with resistance.

Creating a culture of safety

Creating a culture of safety is a key component in improving medication safety. It requires an organizational commitment at all levels to continuously monitor, report, and develop processes toward improving safety. Senior management must make safety a priority and remain engaged in activities directed toward this goal. This includes committing necessary resources to implement prevention strategies that have been demonstrated to be effective in reducing medication errors and harm [8]. Efforts toward promoting a culture of safety can be achieved by establishing a shared vision within an organization, where everyone aims toward a common goal in which patient safety is the primary tenet of patient care, including medication safety [37].

Summary

Medication safety represents an important problem in obstetrics and gynecology, as in other domains. Achieving substantial improvement in

medication safety in obstetrics and gynecology will require adopting a number of technologies, including computerized physician order entry, bar-coding, and smart pump technology in the hospital, and computerized prescribing and use of electronic health records in the outpatient setting. However, patient safety is a state of mind, not technology. All these technologies represent tools that must be properly designed, used well, assessed on an on-going basis, and the associated decision support needs to be refined and updated. Moreover, in all settings, building a culture of safety is pivotal for improving safety, and many nontechnologic approaches, such as medication reconciliation and teaching patients about their medications, are also essential.

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Transparency, Apology and Disclosure of Adverse Outcomes

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Medical errors gained widespread attention with the release of the Institute of Medicine's "To Err Is Human" in November of 1999. This release reported that as many as 98,000 people die each year from inpatient medical errors. Putting this into perspective, deaths from medical errors surpassed deaths from breast cancer, motor vehicle accidents, and AIDS. Furthermore, medication errors account for more deaths annually than workplace injuries [1,2]. With these alarming facts, few studies attracted more attention than this one; 51% of Americans surveyed stated that they "closely followed" this report, and the concerned public reaction was not surprising [3].

As a result, medical errors became a common topic of conversation, and attention to medical errors became a necessity for health care organizations and providers. Language such as *root cause analysis*, *disclosure*, *safer health care*, *risk management*, *quality assurance*, *adverse events*, and *nonpunitive reporting* began to appear in the medical and lay press.

This article addresses the communication of adverse outcomes to patients (disclosure) through transparency and apology. The concept of saying "I'm sorry" to patients is relatively new and one that still generates mixed emotions and opinions.

First, practitioners must appreciate that, although to patients many if not all adverse outcomes equate to a medical error, adverse or unanticipated outcomes can occur without an associated error. The Bayer Institute for Healthcare Communication clearly recognizes the various causes of unanticipated outcomes in its disclosure workshop. According to them, unanticipated outcomes can arise from unreasonable or uncorrected patient expectations,

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biologic variability, or low probability risk in side effects. None of these constitutes an error [4].

Error, as defined by Stedman's Medical Dictionary, is "a defect in structure or function. A mistaken decision" [5]. Therefore, one can see how patients can equate unanticipated outcomes with errors. Communication/disclosure of these outcomes is extremely important in correcting this disconnect in understanding between provider and patient. Wu and colleagues [6] define medical error as "a commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were any negative consequences."

Errors are common in medicine. Fortunately, most errors do not result in significant harm [6]. Unanticipated outcomes are not necessarily the result of medical error. Common causes of medical errors leading to unanticipated outcomes include limited knowledge, insufficient experience, fatigue, and carelessness [7]. Unanticipated outcomes not associated with medical error are caused by unrealistic, uncorrected expectations; biological variability; and low-probability, low-risk side effects. Those that are associated with medical error are caused by limited knowledge, inadequate experience, carelessness, and fatigue or faulty medical judgment.

Adverse outcomes are really a result of deficiencies in medical judgment rather than medical knowledge [7]. For example, interpretation of the history and physical examination will prompt the ordering of tests or consults. This clinical interpretation is subject to four common sources of error: (1) wrong synthesis (lack of knowledge about a disease), (2) premature closure, (3) inadequate synthesis (conclusion not supported by data), and (4) omission (key diagnostic information not obtained) [7].

Although these sources of error may not seem inherently vital to disclose, patients affected by adverse events from medical errors are very concerned about what will be done to prevent a similar occurrence. Understanding of the underlying factors contributing to the error will prevent others from being harmed. Also, little attention has been directed to the emotional impact of medical errors on the practitioner, which may contribute to the disclosure being handled in a dysfunctional fashion [8]. Wu [9] coined the term *second victim* to underscore how harm from error is not only traumatic to the patient but also emotionally devastating to the provider involved with the care.

Before 2001, there was no general acknowledgment of the frequency of adverse outcomes in the medical profession or the need for health care providers to be trained in disclosure. In 2001, The Joint Commission and Accreditation for Healthcare Organization (JCAHO) sought to make disclosure of unanticipated medical outcomes a requirement [10]. Research supports that lack of disclosure can be an alienating factor in the physician–patient relationship [11]. Predating both the JCAHO recommendation and the IOM's report, a study in 1996 by Witman and colleagues [11] showed that 98% of patients wanted to be informed of even a minor error,

and the more severe the occurrence, the more desired the information. Another study showed that 92% of patients but only 60% of physicians believed that patients should always be informed of complications [12]. This disconnect in the case of an adverse outcome can be misinterpreted by patients and their families as a lack of care or concern.

In the event of an adverse outcome, patients have clearly voiced their needs and wants, which are: (1) to know the truth about the event and occurrence, (2) for health care organizations to accept responsibility, (3) an apology in recognizing patient trauma, and (4) an apology from the health care practitioner. Monetary reimbursement was not one of the top desires. The need for monetary compensation is exceeded by the patient's desire for human interaction and communication [13]. Not only is the provision or lack of communication a key factor in malpractice litigation, but the lack of physician communication with disclosure of adverse events is disparaging to patients.

However, many health care providers and organizations have been reluctant to provide full disclosure for fear of increased litigation. Although this fear is undoubtedly real, whether reporting medical errors actually leads to a dramatic increase in malpractice claims is still unclear. Determining the impact of disclosure on litigation is difficult because data are reported in an aggregate fashion and not individually [14].

The tort law governs medical malpractice with damages awarded to injured plaintiffs allegedly to provide compensation to those who have been injured and to deter future wrongdoing [15]. In the follow-up of the Harvard Medical Practice study, Brennan and colleagues [15] showed that malpractice suits correlate poorly with the actual occurrence of injuries resulting from negligence. Most patients injured through medical negligence do not seek litigation [16].

Although a perceived barrier to disclosure is the fear of increased litigation; poor communication is actually a greater risk for litigation. Improved communication can minimize malpractice suits and decrease perceived adverse events. Poor interprofessional communication is a key contributor to adverse events. Poor patient–provider communication, even without an adverse event, may leave patients with a perception of a medical error. These miscommunications, even when no adverse event occurred, also led to obvious patient dissatisfaction and the threat of litigation [17,18]. Communication is the key to preventing dissatisfaction, preventing perceived medical error/adverse outcomes, and dealing with adverse outcomes. Although disclosure may be therapeutic for a physician, emotional distress involved with medical errors/adverse outcomes may cause physicians to experience shame and disgrace. Physicians have minimal, if any, experience in disclosure during residency or fellowship training. For many physicians, their first disclosure conversation occurs after residency and often without guidance [8].

Opinions on the value of disclosure range from commitment to full disclosure to complete skepticism. Even to risk managers the value of full

disclosure is unclear. A survey in 2000 mailed to more than 3300 risk managers asking them to evaluate five hypothetical scenarios of medical error and provide disclosure recommendations showed a lack of key consensus on full disclosure of all the known facts. The respondents agreed with the philosophical principle of disclosure, but many believed full disclosure was necessary only if the error clearly caused patient harm. In the five scenarios, respondents believed that full disclosure was appropriate 14% to 66% of the time. The risk managers consistently cited three most common barriers to disclosure: (1) fear of litigation and negative publicity, (2) lack of communication skills and education on how to conduct a disclosure, and (3) physician concerns over disclosure [19].

In 2002, Pennsylvania became the first state to require hospitals to notify patients in writing of a serious event within 7 days of its occurrence [20]. As defined by law, a serious event is "an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated outcome requiring the delivery of additional health care services to the patient" [21]. Nevada and Florida followed Pennsylvania's lead in requiring hospitals to notify patients. These states require that patients be informed in person after a serious event/injury [22,23]. In addition, JCAHO standards mandate that a disclosure conversation occur and that health care providers become skillful in these conversations. Witman and colleagues [11] showed that patients are less likely to seek litigation if physicians honestly and directly disclose events, rather than patients learning of their occurrence later through other means. The benefit of full disclosure is evidenced by the experience of the Lexington Kentucky VA Hospital. After implementation of a hospital-wide policy for full disclosure, an overall reduction in malpractice payouts occurred, although the frequency of claims increased [24]. Despite these studies supporting the benefit of full disclosure, physicians and health care providers remain fearful of disclosing errors and offering apologies.

Changing the paradigm is important. Techniques include development of performance standards, nonpunitive error-reporting systems, and safety systems within health care organizations [25]. Training physicians in disclosure is a fundamental and necessary step toward this change. Like any other procedure, communication in the form of disclosure can be learned. Training physicians in disclosure conversations and developing and implementing hospital policies for a full and timely disclosure of adverse events are essential to changing this paradigm. As stated by Potylycki and colleagues [26], "This first step requires health care administrators to create and adapt a culture that accepts the imperfection of human performance and solicits the assistance of team members in the development of safeguards in error prevention." Lehigh Valley Hospital and Health Network, an academic community hospital in eastern Pennsylvania, has adopted a "just" culture. This network acknowledged that a culture of punishment is counterproductive to patient safety and embraced an initiative entitled *Primum Non Nocere*

(first do no harm). This new culture emphasized a systems approach and specific projects for improving care and reducing medical errors. It became clear that a major barrier to the reporting of medical errors by the staff was the fear of retaliation. The hospital developed a task force that showed that a nonpunitive approach to reporting patient safety issues, particularly those of medication errors, improved staff reporting of medical errors and thereby improved patient safety [26].

Staff must receive appropriate training in error reporting in conjunction with a nonpunitive system to establish a successful risk management program. Furthermore, educational activities for training or teaching of disclosure techniques must involve aspects of the three learning styles: (1) reading, (2) watching, and (3) doing. Disclosure training must include teaching of disclosure principles, active participation in training scenarios, and practice opportunities before having to perform the disclosure "live" in a stressful situation [27].

To frame the process of a timely and accurate disclosure, understanding and remembering *who*, *what*, *when*, *where*, and *how* is helpful.

Who

As specified by JCAHO standard on disclosure, attending physicians or their designee should lead the discussion. Every effort should be made by the physician to provide the disclosure and not delegate, which might be perceived by the patient as avoidance or abandonment. However, if the physician cannot be present, it is preferable for a senior member of the health care team to lead the discussion. The circumstances of the adverse event will often dictate what other members of the health care team must also be present (eg, nursing, administration, ethics, residents, students, risk management, patient advocate) [28].

What

Some uncertainty or disagreement may exist within the health care team; only factual information must be communicated to the patient. Speculation about the events resulting in harm can lead to misinformation and confusion for patients. The natural tendency to speculate in trying to explain the events must be avoided. All individuals involved in disclosure must understand that it is an ongoing process, and not just one conversation, and that all facts may not be known at the initial discussion. Patients must be reassured that as additional, reliable information is obtained, they will be notified promptly [28].

When

Even if all details of the incident are not known, disclosure must be timely. Slow and ineffective disclosure of the adverse events increases

negative perceptions by patients [29]. Disclosure should occur as soon as reasonably possible, while emphasizing to patients that it is an ongoing process of communication. Sharing what is known about the event when it is known helps prevent patients and families from speculating or making inquiries when answers are not known. Providing a timely disclosure can be challenging, particularly when all facts are not known. A balance must be struck between timeliness and accuracy of disclosure. Patients should be informed about what additional reviews will occur and when they can anticipate additional communication [28].

Where

Disclosure should occur in a quiet and confidential setting; one which will be most comfortable to the patient.

How

Patient dignity must always be respected. Disclosure conversations should include empathy for and acknowledgment of what patients and their families have experienced [28]. Although a disclosure conversation does not imply fault or liability, patients deserve empathy, which may include the expression of "I'm sorry." A lack of consensus exists about the concept of apology, and "I'm sorry" is even more intensely debated.

Patients desire an apology for medical errors. If they do not receive an apology, they may perceive the physician as cold and impersonal. Physicians are often reluctant to apologize because they feel it is an admission of guilt and have a fear of increased litigation [30]. The most common concerns cited by physicians for lack of full disclosure and apology can be characterized by the following quote, "apologies for medical errors are used against you in the court … making an apology is an open invitation for a suit" [31]. Resolving this dilemma and disconnect is critical in maintaining the physician–patient relationship after a medical error.

In February 2005, a group of doctors, insurers, lawyers, and patient advocates launched the Sorry Works Coalition (www.sorryworks.net) on the premise that upfront apologies and possible compensation for medical errors could reduce anger of patients and families and reduce lawsuits [32]. Furthermore, in July 2001, the University of Michigan Health System adopted a new policy for handling malpractice claims. The policy was based on three principles: (1) provide quick and fair compensation when reasonable medical care caused injury, (2) defend staff and institution vigorously when case was reasonable and/or when no cause of patient injury was present, and (3) learn from mistakes and experiences of patients. After the first year, they reported a savings of $2.2 million, and the savings continued over subsequent years. The principled approach of full disclosure and apology

when indicated was linked to quality improvement, peer review processes, and a major patient safety/patient communication effort [33]. Despite this favorable experience, much discourse continues on the benefit of apologies in the event of medical errors. Even within the legal profession no consensus has been reached on the value and possible ramifications of an apology. Although some attorneys equate physicians saying ''I'm sorry'' to jumping out of one's car after an accident and saying ''I'm sorry, the accident is all my fault,'' others argue that it is not an admission of guilt [34].

Is the apology an admission of guilt or an expression of sympathy or remorse? The answer may vary depending on circumstances. For example, an inadvertent bowel injury during surgery requires full disclosure and, perhaps instead of an apology, a statement expressing regret that the injury occurred.

Currently, several states are considering so-called ''apology laws,'' which would prohibit a physician's apology from being used in litigation. Colorado, Florida, Kansas, and New York have established statutes for legal reporting requirements, and Pennsylvania, South Carolina, and Washington have established regulations as a legal reporting system. Statutes provide a stronger legal basis for reporting system requirements, because enacting a statute is clearly within the scope of a state legislature's authority as long as it does not infringe on the state or federal constitutional rights of the affected parties, whereas regulations are subject to challenge based on the grounds that they may exceed the agency's rule-making authority. Therefore, statues were established to overcome these challenges [34]. Furthermore, when polled, jurors respond favorably to physician apologies and tend to be sympathetic to the physician [35]. For now, lawyers advise physicians to look carefully at the circumstances surrounding the medical event or outcome and thoroughly consider the decision before making an apology [35]. Finally, although disclosure and apology are often used together when addressing medical events or errors, the difference between them is important to understand. Many believe total disclosure is an ethical imperative, essential for healing, and the right thing to do [36]. An apology is an expression of remorse acknowledging responsibility for an event. An apology may accompany a disclosure, but the two are not synonymous. An unsuccessful high-risk surgery may involve a disclosure but not an apology [37,38].

Apology, unlike disclosure, is not an ethical right, but rather a therapeutic necessity that shows humanity, fallibility, and remorse. A true apology with responsibility and remorse may make amends and help patients with forgiveness and psychologic healing, however, the apology must be sincere with sympathy, empathy and remorse. Otherwise, the apology may be more detrimental than no apology at all [36].

Therefore, the key to an apology is its structure and content. Lazure [37] describes the four parts of an apology as follows: (1) acknowledgment of the offense, (2) explanation for committing the offense, (3) expression of remorse, shame, or humility, and (4) reparation for the offense. When performed

properly with remorse and sincerity, an apology can help restore patients' dignity and reassure them that the physician cares about their well-being.

Although apology can be a very positive tool in the healing process and for fostering the physician–patient relationship, many physicians are still resistant for reasons beyond litigation. In contrast to patients benefiting from an apology through restored dignity and self-image, physicians may fear the loss of self-image and an admission of being too emotional and weak. An apology may be viewed by some physicians as an unnecessary demonstration of vulnerability and exposure of emotions. However, an apology may help physicians heal through diminishing their sense of guilt or shame about the medical event [37].

Although apologies can have a profound beneficial effect on patients and providers, they can fail from lack of sincerity, causing patients to perceive the insincerity as an insult and be offended. When deciding to offer an apology, providers must be cognizant of not only the substance but also the tone; the apology must be direct, specific, and avoid vagueness, such as "I'm sorry for whatever happened." The event should be specifically acknowledged [37].

Summary

Full disclosure of medical errors and unanticipated outcomes or events has received much attention since the release of the Institute of Medicine's "To Err Is Human." Patients and their families want and expect to be informed truthfully, sincerely, and in a timely fashion about these occurrences. Physicians, the health care team, and the health care institution can foster better patient relationships and trust through disclosure and, when appropriate, an apology.

Healthcare providers should receive education, training, and practice in disclosure, and health care institutes should establish nonpunitive policies of medical error reporting and implement full disclosure policies. Full disclosure and, in the case of a medical error, an apology have been shown to decrease malpractice exposure, strengthen the physician–patient relationship, foster improved trust, and promote emotional healing for patients and providers.

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Electronic Health Records and Electronic Prescribing: Promise and Pitfalls

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Ms. X is a 24-year-old Gravida 2, Para 1 (G2P1) who presents to labor and delivery at 3 AM complaining of contractions. All prenatal records from the office were copied after the first visit and at 24, 32, 36, 38, and 40 weeks. However, this patient's records cannot be located. She is a poor historian. Her stated estimated date of confinement would put her at 37 weeks, although her fundal height is noted to be only 28 cm. On fetal heart tracing the fetal heart tones are 150s, and reactive, with contractions every 5 minutes. The patient states that an ultrasound done in the office that day showed that the baby was "small," but that she had had monitoring that was "normal." She states that her physician recently took cultures and told her she had to "have antibiotics when in labor." On examination, her blood pressure is 140/90 mm Hg and her cervix is 2 cm dilated, 80% effaced and -1 station (2/80%/-1). She states that her blood pressure is "always high" and cannot remember if her cervix has been dilated. Her first daughter was born "early," but the patient is unsure as to how early, stating "I gave them all my records from my last doctor." A search of the office fails to locate the paper chart. With no records to guide her, the covering physician gives the patient subcutaneous terbutaline, orders an ultrasound for dating, collects a rapid group B streptococcus culture, and sends laboratory tests to rule out preeclampsia. The physician does her best to quickly piece together a picture to guide decisions on whether or not to treat for preterm labor, preeclampsia, or group B streptococcus.

Health information technology (health IT), especially electronic health records (EHRs) and electronic prescription (e-prescribing) systems, is believed to be the cornerstone for improvements in quality of care, patient safety, and efficiencies, all leading to cost benefits. In its earliest days, there was little awareness of health IT outside of large academic centers. Those

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who wanted to implement these systems had few options, and many developed their own. With time, more options became available as vendors began developing commercial systems, but adoption remained slow. Then, in 2004, President George W. Bush announced at his annual state of the union address that most Americans would have an electronic health record by 2014. Momentum since that time has been building, with numerous federal, state, and local initiatives under way.

With increasing requirements for quality reporting and with new pay-for-performance programs being initiated by insurers, many physicians are asking if it is time to invest in these technologies. However, as those who have already made this decision have found, adopting EHR and e-prescribing systems is not an easy task: our colleagues resist their use; they are costly; the case for a return on investment for an ambulatory practice has not been well established; incentives to use are misaligned; implementations may be difficult; and often such systems disrupt or inhibit workflow. This article examines EHR and e-prescribing systems and describes the potential benefits they offer along with the barriers to their implementation.

What is an electronic health record?

There is a dizzying array of acronyms for software designed to enhance the practice of medicine (Box 1) [1]. This article will use only the term EHR, which is defined by the International Organization for Standards (ISO) [2] as a ''repository of information regarding the health of a subject of care, in computer processable form.'' Although there are clinicians using word processors and customized databases to document care, a true EHR has functionality that goes beyond these rudimentary tools. The Institute of Medicine (IOM) specifies eight core functions of an EHR: health information and data, results management, order

Box 1. Examples of acronyms for software used in medicine

AMR: automated medical record
CDR: clinical data repository
CMR: computerized medical record
CPR: computerized patient record
CPRS: computer-based patient record system
EHR: electronic health record
EMR: electronic medical record
EPR: electronic patient record
LDR: lifetime data repository
VHR: virtual health record
VPR: virtual patient record

management, decision support, patient support, administrative processes, reporting, and electronic communication and connectivity [3]. Others define EHR functionality more succinctly, stating that EHRs at a minimum should offer functions for documenting care, ordering and viewing laboratory results, ordering medications, and providing some level of decision support [4].

An EHR system may or may not use an integrated e-prescribing component to carry out medication ordering. E-prescribing is defined as "entering a prescription for a medication into an automated data entry system, and thereby generating a prescription electronically, instead of handwriting the prescription on paper" [5]. A true e-prescribing system is a closed-loop system in which the entire process of prescribing a medication is electronic from beginning to end: a clinician prescribes medications, those prescriptions are sent electronically to a pharmacy, and feedback comes back to the clinician when the patient collects the prescription. Intermediaries of paper printouts, faxes, and e-mails are unnecessary. No information is re-entered. Prescriptions undergo medication checking for errors and formulary compliance, and are legible.

Benefits of electronic health records and e-prescribing

As the introductory case illustrates, a tremendous benefit of EHRs to the obstetrician/gynecologist is the ability to quickly gain access to all available clinical information on a patient at the point of care. However, there are other benefits to the use of an EHR beyond access to information: improvements in quality of care and patient safety, increased efficiencies, and cost savings. These benefits make the decision to purchase an EHR a seemingly logical and necessary step to take.

Access to information: clinical data

For obstetrician/gynecologists, the benefits of an EHR should be more obvious than to their colleagues in other specialties. We have a strong need for current data on our patients that, if unavailable, may at least push us to order duplicate laboratory tests and ultrasounds, and at worst may compromise care. In the traditional paper world, it is typical to be caring for a patient in labor without an up-to-date record. However, to provide optimal care to these patients, we must know recent glucose test results, group B streptococcus (GBS) status, blood pressure measurements, weight trends, and ultrasound findings. Lack of access to patient data leads to inefficiencies, delayed diagnoses, delayed care, unnecessary costs, and, in some cases, less than optimal care.

Today we often practice medicine with only a subset of patient data. Care is conducted in silos, without knowledge of the care being given to our

patients by other clinicians. In addition to not having access to data collected outside our offices, we frequently do not have data collected from within our own offices: results sitting on clinicians' desks awaiting signatures; results waiting to be filed in the paper chart; and paper charts that cannot be located when needed. On average, we are missing four pieces of clinical data at the time of a patient encounter, such that 80% of the time we are forced to delay our clinical decisions or proceed with making decisions without that information [6].

An EHR allows us to access all available clinical data on our patients at any time and from any location, making paper charts obsolete. For those practicing medicine in areas with data exchanges, clinical data from other encounters outside our own offices becomes available. With remote access, we may view patient data during off hours and while off site, making care of patients after hours or in other locations, such as in the emergency department, more efficient and less prone to error.

Access to information: medical data

EHRs improve our ability to gain access to other types of information, such as information about medications, guidelines, protocols, and current research on clinical care. Attempts to stay abreast of new research have long been recognized to be inadequate. In 2000, it was estimated that it took 17 years from the time a study was published to incorporate the findings of that study into standard practice [7]. There is evidence that patients today are receiving only 55% of recommended care for both chronic and acute conditions [8]. The sheer volume of emerging medical research is staggering. In 2001, the Cochrane Collaboration estimated that 6000 journal articles were being published a day, with over 180,000 articles a month, in over 20,000 journals [9]. Any strategy physicians had in the past for staying abreast of current findings in medicine cannot be applied to this volume of new research. We either continue to fall behind, or need the assistance of technology to help us stay current.

EHRs address this issue by presenting current medical findings to the clinician both actively and passively. An EHR system may serve merely as a gateway to the Internet, allowing for efficient retrieval of information. Alternatively, by making available to the clinician protocols and recommended care across both acute and chronic conditions, the EHR can bring information about patient-directed recommended care to the clinician at the point of care. In addition, this technology may have built-in rules, alerts, or reminders that act to remind clinicians about care that is due for patients, both for preventive care and for chronic disease management. In more advanced systems, these rules, reminders, and alerts may allow for resolution of the issue at the point of care, allowing a clinician to resolve the issue from within the alert itself.

Access to information: population data

Many EHRs incorporate reporting functionality that allows a practice to have greater knowledge of its patient population as a whole. Queries can determine those patients due for mammograms or Pap smears. Electronic tickler systems allow for more efficient follow-up of patients with abnormal Pap smears. Reports may also be generated to assist in tracking metrics that are required as part of pay-for-performance initiatives. In addition, these systems can help providers track laboratory, pathology, mammogram, and radiologic tests to ensure that patients have completed recommended testing and have received their results and appropriate follow-up.

Safety, quality of care

In 2000, the Institute of Medicine (IOM) released its now well-known report *To Err is Human* [10]. The report estimated that up to 98,000 patients were dying each year in the United States because of medical errors—more than the number of deaths from car accidents and breast cancer combined. At the time, this estimate was met with anger, cries of foul, and denial, a reaction that has become tempered with time as more evidence has been published supporting the IOM's claims [11]. In fact, there is evidence that the IOM may have underestimated the numbers of errors occurring, with recent reports suggesting the deaths due to errors may be as high as 225,000 a year [12].

To Err is Human does not talk about bad doctors and malpractice, but instead emphasizes that humans will always be prone to making errors. All of us in health care must work to establish processes to minimize errors, and to create defensive barriers to prevent those errors that still occur from harming patients. Based on the success of the aviation and banking industries, where technology has been used to reduce human errors, we have good reason to believe that applying technology to health care is an important tool to error reduction.

Medication errors

Medication errors are well documented in the ambulatory space [13–16], estimated to occur in 25% of patients [17]. Medication errors include any errors in dose, route, frequency, and drug choice. Errors also include both those that lead to patient harm and those that don't. For example, prescribing sulfamethoxazole and trimethoprim double strength oral three times a day instead of twice a day is an error, but is unlikely to cause harm. Adverse drug events (ADE) may or may not involve a medication error and are defined as an "adverse event involving medication use" [18]. For instance, prescribing penicillin to someone with a previously undiagnosed penicillin-allergy will result in an ADE, but is not an error. To distinguish ADEs caused by errors from those that occur without error, the term "potential ADE" is used (Box 2).

Box 2. Common definitions: Agency for healthcare research and quality: Patient safety network glossary

Adverse drug event (ADE): an adverse event involving medication use
Adverse drug reaction: adverse effect produced by the use of a medication in the recommended manner
Adverse event: any injury caused by medical care
Error: an act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or significant potential for such an outcome
Near miss: an event or situation that did not produce patient injury, but only because of chance
Potential ADE: a medication error or other drug-related mishap that reached the patient but happened not to produce harm

Some ADEs significantly harm patients. According to estimates, 7.6% of all outpatient prescriptions contain errors, with 3% of them being preventable ADEs [19]. An estimated 2.5% of emergency department visits are due to ADEs [20]. Of those, 17% result in admission. Moreover, an estimated 3.1% to 6.2% of all admissions are likely due to ADEs [21]. Deaths from adverse drug reactions have been estimated at over 100,000 a year. Despite efforts to reduce these errors, they appear to be on the rise. Recently, the Food and Drug Administration (FDA) analyzed data between 1998 and 2005 from its Adverse Event Reporting System [22]. The FDA noted that serious adverse events rose over this period, with a tripling in reported injuries, disabilities, and deaths attributed to medications.

Medication errors are quite costly. The cost of ADEs in the ambulatory setting has been estimated at $76.6 billion [23]. This figure results in an almost one-for-one relationship: For each dollar of medication expense in the outpatient space, another dollar is spent to manage the consequences of ADEs [24]. Technology can contribute significantly to the reduction in these errors. The Center for IT Leadership in Boston has predicted that, of the estimated 2 million preventable ADEs per year, ambulatory order entry systems could prevent 136,000 life-threatening ADEs and 190,000 admissions due to ADEs at a savings of $2 billion a year [25].

Health care technology reduces medication errors with the use of drug-checking software, which checks the medication dose, potential interactions with other medications the patient may be taking, and the patient's known allergies. This drug-checking software may be part of the EHR or of a free-standing e-prescribing system. Integrated EHRs are able to calculate dosing based on a patient's weight, and carry out other contextual medication

checking against a patient's laboratory results, age, and disease states. In addition, computer systems provide pick lists of each clinician's favorite medications with prepopulated dose, frequency, and route, reducing the opportunity for clinicians to order inappropriate amounts of medications with the wrong frequency and route.

Adding e-prescribing functionality to an EHR improves the efficiency and safety of medication ordering. e-Prescribing makes electronic the entire process of medication ordering, without the use of intermediaries, such as paper printouts, faxes, and e-mails, and without re-entry of information. These systems integrate the four axes of prescribing: the physician, the patient, the pharmacist, and, for patients with insurance, the pharmacy benefit management company.

Benefits can be gained when any part of the prescribing process is done electronically. However, most benefits are gained when the prescribing process is electronic from start to finish. Entering medications into an electronic system able to conduct medication checking improves safety. Including the insurance company in the loop means that up-front formulary checking is conducted, patients can be apprised of their financial liability for the prescription, and appropriate medication choices can be made for the patient, all before leaving the physician office. This process results in a marked reduction of clarification calls from the pharmacy [5].

Legibility of prescriptions and completion of prescriptions are major issues. One review of 1425 prescriptions received at a community pharmacy reported illegible handwriting 15% of the time and were incomplete 10% of the time [26]. e-Prescribing improves the legibility of prescriptions and the rate of completed prescriptions. Patients no longer need to carry paper copies of a prescription to a pharmacy and are more likely to have formulary-compliant medications prescribed for them and to find their prescriptions waiting for them when they arrive at the pharmacy. This leads to greater patient convenience, shorter wait times, and increased compliance with formulary requirements.

Errors have been shown to occur in 21% of prescriptions [27] and the use of e-prescribing systems leads to a reduction in prescription errors. A study done by Tamblyn and colleagues [28] showed an 18% reduction in inappropriate prescriptions when providers had access to complete drug profiles on their patients and had computer-generated alerts regarding potential prescribing issues . These reductions have the potential to result in large cost savings. e-Health Initiative has estimated that the adoption of e-prescribing could save up to $27 billion a year [29].

Improved efficiencies

EHR and e-prescribing systems offer the potential to increase efficiencies, save money, and reduce duplicate laboratory and radiologic tests, paper handling, and the need for dictation services.

As the case at the start of this article illustrated, a lack of clinical information when and where we need it frequently results in ordering duplicate laboratory and radiologic tests. EHR systems reduce this duplicate ordering by making current information available to the clinician. According to estimates, 14.3% of tests are unnecessary duplicates. With access to existing laboratory results, 2.61% to 13.7% of laboratory tests could be eliminated with a potential savings to the nation of $32 billion [30]. A similar analysis has been done for redundant radiologic tests, with an estimated savings of $26 billion a year by reducing these duplicates.

As patient data become increasingly electronic, filing clerks spend less time handling paper. The cost to pull a chart has been estimated to be between $3 to $5 per chart [31,32]. The elimination of manual chart pulls results in administrative savings. One large group in Utah estimated that in the first year of implementation of an EHR system, they had a 35% to 40% reduction in chart pulls [33]. In large practices, this may result in a reduction in full-time employees; in smaller offices, the individual currently filing in the office could be freed up to perform other duties.

Eliminating costs associated with dictation can lead to savings as well. Adoption of an electronic transcription service by the Franciscan Medical Group in Tacoma, Washington, resulted in a first-year savings of $55,000, despite only a 25% adoption rate [31]. Partners Healthcare in Boston reported a 28% decrease in their transcription costs with their EHR implementation [32]. Grieger and colleagues [34], in their practice of 28 physicians, found over $300,000 in annual savings with their implementation attributed to savings in chart pulls, as well as to the reduction of new paper charts, filing time, support staff salary, and transcription costs.

Additional efficiencies are seen in offices when using an e-prescribing system, with or without an EHR. One to five percent of all written prescriptions result in callbacks from pharmacists for clarification [35–38]. These callbacks add to the workload of the office staff, cause frequent interruptions to the work of physicians, and are disruptive for the patient being forced to wait for the prescription. e-Prescribing systems markedly reduce the number of callbacks. Also, because pharmacists are able to read prescriptions clearly, fewer dosing, frequency and routing errors are made.

Evidence exists for significant savings with e-prescribing systems. Since implementing their system, Southwest Medical Associates, a group employing 200 physicians, found a decrease in calls from pharmacies, an increase in patient satisfaction, and an increase in the use of generic medications from 53% to 63% [39]. The Henry Ford Health System in Detroit reported in their first year of using e-prescribing that there had been 80,000 changes or cancellations of prescriptions due to alerts regarding drug–drug interactions. In addition, physicians received 6500 alerts secondary to potential allergies, and 50,000 prescriptions were changed or cancelled after formulary alerts. The group estimates that the 7.3% increase in use of generic medications saved $3.1 million over 1 year [40]. The Maryland-based CareFirst

e-prescribing project has been estimated to have avoided $1.3 million in costs due to a reduction in prescribing errors [41].

Electronic health records and e-prescribing: pitfalls and barriers

Four years after President Bush declared his goal of bringing EHRs to most Americans, adoption has accelerated, but most clinicians continue to practice without this important tool. Clinician resistance remains the major barrier to adoption. However, there are many other barriers, including implementation cost, lack of clarity on the return on investment, misaligned incentives, the difficulty of implementation, and negative impact on workflow.

Adoption rate

The true rate of adoption of EHRs has been difficult to determine. Current estimates range from 6% to 24% [4,42–45]. Clinicians are using a wide range of technologies in their offices today and thus many attempts to measure usage rates have become an exercise in making comparisons of vastly different things. There is a natural continuum of technology ranging from no use of technology, to use of the Internet, to use of a personal digital assistant (PDA), to use of an EHR [42]. A survey conducted by Deloitte found that 96% of physician respondents used some form of technology to conduct their work, be it an EMR, PDA, or the Internet. However, the favored technology overwhelmingly was the Internet while only 13% used an EMR. [42].

A study sponsored by the Robert Wood Johnson Foundation and the Office of the National Coordinator for Health Information noted that 23.9% of physicians use some form of an EHR in their care of patients [4]. In this study, however, only 9% of physicians used a "fully operational" EHR, which the study defined as a system that included some decision support, the ability to order and view tests, the ability to order medications, and the ability to record patient data. These more robust systems have been found to reduce errors and lead to improvements in efficiency.

Clinician resistance

Clinician resistance remains a daunting barrier to the adoption of EHR and e-prescribing systems. If clinicians are not using a system, regardless of its quality, it will fail, while even a low-quality system will succeed if clinicians are willing to adopt it. In the recent past, an unwillingness to practice "cookbook" medicine, a fear of technology, concern over a negative impact on the doctor–patient relationship, and impact on workflow were seen as contributing to clinician resistance [46]. While some still resist the use of guidelines and protocols, most clinicians have embraced the use of evidence

to guide their care [47]. With new physicians having grown up in a digital age, discomfort with technology is a thing of the past. The Deloitte survey cited above debunks the picture of the technophobic clinician, with 96% of clinicians using technology at work to some degree [42]. Today, costs, impact on workflow, lack of widespread interoperability, security and privacy concerns, application speeds, and system maintenance requirements are all cited as reasons for clinician resistance [48].

Key to adoption is strong leadership, most importantly in the form of a physician champion. A push toward technology must come from within by a champion who understands how technology can be integrated into a clinical practice and what impact that technology will have in terms of their time and workflow. A physician champion need not be the computer geek in the office, but instead an individual others look up to, respect, and go to for advice. These clinicians lead by example and by their belief that EHRs bring improvements in care, reduction in errors, and increased efficiencies. The champion clarifies to colleagues the larger picture of why an implementation is occurring, giving encouragement to work through short-term pain for the longer-term benefits of improved safety, quality, and efficiencies.

Costs

The cost of an EHR and e-prescribing systems can be high, and has been cited as a barrier to implementation. Costs vary widely, depending on functionality of the system. Less robust systems may be found for under $3,000 for the software alone [49], while a more robust EHR and e-prescribing system is estimated to be $15,000 to $30,000 per physician in start-up costs, and $5,000 to $15,000 a year in maintenance costs [25,50]. When estimating costs, consideration needs to be made not only to the cost of software, but also for hardware, implementation, training, and support costs. For those physicians operating at low margins, these costs may feel prohibitive.

Questionable return on investment

Despite the potential for cost savings, many who have implemented these systems are not realizing savings. Determining a return on investment can be difficult. First, it is not enough to implement a system that only allows for documentation and, second, clinicians must actually use the system for it to produce efficiencies. Cost savings are seen with robust EHRs that have at least the capability for clinicians to document notes, order and receive test results, order medications, and receive some clinical decision support [25]. More robust systems adding contextual decision support, such as checking medications against disease state, laboratory results, and weight, are able to provide even further savings. A solo practitioner who has installed a system that only allows for note documentation may experience

efficiencies in their documentation, but is unlikely to realize any real cost savings.

In addition, the smaller the group, the less likely clinicians can realize any labor savings. The reduction in pharmacy callbacks, filing needs, and in-house transcription will result in time savings. However, in groups that have hired a single person to manage most, if not all, front-office activities, labor-cost savings will probably not be realized. This individual may be used for other activities, however, making for a more efficient office.

Standalone e-prescribing systems may be an area where even small groups can make a minimal investment up front and quickly realize efficiencies. While most EHRs have an e-prescribing component, one can use an e-prescribing system without an EHR in place. These systems are cheaper than a full-scale EHR. In addition, many states—Massachusetts, Rhode Island, and California—have initiatives underway to implement e-prescribing widely, giving financial assistance to those wishing to implement [51]. The National E-Prescribing Patient Safety Initiative has begun a program giving to all interested physicians in the United States access to an e-prescribing system via the Web (www.nationalerx.com).

Misaligned incentives

Misaligned incentives represent another major barrier. Much of the savings potential of an EHR rests in its ability to reduce errors and to improve compliance to guidelines. However, the savings incurred with these functions largely go to payers and not to providers. If an EHR and an e-prescribing system prevents a patient from having an allergic reaction to a prescribed medication, the savings from that prevented adverse event are to the insurer or, if uninsured, to the patient. However, the entire cost of the EHR is borne by the provider. Indeed, it is estimated that providers only reap 11% of the total benefit of these systems, while the remaining benefit goes to the payers [25]. Evidence that this is a barrier is strengthened when one looks at closed health care systems, such as the Veteran's Health Administration, where physician adoption rates of its EHR are high. This misalignment of incentives is being recognized by payers, who have begun to assist clinicians in purchasing these systems. For instance, Blue Cross Blue Shield of Massachusetts has committed $50 million to the Massachusetts eHealth Collaborative in its efforts to implement EHRs in physician offices in three communities in the state.

Implementation

The journey from the decision to purchase an EHR, to implementation of a fully functional EHR, can be long and difficult. We are not yet at a point where we can go to a retail store and purchase an off-the-shelf EHR or e-prescribing system. There are dozens of vendors selling products in this area, making it extremely difficult to compare and contrast features, prices,

and implementation options. Careful planning is critical to a successful implementation. In choosing a system, the first step should be to assess the needs and goals of the practice. Why is the group undertaking this initiative? What does the group hope to achieve? Is it avoiding errors; making guidelines more accessible; improving efficiencies; saving money? The answers to these questions will help the group develop a needs assessment and requirements, which will drive its selection of a vendor. For instance, if the primary goal is to improve compliance with guidelines, then one of the system requirements might be inclusion of built-in guidelines.

Essentially all commercially available EHRs and e-prescribing systems require some customization. Clinicians will need to make decisions about guidelines to be incorporated, rules to be used, templates to be built, and reminders to be implemented. Some EHRs have this content included. Others require clinicians to build them into the systems themselves. The greater the degree of customization needed, the longer the implementation phase takes.

Fortunately, embarking on this path is not the lonely journey into the unknown that it once was. Those who believe that these tools are keys to improving safety and quality of our health care system have fostered a spirit of cooperation and a willingness to share tools and lessons learned. Our colleagues at the American Academy of Family Physicians have been active in this area, making tools available via its Center for Health Information Technology (www.centerforhit.org), many available to nonmembers. The Certification Commission for Healthcare Informatics (CCHIT) began certifying ambulatory EHRs in 2006, greatly assisting purchasers in making more-informed decisions. Choosing an EHR that is 2007 CCHIT certified ensures that users will be able to prescribe electronically, view laboratory results, conduct medication checking, generate patient reports, and maintain security of patient data. A list of all certified ambulatory EHRs and the criteria used to make them certified may be found at www.cchit.org.

Several Web sites offer health IT knowledge repositories, such as the Agency for Healthcare Research and Quality's National Resource Center for Health Information Technology (www.healthit.ahrq.gov). eHealth Initiative has a free toolkit, including a readiness assessment found at www.ehealthinitiative.org. The Scottsdale Institute has a large library of presentations from experts in the field of health IT available via membership (www.scottsdaleinstitute.org). The American Medical Informatics Association (www.amia.org), the Healthcare Information and Management Systems Society (www.himss.org), and the California HealthCare Foundation (www.chcf.org) are all good sources of information.

Impact on workflow

Clinicians are concerned that the implementation of an EHR will slow down their work. With the low margins and increasing time pressures that many practices are working under today, any risk of reducing productivity,

even temporarily, may not be tenable. For many, the use of an EHR makes documentation slower than traditional methods, although evidence for this in the literature is mixed [52,53]. A Kaiser Permanente study found that clinicians initially were less productive after their EHR was installed, but returned to their paper-based productivity levels within 30 days [54]. While some effort has been made with these systems to mimic current workflow, the alteration of workflow is inevitable and requires adjustments on everyone's part. The implementation of technology forces us to examine every facet of how we see a patient. However, in the process, implementation also forces us to examine workflow to determine the most efficient way to see a patient. Thus EHRs enable more efficient workflow in our practices so that, with time, use of an EHR system makes workflow faster than in the paper world.

The possible slowdown in workflow with an EHR may be mitigated by embracing the use of templates and forms. Prior to implementing an EHR, paper templates should be created around all commonly seen diagnoses, such as vaginal discharge, urinary tract infection, and follow-up Pap smears. These paper templates are used before implementation to allow everyone to become familiar with charting on templates. The forms are built into the EHR so that the transition to this type of documentation is less disruptive. Templated notes are more complete; are faster to use than handwriting, dictating, or typing; and can serve as guidelines to ensure that recommended care is performed for acute and chronic conditions. In addition, improvements in documentation allow for proper coding of visits and help to improve adherence to pay-for-performance initiatives.

As anyone who uses computers knows, alerts that interrupt our work can become annoying and are easy to click through and ignore. Alerts and reminders in EHRs have a similar effect. Some drug-checking software provides alerts with the same urgency for minor interactions as for potentially fatal interactions. Those minor alerts become annoying and may cause clinicians to become less responsive to the more serious alerts. A recent review of the literature found that clinicians override medication alerts 49% to 96% of the time [55]. Some alerts appear at inappropriate times, interfering with a clinician's workflow. A reminder about a patient's need for a mammogram when a physician begins to review a chart is an annoyance. That same alert occurring when the physician is making orders at the end of a visit is more helpful. Any alert that forces a clinician to leave a current field in the EHR to address the issue is more likely to be ignored than an alert that can be acted on directly from within the alert itself. For instance, if an alert indicating the need for an influenza vaccine also allowed the clinician to click "yes" to order the vaccine, there would be minimum disruption to the clinician.

Mitigation of alert fatigue may be achieved by turning off minor alerts, having alerts appear at appropriate times in the workflow, and having

them directed to others when appropriate. For instance, reminders about mammograms or colonoscopies might be incorporated more smoothly into the office workflow if designed to be sent to the individuals responsible for scheduling these exams. For systems that do not allow alerts to be diverted to others, running regular reports on those patients due for care, such as for mammograms, will reduce the number of interruptions for the clinicians.

Summary

The use of technology in health care is accelerating and becoming more routine. Today it is less a question of "if" but "when." EHRs and e-prescribing systems lead to safer, higher-quality care, help us to stay up to date with current medical research and recommended guidelines, help improve efficiencies within our practices, and have the potential to save us money.

However, these technologies have pitfalls. Implementations are met with resistance and can be costly and time consuming. The initial impact on workflow can decrease our efficiency in seeing patients and it may be difficult to realize a return on investment.

Technology is becoming more pervasive in health care, however, and there will come a day where health IT is ubiquitous in our practice environments. To be in denial of the inevitability of this change will leave some scrambling to catch up. Tremendous resources are available to clear our paths, and more initiatives are underway to help ease the difficulties encountered in implementations. Careful planning, strong leadership, and clear identification of goals, all while maintaining healthy skepticism, will help to improve the likelihood of success.

Returning to the case history at the beginning of this article:

> Ms. X is a 24-year-old G_2P_1 who presents to labor and delivery at 3 AM complaining of contractions. The office has an EHR and the patient's doctor is able to review her chart before triaging the patient. The patient's first child was delivered at 35 weeks' gestation. Her estimated date of confinement by last menstrual period confirmed by a 5-week ultrasound puts her at 30 weeks' gestation. An ultrasound done in the office that day showed normal growth. She had been complaining of contractions so she'd been monitored, showing a reactive tracing and no contractions. Her cervical examination had been long, thick, closed and -2 station. She recently had plus 2 leukocyte esterase on a urine dipstick and thus a culture was run which was negative. Her blood pressures have been normal throughout her pregnancy running in the range of 120/60 mm Hg. Her blood pressure in triage is 140/90 mm Hg, tracing is reactive with contractions every 5 minutes, cervix is 2/80%/-1. With records available, the covering physician is able to proceed immediately with tocolysis and an evaluation for preeclampsia.

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Team Function in Obstetrics to Reduce Errors and Improve Outcomes

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Crew resource management (CRM) has been defined as "error countermeasures that are employed to avoid error, to trap errors committed, and to mitigate the consequences of error" [1]. CRM was originally known as cockpit resource management and applied first in the 1980s to improve the safety of air operations in the United States. The roots of CRM may be traced back to a workshop entitled "Resource Management on the Flightdeck," which was sponsored by the National Aeronautics and Space Administration in 1979 [1]. The implementation of CRM highlighted the inherent fallibility of humans and machines and the need for combining the vigilance of all crew members with the technical capability of the devices used to ensure that timely and accurate information was available to rapidly make the best decisions. The 1978 crash of a United Airlines DC-8 while attempting to land in Portland, Oregon, highlighted the need for implementing a system that could reduce the likelihood of human error. In this particular accident, the pilot's error was an inability to maintain awareness of the critical aspects of flying the aircraft under highly stressful conditions [2]. The complexity of aviation, like the complexity of modern medicine, dictated that one person could no longer be the lynchpin expected to know, in isolation from everyone else, all the relevant information and make all the important decisions. Now pilots, with CRM assistance, interact with other members of the crew as well as with the flight management computer. The automation of aviation has not proven to be the impregnable safety net against error that engineers envisioned. Still, it has reduced errors while at the same time giving aviation crews access to vastly more information. This volume of information has heightened the need for more orderly,

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streamlined, and regular communication among members of the aviation crew, thus requiring more teamwork [2].

Medicine can learn from aviation's experience in implementing CRM and in handling the challenge of changing the attitudes and behavior [3]. The US Navy has demonstrated that the majority (56%) of aircraft-related mishaps between 1990 and 1996 involved at least one CRM failure despite implementation of CRM programs [4]. Some of the obstacles to successful implementation of CRM have to do with the professional and business cultures.

The culture of an organization is important in determining the success or failure of CRM because the culture can promote or inhibit the incorporation of CRM concepts into procedures and management practices on a daily basis. The professional culture of physicians is similar to that of pilots. Because of that culture, many physicians, like pilots, have a heightened sense of individualism, professional pride that denies susceptibility to stress, and invulnerability [2]. These traits made implementation of CRM challenging in aviation and led to at least five generations of implementation strategies (over about 20 years) before an effective form of integration into the professional and business culture was identified [1].

Based on study of effective crew coordination in aviation, two factors critical for success were identified: the personalities of crew members and their attitudes regarding the appropriate governance of the flight deck [5]. Helmreich defined the ideal crew as "strongly oriented toward teamwork and a consultative style of leadership in which junior officers felt encouraged to speak up to share information and advocate alternative courses of action" [2]. In addition, Helmreich stated that the crew would "adhere to standard procedures but could still use their judgment to deviate from rules in the interest of safety" [2]. Pilot training and selection strategies may also be critical to advancing CRM. Evaluating CRM skills is as important as flying skills for pilots. This CRM skills test, known at the Situational Test of Aircrew Response Styles, helps identify individuals who might be more successful than others in implementing the CRM aspects of a pilot's duties [6]. These definitions and evaluations of an ideal crew resonate well with those of other professions involved in high-risk environments, such as the nuclear power industry, the petrochemical industry, and medicine.

Application to medicine

CRM principles have been adapted for medicine from aviation as one strategy to improve the quality of health care in the United States. Following the publication of two Institute of Medicine (IOM) reports that highlighted errors in medicine as a significant killer of patients in the United States, teamwork training as defined by principles of CRM was advocated as a possible means of reducing medical errors and improving patient safety [7,8]. These principles have been applied to a wide range of medical specialties and

locations within hospitals, including the intensive care unit, the operating room, the emergency department, and labor and delivery [9–12].

In 2000, an IOM report stated that systems in medicine should be designed so that it is "harder for people to do something wrong and easier for them to do it right" [7]. McGreevy [13] makes several practical suggestions (taken from CRM) to accomplish this task. These include requiring teamwork communication training for hospital credentialing, holding briefings before and debriefings after specific events and procedures, creating standards for procedures, recognizing fatigue and age as factors in surgeon performance, scheduling morbidity and mortality conferences that focus on system deficiencies and minimize individual blame, and testing all staff randomly for drugs [14]. These suggestions, if implemented, will encourage communication about errors and near misses with resultant system change to prevent recurrence. One study found that more than 50% of physicians and nurses found it difficult to discuss errors secondary to one of three major factors: personal reputation, threat of malpractice, and the egos of other team members [14]. Changing the culture of the organization requires teaching teamwork skills as well as changing the frequency and process of interacting with colleagues, patients, and families.

Application of teamwork strategies in perinatal medicine has been advocated by the Institute for Healthcare Improvement through its Innovation Series white paper entitled "Idealized Design of Perinatal Care" [15]. This model has as its goal a comprehensive redesign that would enable a care system to perform substantially better. The outcome, therefore, is a new level of safer, more effective care that minimizes risks. This white paper advocates components that fall into one of three basic categories: patient and family-centered care, teamwork implementation, and clinical "bundles" monitoring [15]. The redesign envisions high functioning care teams that are prepared and activated and that allow productive conversations with the mother and family, who are seen as part of this team. Outcome targets for this idealized perinatal care include:

- Reduction in birth trauma (ie, neonatal injury as defined in the Agency for Healthcare Research and Quality [AHRQ] Patient Safety Indicators) to a maximum of 3.3 adverse events per 1000 live births.
- Improvements in communications so that 95% of the time the entire care team understands and respects the wishes of mothers.
- A 50% improvement in culture survey scores of perinatal units (Two examples of culture survey tools are the Safety Climate Survey developed by the Centers of Excellence for Patient Safety Research and Practice, University of Texas; and the AHRQ's Hospital Survey on Patient Safety Culture [16,17]).
- The establishment of strong internal standards, including consistent documentation and no lapses in communication, so that all liability claims or allegations are defended.

These outcomes reflect an emphasis on implementation of the three principles outlined in this white paper: (1) patient- and family-centered care, (2) teamwork implementation, and (3) clinical "bundles" monitoring. Each of these principles require some degree of culture change and are difficult, if not impossible, to implement without senior leadership providing understanding and support. Implementation of these principles also requires changes in the way groups of health care providers interact with each other and with patients and families.

Error theory

To provide the proper environment for culture change, it is critical to understand the precursors of medical error and the interventions designed to prevent them. Normal accident theory, in seeking the precursor for error, asserts that errors result from system failures. In a sense, accidents are "normal" or expected to happen. Errors are seen as a consequence rather than a cause of the problem [18]. This theory must be embraced by organizations and their leaders before culture change is possible. Minimization of accidents rather than total avoidance is the goal in medicine because it is impossible to anticipate all potential sources of error in a system as complex as health care. In this theory, accidents are the results of either active failures, which are unsafe acts by people in direct contact with patients; latent conditions, which arise from designs, management decisions, or current procedures, and which lay dormant for months or years; or both. The brightest people are capable of making the worst errors as a result of latent conditions, implying that the system is often to blame.

High-reliability organization theory is designed to minimize errors and mitigate harm. This theory asserts that humans operating and managing complex systems are not able to sense and anticipate all problems generated by the system. However, if organizational leaders structure people, processes, and technology properly, individuals and teams are able to deal with these complex activities with few errors and no harm [18].

Importance of leadership in culture change

Leadership is required to build a safety culture that will promote a high-reliability organization. This safety culture is best supported by creating an environment that provides for decision migration (decision-making at the point of care), by managing by exception (rapid problem identification by front-line staff), and by encouraging understanding of the "big picture" [19]. Shifting safety from a priority to a core value will also enhance the culture of safety. Priorities are subject to change due to external forces whereas values become part of the fabric of the organization.

Four subcultures are required to engage a culture of safety: a reporting culture, a just culture, a flexible culture, and a learning culture. In a reporting

culture, people willingly report accidents and near misses. This outcome is only possible when leadership encourages and rewards the disclosure of patient safety information and people trust that this information will be handled in a just manner. A flexible culture requires that control of certain situations shifts from conventional hierarchical structures to a flat, professional structure in which experts are used for their expertise. Those individuals most able to respond to an unsafe situation take control irrespective of "rank." This shifting of control requires mutual respect on the part of all involved, especially senior leadership, who must give up some control. Finally, the organization must be willing to look carefully at the safety information systems in place and come to the proper conclusions regarding changes to the system when indicated [20]. This learning culture is much like the professional expectation of continuing medical education and life-long learning required of physicians. In fact, learning is only a portion of what is required; change in practice is also necessary—both for individuals and organizations.

Role of Department of Defense and Agency for Healthcare Research and Quality in focusing efforts and development of Team Strategies and Tools to Enhance Performance and Patient Safety

Based on the government and military's long-standing commitment to CRM, implementation and further refinement of teamwork training in medicine began in the late 1990s in emergency departments and progressed to obstetrics and labor and delivery units within the military health care system [10,11]. From this experience, a broad-based application of teamwork training, known as Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS), was developed. TeamSTEPPS, developed by the Department of Defense (DoD) and the Health and Human Services' AHRQ, was released to the public domain on November 2, 2006. More than 300 trainers at 23 military treatment facilities provide initial and ongoing training for this program. However, more than intellectual understanding and coursework is required to initiate and sustain a culture of teamwork. Experiential learning is critical. The process must become part of the unit's daily routine. The structure and component members of handoffs must be changed and include all members of the team.

TeamSTEPPS is composed of four competencies: team leadership, situation monitoring, mutual support, and communication. Team leadership teaches the ability to direct and coordinate activities by assigning tasks, motivating team members, planning, and organizing. Situation monitoring supports the capacity to develop a common understanding of the team environment and to monitor teammate performance. Mutual support requires evaluations of each team member's performance and a willingness to shift workload accordingly. Help should be requested when needed and freely offered to others. Finally, examples of practical communication tools are taught, including the two-challenge rule. According to this rule, team

members are expected to respectfully challenge orders or information that they suspect or know to be incorrect or unsafe. If the leader is nonresponsive to the first challenge, a second and more assertive challenge is required. These competency areas, once taught in the classroom, must be implemented with changes to the way an organization executes daily business. As with other technical skills in medicine, team skills must be practiced and constantly reinforced. For example, implementation of teamwork in the labor and delivery unit at Madigan Army Medical Center (MAMC) has included teaching the didactic components of TeamSTEPPS and changing the way disciplines interact on the unit. Resident teaching rounds are performed immediately before team rounds where the key components of individual patient and workload management are discussed. Participation at team rounds (which occur twice daily) is mandatory for the attending obstetrician, the resident coordinating labor and delivery, anesthesia providers, nurses, and support staff. These rounds, often lasting less than 15 minutes, provide the resident with an opportunity to practice transmitting clear and concise patient management information to the team. These rounds also ensure that all members of the team contribute to an understanding of how these plans will be executed. It is expected that team members will provide additional pertinent information or will challenge those plans that may be inappropriate or difficult to execute because of workload management problems, medical issues, or patient and family concerns.

The DoD and the AHRQ have a commitment to improving patient safety and have made the TeamSTEPPS curriculum available free of charge through the Uniformed Services University of the Health Sciences Web site (http://www.usuhs.mil/cerps/teamstepps.html) or via a CD-ROM and DVD multimedia curriculum kit (AHRQ Publications Clearinghouse at 1-800-358-9295 or ahrqpubs@ahrq.hhs.gov). The widespread implementation of teamwork training should be viewed as a priority for leadership at every health care organization and this tool will provide the training and guidance.

Introduction of crew resource management to labor and delivery

Suzanne was a patient admitted to the labor and delivery unit at Beth Israel Deaconess Medical Center (BIDMC) in November 2000 for induction of labor. In the course of events, this patient suffered a ruptured uterus, complete abruption, fetal death, cesarean hysterectomy, and prolonged hospitalization. A number of systems issues were identified in the analysis of the case, including the large number of providers involved in her care, failure to establish a plan of care that was communicated to all providers, excessive and unbalanced workload, fatigue, and failed conflict resolution. All contributed to her adverse outcomes. This case was settled quickly. The hospital and providers admitted that mistakes were made in her care, informed the family, and issued an apology with the settlement. The details of the case and process improvements have been published elsewhere [21]. This patient,

the system failures, and the poor outcome had a profound impact on individuals and the organization involved with her care.

Coincidentally, within a few months of the adverse event, the DoD and Harvard's Risk Management Foundation approached the BIDMC to be a lead hospital with MAMC in a randomized clinical trial translating the concepts of CRM used in the military and commercial aviation to the labor and delivery environment [11]. The DoD supported a previous study applying CRM to emergency medicine [10].

The responsibilities of the lead hospitals included translating the curriculum of a CRM course from emergency medicine and aviation to labor and delivery. The original curriculum included an 8-hour didactic course, which was reduced to 4 hours. In subsequent curricula development, a large emphasis has been placed on implementation of the teamwork concepts. The other major role of the lead institutions was the development of a set of useful quality measures to assess changes in care resulting from the teamwork training initiative. Patient safety groups from both BIDMC and MAMC contributed to the curriculum of the TeamSTEPPS program discussed previously and funded by the DoD and the AHRQ. The BIDMC group is currently using its third revision of the curriculum for teaching teamwork-based safety programs and the DoD is deploying TeamSTEPPS throughout the military health care system.

Attributes of a team

Medical practitioners often work in teams (Fig. 1). However, very few ever participate in teamwork skills training. While we often work in multidisciplinary settings, we bring varied skills to the work arena, especially

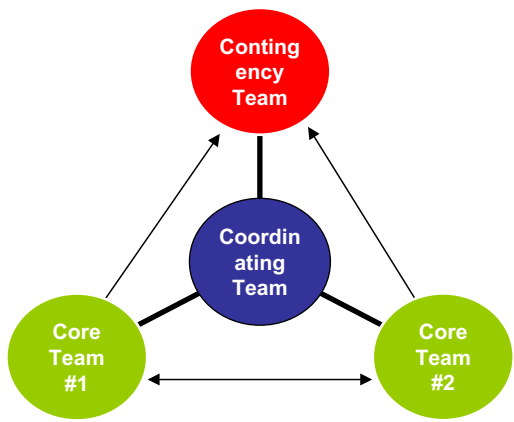

Fig. 1. Teamwork structure. (*Adapted from* Mann S, Marcus R, Sachs B. Lessons from the cockpit: How team training can reduce errors on L&D. Contemporary OB/GYN 2006;51:34–45; with permission. Contemporary OB/GYN is a copyrighted publication of Advanstar Communications, Inc. All rights reserved.)

communications skills. Through many years of research in the military, Salas and colleagues [22] defined four fundamental attributes of a team that functions well: (1) Two or more members must be involved in the process; (2) the members must have assigned roles or tasks that are known by the other members of the team; (3) all members must share a common goal; and (4) the tasks that the members perform must be interdependent. Teams are continually forming and disbanding based on the tasks at hand.

With this definition in mind, it is easy to understand how medical professionals may have difficulties performing as a highly successful team without adequate training. Roles often are not clearly assigned in many health care settings. While individuals usually share common goals, such as best possible health of mothers and babies, the plan of care is not always articulated and shared with all members involved in the patients' care. Decisions regarding a patient's plan of care that are not articulated or shared with team members can have a deleterious effect on patients and the performance of the team. Practitioners often do not recognize these ramifications.

Teamwork curriculum

Introducing a teamwork-based change in culture in labor and delivery requires all members of the staff, including physicians (both obstetrics and anesthesia), nurses, support staff (scrub technicians, unit secretaries), and leadership, to learn and train together. Preferably, the classes are made small (no more than 20 individuals) and multidisciplinary. The teamwork curriculum should be divided into two parts. The first part addresses the concepts that are critical for all members of the team to understand and embrace for culture to change. The second portion of the curriculum is devoted to the tools and structure that support the implementation of team behaviors. In an emergency, the best communication tools will not help if the rest of the team is not available.

The major concepts of the teamwork curriculum are adapted from CRM and based on years of research on teams, especially in the military setting. The curriculum initially used in the labor and delivery trial [11] was adapted from the curriculum used in the emergency medicine study [10]. The curriculum continues to be updated from the most current literature evaluating what makes teams successful as well as lessons learned from implementation of these concepts in different types of institutions, both civilian and military, as well as teaching and community hospitals [23]. The conceptual portion of the training includes the modules of communication, situation monitoring, mutual support, and leadership. The description of the modules and the skills necessary are listed in Table 1.

Communication failures cause many sentinel events in obstetrics [24]. There are many possible reasons for these failures, including fatigue, excessive workload, inadequate handoffs, incomplete information, interruptions, and multitasking. The course for teamwork teaches causes of communication

Table 1
Modules and skills taught in teamwork curriculum

Module	Skill	Description
Communication	SBAR	Structured technique for presentation of relevant patient information
	DESC	Structured technique for conflict resolution
	Two-challenge rule	Concept that clinician must verbally express concern about patient safety at least twice if problem is not corrected
	Check back	Practice of person receiving an order or instruction repeating back those orders or instructions to the person giving them to ensure that the receiver has understood the message correctly
	Call out	Practice of calling out important events, especially during rapidly changing situations, to facilitate anticipation of next steps
Situation monitoring	Situation monitoring	Active scanning of the unit to assess patients and their plans of care, team member performance, and the environment; and to look for potential errors
	Situation awareness	The state of knowing one's surroundings and what factors affect the environment
	Shared mental model	Situation where caregivers are aware of the same information, and are thus able to plan and solve problems together
Mutual support	Task assistance	Asking for or offering assistance when one team member is overworked
	Advocacy	A form of verbal support that requires staff to advocate for patient safety
	Feedback	A form of verbal support that helps colleagues improve their teamwork
Leadership	Role clarity	Leader responsibility for ensuring that team members know their roles and responsibilities.
	Resource management	Leader responsibility for appropriately reallocating resources or workload to ensure no patient is at risk due to overworked staff
	Teamwork behaviors	Leader responsibility for ensuring that team meetings, briefings, debriefings, and other teamwork activities occur
	Conflict resolution	Leader responsibility for helping to resolve interpersonal or medical conflicts using structured language and a chain of command

Abbreviations: DESC, (D) describe the behavior, (E) express concerns, (S) specify a course of action, obtain (C) consensus; SBAR, situation/background/assessment/recommendation.

failures and provides techniques and tools to improve communication between providers. An example of a tool that many institutions are familiar with is the called the situation/background/assessment/recommendation (SBAR) [25]. This is a tool for communicating crisply and succinctly between providers and clearly states what is the concern and expectation (Box 1).

The SBAR tool (and the example in Box 1) provides a template for communicating information rapidly and allows the individual communicating to make a strong recommendation for action. Other important skills or tools that confirm information exchange include the use of call-outs—asking a specific individual to perform a duty instead of stating an order to a group—and check-backs—asking individuals who are assigned a specific task to repeat this request back to you for confirmation that the request was accurately conveyed. Another important aspect of the communication module is management of conflict between providers. It is important that all providers learn to advocate for the safety of patients. However, this advocacy may sometimes lead to conflict. Two tools are used for managing conflict: the two-challenge rule, already described, and the script known as DESC for "(D) describe the behavior, (E) express concerns, (S) specify a course of action, obtain (C) consensus."

Situation monitoring is the component of the curriculum that also includes the concepts of situation awareness and shared mental model. Situation monitoring is the act of scanning the environment to gain an understanding of individual patients as well as the plans of care for the other patients and the workload of the entire unit. Situation awareness is the state that results

Box 1. Example of SBAR

A nurse contacts you concerning a colleague's patient on labor and delivery and informs you about the patient in the following manner: "Dr. Smith, Mrs. Jones in room 3 is having difficulty breathing and has an increased respiratory rate."

Background: "She is a gravida 1 who just delivered 3 hours ago by spontaneous vaginal delivery and had no history of medical complications during her pregnancy. She became acutely short of breath about 10 minutes ago with a respiratory rate of 30 breaths per minute, has normal blood pressure, and arterial oxygen saturation of 86%. She also has normal lochia and no abdominal pain."

Assessment: "The patient has acute shortness of breath with hypoxia."

Recommendation: "I feel this patient should be seen as soon as possible because she has developed rapid deterioration in her vital signs and I am concerned."

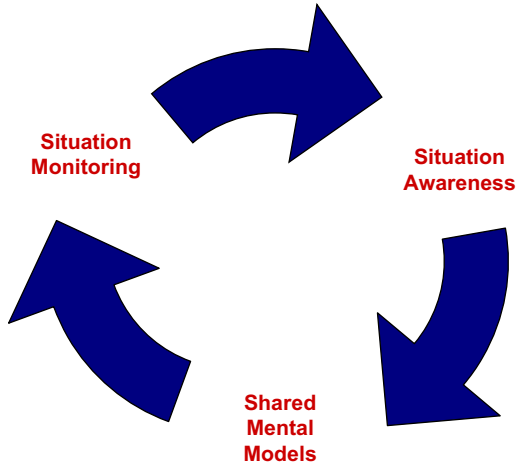

Fig. 2. Interactions of situation monitoring, awareness, and shared mental model. Situation monitoring allows for the development of situation awareness and shared mental models, which allows a high-functioning team to identify potential errors. (*Adapted from* Mann S, Marcus R, Sachs B. Lessons from the cockpit: How team training can reduce errors on L&D. Contemporary OB/GYN 2006;51:34–45; with permission. Contemporary OB/GYN is a copyrighted publication of Advanstar Communications, Inc. All rights reserved.)

from situation monitoring in which a provider understands his or her environment and is aware of what factors can affect it [26]. In a shared mental model, providers share their plans and concerns with one another. Fig. 2 demonstrates how these three concepts are interrelated. If one monitors the situation, obtains situation awareness, and is able to develop a shared mental model with other team members, the team is better prepared to identify potential errors and deviations from the plan of care. The use of a multidisciplinary team meeting with obstetricians, nurses, anesthesiologists, and support personnel allows for the development of the situation awareness and shared mental model.

Mutual support is critical for developing and sustaining teamwork behaviors. Team orientation is the sense that one performs better as part of a team than as an individual alone. Learning to ask for or offering support to an overworked team member assists in the development of team orientation. Advocacy is a form of verbal support that requires staff to advocate for patient safety. It is a skill that can be difficult to perform against an authority gradient and often requires coaching. Feedback is a form of verbal support that helps colleagues improve their teamwork.

Leadership is the final element crucial for teamwork. The leader is responsible for ensuring that team members know their roles and responsibilities. Leaders are necessary for reallocating resources or workload based on situational changes that jeopardize patient safety. It is the leaders who ensure that multidisciplinary team meetings, briefings, debriefings, and other teamwork activities during the shift take place. Briefings occur to develop

shared mental models for all team members before treating complicated cases. Debriefings occur after complicated cases for team learning and quality improvement. Finally, when conflict arises, it is the role of the leader to help resolve interpersonal or medical conflicts using structured language and a chain of command policy instead of personalizing the issue. TeamSTEPPS contains templates to help structure team meetings, briefings, debriefings, and the DESC script.

The second part of the curriculum develops the structure needed for these teamwork behaviors to be successfully implemented into a labor and delivery setting. Most labor and delivery environments do not have well-described structures for triaging and decision-making. One recommended structure in a labor and delivery unit includes three types of teams. The first type of team and most easily understood is the core team. The core team directly cares for patients and its members include nurses, obstetricians, anesthesia staff members, scrub technicians, unit secretaries, residents, and medical students. The core must have situational awareness about their patients. The second type of team is the coordinating team, which consists of a charge nurse, anesthesiologist, obstetrician, and chief resident (where applicable). The role of the coordinating team is to take the 30,000-ft view of the labor and delivery environment to make decisions regarding workload and assist in conflict resolution among and between the core teams. The types of decisions made by this team may include deciding which cesarean delivery should be done first or whether to delay an elective induction when the workload is excessive. Previously, on most units, the charge nurse made these decisions, often in isolation and with little support. The third type of team is the contingency team, whose members are designated at the beginning of a shift to respond to emergencies with identified roles and tasks, such as assisting in preparing the patient for an emergent cesarean delivery or assisting in the preparation of the operating room.

Team behaviors must continually be reinforced with coaching, recognition, and rewards. To sustain the change to a culture of teamwork, this behavior must be publicly acknowledged as important to improving safety.

Measuring outcomes

To validate teamwork as part of a clinical trial in obstetrics, a new set of outcome measures were developed to identify adverse events. The process used for the development of these measures has been published elsewhere [27]. These measures have been developed to be clinically meaningful and easily gathered from discharge data. The tools are the Adverse Outcome Index (AOI), the Weighted Adverse Outcome Score (WAOS), and the Severity Index (SI). Prior to the development of these tools, there were no accepted, clinically relevant, global outcome measures in obstetrics. The AOI is defined as the percent of women who experience one or more of the events listed in Table 2. The American College of Obstetricians and

Table 2
Adverse events and points used for AOI and WAOS

Outcome measure	Score
Maternal death	750
Intrapartum and neonatal death (>2500 g)	400
Uterine rupture	100
Maternal admission to intensive care unit	65
Birth trauma	60
Return to operating room or labor and delivery	40
Admission to neonatal intensive care unit > 2500 g and for > 24 h	35
Apgar < 7 at 5 minutes	25
Blood transfusion	20
3° or 4° perineal tear	5

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Gynecologists' Quality Improvement and Patient Safety Committee, through an expert consensus process, provided the weighting of scores to assess severity of these outcomes. The WAOS is the sum of the adverse outcome scores of all events divided by the total number of deliveries. This provides the average number of adverse event points per delivery using the scoring system in Table 2. This parameter reflects the acuity of the labor and delivery unit. The SI is the average number of points per woman who had an adverse event. This parameter reflects the potential intervention and prevention of worsening outcomes for a patient with an adverse outcome.

The following example illustrates how these metrics may be used to assess quality and performance over time. At BIDMC, AOI, WAOS, and SI data were obtained from the National Perinatal Information Center. The AOI was retrospectively measured from 1999 through 2001, the 3 years before implementation of teamwork behaviors, and compared with the AOI from 2003 through 2006, the 4 years after implementation was complete. Excluded from the data were data from 2002, the year the department implemented team culture. Of 14,271 women who delivered at BIDMC between 1999 and 2001, 836 experienced at least one adverse event, for an average AOI of 5.9% (annual range 5.3–6.5%). The average WAOS and SI were 1.15 and 19.59 respectively. During the 4 years after teamwork was implemented, 19,380 women delivered and the average AOI decreased to 4.6%, with an annual range from 4.1% to 5.2%. This represented a 23.0% decrease in adverse obstetric events. Similarly, the WAOS decreased from 1.13 to 0.75 or 33% postimplementation and the SI decreased from 19.9% to 16.8% or 16%. A 1.4% absolute drop in the AOI in the 4 years postimplementation of teamwork behaviors meant that approximately 291 fewer women experienced an adverse event, or about 1.5 fewer women per week.

Data were obtained from Harvard Risk Management, the malpractice carrier for BIDMC. Twenty-one lawsuits, claims, or observation cases were identified (those of such severity that the carrier opened a file and reserved money) during the 4 years and 19,960 deliveries before training. Of these, 13 (61.9%) were considered high severity. In the 4 years after team training, the rate had decreased to 16 total cases in 20,031 deliveries, of which only 5 (31.3%) were high risk. This represented a nearly 62% decrease in the number of high-severity adverse events after teamwork training.

Additional measures for demonstrating the impact of teamwork include process measures (eg, decision to incision for scheduled, urgent, and stat cesarean deliveries). Patient satisfaction questions are also important measures. These questions address such issues as whether or not the plan of care was consistent among caregivers and provide ratings for teamwork between the nurses and physicians. Staff safety questionnaires, such as the AHRQ Culture of Safety tool or the Sexton Safety Attitude Questionnaire used pre- and postimplementation of teamwork behaviors, are also important metrics [12].

Summary

CRM has been adapted from aviation for the practice of medicine. Changing to a teamwork culture of practicing these new concepts requires leadership to fund an initiative and hard work to train, coach, and sustain the behaviors. It also requires patience as it can take at least a year for the culture to change. Some practical methods that may be implemented in clinical practice include regularly scheduled team meetings with staff members who do not typically interact to ensure coordinated patient care and situation awareness. These activities, when made part of a daily routine, will provide the basis for modeling teamwork skills and set the stage for sustained culture change. These changes can be measured through the new tools of the AOI, WAOS, and SI process measures, as well as patient and staff satisfaction instruments. This culture change can also reduce the number of adverse events suffered inadvertently by our patients while increasing employee retention and improving patient satisfaction.

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Simulation in Obstetrics and Gynecology

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The days of learning "by trial and error" or "see one, do one, teach one" are passing as the leading approaches to the acquisition of health care–related knowledge, skills, and abilities and to the provision of clinical care to the surgical or obstetric patient. Simulation is a practical and safe approach to the acquisition and maintenance of task-oriented and behavioral skills across the spectrum of medical specialties, including obstetrics and gynecology. The idea of practicing on inanimate objects before human beings dates back to antiquity. However, the idea of systematically embedding simulation within the fabric of a graduate or postgraduate medical curriculum or of using this technique as an integral part of professional certification or credentialing programs is relatively new. Since the 1990s, the profession of obstetrics and gynecology has developed a greater appreciation of the value of simulation and major steps are being taken toward incorporating this technique into specialty-specific training, evaluation, and credentialing programs. This article provides an overview of simulators and simulation in health care and describes the scope of their current use and anticipated applications within the specialty of obstetrics and gynecology.

Overview of simulators and simulation in health care

A "simulator" is a generic term referring to a physical object, device, situation, or environment where a task or a series of tasks can be realistically

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and dynamically represented [1,2]. Simulation typically involves the use of one or more simulators for educating, training, or evaluating learners from across the spectrum of experience from novice to veteran [3]. Depending on the educational goals and objectives of the curriculum, some or all portions of a routine or critical event can be reenacted using a combination of verbal role playing, standardized characters or actors, devices, mannequins, or environments. Full immersion medical simulation is when a complex set of tasks takes place in a re-created, realistic health care setting in which clinicians interact with each other and care for standardized or mannequin patients.

Simulator taxonomy

Simulators in health care range from simple objects or training devices to technologically advanced mechanical or haptic systems representing a patient or clinical work environment. Simulators are sometimes distinguished from training devices. For example, Good and Gravenstein [1] reserved the term "anesthesia simulator" for systems that mimic patients and realistically portray the anesthesia environment. Regardless of their level of sophistication or fidelity, training devices or "part-task trainers" are important for introducing learners to key components of a clinical procedure and for refining or assessing procedural technique. Part-task trainers replicate a body part or internal organ and are used to practice a clinical task, technique, or procedure. A model-driven simulator is typically a full-size mannequin that resembles and responds physiologically like a human being to medical interventions. Virtual reality (VR) simulators are computer based, having software designed to re-create a real-world, three-dimensional environment that may be confined to a computer screen display. VR simulators may be augmented by tools, known as haptics, that facilitate various sensory and tactile aspects of the real-world experience. Simulators, including part-task trainers, have been classified by such categories as capability, fidelity, user feedback, and cost (Table 1) [4]. Cost ranges from less than $100 for part-task trainers to well over $100,000 for VR or haptic simulators. Recognizing

Table 1
A simulator taxonomy

Simulator capability					
	Part-task trainer	Instructor-driven simulator	Model-driven simulator	Computer screen–based simulator	Virtual reality/ haptic simulator
Fidelity	Low	Intermediate	High	Low to high	Intermediate to high
User feedback	Nil	Nil to some	Yes	Yes	Yes
Cost	Low to moderate	Moderate	High	Moderate to high	Very high

the lack of a standardized taxonomy, Cumin and Merry [5] recently proposed a schema for classifying anesthesia simulators by their attributes, including those related to (1) use for teaching (knowledge, cognitive skills, psychomotor skills), (2) user interaction (hardware-based, computer-based, VR-based), and (3) simulated physiology (none, script-controlled, model-controlled). It is not yet known if their schema will be widely adopted by anesthesiology in particular and health care in general. However, as Gaba [6] noted in 1997, no single classification system will be devoid of overlap and shades of gray.

Human patient simulation

The first reported computer-controlled patient simulator, SimOne, was created by Denson and Abrahamson [7] in the late 1960s. SimOne, modeled after a 6-ft tall male weighing 195 lb, was designed to be interactive and geared toward training anesthesiologists. Denson and Abrahamson [7] designed a system for students to learn necessary manual and decision-making skills before anesthetizing real patients. Their simulator, clearly ahead of its time, did not attain widespread use and was largely forgotten. Human patient simulators resurfaced when Gaba and DeAnda [8] created an interactive, comprehensive mannequin-based anesthesia simulation in the late 1980s. The Comprehensive Anesthesia Simulation Environment (CASE) was designed to facilitate assessment of anesthesiologists' technical and behavioral skills. Gaba, Schwid, Howard and colleagues [8–10] appreciated the role of simulation-based training in non–health care industries and likened human patient simulation to cockpit simulation, an experiential learning environment used in aviation for professional education and training. Medical simulation was seen as a means to augment didactic instruction, providing an out-of-the-chair and hands-on experience in a safe environment without harming real patients. The practice of anesthesia-related procedural and behavioral skills for better managing routine and critical clinical events could safely take place in such an environment. The aviation and nuclear industries were among the first to confront the problem of human errors as contributing factors in accidents and to address the need for various skilled professionals to learn to work together better and communicate more effectively [11]. Crew resource management (CRM) embodied the aviation industry's approach to optimizing teamwork behaviors, solving problems, and improving situation awareness for better error recognition, management, and recovery [12]. Gaba and associates [13] adapted aviation CRM to anesthesia in 1989, calling it anesthesia crisis resource management (ACRM). The hands-on simulation experience with CASE was followed by reflective debriefing, guided discussions about what went well, what did not go well, and how principles of ACRM could assist in better managing future simulated or real clinical events. The original CASE system has since been replaced by more technologically advanced mannequins, firmly grounding human patient simulation within the field of anesthesia

for training, evaluation, and research. Human patient simulation has spread from anesthesiology into a number of health care specialties and domains, such as emergency medicine [14,15], critical care medicine [16,17], neonatology [18], obstetrics [19,20], invasive cardiology [21], nursing [22,23], and graduate and postgraduate medical education [24,25].

Fidelity and realism

Some degree of simulator and simulation fidelity is required to engage participants in a learning or evaluation activity. Physical fidelity, the degree to which a simulator looks and feels like the real thing; conceptual fidelity, the degree to which a simulation behaves appropriately; and emotional fidelity, the degree to which a simulation draws the participant into the situation, are all required in some measure to achieve engagement [26]. Attaining a high degree of realism is but one route to this end. For example, practicing an injection with a syringe, needle, and an orange does not have much realism, but has sufficient physical, conceptual, and emotional fidelity to engage the novice. Depending on the purpose of the simulation, be it task training or teamwork practice, the precise recipe for physical, conceptual, and emotional fidelity differs and is a matter of debate [27]. Moreover, fidelity is not a quality possessed exclusively by the simulator and simulation. Trainees involved in simulation have a vital role in the perception of fidelity and realism. They must recognize that simulators are proxies for the real item and that simulated scenarios take the place of or represent what has happened or could happen in the real world. Simulation participants do not "suspend their disbelief" so much as they agree to believe and behave as if the situation were real [28,29]. This agreement is facilitated by the design of the curriculum, the expertise of the instructors and trainees, the fidelity of the simulator, and the realism of the environment or system. Dieckmann and colleagues [29] regard the "as-if" concept as the cornerstone of effective simulation. The choice of simulator and how much realism is necessary to engage the participant for purposes of education, evaluation, or research depends on the goals and objectives of the task and the curriculum and the expertise of the instructors and participants [27,30]. Successful engagement of the participant does not hinge entirely upon the precision with which a simulator or simulation replicates reality. The educator's knowledge of the subject matter, the simulators, and their attributes facilitates the process by which a simulation can best achieve the goals and objectives of the curriculum. Application of simulators in health care simulations may take place in centers designated for such purpose—so-called centers for medical simulation—or within contextually relevant health care settings—so-called "in situ" simulation.

Medical simulation centers

Centers dedicated for the purpose of medical simulation initially focused on the specialty of anesthesia and were established during the early 1990s in

North America and Europe. Among the first in North America were the Center for Medical Simulation of Harvard Medical School in Boston, Massachusetts [31]; the Peter M. Winter Institute for Simulation Education and Research of the University of Pittsburgh Medical Center in Pittsburgh, Pennsylvania [32]; the University of Rochester in Rochester, New York [33]; the Veterans Affairs, Palo Alto Simulation Center of Stanford University School of Medicine in Palo Alto, California [34]; and the Canadian Simulation Center for Human Performance and Crisis Management Training of Sunnybrook Health Science Center, Toronto, Ontario, Canada [35]. Among the first medical simulation centers established in Europe were the Swiss Center for Medical Simulation of the University Hospital in Basel, Switzerland [36]; the Danish Institute for Medical Simulation, Herlev University Hospital, in Copenhagen, Denmark [37]; and the Belgium Anesthesia Simulation Centre in Brussels, Belgium [38]. Since then, hundreds more have been established worldwide at various universities, hospitals, nursing schools, small colleges, technical colleges, and community colleges. Expanding beyond the domain of anesthesia, simulation programs are now used for procedural and behavioral skills training, performance evaluation, and competency assessment across the spectrum of specialties and disciplines. Simulation programs are also employed in technology research, development, and device testing. Simulation-based training programs in obstetrics and gynecology are among those offered in medical simulation centers worldwide.

Simulation in obstetrics

Obstetrical simulation is the reenactment of routine or critical clinical events involving a woman who is pregnant or recently delivered and her fetus or newborn for procedural or behavioral skills training, practice, evaluation, or research. The overall goal of obstetric simulation is to improve the quality and safety of care for women and newborns [4].

History of obstetric simulators

The use of small wax or wooden figures to illustrate reproductive processes of childbirth dates back to the ninth century [39]. Buck [40] reviewed the development of simulators in medical education and reported that obstetric mannequin torsos were among the earliest examples of simulators used in the history of medicine. Known then as ''phantoms,'' such obstetric simulators were developed in the 1600s as a way to teach midwives how to better manage difficulties of childbirth. Father and son surgeon-accouchers, Gregoire the elder and the younger of Paris, developed an obstetric simulator made of wicker and used this and a dead child for simulating normal and abnormal processes of childbirth to teach midwives during the 1700s. Sir William Smellie, the father of British midwifery, refined the Gregoire approach by using a pelvis fashioned from human bones covered by leather,

a mannequin fetus made of wood and rubber and complete with articulating limbs, and a placenta made of leather [41]. Around the same time, Sir Richard Manningham, another strong proponent of practicing obstetric maneuvers with phantoms, fabricated a glass machine for simulating childbirth and showing midwives in London the maneuvers of the fetus as it passed through the birth canal [39]. Madame du Coudray, midwife in the court of King Louis XV, continued the use of childbirth simulators for training midwives of France [42]. She was known in the 1700s for creating "the Machine," an anatomically correct, life-size mannequin birthing pelvis, made of wicker, flesh-colored fabric, and leather and padded with sponges, and mannequin babies, made of cloth (Fig. 1). Her mannequins were highly regarded for their lifelike appearance and she traveled with them throughout the French countryside, teaching village midwives how to deliver babies and perform maneuvers for managing childbirth-related complications. The phantoms or "machines" of the 1600s and 1700s are best classified as part-task trainers.

The use of obstetric phantoms for teaching obstetrics continued through the 1800s and 1900s. Professor B.S. Schulze, Director of the University Women's Clinic in Jena, Germany, during the 1890s, modified obstetric phantoms by creating interchangeable pelvic floors and sacral promontories to better simulate pelvic anatomy for teaching clinical pelvimetry (Fig. 2) [43]. Dougal [44] of Manchester, England, was a strong proponent in the early 1900s of using lectures in combination with practical hands-on experience with mannequins for teaching obstetrics. Concerned by the high cost of obstetric phantoms, he commissioned the creation of simple, inexpensive glazed earthenware obstetric "basins" to simulate a female pelvis. He used these in combination with stillborn fetuses and their placentas to teach

Fig. 1. "The Machine" obstetrical simulator of Madame du Coudray. (*Courtesy of* the Musée de Flaubert, Rouen, France; with permission.)

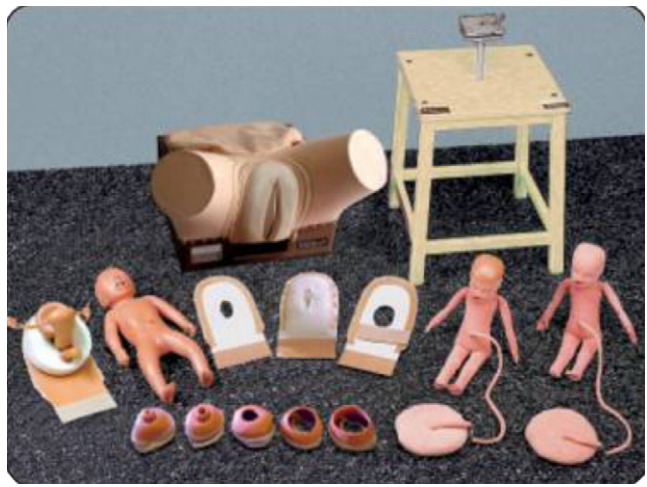

Fig. 2. Obstetric phantom (*Courtesy of* Schultes Medacta, Herten, Germany; with permission.)

obstetric maneuvers. Transparent models resurfaced through the work of Wakerlin and Whitacre [45] were inspired by the University of Illinois' "greater than life-size transparent model of a pregnant woman" at term. They were avid proponents of transparent mannequins for teaching normal labor and operative delivery and collaborated to create a transparent, plastic female abdominal-pelvic torso modeled on the anatomy of a typical European female. In 1947, Eloesser [46], a thoracic surgeon of San Francisco, California, described how he modified this simulator by outfitting the transparent plastic pelvic canal and abdominal cavity with a rubberized abdominal wall and external genitals. His goal was to create a phantom that was lightweight, inexpensive, and easy for a midwife-instructor to transport in medically remote or underserved areas around the world.

A range of obstetric part-task trainers has since been created for training in such procedures as determining cervical dilation, repairing episiotomies, and applying forceps. The transition from the use of obstetric birthing pelvises to the use of realistic, full-size interactive birthing simulators took place during the 1970s. During this time, Knapp and Eades developed a mechanical female birthing system outfitted with an electro-pneumatic device capable of generating sufficient fluid pressure to push out a mannequin baby and simulate vaginal birth [47]. This device did not gain traction in the obstetric arena and, like SimOne, was not commercially produced. Eggert, Eggert, and Vallejo took a different approach in the 1990s by installing a motorized mechanism that pushes a life-size mannequin baby out of the pelvis for simulating vaginal delivery [48]. They outfitted their life-size female birthing mannequin with a self-contained, indwelling, audible, fetal heart tone simulator. Now known as Noelle, this high-fidelity, human patient mannequin was patented as a "computerized education system for teaching patient care" (Fig. 3).

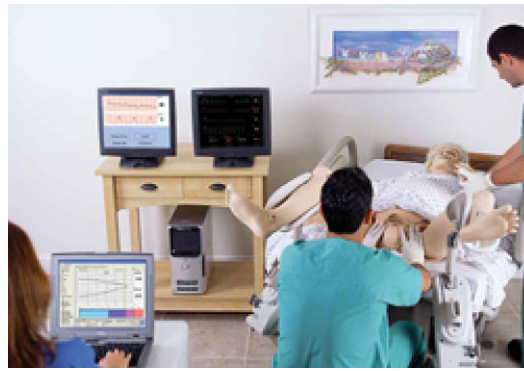

Fig. 3. Noelle S575 (*Courtesy of* Gaumard Scientific, Miami, FL; with permission).

Current obstetric simulators

Currently available obstetric simulators range from part-task trainers to high-fidelity life-size female mannequins, situations, and environments for realistically representing obstetric events. Table 2 displays select features of commercially available obstetric simulators. High-fidelity birthing simulators currently available are equipped with motor-driven mechanics that move the mannequin fetus out of the birth canal. The most technologically advanced models are outfitted with wireless computer-based software that allow for remote control. Low- and high-fidelity simulators are useful for teaching and practice, depending on the goals and objectives of the curriculum. A low-fidelity birthing pelvis can be paired with a high-fidelity adult-size mannequin to enhance the capability or achieve the desired effect needed for an obstetric scenario. A birthing pelvis can also be held by a live person close to her own body so that the human and mannequin seem as one. The pairing of simulators with other simulators or with humans creates so-called ''hybrid simulators,'' useful for more realistically simulating a patient or a clinical environment (Fig. 4). Hybrid simulation techniques can augment realism at little to no extra cost. Such techniques are especially useful where resources or storage capabilities are limited or where portability is essential.

Current use of obstetric simulation

Much has been written about the use of obstetric simulators since their introduction during the 1600s. Since Eloesser's [46] article on the transparent phantom in 1947, most of the published literature involving obstetric simulation has focused on acquisition and training of procedural skills. For example, Burd, Motew, and Bieniarz [49] in 1972 described a simulator they created for teaching how to perform fetal scalp sampling. Many articles have since been written describing the creation or use of a variety of obstetric simulators for teaching such skills as assessing cervical dilation [50]; performing ultrasound-guided amniocentesis [51,52]; using forceps [53,54]; determining fetal

Table 2
Some commercially available obstetric simulators

	Simulator capability	Company	Cost
Postpartum suturing trainer	Part-task trainer	Gaumard	Low
Episiotomy or anal sphincter trainers	Part-task trainer	Limbs and Things	Low
Breast milk hand expression trainer	Part-task trainer	Limbs and Things	Low
Birthing pelvis	Part-task trainer	Gaumard	Low
Obstetrical mannequin or birthing pelvis	Part-task trainer	Simulaids	Low
Forceps, vacuum delivery obstetric mannequin	Part-task trainer	Simulaids	Low
The Obstetric Phantom	Part-task trainer	Schultes Medacta	Moderate
Maternity Model Type 1 (with fetal heartbeat)	Part-task trainer	Koken	Moderate
Midwifery practice model	Part-task trainer	Koken	Moderate
Full-body pregnancy simulator	Part-task trainer or instructor-driven simulator	Koken	Moderate
Practical Obstetric Multi-Professional Training birthing simulator	Part-task trainer or instructor-driven simulator with force monitor	Laerdal; Limbs and Things	Moderate
FetalSim	Instructor-driven simulator	Advanced Medical Systems	Moderate
UltraSim	Instructor-driven simulator	MedSim Advanced Medical Systems	High
Newborn Pedi Simulator or Nita Newborn	Instructor-driven simulator	Gaumard	Moderate
Noelle Birthing Torso	Instructor-driven simulator with automated capability	Gaumard	Moderate
Noelle Maternal, Neonatal Birthing Simulator	Instructor-driven simulator with automated capability	Gaumard	Moderate
Noelle Interactive Maternal, Neonatal Birthing Simulator	Model-driven simulator	Gaumard	Moderate to high, depending on model
Newborn Hal	Model-driven simulator	Gaumard	High
BabySim	Model-driven simulator	Medical Education Technologies	High
SimBaby	Model-driven simulator	Laerdal	High

Fig. 4. Example of a hybrid technique that pairs a low-fidelity obstetric simulator with an actor to simulate shoulder dystocia. (*Courtesy of* Brigham and Women's Hospital, Boston, MA; with permission.)

station [55]; conducting breech birth [56]; managing shoulder dystocia [57–59]; managing obstetric emergencies and trauma [60–63]; managing the obstetric airway [64,65]; performing intubations [64,65]; and inserting epidural catheters [66]. Since 2004, obstetric simulation–based research has been increasingly used to address issues related to teamwork [61–63], team performance [67–69], the identification of clinical errors [70–73], the reduction of clinical risks [74,75], and the improvement of clinical outcomes [76–78].

Shoulder dystocia

A number of articles have been published in the obstetric literature involving simulation related to research about, training for, and management of shoulder dystocia. The earliest research in this area was led by Gonik, Allen and colleagues, [79–81] in the late 1980s and early 1990s. To study the applied pressure or force on the brachial plexus, Gonik and colleagues [82] in 2003 used a "computer software crash dummy" modified with a female pelvis and a mannequin fetus and outfitted with a spring device to represent the brachial plexus. They discerned that stretch on the brachial plexus varied with the degree of force applied, the position of the pelvis, and the position of the fetal head within the pelvis. They also found that the McRobert's maneuver reduced stretch of the brachial plexus. Deering and colleagues [58] in 2004 reported on the positive impact of using simulation for teaching residents the maneuvers for managing shoulder dystocia and for promoting best practice

for residents in medical record documentation of such clinical events [83]. Kim and colleagues [84] and Gurewitsch and associates [85], with Allen and colleagues, created a biofidelic maternal birthing simulator they have since used in research involving various aspects of shoulder dystocia. In 2005, they compared the force applied on the brachial plexus during McRobert's maneuver with that of the Rubin's maneuver and found less force was generated with Rubin's maneuver [85]. In 2007, Allen and colleagues [86] discerned greater stretch on the posterior brachial plexus was generated during second stage of a simulated routine vaginal delivery compared with one complicated by shoulder dystocia, but before the application of clinician-applied traction. They concluded that even though the fetal posterior brachial plexus may stretch as it traverses the pelvis during the second stage of labor, clinicians should aim to minimize applied traction, especially lateral traction, in all deliveries to reduce the risk of brachial plexus injury. Crofts and colleagues [87] in 2005 discussed the use of a new birthing simulator they helped develop for training in shoulder dystocia. After the training program, none of the trainees applied greater than 100 N of traction, a degree of force beyond which is associated with fetal injury. In 2006, they presented results of a randomized controlled trial of simulation-based training in Bristol, United Kingdom, involving shoulder dystocia scenarios with the Practical Obstetric Multi-Professional Training (PROMPT) birthing simulator (Fig. 5) [57]. They compared training with a high-fidelity mannequin with force monitoring to training with a low-fidelity mannequin and found that all training improved performance of basic maneuvers ($P = .002$), the achievement of

Fig. 5. The PROMPT birthing simulator. (*Courtesy of* Limbs and Things, Bristol, United Kingdom; with permission.)

successful deliveries ($P<.001$), and communications with the patient ($P<.001$). High-fidelity simulation with force monitoring led to more successful deliveries ($P = .002$), lower applied force ($P = .006$), and shorter head-to-body delivery ($P = .004$). This study underscores the importance of training for managing shoulder dystocia and demonstrates how force monitoring in simulated vaginal births heightens clinician awareness of what they can potentially generate in the process of managing birth complicated by shoulder dystocia. In 2007, Crofts and colleagues [88] described the use of PROMPT in a standardized shoulder dystocia scenario to assess the force applied by obstetricians and midwives to the fetal neck. They found a wide range of variation in the pattern and degree of applied force, ranging from 6 N to more than 250 N, and over two thirds of study participants exceeded 100 N, an amount of force considered excessive. While the force applied during simulated shoulder dystocia may not exactly represent what occurs in real cases, this study reiterates the value of educating clinicians about the degree of force they are capable of generating, and reinforcing the importance of accurately using maneuvers to successfully achieve a safe delivery. In a separate study using the PROMPT mannequin, Crofts and colleagues [89] assessed retention of skills at 6 and 12 months after obstetric providers attended a structured training program on shoulder dystocia. They found a high percentage ($>80\%$) of participants, including those who had failed to successfully deliver the mannequin baby before training, were able to successfully deliver the mannequin baby at 6 months and 12 months after training. This study suggests that annual training is likely appropriate for those who demonstrated proficiency before training. For others, more frequent training sessions may be warranted to reinforce such skills.

Fetal station and the use of forceps

In 2005, Dupuis and colleagues [55] conducted a prospective, randomized trial for assessing reliability in determining fetal station. They constructed a laboratory birthing simulator consisting of a female pelvis and a mannequin fetus with an anatomically correct fetal skull. They then compared the assessment of fetal station, ranging from -5 to $+5$, and engagement conducted by residents and attending physicians. They found that 88% of residents and 67% of attendings misdiagnosed "high" fetal station, and about 12% of both groups incorrectly classified engagement of the fetal head. In view of these findings, Dupuis and colleagues advocated simulator-based training as a way to improve skills for determining fetal station and engagement. In 2006, Dupuis and colleagues [53] combined computer screen–based or virtual capabilities with a birthing pelvis and equipped forceps with spatial location sensors to teach and assess forceps application. These sensors made it possible to monitor forceps blade trajectory in a simulated operative vaginal delivery, and to compare forceps application by attendings and residents. Forceps blade trajectory was excellent, very good, or good in 92% of cases involving

senior obstetricians and in 38% of cases involving junior obstetricians ($P < .001$). Dupuis and colleagues concluded that simulation provides a safe way to acquire and practice skills in forceps application before trying it on real patients, and can be used to certify skills in the use of forceps. Moreau and colleagues [90], including Dupuis, are now using forceps trajectory patterns created by experienced obstetricians as templates for training residents.

Virtual reality and haptic simulation

Applications of VR and haptic simulation to the field of obstetrics are few but have increased over the past decade. Three articles published in the 1990s and three since 2002 focused on VR simulation in obstetrics [91–96]. In 2002, Letterie [94] assessed the use of VR in a variety of non–health care and health care industries, exploring potential applications in obstetrics and gynecology. He concluded that VR environments could assist residents and medical students in surgical skills training and in developing better conversing skills with patients. In 2004, Obst and colleagues [95] created a virtual obstetric environment with feedback mechanisms embedded in the simulator to assist learners in acquiring skills for managing normal and complicated deliveries. In 2005, Lapeer [96] of the United Kingdom assessed the feasibility of using VR technology to create a mechanical model augmented by haptic feedback for simulating forceps delivery. He demonstrated that such a device could facilitate skill acquisition and performance of forceps application. His findings align well with those of Dupuis' forceps-related research in France.

Structured simulation-based training programs

Several multidisciplinary obstetric skills training programs have been established in the United Kingdom, the United States, and Canada. These programs include Managing Obstetric Emergencies and Trauma [62] and Multidisciplinary Obstetric Simulated Emergency Scenarios (MOSES) [68] of the United Kingdom; the Advanced Life Support in Obstetrics [97–99] of the American Academy of Family Physicians in the United States; and Advances in Labor and Risk Management [100] and Managing Obstetrical Risk Efficiently [101] of the Society of Obstetricians and Gynecologists of Canada. These procedural skills and team training courses have been offered in some cases for over a decade and have generally been well received by clinicians in their respective areas.

Leaders in obstetrics and gynecology and simulation researchers within the military medical corps have long been proponents of simulation-based training in obstetrics and gynecology. Macedonia and colleagues [20] described the integral role that medical simulation has in the training and practice of obstetrics and gynecology, highlighting aspects of their obstetric skills simulation curriculum at the National Capital Area Medical Simulation Center of the Uniformed Services University of the Health Sciences in Bethesda, Maryland. More recently, members of the Madigan Army

Medical Center announced the development of a mobile obstetrics simulator, Simulator for High Acuity Deliveries, to facilitate training for managing obstetric emergencies [102]. Plans are in place to deploy these units to military treatment facilities to help obstetric clinicians maintain and update clinical skills for managing high-acuity, low-frequency perinatal events.

Reducing risk

Several articles published since 2005 target the use of obstetric simulation for identifying clinical error, reducing clinical risk, and improving clinical outcomes. Cioffi and colleagues [77] conducted a pilot study using simulated scenarios for teaching clinical decision-making to midwives. The study showed a positive effect of this approach on clinical decision making in simulated clinical settings. The investigators noted that translating this effect into the real world setting was inconclusive. Draycott and colleagues [78] assembled a retrospective cohort of births between 1998 and 2003, and investigated whether simulation-based training in Bristol, United Kingdom, made a difference in perinatal outcomes after clinicians attended a day-long simulation-based training session for managing obstetric emergencies. They compared pretraining (1998–1999) to posttraining (2001–2003) outcomes for singleton, cephalic term births at tertiary care and teaching hospitals. They found that 5-minute Apgar scores of less than six decreased from 86.6 to 44.6 per 10,000 births ($P < .001$) and hypoxic-ischemic encephalopathy decreased from a rate of 27.3 to 13.6 per 10,000 births ($P = .032$). Theirs is the first study whereby an obstetric simulation-based educational program has been associated with improved perinatal outcomes.

Error identification and management

Simulation can assist in identifying recurrent pitfalls in managing obstetric emergencies. Maslovitz and colleagues [72] in 2007 described using simulation to identify mistakes in obstetric management. They observed team performance of residents and midwives during simulated obstetric emergencies, such as eclampsia, hemorrhage, shoulder dystocia, and breech birth. The most common errors involved delay in transport to the operating room (82%), lack of familiarity with medications for treating obstetric hemorrhage (82%), poor techniques in using cardiopulmonary resuscitation (80%), and inadequate documentation of shoulder dystocia (80%). They acknowledged that although simulation is useful for training, the transfer of skills acquired in simulated emergencies to managing real clinical events is uncertain and remains an important area of research.

Teamwork, team performance

Simulation facilitates multidisciplinary team training and improves team performance in obstetric emergencies and trauma as demonstrated by Freeth

and colleagues [68] in 2006. MOSES, launched in the United Kingdom as a day-long program, aimed at improving multidisciplinary team performance via lectures, workshops, and skills training sessions, concluding with a post-course evaluation. While not yet proven, this program is expected to reduce by 25% the occurrence of harmful adverse events in obstetrics and gynecology that result in litigation.

Tools for evaluating team performance in simulated obstetric events are the subjects of much research. Scavone and colleagues [103] in 2006 developed and piloted a scoring system for assessing the performance of anesthesia residents during emergency cesarean delivery. They found the scoring instrument useful and the simulator contextually valid and reliable. Morgan and colleagues [70] in 2007 investigated tools for evaluating performance of multidisciplinary obstetric teams during simulated obstetric emergencies. They concluded that obstetric-domain–specific behavioral markers and assessment tools should be developed instead of using or modifying existing tools, such as the Human Factors Rating Scale and the Global Rating Scale.

Several investigators have recently explored the question of whether simulation offers advantages over a traditional didactic approach. Jude and colleagues [69] in 2006 compared third-year medical students who received simulator-based training in vaginal delivery to those who received traditional instruction. They found that students with simulated experiences expressed greater confidence in their own abilities to assist or attempt vaginal delivery in real clinical settings. Ohlinger and colleagues [104] reported that video simulation was a useful methodology for teaching effective communication and improving teamwork among perinatal care providers during deliveries. Birch and colleagues [71] in 2007 compared lecture-based methodology with a simulation-based approach and with a combined lecture- and simulation-based approach for teaching teams to manage postpartum hemorrhage. Six multidisciplinary teams, randomized to one of these three methods, all demonstrated improved fund of knowledge and skill performance. However, teams trained with simulation demonstrated sustained improvement in clinical management, interdisciplinary communication, and self-confidence when tested 3 months later. Teams taught by simulation also improved their interdisciplinary communication skills compared with those taught exclusively by lecture. Although not powered for statistical significance, this study indicates that simulation-based training offers advantages over traditional lecture-only methodology. It remains to be seen if such improvements are long-lasting and how frequently simulation-based team-training coursework should be repeated to maintain clinical proficiency.

Simulation in gynecology

Simulation in gynecology involves the reenactment of routine or critical gynecologic events involving women across the lifespan for procedural or behavioral skills training, practice, evaluation, or research. As such, the full

spectrum of verbal role playing, standardized characters or actors, devices, mannequins, and environments can be used alone or in combination to achieve the desired educational goals and objectives of a curriculum. The focus here will be confined to simulation involving surgery and hospital-based care of women with reproductive or post-reproductive age-related gynecologic conditions. However, much of what will be addressed can be modified or adapted to reflect routine and critical events and simulation environments typical of the primary care or outpatient settings. Simulation targeting the female newborn and pediatric age groups will not be addressed, nor will simulation involving use of animals or cadavers.

Gynecological simulators

The history of gynecology simulators dovetails with that of obstetrics as small wax or wooden figures have been used since antiquity for illustrating reproductive processes, contraceptive techniques, and other gynecologic conditions that women experience [39]. A number of objects or more elaborate part-task trainers have been developed for training in and practicing of procedures and surgical techniques or for examining the female breast and pelvis. These objects and trainers include suture trainers; training devices for proper placement and positioning of barrier, subcutaneous, and intrauterine contraceptives; and devices for practicing placement of periurethral slings. Pelvic ExamSim (Medical Education Technologies, Sarasota, Florida) is an example of an elaborate part-task trainer equipped with sensors and computer-based software that feeds back information to the learner about his or her performance [105,106]. High-fidelity, physiologically interactive, life-size human female mannequins are available and can be used for simulating gynecologic surgery scenarios in a simulated or real operating room environment. However, mannequin technology currently available is inadequate for realistically simulating open laparotomy involving major abdominal and pelvic organs, such as a benign or radical hysterectomy, an oophorectomy, or major vaginal surgery, such as hysterectomy, fistula repair, or vaginal vault suspensions. Gynecology-related video simulation or VR, computer screen–based or haptic systems currently offer greater opportunities for such purposes [107]. Few gynecology-oriented, total immersion VR-haptic environments exist and are primarily used in research. Hysteroscopic and laparoscopic simulators are best classified as part-task trainers ranging in fidelity from simple box trainers, or ''physical simulators,'' to hybrid mechanical-virtual or haptic systems.

History of minimally invasive surgery simulators

The acceptance and integration of laparoscopy as a credible technique for abdominal and pelvic surgery triggered growth in the number and variety of minimally invasive gynecologic simulators. The first endoscopy may have occurred in Greece during the time of Hippocrates. However, not until

1806 was an instrument created instrument that could be inserted into the body for visualizing internal organs. This was the invention of Phillip Bozzini of Germany. His idea, although never tested on humans, was ultimately reintroduced and accepted by physician-surgeons in the late 1800s [108]. Visualization of the stomach and urethra was first accomplished. Then visualization of the organs of the abdomen and thorax was made possible when Kelling of Germany created the technique of pneumoperitoneum in the early 1900s [109]. The technique was adapted for use in gynecology in the late 1930s by Telinde and in the early 1940s by Palmer shortly after introduction of the Veress needle for creating a pnuemoperitoneum. Semm [110], a gynecologist in Germany, invented an automatic insufflator in the 1960s, a device that the American medical community embraced for its simplicity and safety features. Semm used the term pelviscopy to describe his surgical procedure. The American Association of Gynecological Laparoscopists was founded in 1971, but it was not until 1981 that the American Board of Obstetrics and Gynecology mandated that laparoscopy training be included in residency training programs. Semm [111] created the first laparoscopy training device in 1985 for colleagues to practice their surgical techniques. His ''pelvi-trainer'' had a clear cover that permitted novices to directly view their techniques. An opaque cover could be used in place of the clear cover. A video screen was later added to the system for more realistic simulation of the laparoscopic procedure. Application of VR technology was initially proposed by Satava [112] in 1993, but was slow to be adopted and integrated into surgical training programs. VR technology is now commercially available and is an integral component of advanced minimally invasive surgical simulators. Gallagher and colleagues [113] defined VR as a ''computer-generated representation of an environment allowing sensory interaction,'' giving an impression of realism. They noted in 2005 that the two most likely reasons for delayed adoption of VR technology in surgical simulation included the lack of solid scientific proof supporting its use for skills training and the lack of knowledge of how best to incorporate simulation within a surgical training program.

Current use of gynecologic simulators

Minimally invasive gynecologic surgery simulators should be able to differentiate between the experienced clinician and the novice and to discern improvement with successive use [114,115]. Ideally, such a simulator should be affordable and user-friendly as with a simple box trainer or physical simulator. Physical simulators are mannequin torsos or similar objects that can be placed on a table or platform and that can accommodate the insertion of laparoscopic instruments and the operation of such instruments to grasp or manipulate small objects within the simulator resembling or representing internal organs. Physical simulators permit the use of the same or similar instruments and camera equipment employed in real operating rooms and

give learners the opportunity to perform surgical gestures similar to those used in real cases, providing realistic depth perception and tactile feedback to the student. The original VR simulators were expensive and not equipped to provide the depth perception and tactile feedback typical of real cases. Such limitations have been addressed with newer models that benefit from advances in computer technology and increasing demand for safer and more practical ways for clinicians to acquire and practice their skills without harming patients. However, VR simulators continue to be more costly than physical trainers. Examples of VR laparoscopic simulators include the Minimally Invasive Surgical Trainer–Virtual Reality (MIST-VR) simulator (Mentice, Gothenburg, Sweden); the LapSim virtual reality laparoscopic simulator (Surgical Science, Gothenburg, Sweden) (Fig. 6); the Xitact instrument haptic port simulator (Gothenburg, Sweden) (Fig. 7); the Lap Mentor simulator (Simbionix USA, Cleveland, Ohio); and the Computer Enhanced Laparoscopic Training System (Center for Integration in Medicine and Innovative Technology, Boston, Massachusetts).

Skills acquisition and training

Much has been written about the use of minimally invasive surgery simulators for skill acquisition and practice. These reports have investigated whether or not such simulators facilitate training and their ability to detect change in performance. The following selection of recently published articles in the gynecology and surgery literature illustrates the utility of laparoscopic

Fig. 6. LapSim-VR. (*Courtesy of* Surgical Science, Gothenburg, Sweden; with permission.)

Fig. 7. Xitact instrument haptic port. (*Courtesy of* Mentice, Gothenburg, Sweden; with permission.)

simulators for skill acquisition and training. Fichera and colleagues [115] in 2002 to 2003 investigated the use of physical trainers for skills acquisition, clinical training, and differentiation of novice from veteran gynecologic and surgical laparoscopists. Using the LTS 2000, Fichera and colleagues showed that this device reliably detected laparoscopy expertise and change in performance over time with improved suturing and coordination scores ($P < .05$). Scott and colleagues [116] in 2000 compared surgical skills of residents using physical trainers to the skills of residents who did not use the trainer. They found higher global assessment scores during real-time laparoscopic cholecystectomy for the simulator-enhanced training group compared with those without such training. The improved global scores were accompanied by improved respect for tissue, skills in handling instruments, use of surgical assistants, and overall performance. These findings demonstrated that physical trainers are a viable alternative to VR simulators.

VR simulators have been scrutinized in a similar fashion and their use has also been shown to reliably detect laparoscopy expertise and change in performance over time.

Seymour and colleagues [117] in 2002 used a randomized, double-blind controlled trial methodology to evaluate VR simulator–based training. They found that such training improved performance in the operating room. Additional studies have used the MIST-VR system, a skills-oriented trainer without haptic feedback that requires the student to perform six tasks: (1) acquire and grasp, (2) transfer and place, (3) traverse a segment, (4) withdraw and insert, (5) perform a diathermy, and (6) perform

a diathermy and manipulate. Gallagher and colleagues [118] and Grantcharov and colleagues [119] found that prior laparoscopic experience was highly correlated with technical skills using the MIST-VR system. Munz and colleagues [120] in 2004 investigated whether laparoscopic VR trainers were superior to box trainers and found no significant differences in laparoscopic skills acquired between groups of novices who trained with either of these simulators. Grantcharov and colleagues [121] also investigated whether or not skills acquired in the laparoscopic simulator would transfer to the real surgical arena. They randomized surgical residents to usual training or usual training enhanced by MIST-VR training. Evaluated with global rating forms, surgical residents who trained with the simulator demonstrated shorter operating times and more efficient surgical gestures during real laparoscopic cholecystectomy compared with those who had not.

Hart and Karthigasu [122] in 2007 reviewed the use of VR simulators for laparoscopic surgery and noted that the MIST-VR is the most widely used, studied, and validated simulator system for general surgery training in the United States. The MIST-VR is also the simulator most demonstrated to be of value for the education and training of gynecologists. However, LapSim remains a useful system because it provides more realistic simulations. For example, it can simulate bleeding organs that deform and change as the procedure evolves. Aggarwal and colleagues [123] reported in 2006 on the use of the LapSim for training technical skills in managing ectopic pregnancy. Using LapSim in successive sessions, they compared experienced and novice gynecologists in their performance of tasks involved in such surgery. They found that novices demonstrated significant improvement in their surgical gestures, whereas experienced gynecologists demonstrated little change over time. LapSim appears to be useful for facilitating skill acquisition for novice surgeons who plan to perform laparoscopic surgery for ectopic pregnancy. Hamilton and colleagues [124] found that surgical trainees considered the box trainer more realistic because it provided better tactile feedback and depth perception compared with other simulators. Similar findings were noted more recently by Madan and colleagues [125] in 2005. Laparoscopic simulators, either box trainers or VR trainers, facilitate skill acquisition and training, especially for the novice, and such training is translatable to the operating room.

Assessment

Assessment of skill performance and competence is possible with the box trainer and the VR laparoscopic system, each having its own advantages and limitations. Chou and Handa [126] appreciate a more promising role for VR systems. Objective data can be recorded by the software and later analyzed for such factors as accuracy of task performance and completion times, efficiency of surgical gestures, and handling of thermal-generating devices. Feedback is provided in an unbiased manner and reports can be

generated showing change over time. Gor and colleagues [127] evaluated the use of a VR system (MIST-2) and found it useful as an objective measure of laparoscopic skills demonstrated by gynecologic surgeons. By comparison, box trainers require the presence of an instructor to observe performance and provide feedback, which can be biased and unreliable. Structured assessment programs have been developed to standardize the process and minimize observer bias. One such program is the McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) [128]. MISTELS requires users to perform a series of five tasks. These tasks are scored using an objective system that has met reliability criteria for high-stakes testing. However, the box simulator and the VR systems can be used to objectively assess competency and proficiency in task performance, making it possible to discern skills of novices from those of veterans and to identify improvement in skill acquisition over time. These simulators may assist trainees in making career choices, especially those trainees unable to demonstrate proficiency in basic surgical skills [118], and in practicing new skills or new procedures before trying them for the first time on live patients [122].

Credentialing

Simulation is being used in various accreditation programs around the world. The Israel Center for Medical Simulation is at the cutting edge in the use of simulation for summative evaluation and accreditation programs, including the medical school selection process, national board examination in anesthesiology, and national accreditation for paramedics [129]. Ziv and colleagues describe how prospective candidates for medical school must complete various questionnaires and behavioral assessments, and participate in observed structured clinical examination–like (OSCE-like) stations that include simulation of patient encounters with role-playing and standardized patients. The experience with these endeavors thus far has been positive. However, validity of this approach will be assessed and monitored as medical students selected progress through their training. The Israeli board examination in anesthesiology lacked a performance evaluation component until about 4 years ago. Capitalizing on the experience of the Fellow Royal College of Anesthesiology in the United Kingdom, the board examination committee joined with a panel of experts in testing and evaluating to create a series of simulation-based OSCE-like stations representing core problems that anesthesiologists encounter in the course of clinical practice. Subjective feedback with the process and satisfaction with the realism of the scenarios thus far has been favorable. The mean interrater correlations of examiners were high (0.89 to 0.76), the rate of incongruence was low ($<15\%$), and the correlations for intercase reliability were significant ($P<.01$).

The Accreditation Council for Graduate Medical Education supports rigorous competency assessment of residents in a number of areas, including

those related to interpersonal and communication skills, professionalism, and systems-based practice [130,131]. With this in mind, Julian and Rogers [132] recommend changes in the way gynecologic surgeons are trained. They propose a model guided by evidence-based educational studies and evidence-based clinical reports. They further propose standardizing the measurement of surgical teaching outcomes and surgical education curricula. They argue that students should practice basic surgical skills before assisting in surgery on live patients. They thereby support the use of simulation. They state that "the acquisition of core surgical knowledge, judgment, leadership qualities, and skills before the resident participates in live surgeries is the keystone in fulfilling the mandate to improve the ethics and effectiveness of training gynecologic surgeons."

The future of simulation in obstetrics and gynecology

The specialty of obstetrics and gynecology is taking measured steps toward seamlessly integrating simulation within the fabric of education, training, and assessment of obstetrician-gynecologists. The experience chronicled above illustrates the great progress made thus far in appreciating the value of simulation in such endeavors. Driving these efforts are multiple factors both within and outside of the profession. These factors include restrictions on work hours of residents [133]; reductions in the medical work force coupled with increasing demand among health care workers to balance work with lifestyle preferences and family obligations [134–136]; rising malpractice premiums, threats of litigation, and payouts by juries ruling against defendants [137,138]; and diminished clinical opportunities for trainees when patients refuse to permit their involvement [139–141]. Specialty and subspecialty examining boards are establishing mechanisms for assessing task-oriented and behavior-based competencies for professional certification, validation, and re-entry. Professional organizations are considering or requiring simulation-based experiences for credentialing and recredentialing [130,142–145]. The need for competency assessment has triggered development and validation of task-oriented and behavior-based tools that discern proficiency in clinical endeavors [70,103,104], and these efforts will intensify. In some cases, professional certification and hospital credentialing programs now require core competency assessment of procedural and behavioral skills, including skills that demonstrate teamwork and professionalism [130,144,145]. Since the Institute of Medicine's report on human error in 2000 [146], pressure has been growing to reduce adverse events and improve the safety and quality of patient care. Steps being taken toward this end include the implementation of requirements or strong recommendations to conduct obstetric emergency drills and skills training [60,147–150]. There are sporadic reports of medical professional liability insurers who now offer insurance premium discounts for participation in obstetric simulation-based and didactic team training programs [151–153]. It is unclear if this "carrot" approach toward facilitating

patient safety and mitigating medical error in the obstetric arena will be implemented by other medical professional liability insurers. Similar efforts have been made in providing an insurance premium incentive to clinicians who successfully complete training programs in fundamentals of laparoscopic surgery [154]. There are also reports of using simulation for remediation. For example, the New York State Department of Health's Office of Professional Medical Conduct recently used simulation as a key component in their efforts to remediate anesthesiologists [155]. If deemed successful, this approach may be more widely adopted across the medical specialties, including obstetrics and gynecology.

Challenges to seamless integration of simulation into professional training of obstetrician-gynecologists include such factors as the high costs and limited quality of currently available simulators, limits on time and space available for such purposes, and lack of sufficient personnel skilled in their use. Trainees grapple with the caliber of fidelity and realism of current mannequin technology. Mannequins that look and feel more humanlike, equipped with realistic organs and tissue layers that bleed, would enhance the immersive quality of simulated scenarios. Research is needed to determine suitable environments that best meet the educational needs of trainees, identifying essential characteristics of simulators that facilitate acquisition, training and competency assessment of procedural and behavioral skills. As simulation technology and its use evolves, there will soon be a day when (1) the methods and techniques necessary to facilitate learning are well understood, (2) all members of the team will be trained in the safest way possible to manage all manner of obstetric and gynecologic events, and (3) all trainees will demonstrate procedural and behavioral proficiency in a simulator before being permitted to treat human beings, regardless of specialty or level of experience. The day is coming when simulation-based activities will be required for practice, and no longer will a novice try a procedure for the first time on a real patient without having performed it in simulation.

Summary

The technique of simulation for education and training in obstetrics and gynecology is not new. A brief review of the history confirms that this technique has solid roots deeply planted within the field of obstetrics and gynecology. However, until recently, technological limitations and other factors inhibited the use of simulation. Now, an appreciation for the potential value of simulation in health care education, training, and research is emerging and more applications are appearing. The days of relying on the apprenticeship style of learning in obstetrics and gynecology have passed. Simulation offers clinicians a safe, practical, and credible means to acquire skills and learn how to optimally manage clinical scenarios from the routine to the most uncommon or unusual events in contextually relevant settings. The effectiveness of simulation in reducing adverse outcomes is a matter of

debate and the focus of much research within the simulation community. Dutta and colleagues [156] assert that despite the lack of incontrovertible proof that simulation directly reduces adverse outcomes, "…we must recognize that no hazardous industry has anything remotely approaching level 1A 'evidence' to support their practices …" Securing such proof may be as elusive in health care as it has been in aviation. The medical simulation community should instead focus on defining the key attributes of simulation environments across the spectrum of health care specialties that will best serve the needs for education and training [3]. The published literature in obstetrics and gynecology thus far supports simulation for practicing routine and uncommon but critical procedures and events, for improving technical proficiency, and for building self-confidence and teamwork among clinicians. As the science of simulation evolves in obstetrics and gynecology, adherence to sound educational objectives will best guide its development and inform the extent to which realism and fidelity of a specific simulated clinical experience is necessary. VR environments in obstetrics and gynecology are ripe for research and development [53,54,84,112,114], offering the greatest opportunity for training in the most realistic settings possible without harming real patients. Most VR simulators currently focus on surgical specialty skills and procedures. However, Chou and Handa [126] admonish that gynecologic surgery is not simply general surgery of the pelvis. VR product design must be mindful of the unique tasks specific to gynecology, and so too with obstetrics. Whether virtual or not, simulated obstetric and gynecologic environments should be designed to address the unique tasks specific to care of women across the lifespan so that, in the words of Sir Richard Manningham, "…where every Case that can happen may be represented and repeated as often as we deem necessary, you will have the greatest opportunity of forming your Hands for Practice" [39]. Effectively forming one's knowledge, skills, and abilities for the practice of obstetrics and gynecology is a matter of safety and quality; indeed it is our ethical imperative.

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Elements of a Successful Quality Improvement and Patient Safety Program in Obstetrics and Gynecology

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No goals in health care delivery are more critical than keeping patients safe from harm during treatment and improving the processes and outcomes of their care. In 1914, Ernest Codman, a well-respected Boston physician, recognized this and stated that ''Every hospital should follow every patient it treats long enough to determine whether the treatment has been successful, and then to inquire 'If not—Why not?' with a view to preventing similar failures in the future.'' When he tried to establish a registry to track the outcomes of clinical care at Massachusetts General Hospital he was expelled from the medical staff and removed from the Harvard faculty. Fortunately he carried on his work elsewhere and inspired others over the years to add to an impressive body of knowledge that now exists about quality improvement and patient safety. Although Codman never used the term ''patient safety'' it is clear from his writings that he considered the safety of the patient as an important outcome of success, and any preventable medical or surgical error as failure [1].

Today, both managers and clinicians in health care are well aware of the importance of patient safety and the need to continuously improve the care that they deliver, and are almost always supported by top leadership to establish processes that address these issues. The establishment of the Joint

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Commission on Accreditation of Health Care Organizations (TJC), inspired by the work of Codman and others, has provided the expectation that hospitals and other health care facilities promote and perform quality improvement and patient safety activities.

Obstetrics and Gynecology as a specialty has an impressive record with respect to Patient Safety and Quality Improvement programs including those sponsored by the American College of Obstetricians and Gynecologists (ACOG). ACOG as well as other women's health specialty organizations around the world are providing educational materials and tools to guide these processes.

In North America, the specialty of anesthesia is credited by many as the discipline in health care that initially focused and published on safety using the term "patient safety." The now well-known monograph by the Institute of Medicine (IOM) of the US Academy of Sciences, "*To Err is Human*," and its follow-up publication "*Crossing the Quality Chasm*," called attention to how common medical and surgical errors are [2,3]. These publications and others [4,5] have put patient safety and the reduction of error at the top of the list of quality improvement efforts.

It is easy to become confused by the lexicon and jargon that exist in the field of quality improvement in health care and forget that all activities, whatever they are called, are ways to improve performance periodically or on an ongoing basis. Berwick's seminal article on health care improvement correctly emphasizes the need to prospectively and continuously improve the processes of care [6]. The best and most effective overall approach to improving quality, however, is to incorporate other important and useful improvement activities, some of which are retrospective and periodic.

Risk management is traditionally performed retrospectively and is one of the activities and terms that may now cause some confusion. Risk management in North America was mainly undertaken to protect institutions from any medico-legal liability as a result of medical and surgical errors. Around the world and even now in North America a more prospective process of *clinical* risk management is being developed to study ways to identify and "manage risk" and prevent errors from happening [7].

Thus quality assurance or QA, continuous quality improvement or CQI, risk management or RM, and patient safety are all part of the lexicon of "improvement" and represent distinct activities in health care delivery. Each has its unique characteristics, strengths, and weaknesses; and each has an important function in the movement to improve health care delivery (Fig. 1).

In this article we present the elements of one approach to quality improvement and patient safety that we believe can be successful and sustainable in the field of obstetrics and gynecology, along with several strategies (and caveats) that have worked and are working in academic and nonacademic institutions in the UnitedStates. Box 1 contains several noteworthy definitions of quality, and is included to provide some additional perspectives on what is meant by *quality* in health care. All of us as

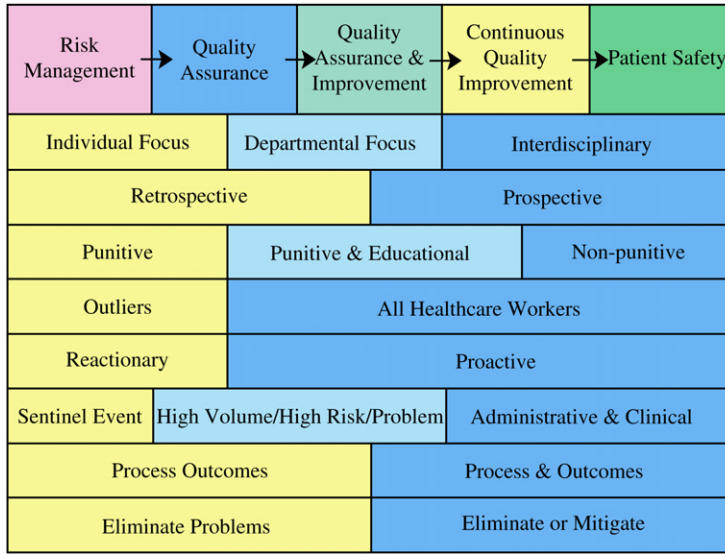

Fig. 1. Comparative characteristics of performance improvement activities, risk management (RM), quality assurance (QA), continuous quality improvement (CQI), and patient safety. (*Adapted from* Berek JS. Berek & Novak's Gynecology, 14th edition. Baltimore: Lippincott, Williams and Wilkins, 2007; with permission.)

consumers can state legitimately that we know what quality is when we see or experience it. The last anonymous definition in Box 1 further implies that consideration of cost or *value* is a necessary component of *quality*.

Three approaches to quality assessment and improvement

Fig. 2 illustrates the continuum of clinical practice presented in the form of a "normal curve" from worst performance on the left to best performance on the right. The three approaches to Quality Assessment and Improvement

Box 1. Definitions of quality

- Doing the right thing the first time—The Joint Commission
- Exceeding the customer's expectations—W. Edwards Deming
- The degree to which health services…increase the likelihood of desired health outcomes and are consistent with current professional knowledge—Institute of Medicine (IOM)
- Doing the right thing; Doing the right thing right; Doing the right thing right the first time; Doing the right thing right the first time and at the right cost—Anonymous

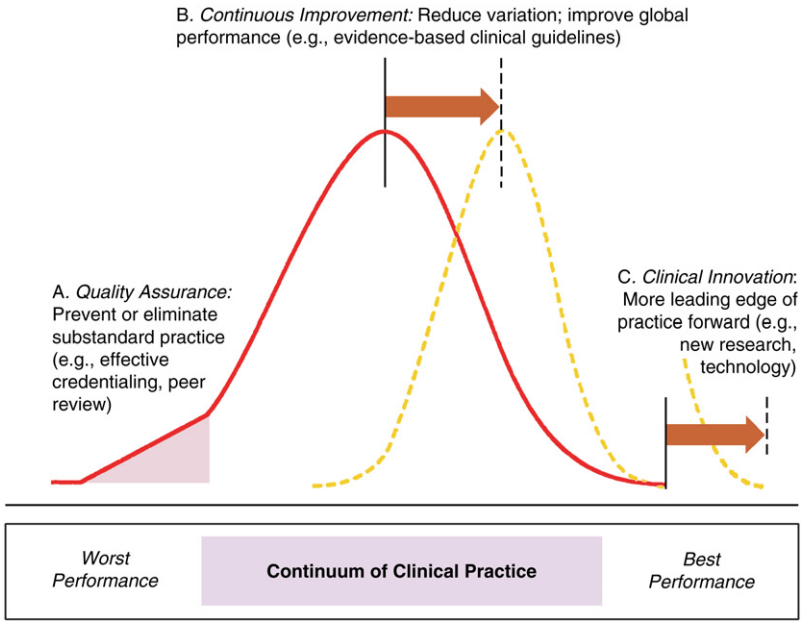

Fig. 2. Clinical improvement activities. Quality assurance (A), continuous improvement (B), and clinical innovation (C). (*Adapted from* Hacker NF, Moore JG, Gambone JC. Essentials of Obstetrics and Gynecology, 4th edition. Philadelphia: WB Saunders, 2004; with permission.)

opportunities are represented as Quality Assurance (A) on the left of the curve, which is designed to prevent or eliminate substandard practice. These activities tend to focus on individual practitioners who are ''outliers'' and may involve sanctions. Such activities include credentialing and privileging, peer review, traditional risk management, and other primarily retrospective tools. Continuous Quality Improvement (B) is prospective and is designed to improve performance in ''real time.'' Activities include evidence-based practice and practice guidelines and efforts to reduce unnecessary variation in health care delivery. The focus of these activities is on ''systems of care'' and teamwork rather than on individuals and punitive measures and sanctions are not appropriate or effective. Usually, a continuous improvement tool such as the FOCUS-PDCA method (Fig. 3) is adopted. The goal of Continuous Improvement activities is to move the curve in Fig. 2 to the right using best-performance standards as benchmarks. Finally, Clinical Innovation (C) on the right side of the curve in Fig. 2, represents best clinical performance and leading edge practice. These activities typically include new ways of practicing, sometimes using research protocols with informed consent, as well as new ways to improve care at the organizational level such as the use of electronic medical records. Note that all of three of these activities, and therefore most opportunities for improvement in health

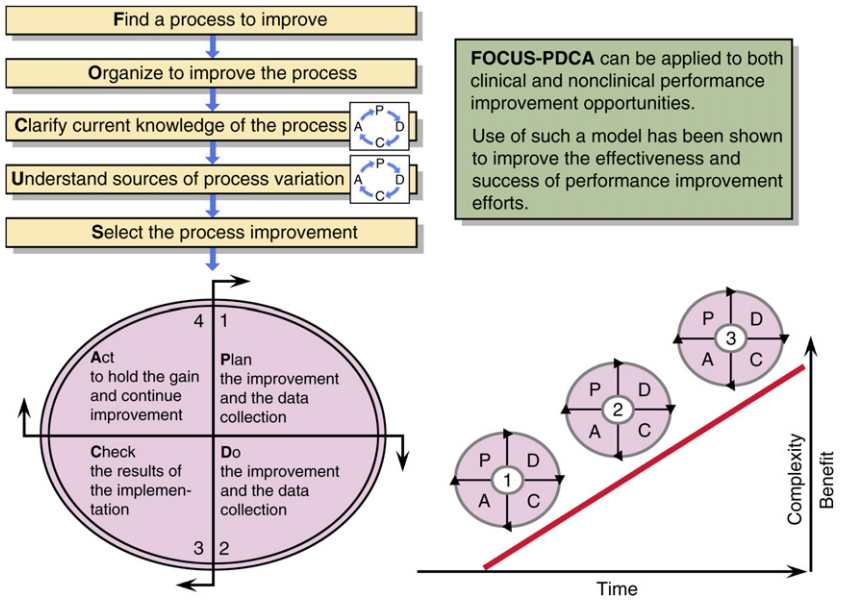

Fig. 3. FOCUS-PDCA. A continuous improvement model to guide the process of making improvements now widely used in health care. (*From* Langley DJ, Nolan KM, Nolan TW. The foundation of improvement. Silver Spring, MD: API Publishing; 1992; with permission.)

care, move the overall standard of care toward the right side of the curve, toward better performance.

Elements of a successful and sustainable improvement program

There are seven elements or steps that can be applied to initiate a successful and sustainable quality improvement and patient safety program in obstetrics and gynecology. These steps are based in part on the *Quality Improvement in Women's Health Care* manual published by ACOG [8] and modified by us for the ACOG postgraduate course on Quality Improvement and Patient Safety. The seven steps are listed in Box 2.

The goals of a quality improvement and patient safety program should also include overall organizational improvement at your institution. Important administrative and nonclinical processes such as appointment scheduling and even food service should be studied and improved because they impact not only patient satisfaction but also the quality of care and affect health outcomes.

Institutions must reduce medico-legal risk by both retrospective review and also by prospective clinical risk management to prevent errors that can lead to harm to patients and to financial liability. However, they need to do this while maintaining appropriate due process for medical and professional staff. Finally, it is becoming increasingly important that health

Box 2. Seven steps for quality improvement

- Getting Organized
- Identifying Priorities
- Measuring Performance
  - Select Quality Indicators
  - Establish Standards
  - Gather and Analyze Data
- Identifying Opportunities for Improvement
- Identifying Breaches of the Standard of Care
- Taking Action and Making Changes for Improvement
- Ongoing Monitoring of Results

care organizations be able to document measured safety and quality (including value) for their customers (patients, payers, and the public). The movement toward "pay for performance" is making this activity essential. For a program to be successful and sustainable all of these elements and activities must be included, performed, and documented.

Getting organized

Obstetricians and gynecologists are usually organized to assess and improve the quality of the care that they provide at the departmental level. To carry out all of the activities outlined in Fig. 1, however, it is usually necessary to participate at the hospital or even health system level.

Health care organizations in the United States have a unique governance structure called the medical staff. Although the ultimate accountability for patient care rests with the administrative "governing body" of a health care organization, this responsibility is delegated to staff clinicians and other professionals as members of the medical or professional staff. This arrangement is designed to maintain independent management and review of patient care so that its quality is not adversely influenced by administrative edicts or inappropriate institutional financial management. TJC requires only one medical staff committee, the executive committee of the medical staff, but it does require a number of important functions such as peer review, credentialing, and quality assessment, and most organizations form separate committees that report to the executive committee to carry out these functions.

Each department or division of a medical staff will usually have its own quality assessment and improvement committee. The chair of the department is responsible and accountable for the assessment and improvement of the quality of care in his or her specialty and how they interact with other departments. The chair usually delegates this activity to a clinical member of the department who should be senior enough to have an impact and

respected enough within the department and throughout the health system to be listened to. A quality assessment and improvement committee is formed and is generally made up of three to five members in addition to the chair of the committee. Nonphysician clinicians who are members of the medical or nursing staff and provide another important perspective are usually included.

Problems can occur when the number of individual practitioners in a department is very small (or direct competitors), making peer review difficult. The important functions of quality assessment and improvement may need to be performed with the help of other departments (eg, pediatrics for obstetrics or general surgery for gynecologic procedures) and external consultants may need to be involved for case reviews. Even if there are a sufficient number of clinicians within the department to conduct important quality assessment and improvement activities, a close relationship with the hospital or health-system–wide program is essential.

Effective assessment and improvement efforts in health care begin at the specialty department or division level and the overall hospital or system-wide program will be significantly weakened and compromised when just one department is not functioning properly. Obstetricians and gynecologists have many resources available to assist them in the development and ongoing function of their quality improvement and patient safety programs.

Identifying priorities

First, the departmental infrastructure should be set up and functioning with appropriate lines of communication well established between departments and with the overall quality program. An early and critical task is the identification of improvement priorities. Important criteria for identifying these priorities include looking at *higher-volume* or frequently performed procedures, those conditions and procedures that are *higher risk,* and *new* or *problem-prone* procedures and all *sentinel events* that may occur. Because administrative and organizational activity can affect health care delivery, *nonclinical performance* processes should also be studied for improvement opportunities.

Willie Sutton, the infamous bank robber, when asked why he robbed banks answered, "Because that's where the money is." *Higher-volume* clinical activities in obstetric and gynecologic practice are good places to start looking for opportunities to improve care. More activity generally increases the odds that there will be more opportunity to improve performance. These could include vaginal deliveries, cesarean and other operative deliveries, and endoscopies. *Higher-risk* patients could include those obstetric patients with preeclampsia or diabetes and gynecologic patients undergoing *new* or *problem-prone* procedures such as new laparoscopic or hysteroscopic techniques. All *sentinel events* or other significant adverse events such as maternal, gynecologic, or fetal death must be investigated by root-cause analysis for improvement opportunities and for meeting TJC reporting requirements.

Departments should also study and improve *nonclinical* processes that may not be functioning well within their specialty or between them and the rest of the hospital or health system. Examples could be their appointment system, the organizational structures of consulting services that they provide or receive from other departments, or the wait times that patients and other customers may experience. All of these activities can adversely affect quality and even health outcomes if they are not functioning at an optimal level.

The process of identifying priorities should spread a wide net across clinical and nonclinical activity and should be performed objectively. There is always be a tendency, albeit unintentional, to select those things that are going well for "show and tell" at your institution. The step of identifying priorities is a key one before beginning the process of measuring performance.

Measuring performance

Without ongoing measurement, the current performance of any activity cannot be adequately assessed or compared. Making improvement changes in any process must begin with data and measurement. It has been said that, "If you don't measure, you cannot manage." Interestingly, managers of quality improvement commonly find that simply measuring a process may lead to improvement. Measuring performance in health care with the intent to improve performance can be facilitated by three activities: selecting indicators, establishing standards, and gathering data for analysis.

A quality assessment indicator is a measurable dimension such as a medical event, a procedure or test, a diagnosis, or an outcome that can be considered an important aspect of care. Most indicators are not direct measures of quality, but rather tools to assess performance on key process and outcomes [8]. QA indicators may be used to identify variance from minimal standards and QI indictors for variance from average or best practices. Table 1 lists examples of quality assessment indicators that are clinical or organizational and either outcomes or processes of care. ACOG provides a suggested list of gynecologic and obstetric (including neonatal) clinical indicators that have been tested, evaluated, and even modified over time on at least one occasion [9]. Starting with ACOG's indicators and modifying or adding to them to accommodate local needs is a good way to begin the process of measuring performance. When new quality indicators are added or existing ones are modified or replaced, the IOM suggests that "SMART" criteria be used to select them: the indicators should be *S*pecific, *M*easurable, *A*cceptable, *R*easonable, and *T*ime-framed.

Establishing standards is necessary to evaluate and compare measurements of quality and to set goals for improvement. Standards may be criteria-based and used to assess the appropriateness of care. ACOG recommends that their criteria-based screening tools (originally called criteria-sets)

Table 1
Examples of quality assessment indicators

	Outcomes	Processes
Clinical	Adverse drug reactions	Patient examination
	Patient satisfaction	Medication administration
	Readmission within 72 hours of discharge for same problem	Meal tray preparation and delivery
	Maternal mortality	Patient/family education
Organizational	Regulatory body citation	Product selection
	Delayed discharge	Preventive maintenance
	Procedure delay	Results reporting
	Staff turnover rate/vacancies	Patient registration
		Sequence of test scheduling
		Recruitment procedures

Data from Kazandjian VA, Strenberg EL. The epidemiology of quality. Gaithersburg, MD: Aspen Publishers; 1995. p. 128, Exhibit 8-1.

be used to assist retrospective review of procedures that have been performed [8]. Standards may also be rate-based and numerical to allow for evaluation of trends, and variance from internal, local or national benchmarks. Performance can be measured and expressed in terms of percentiles or other rate-based numbers for comparison.

Gathering data for analysis from QA and QI indicators through the prism of established standards should be supplemented by other sources of existing data. These may include sources such as log books, informal referrals of cases where there may be some concern about performance, and random chart review. Data for analysis can be enhanced by establishing voluntary incident reporting systems and informal and formal surveys. Also, minutes from other departmental and medical staff committees, such as infection control, pharmacy, and therapeutics, should be monitored by the department quality assessment and improvement committee.

Many hospitals and health care organizations participate in regional and national patient and other customer survey services that can provide objective information about performance. They are usually able to provide very detailed internal and external comparisons for benchmarking. Fig. 4 is an example of survey results for overall satisfaction with obstetric care over time expressed in percentiles for comparison.

Identifying opportunities for improvement

All data gathered from QA and QI quality indicators and other sources of information about performance are then compared with preestablished standards and goals. The quality assessment and improvement committee should then review this information and identify any opportunities for improvement. During this process the initial evaluation should be to quickly

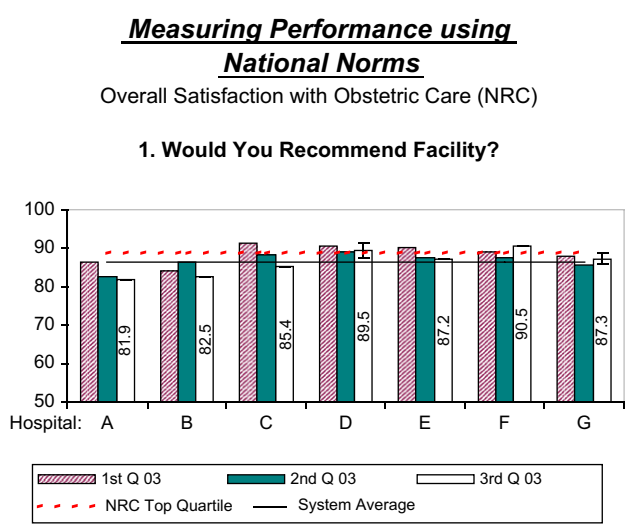

Fig. 4. A comparison by percentile ranking of overall satisfaction with obstetric care among various providers of care designated alphabetically. The survey question was, "Would you use this facility for obstetric care?" and the results are presented over time. NCR is a national clearinghouse for health care quality data.

identify any obvious breaches of the standard of care. These cases should be investigated as outlined in the next section.

Most of the information that is gathered and analyzed about performance will be found to meet the standard of care. Further analysis should then focus on whether any processes of care can be improved based on departmental and health-systems goals or compared with best practice. Many specialty organizations and government agencies such as the Agency for Healthcare Research and Quality (AHRQ) publish and circulate examples of practices that have been found to improve performance significantly. AHRQ's Web site at www.AHRQ.gov (and an outstanding companion site developed by AHRQ that contains evidence-based guidelines, http://www.guideline.gov) contains very helpful information about proven improvement efforts. The Institute for Healthcare Improvement (IHI) at www.IHI.org and the National Quality Forum at www.NQF.org also provide useful information and networking opportunities about quality improvement and patient safety issues.

Investigating breaches of the standard of care

In some cases, an analysis of quality assurance data may identify breaches of the expected standard of care in the community or within an institution. Most organizations use the traditional minimal standard for peer review and others establish higher expectations to qualify for initial or renewed membership on the medical or professional staff. The ongoing

collection of performance information, while it may be threatening and uncomfortable for some, is essential to protect patients from medical error. When breaches are identified, a process of formal peer review should occur. This should start with an objective review of the case(s) of concern. In small departments or when possible conflict may arise the use of an outside reviewer is recommended. Review of similar cases of other providers should be performed for comparison. Many medical staffs have a formal peer review committee that can assist in the process. All of the fair rules of due process should be followed as well as any time-related issues specified in the bylaws of the department and the medical staff.

When appropriate review has established that the standard of care has not been met, a corrective action plan is required. This can involve counseling, additional training, or required supervision in extreme or repeated cases. Rarely, restriction or suspension of privileges may be necessary. Some of these remedies will need to be reported such as restriction or suspension of any privileges for greater than 30 days. Appropriate due process should be followed carefully so as to avoid unwarranted damage to a reputation or litigation.

External peer review is becoming more common as a means of ensuring objectivity when investigating possible breaches of the standard of care. ACOG has a program called the Voluntary Review of the Quality of Care or VRQC that can be used when dealing with multiple quality-of-care issues within a department or when problems are interdepartmental in nature. A small committee of reviewers will perform a site visit after review of any relevant requested documents. This site visit is designed to examine overall care within a department so that individual providers of concern may be objectively compared with their peers and to outside performance. This program is described in detail in the article by Lichtmacher elsewhere in this issue.

Other formal peer-review organizations established by county, state, or national medical societies can also be helpful. They can provide advice about establishing community and national standards of care for use in the peer-review process.

Taking action and making changes for improvement

The key steps that are recommended to move from measurement to management are step 4, identifying opportunities; step 5, investigating standard of care breaches; and step 6, taking action so that appropriate changes can be made for improved performance. In most cases the standard of care will have been met but an opportunity to improve performance beyond minimal or average practice may be identified. Sometimes an obvious quick fix of a care process can be performed. Information about these changes should be communicated through department-wide or in some cases a system-wide education program such as a grand rounds presentation or an "in-service" session so that everyone involved in a process of care can understand and

incorporate the changes. Usually a care process that needs improvement and significant local input will require the work of a multidisciplinary team and the use of an improvement tool such as PDCA (see Fig. 3). A guideline or protocol can be developed or an existing one may be found in the published literature. Frequently specialty groups help to develop guidelines that are tested and available for incorporation into practice. During guideline or protocol development it is important to document the process and communicate the recommended changes widely before implementing any action plan. Results of changes should be monitored.

Ongoing monitoring of results

Periodic review of performance frequently leads to periodic and temporary improvement in health care delivery. Continuous improvement requires an ongoing process that operates on a daily basis to measure, study and then make changes to clinical and nonclinical activities of care. Once changed, these activities must be monitored frequently to insure that patient outcomes are optimized and that any needed refinement of a change is made so that clear evidence of improvement is documented [10].

Quality assurance (QA) and peer review (PR) evaluations and reports are hopefully relatively infrequent, and should be kept confidential. Most states have laws that protect the confidentiality of QA and PR documents and minutes of meetings provided that the health care organization takes steps to keep them confidential. Members of the medical staff or others who participate in QA and PR activities should sign a confidentiality agreement and all documents and minutes of meetings should be marked ''confidential'' and kept in secure locations. When documents inadvertently fall into public hands, courts have ruled that they are no longer protected.

Health care organizations are coming under greater pressure to report the results of the quality of the care that they provide. Information about both clinical and financial outcomes may be requested by payers and ''pay-for-performance'' is becoming a common component of health care contracting and government programs. Hospital and individual provider ''report cards'' are now available in some areas based on public-domain information about outcomes. The quality and validity of these reports can be a problematic because of wide variation in the validity of the measures and the methods used to assess them. The best strategy may be to compile accurate performance information within a department or health system that will more accurately document the quality and value of care that is being delivered.

Additional strategies for success and sustainability

Several strategies may increase the odds that a program for quality improvement and patient safety in obstetrics and gynecology is successful and lasting. One of these is to use a broader definition of health care quality.

A useful framework that delineates and expands the concept of quality in health care is the Six Aims of Quality (Box 3). Developed and published in 2001 by the IOM [11], these Six Aims have been endorsed and approved by the National Quality Forum (NQF), the American Hospital Association (AHA), and the Centers for Medicare and Medicaid Services (CMS). An important strength of the Six Aims, which state that health care quality should be safe, effective, patient-centered, timely, efficient, and equitable, is that they address affordability and access to health care. These characteristics are increasingly recognized as essential components of health care quality and value. Improving clinical and organizational processes to make health care delivery more efficient and affordable is a key to expanding access.

Other strategies have been compiled and deployed in the health system setting by one of us (R.C.R.), which can be used to evaluate and critique clinical improvement efforts. These proven principles of improvement have been selected and modified from multiple leading organizations (health care and non–health care) and authors who have been at the forefront of successful quality improvement and patient safety efforts nationally.

The first principle states that *the centerpiece of improvement work is the core patient care mission of any organization*. Leadership at all levels but particularly at the top of the organization must value and provide resources for significant improvement work. Departmental quality assessment programs can only have limited success without strong and enlightened leadership

Box 3. Expanding the concept of quality

- Developed in 2001 by the Institute of Medicine (IOM)
- Endorsed and approved by the National Quality Forum (NQF), American Hospital Association (AHA), and CMS (Centers for Medicare and Medicaid Services)
- **Clinical Quality** is defined as care that is uniformly:
  - ***Safe:*** patients are *not harmed* by care intended to help them
  - ***Effective:*** based on *evidence* and produces *better outcomes* than alternatives
  - ***Patient-centered:*** focuses on *patient's experience*, needs, and preferences
  - ***Timely:*** provides seamless *access* to care *without delays*
  - ***Efficient:*** avoids *waste* including unnecessary procedures and rework
  - ***Equitable:*** assures *fair* distribution of resources based on patients' needs

The aims establish that **Value** and **Access** are important components of Quality.

at the top of the organization. The second principle states that *improvement work is continuous*. Good enough never is (good enough)! The old adage, ''If it ain't broke don't fix it'' becomes ''If it ain't broke, break it and make it better.'' This is not a call for constant change just for the sake of change, but rather a culture or mind-set that always asks, ''how can we do this better?'' The third principle is that *improvement work and decision making are data- and evidence-based*. Opinion by experts is only acceptable as an alternative for decision making when evidence is lacking. Looking for and creating scientifically valid data that guides the way care is provided is the goal.

The fourth principle states that *quality work should be benchmarked against best practices rather than the average*. Significant improvement in performance and better outcomes are only delayed by striving to just meet the traditional minimum standard of care. Our legal system and its tort process for resolving medical liability fosters the concept that the standard of care is the minimum that is acceptable and required in the community. This legal standard is based on the average (or less) rather than on the performance of those who perform at a much higher level (best practices). Although the necessity of establishing a standard of care is unavoidable for litigation purposes, it is not the most effective way to guide and advance improvement work. The fifth principle states that *the vast majority of improvement opportunities (problems) are seen as involving systems and not individuals*. Considering that any problem is due to a flawed process that can be studied and improved rather than a *guilty individual* who should be blamed and punished is seen as the most effective way to rally teams to improve the way care is delivered. Again, the legal tort system in the United States requires that blame be placed to resolve medical liability cases. This attitude should not affect improvement work. The sixth principle is that *quality is seen as optimizing value and improving financial performance*. This is one of the most important proven principles for improvement. Avedis Donabedian [12], another early pioneer of improvement work in health care graphically demonstrated the difference between optimal (A) and maximal (B) care (Fig. 5). Using limited resources in the face of diminished returns in benefit may be viewed as lower quality. The seventh principle of improvement is that *process owners and teams lead improvement work and take accountability for results*. This replaces the ''Captain of the Ship'' principle that has led to blame, slower improvement, and lower safety over the years in health care and in other fields such as aviation safety [13]. Health care and other forms of high technology practice have become too complex to expect individuals acting alone to perform without error on a consistent basis. A recent study by AHRQ found that nearly 70% of medical errors made by individual nontrainee physicians were the result of human factors such as fatigue or judgmental biases (such as a recent extreme case) rather than a lack of technical knowledge. Practice guidelines and other decision-support systems could help to reduce these types of errors. The eighth principle is that *data transparency is embraced and seen as the foundation of*

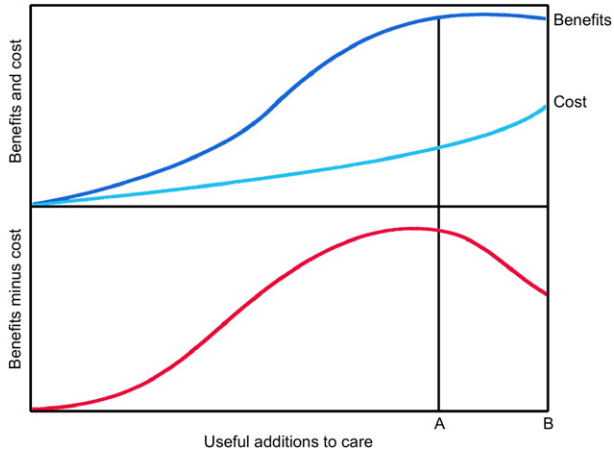

Fig. 5. The optimal (A) versus the maximal (B) benefits and costs of health care. The top panel plots the benefits to health status and their costs. The bottom panel plots costs subtracted from benefits illustrating that maximal care may detract from benefits. (*From* Donabedian A. The quality of care: how can it be assessed? JAMA 1988;260:1743–48; with permission.)

accountability. Internal and even external or publicly distributed information (such as report cards) about safety and improvement efforts is now strongly encouraged and even required. The ninth principle is that *the voice of the customer is included in improvement work*. One of the best definitions of quality (see Box 1) is "exceeding customer expectations," and efforts to understand patient and other customer needs, preferences and expectations are now essential for improvement work. The final and tenth selected proven principle of improvement in health care is that *distinction and fame should be the by-product and not the goal of quality*. This may be one of the more difficult principles to follow. Many organizations view "quality" as a marketing tool and may justify improvement efforts for their public relations value. Leadership and improvement team members should focus on improving processes of care first and then if their efforts result in "good press" so much the better.

One strategy that has worked for one of us (J.C.G.) to increase and energize improvement work in obstetrics and gynecology and other departments in an academic and community health system is the value analysis experience at UCLA Health Care (University of California at Los Angeles Health System). Because members of the medical staff are not always keen to participate in quality improvement efforts, finding an activity such as technology assessment (referred to as value analysis) that is important to them in their practice can be a way to stimulate improvement and patient safety activity. This process, taken on by practicing members of the medical staff eager to get approval for new technology, can result in significant savings and also protect patients from potential harm from invasive technologies that are not effective.

Members of a department or division within an organization who seek approval for new devices or procedures are expected to participate actively in the monitoring process for safety and effectiveness. By making this a condition for temporary approval of technologies that are not clearly proven in independent studies quality improvement and patient safety activities can be embedded into clinical practice [14].

Final thoughts for quality leaders

Leaders in Women's Health Care are fortunate to have the resources of ACOG and other national and local organizations to facilitate quality assessment and improvement efforts. A careful search for quality improvement tools that already exist and have been tested can save valuable time and effort. New tools and methods are being developed frequently and most of them will have value as part of a quality improvement and patient safety program.

It has been pointed out by Stephen Covey, a noted management expert, that every system is perfectly designed to achieve precisely the results that it produces. When results and outcomes are not as good as they should be, the problem is much more likely to be systemic than due to individual providers. Good people working within a flawed system will produce less than optimal results. Redesigning health care systems based on honest measurement will frequently result in improved performance and outcomes. Blaming individuals when problems are systemic is not likely to result in productive change and can do harm by making the process threatening and punitive.

And finally, intelligent, data-driven decision making is the only path to continuous improvement. One definition of insanity originally attributed to Benjamin Franklin is "doing the same thing over and over and expecting something different (and better) to happen." Following the steps and principles outlined in this article should help to establish an effective and sustainable quality and safety program in obstetrics and gynecology departments.

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Quality Assessment Tools: ACOG Voluntary Review of Quality of Care Program, Peer Review Reporting System

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The concept of the Morbidity and Mortality conference is well-known to every physician in training [1,2]. Its purpose is to review the care rendered to a patient and to use the experience as an educational tool. As an adjunct, peer review activity represents another opportunity to review the care provided by individual physicians and systems and to use the process as an educational tool to improve care and assess the physician's clinical practice. This evaluation of clinical activity is a required function of the medical staff [3]. Peer review in the hospital setting has traditionally been performed as a retrospective process. It was generally prompted by some type of adverse outcome and usually included an assessment of the medical record documentation and a gathering of input from involved providers. The purpose of these activities is to provide an opportunity to learn from possible errors and initiate some type of remedial activity to potentially prevent a similar problem from recurring in the future.

The peer reviewing the care provided was usually a colleague or sometimes a competitor practicing in the same institution. Some hospitals with a small medical staff had no available peer practicing in the same specialty and therefore appropriate expertise and training were sometimes not available. The process was hampered by the peer reviewer's lack of clinical knowledge. Additionally, experts were often reluctant to criticize the care provided by a competitor or colleague because of fear of legal or social repercussions if an unfavorable assessment occurred from this review.

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Therefore, the problems identified were often deemed to be acceptable complications or risks of the care provided and not preventable, and no remedial or corrective action or system change occurred. The end result was that no constructive change would be effected and the problem was destined to repeat itself. Although large institutions may have had professional staff who possessed adequate skills to critically evaluate local care, these were also somewhat hampered by local relationships. No true national peer review programs were available for local institutions to objectively evaluate their delivery of obstetric and gynecologic care and benchmark against nationally accepted standards.

In response to this need, the American College of Obstetricians and Gynecologists (ACOG) introduced the Voluntary Review of Quality of Care (VRQC) program [4]. It became one of the early true national specialty peer review programs that allowed physicians at local hospitals access to peers within their specialty who could be impartial in their evaluation of an obstetric and gynecologic program, brought a broader perspective that was not influenced by local medical practice customs, were experienced in peer review activities, and possessed a broad clinical experience. The program is backed by evidence-based literature, and uses clinical information that is available to all fellows of the American College of Obstetricians and Gynecologists and the general medical community.

The program began in 1986 and has matured over the past 20 years. The process has been refined in response to changing trends in clinical practice and evolving medical knowledge. The scope of the reviews has also changed over the years, as evidenced by the elimination of focused reviews, which were performed between 1993 and 2004. They were narrow in their scope and evaluated a specific problem or individual physician. They were eliminated because the program participants recognized that evaluating a specific physician without having a broader view of how the obstetrics and gynecology department functioned within the context of the entire system resulted in an uneven application of recommendations. Most reviews were comprehensive and are the only type performed today. The basic concept, however, has remained the same over the years.

How the process works

The review is initiated by a hospital that makes a request to ACOG to perform a VRQC review. The request may be made because of a poor clinical outcome, a problem physician, difficulty with a particular procedure, or simply a desire to have an outside perspective on how the department of obstetrics and gynecology is performing. Occasionally a regulatory agency or the institution's professional liability carrier, in response to a poor outcome, requires the hospital to invite an outside review that is objective and unbiased. Problems that prompt the call for a review can take the form of clinical issues, such as a high cesarean delivery rate, or occasionally

behavioral problems that the hospital's normal processes have been unable to correct. Very often the local institution lacks the available tools, impartiality, objectivity, or available clinical knowledge to perform a self-assessment. In these cases, the hospital's leadership seeks an outside expert to assess the clinical outcomes, evaluate the function of the obstetrics and gynecology department, and determine whether they meet expected national outcomes.

Once the review is scheduled, the hospital is requested to provide background information, including demographics on the local community and the hospital itself, and available local medical resources. Information on the obstetrics and gynecology department membership and the clinical data for the individual members of the department are requested. Aggregate clinical information is also collected, allowing for comparison of the medical practice activity of all department members. Summary totals of obstetric and gynecologic procedures are collected. Difficulty in gathering data is symptomatic of inadequate information systems critical for valid quality assessment. Minutes of departmental meetings and peer review activity are also supplied by the hospital. The team is then selected from a panel of trained reviewers. Team members from various parts of the country are assembled to gather a broad geographic representation of clinical styles. Additionally, reviewers from the same locality and state as the hospital's location are not used to avoid possible conflict of interest. The creation of a geographically diverse team introduces an element of a nationally accepted minimum practice standard that would be expected from any physician practicing good medicine. This system also eliminates any local or regional practice pattern bias that might be introduced in the assessment of the hospital's clinical services. The review team includes three practicing physicians, a nurse reviewer, and a medical writer who acts as the team administrator. Occasionally, a nurse midwife, subspecialist, obstetric anesthesiologist, or family practitioner is added to the team in response to specific concerns in those areas of practice.

The hospital indicates the reason for the review and outlines the areas of concern. A physician member of the review team acts as the team leader and, after discussion with the hospital's representatives, further determines the scope of the review. The review team evaluates the demographic information before arriving on site. The review focuses on the needs of the requesting hospital and the specific clinical areas of concentration are chosen in response to the hospital's requests. An overall assessment of the function of the department is included in the process. A 4-day on-site visit then occurs that includes an introductory entrance conference with the hospital's leadership representatives and the review team. The process is described to the assembled participants and questions are answered. The voluntary and nonpunitive nature of the review is stressed to ease the anxiety that often accompanies any type of outside review. A tour of the facility then allows the team to evaluate the available resources that the local providers can

use in patient care. The next step in the process is confidential interviews conducted with various physicians, including obstetrician gynecologists and other departments, such as anesthesia, radiology, pathology, and emergency medicine, and also clinical, nursing, and administrative representatives of the hospital. This process lasts all day, wherein the review team learns firsthand some of the issues that have prompted the VRQC review. Very often the initial concerns are compounded or overshadowed by other issues discovered by the review team on site. This part may be viewed as a subjective fact-finding mission that helps further frame the issues. Interview of individuals who are intimately involved in a process is a well-established method that is borrowed from the performance of a root cause analysis [5]. In interviewing the hospital's representatives, a clear picture of the core issues is developed.

The next phase in the review process is an objective evaluation of medical records. The selection of specific medical records is based on the nature of the problems that precipitated the review. A group of charts is selected based on a particular procedure performed; this constitutes a study. Medical records are chosen so that each study is conducted in a retrograde manner and includes all physicians in the department of obstetrics and gynecology or, in cases of large departments, involves a representative sample of physicians. An equal number of charts are chosen for each provider for a specifically indicated study to allow an objective comparison of the results of the chart ratings. Each chart and, in obstetric studies, the associated fetal heart rate tracing, are reviewed. A rating of *satisfactory* or *unsatisfactory* is given to each chart for elements of documentation, clinical management, or both based on a consensus of the entire review team. An unsatisfactory rating does not imply substandard care, but indicates that some required elements of care or documentation were missing. The main goal of the review is to assess whether the documentation adequately conveys the thought process involved in the medical decisions, the decisions correct, and the decisions were performed properly. Required elements of documentation and management that should appear in a chart are based on standardized worksheets. These worksheets have been developed from existing ACOG publications and are rooted in evidence-based literature. The absence of these required elements or questionable management of clinical care would result in the assignment of an unsatisfactory rating for documentation, management, or both. This process is the objective portion of the review. Deficiencies discovered in the chart study portion of the review form the basis for some recommendations for improvement in clinical care or documentation. If consensus is reached, problems discovered in the interview portion of the review are the subject of additional recommendations that are formulated based on the collective clinical experiences of the review team.

At the conclusion of the site visit, a brief presentation of preliminary findings and recommendations is offered to the hospital as part of the exit conference. The participants in this portion of the review are usually the

same individuals who were present for the entrance conference. The review team offers recommendations for improvement based on the problems discovered. Off-site, the team reaches consensus about the findings and recommendations, which are collated into a final written report by the medical writer. The report is compiled and further reviewed by the administrative and legal staff at ACOG to be sure that recommendations offered are based on ACOG publications and are consistent. A single final report is provided to the hospital and another is maintained at ACOG headquarters as part of an aggregate collection of statistical data. The review team members destroy or return to the hospital all of the information that was provided to them and any final reports. Strict confidentiality is maintained at each step of the review process. The hospital's leadership ultimately decides how the recommendations made by the VRQC team are shared with the rest of the hospital staff and which changes are adopted. ACOG plays no role in enforcing the recommendations.

Follow-up communication with the hospital occurs some time after the review is completed. Feedback is sought from the hospital as to the usefulness of the review and whether the recommended changes have been implemented. Each member of the review team is also evaluated by the hospital's representatives and the team members themselves. These evaluations are used as criteria for continued participation in the program or promotion to team leader status.

Program organization

The VRQC program falls under the auspices of ACOG's Committee on Patient Safety and Quality Improvement. The director of the program reports to the committee and is responsible for the continued development of the review process. ACOG fellows who practice obstetrics and gynecology are eligible for the VRQC review panel. Inclusion on the VRQC panel is based on the individual physician being accepted for this activity. Application for the program may come directly from a physician or through recommendation from a department chair or other leaders in the specialty. Demonstrated experience in the peer review processes and quality improvement activities and clinical experience are required for inclusion.

A training session for new reviewers and an update for established reviewers is provided every 3 years. Select members of the review panel who have shown extensive experience are included in the subset of team leaders. No academic, administrative, or research experience is required. In fact, an ongoing clinical practice in obstetrics and gynecology is a primary requirement. Physicians who have stopped clinical practice are rotated off the panel to maintain a reviewer pool that is current with practice patterns. In addition to the pool of practicing obstetricians and gynecologists, the panel of reviewers includes a family practice representative, an anesthesia representative, a gynecologic oncologist, a reproductive endocrinologist,

and a midwife. These individuals are trained in quality assessment and are available to participate in reviews that call for specific expertise related to their specialties. In addition to the physician reviewers, the panel includes nursing representatives who are also active in clinical practices and experienced in the peer review process. In addition to training and updating the reviewers, the steering committee for this program is responsible for updating and modifying the worksheets that are used for the chart reviews and the overall review process. This maintenance is performed regularly to keep the worksheets current based on evolving trends in clinical practice and developing medical information.

In the earlier years of the program, the written report provided to the hospital was prepared by the physician team leader. Currently a professional medical writer is included on the team as the team administrator. The reports are now prepared by this individual based on collective input and close cooperation of the team members. These individuals also participate in the training sessions.

Since its inception, the VRQC process has always been voluntary. This nonpunitive approach differentiates this program from reviews that are performed by various regulatory agencies. Reviews that are triggered by regulatory or governmental organizations have potential financial, accrediting, or licensing sanctions attached to them. The VRQC program is fundamentally a consultative service that draws on the collective clinical experience of the reviewers who are its Fellows and offers advice on how to improve the care delivered and patient safety. Recommendations are based on ACOG published literature, which is available to all ACOG Fellows. ACOG as a national specialty organization represents 40,028 fellows and 9536 Junior Fellows [6]. As a national medical specialty organization, ACOG sets a basic expectation for the clinical activities of its members.

Results

Final reports produced as a result of the conducted reviews were archived at the ACOG offices. These reports were the source of the information presented here. An analysis of the first 100 hospital reviews was reported previously [7]. The results of the information presented for the first 100 reviews were summarized from the previously reported series. These earlier reports are no longer available for analysis and therefore any comparisons made between the earlier series and the more recent reviews are based on published information available from the previously reported series and not case review.

According to the most recent data available, 4852 hospitals responded to the American Hospital Association (AHA) survey in 2005, and of these, 2788 offered obstetric services in their facilities [8]. As of the June of 2007, 236 reviews were completed by the VRQC program, representing approximately 8.6% of the United States hospitals offering obstetric

services. Hospitals visited were located in 36 states and 1 United States territory. The geographic and demographic distribution of the VRQC reviews offers a diverse representation of the hospitals providing obstetric services in this country. During the initial years of the VRQC program, the data for the first 100 reviews were analyzed based on a cohort of 3003 hospitals offering obstetric services as of the year 2000 [7]. The updated results of the next 136 reviews are presented here for the first time.

A reduction of 215 hospitals offering obstetric services occurred between 2000, when the initial series was reported, and 2005. This number indicates a decrease of 7.2% of hospitals offering obstetric and gynecologic services during that timeframe, even though the total number of hospitals responding to the AHA survey remained almost the same: 4856 in 2000 compared with 4852 in 2005. The earlier series is compared with the most recent reviews as to hospital demographics and is shown in Table 1. A comparison of the demographics of the first 100 hospitals reviewed in the early years of the VRQC program showed similar hospital size distribution as measured by the number of beds and annual deliveries per institution. In the current series, 11 hospitals visited had associated obstetric and gynecologic residency training programs, representing 8% of the reviewed hospitals compared with only 3% of the hospitals reviewed in the earlier series. There are 251 obstetric and gynecologic residency training programs in the United States [9], representing 9% of hospitals providing obstetric and gynecologic services, indicating that the number of teaching hospitals in this review pool as a proportion of the total number of hospitals reviewed is similar to the general distribution of teaching hospital in the United States. The hospitals reviewed ranged in size from 25 to 1392 beds, with a mean of 220 beds in the most recent series, compared with a range of 42 to 850 beds and a mean of 298 beds reported in the earlier series.

Three basic sets of information are presented, including the reason for the review request, the problems discovered by the VRQC team, and the recommendations for improvement. The initial review request came from the hospital's leadership based on its own perceived problem areas. These

Table 1
Comparison of hospital demographics

Hospital demographics		
Number reviewed	1–100	100–236
Year completed	1986–1997	1997–2007
Hospital beds (mean)	42–850 (298)	25–1392 (220)
Annual deliveries (mean)	148–5762 (1365)	54–6365 (1009)
Obstetrics residency (% of hospitals)	3 (3%)	11 (8%)
Family practice residency (% of hospitals)	2 (2%)	6 (4.4%)

The first 100 reviews represent data from Gluck P, Scarrow P (Gluck P, Scarrow P. Peer review in obstetrics and gynecology by a national medical specialty society. Jt Comm J Qual Saf 2003;29(2):77–84) and the next 136 reviews represent data from ACOG files.

may have included difficulties in specific clinical areas, organizational problems, problems with a specific physician or group of physicians, or simply a desire to evaluate how a hospital's obstetric and gynecologic service meets generally accepted standards of care. Although each review was requested by individual hospitals based on their own needs and resulted in unique recommendations for improvement, common themes nevertheless emerged that allowed the reasons for review to be divided into specific categories: problems with resources availability or allocation; behavioral problems, which also included various communication and interpersonal relationship difficulties; clinical management problems, which may have included documentation or management issues; and finally organizational and process-related problems, which may be related to poorly designed guidelines or practice patterns.

The major categories are further differentiated into those that may be impacted by an individual provider's practice patterns and those that depend on systems functions. The reasons given for the requested review did not always correlate with the actual problems ultimately discovered by the ACOG review team. These problems or deficiencies represent the second set of data presented here. The problems discovered by the review team were subdivided into the same type of categories as identified in the first set of data. Finally, keeping a consistent classification, the recommendations given by the review team to the hospital as possible corrective actions were similarly categorized. Two additional recommendation categories were added, including those for improvement in leadership and the establishment and use of clinical guidelines. Because the data are drawn from confidential reports, only aggregate data can be reported. Individual hospital information is protected.

The most frequently cited initial reasons for the review are presented in Table 2. In some cases, multiple reasons were indicated. The most frequently noted area of concern, found in approximately two thirds of all requested reviews, related to the quality of care delivered by the entire department. This concern was related to either a perceived poor outcome or some other local quality measure. In contrast, concerns about individual practice patterns accounted for only approximately one third of all requested reviews. Poor communication among care givers was cited in slightly more than one fourth of all reviews. Individual physician behavior issues accounted for a small number of requested reviews. Various resource allocation issues in all instances accounted for less than 10% of the reasons for review.

Despite the initial reasons given for the reviews, the objective findings of the VRQC team often found a different set of problems. The most frequently occurring problems discovered through the review included various organizational (systems) and clinical issues (Table 3). Initial evaluation seemed to indicate that individual clinical problems occurred at the same rate as organizational systems issues. Poor documentation of the decision-making process was found in approximately two thirds of all reviews. Management of labor induction was the most frequent clinical issue, with most

Table 2
Reasons for request for review

Reason for review	Category[a]	Responsibility[b]	Percent[c] (%)
Relationships/communication	Behavior	Individual	26.0
Behavioral issues	Behavior	Individual	7.6
Quality of care: individual	Clinical	Individual	32.8
Adherence to guidelines	Clinical	Individual	22.9
Induction of labor problems	Clinical	Individual	16.8
Documentation problems	Clinical	Individual	14.5
Quality of care: department	Organization	System	66.4
Quality of peer review process	Organization	System	14.5
Quality of care: CNM	Organization	System	5.3
Staffing problems	Resources	System	8.4
Increase in size of the service	Resources	System	8.4
Scheduling problems	Resources	System	2.3
Decrease in size of the service	Resources	System	2.3

Abbreviation: CNM, certified nurse midwife
[a] General type of problem.
[b] Impact of problem either individual provider or system.
[c] Percent of 136 hospitals that had specific problem listed as reason for review.

Table 3
Problems identified by Voluntary Review of Quality of Care Program team

Problems found	Category[a]	Responsibility[b]	Percent[c] (%)
Poor MD/RN communication or cooperation	Behavior	Individual	31.3
Lack of team culture or communication	Behavior	Individual	30.5
Disruptive MD behavior	Behavior	Individual	29.0
Poor MD cooperation with others	Behavior	Individual	18.3
Poor documentation of clinical reasoning	Clinical	Individual	66.4
Poor management of Induction of labor	Clinical	Individual	55.7
Poor MD practice patterns	Clinical	Individual	38.9
Poor interpretation of fetal heart tracing	Clinical	Individual	32.8
Poor management decisions for cesarean delivery	Clinical	Individual	32.1
Lack of consent/no discussion of risks or benefits	Clinical	Individual	18.3
Lack of effective QA program	Organization	System	65.6
Lack of effective peer review	Organization	System	59.5
Lack of department leadership/structure	Organization	System	42.0
Policies and procedures are not current	Organization	System	25.2
Poorly designed policies and procedures	Organization	System	22.1
Poor privileging and credentialing	Organization	System	16.8
Lack of department CME	Organization	System	10.7
Inadequate nurse staffing	Resources	System	27.5
Limitations to anesthesia availability	Resources	System	22.9
Poor call coverage or scheduling of procedures	Resources	System	19.8
Poor patient flow/inadequate facilities	Resources	System	8.4

Abbreviations: CME, continuing medical education; MD, medical doctor; QA, quality assurance; RN, registered nurse.
[a] General type of problem.
[b] Impact of problem either individual provider or system.
[c] Percent of 136 hospitals that had specific problem discovered by VRQC team.

errors related to elective inductions that were initiated before fetal lung maturity could be established. Therefore, ACOG published educational bulletins [10] that provide guidance for proper conduct of induction of labor. Problems with this procedure were discovered in more than one half of reviewed hospitals.

Various other specific individual problems were also discovered. Since the objective chart review portion of the VRQC site visit was designed for rating various clinical situations, multiple deficiencies were discovered (Table 4). These individual clinical management problems were mentioned if any providers who had charts reviewed showed unsatisfactory management of that respective clinical situation, even if most handled it properly. Separating and rating the frequency of a particular clinical management problem within a department is difficult.

In contrast to this observation, the system issues discovered are universal throughout the organization, are either present or not, and are not rate-dependant. The most frequently discovered organizational or system deficiency was the lack of an effective quality assessment or quality improvement (QA) program, followed closely by the lack of effective peer review. These weaknesses occurred in almost two thirds of the hospitals reviewed. Because individual providers were viewed as being responsible for how various clinical situations were managed, and with the addition of the various behavioral and communication problems, the individual provider problems seemed to occur at approximately the same rate as the system-wide problems.

In response to the problems discovered by the review team, various recommendations were made for potential areas of improvement. The most frequent recommendations are presented in Table 5, and are subdivided into

Table 4
Clinical problems found by Voluntary Review of Quality of Care Program team

Problems found	Percent[a] (%)
Poor management of induction of labor	55.7
Poor interpretation of fetal heart tracing	32.8
Poor management of cesarean delivery	32.1
Hysterectomy performed despite incomplete workup	16.8
Inappropriate medications use, (eg, oxytocin)	14.5
Poor management of vaginal birth after cesarean	13.7
Poor management of failure to progress in labor	12.2
Poor management of operative vaginal delivery	12.2
Lack of prenatal screening/monitoring	5.3
Laparoscopic complications	3.8
Other surgical complications	3.1
Poor management of pelvic pain	1.5
Poor management of abnormal cervical cytology	0.8
Poor management of urinary incontinence	0.8

[a] Percent of 136 hospitals that had specific problem discovered by VRQC team.

Table 5
Voluntary Review of Quality of Care Program recommendations

Recommendations	Category[a]	Responsibility[b]	Percent[c](%)
Improve teamwork	Behavior	Individual	41.2
Discipline disruptive MD	Behavior	Individual	28.2
Improve documentation	Clinical	Individual	64.9
Improve FHT interpretation	Clinical	Individual	26.7
Improve nursing competency	Clinical	Individual	23.7
Use ACOG documents	Guidelines	System	47.3
Establish/improve Induction policies	Guidelines	System	44.3
Guidelines for oxytocin use	Guidelines	System	19.1
Strong OB leadership process	Leadership	System	38.9
Provide training for OB leader	Leadership	System	38.2
Improve chain of command	Leadership	System	22.1
Improve support from administration	Leadership	System	17.5
Start or strengthen QA process	Organization	System	73.3
Develop effective peer review	Organization	System	60.3
Update policies and procedures	Organization	System	36.6
Increase staffing as per AWOHNN	Resources	System	36.6
Improve flow/facilities	Resources	System	32.1
Improve on call/scheduling	Resources	System	25.2
Improve anesthesia availability	Resources	System	17.6

Abbreviations: ACOG, American College of Obstetricians and Gynecologists; AWOHNN, Association of Women's Health, Obstetric and Neonatal Nurses; FHT, fetal heart tracing; MD, medical doctor; OB, obstetrician; QA, quality assurance.

[a] General type of problem.

[b] Impact of problem either individual provider or system.

[c] Percent of 136 hospitals that had specific recommendation made.

categories that impact either individual providers or the system. Two additional categories were added because they represented a large subset of recommendations; these include issues dealing with leadership roles and the development and use of clinical guidelines. In areas that individual providers can improve, the need for better documentation was recommended in almost two thirds of the reviewed hospitals.

The next most frequent recommendations relate to the development or improvement of the hospital's QA process and improvement of the peer review process. Overall, recommendations that deal with system issues were made more frequently than those that impact individual areas of improvement. Many of these recommendations concerned the need to improve the processes of establishing various policies and procedures and improvements in how hospital staff monitors its adherence to these policies. These activities are important components of peer review and quality improvement. Lack of effective leadership was noted within departments or hospital-wide. Improvements in communication and chain-of-command were also considered to be system issues, because improvements required adherence to policies described in the medical staff bylaws of most institutions and various administrative policies and procedures. Additionally, although some problems

dealt with individual provider practice patterns, recommendations often reflected the need to modify organizational or system procedures to improve quality and safety for the whole department.

Assessment of the results

The strength of the VRQC program is that it is voluntary and the process has no punitive outcomes. The local hospital receives an unbiased appraisal of its obstetrics and gynecology department. This appraisal is based on a national perspective that is free from any regional practice deviations, and it is evidence-based in its evaluation of clinical issues. Some reviews were requested to assess department compliance with ACOG standards. ACOG as a national medical specialty organization does not publish any specific standards that create an expectation for adherence. As a medical specialty organization, it publishes various opinions, educational bulletins, and monographs that update its membership on the current state of medical knowledge and developing trends in practice patterns. These materials are all based on current medical evidence and are updated in response to developing trends in patient care. Despite this position by ACOG, approximately one quarter of the hospitals requested the review to evaluate how their obstetrics and gynecology department adheres to these perceived ACOG standards. The worksheet tools used to evaluate the care provided as part of the VRQC review are based on specialty publications that themselves are created through an evidence-based process. ACOG publications represent a collective body of clinically relevant information that should be the basis of true evidence-based practice guidelines. Appropriate deviations from these patterns may occur, but they would require documented justification for the variation, which is reasonable to a peer who is evaluating the care. The documentation of any episode of care must be clear and concise and convey relevant information that reflects the thought process involved with medical decisions. This national system of peer review promotes the concept that a minimum standard of care should apply to all patients regardless of geographic variation or provider of care.

The reviewed hospitals represent a cross-section of the hospitals delivering obstetric care in this country. Some selection bias may be introduced in the interpretation of the results of this program, because hospitals requesting an ACOG review self-select because of problems they cannot solve. What the hospital leadership perceives as the reason for review is frequently different from the actual problem discovered by the VRQC team, indicating a lack of awareness of problems when relying on an internal self-reported system of evaluation. The issue of the disruptive physician is an excellent example of this underreporting. Reports of disruptive physician behavior are estimated to occur between 3% and 5% [11]. VRQC experience shows that this problem was the stated reason for review in 7.6% of the hospitals. This statistic seems to be similar to the previously reported rates. These low

numbers are generally reported as the products of self-reported surveys; the true incidence may be much higher, because VRQC reviewers discovered evidence of disruptive physician behavior and issued recommendations for improved discipline of these physicians in 29% of the reviewed hospitals.

Another area in which local perception differs from reality is the peer review process within the hospital. Ongoing peer review activity is the responsibility of every hospital's medical staff. The purpose of this function is to maintain a continuous process of self-evaluation and improvement. The structure and process of peer review is often outlined in the hospital's medical staff bylaws or procedure manuals. Although only 14.5% of the hospital reviewed indicated that they had a problem with their peer review process, VRQC reviewers found that approximately 60% of hospitals had ineffective peer review procedures, and issued recommendations for improvements in approximately the same number of hospitals. The ultimate goal of a peer review process is to identify problematic clinical areas, evaluate these problems, and use the information to initiate changes in the delivery systems to improve care. Additionally, the peer review activity relative to any individual provider is used as part of the credentialing process. Although most hospitals outline a peer review program on paper, in practice the various components of the process may fail to interact with each other. Individuals responsible for specific peer review tasks, such as identification of problem areas, collection of data, or review of care, were able to describe their activities but were often unable to describe the entire process and how their roles fit into this system. Frequently, data on peer reviews were continuously collected without any resulting in corrective action. Trending of collected outcomes occurred, but because often no specific threshold was established for when eventual corrective action must be taken, the end result was that corrective action and educational opportunities were applied randomly, opening the entire process to criticism as being unfair. The fear of either social or legal retribution against the medical staff for this uneven application of peer review invariably led to a dysfunctional process.

The continued activity of the VRQC program may ultimately encompass the review of most hospitals that provide obstetric and gynecologic services in this country. In the meantime, it is reasonable to extrapolate the findings of the cohort of hospitals already reviewed to the remainder of the obstetric and gynecologic facilities. The results of these reviews in terms of the problems discovered and the recommendations made for corrective action may indicate the clinical and administrative areas that require improved education or training in this specialty.

A good example of this is the clinical practice of induction of labor. The management of labor induction and its impact on health care has received much attention in the medical press [12], yet the results of these reviews indicate that this clinical area remains one in which appropriate management has not been uniformly achieved. In more than half of the hospitals reviewed, the review team identified problems in the management of labor induction.

A common theme in these reviews was the elective initiation of labor in a pregnancy before fetal lung maturity could be documented. This variation in management caused an increased potential risk to the baby and an increased number of cesarean deliveries [12] with the associated costs and morbidity. This finding may allow for continued educational opportunities in resident education and professional continuing medical education activities to target this clinical issue. This approach to identifying problems and then establishing corrective actions is similar to the process of Root Cause Analysis [13] and is inherent in the peer review process. In this case, a lack of knowledge about appropriate management of labor induction would lead to continued additional targeted educational programs. Subsequent monitoring would then evaluate the impact of this corrective action.

The landmark Institute of Medicine report "To Err is Human" [14] focused public awareness on the issue of patient safety. It also advanced the concept that evaluating and correcting system issues compared with punitive action against individual providers is the preferred method of improving patient safety. The peer review process has moved away from the retrospective review in which focus was invariably on the performance of the individual and has progressed to trending and assessing outcomes as a tool for improvement of patient care and safety. A gradual recognition has developed that system issues are much more frequent and more likely to cause patient problems than are individual providers. This conclusion is partially supported by the outcomes data gathered from this VRQC process. Recommendations addressing systems changes for improvement are more frequent than those for individual provider changes.

Despite a 10-year difference between the first 100 reviews and the more current 136 reviews, the distribution of the results and conclusions has not changed appreciably regardless of the increasing focus on the system rather than the individual. A higher than expected rate of behavioral problems has been found during these reviews. Although more emphasis is placed on systems issues, the lack of proper professional behavior is still a problem that cannot be ignored. Establishing and enforcing specific expectations of behavior must remain a priority.

Although various data are available on the clinical activities of hospitals around the country, these types of data are usually generated because of a mandatory reporting requirement established by regulatory or governmental agency. Occasionally, the data are used as a financial tool to either reward or punish the hospital. Thresholds are established at arbitrary levels indicating what is considered a satisfactory outcome. A rate of cesarean delivery is an example of a widely reportable statistic for each hospital. National goals for cesarean delivery rates have been established [15] based on no specific clinical evidence. For 2010, the goal was set for achieving a primary cesarean delivery rate of 15%, although the country does not seem to be meeting that goal [16]. In contrast to this practice, the VRQC program assesses the process of delivering care. No specific outcomes are deemed

either satisfactory or unsatisfactory; rather, the process itself is reviewed. Evaluation of clinical processes is more time-consuming compared with the easy retrieval of arbitrary outcome measures, but more accurately reflects quality of care.

Summary

The involvement of peers who are experienced clinicians and well versed in the peer review process is the hallmark of the VRQC program. The nonpunitive and voluntary component of this process makes it more acceptable to local practicing providers. Recommendations are viewed as constructive, in contrast with the punitive changes imposed by regulatory agencies. As the program continues to expand and enough information is gathered, some broad conclusions can be made about the care delivered by hospitals. A frequent question asked by a hospital requesting a VRQC review is "How do we compare with other hospitals?" The question itself may be misdirected. To create a completely safe environment for patients, the ultimate goal of institutions should be the elimination or correction of all problem areas, rather than stratifying how one hospital compares with another. The growing pool of data may be used to identify areas requiring correction and improve the care and safety of patients. The VRQC model has shown that a discrepancy exists between self-assessment performed at the local level and the findings of a national, objective review process. This model may be one that can be adopted by other national medical specialty organizations as a tool for peer review and continuous improvement. The peer review process is the first and an essential step in any program designed to improve quality and safety.

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