Legal Aspects of Medicine

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Editors

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Including Cardiology, Pulmonary Medicine, and Critical Care Medicine

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This book is dedicated to the memory of Dr. Vevaina's late father, Dr. Rustom C. Vevaina, MB, MRCP (Lon), DTM., DTH (Lon), DPH (Bom). It is also dedicated to his devoted mother, Goolcheher Vevaina, and his lovely daughter, Zena.

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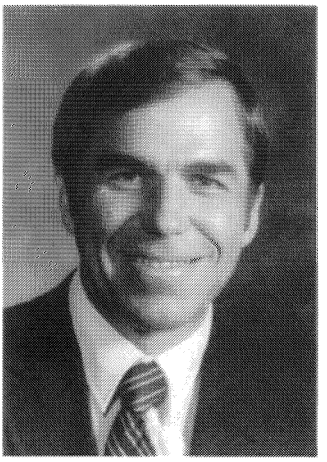

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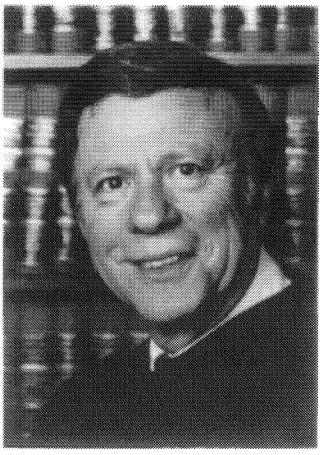

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Preface

The simple reason for creating this book was my impression that the law is having an increasing impact on the practice of medicine. There is hardly a physician I know who has not been deeply troubled by legal problems professionally, economically, and most important of all, psychologically. The past decade has seen medical practice premiums steadily rising. Multimillion dollar verdicts have not been unusual. Having disregarded these vital issues for many years, physicians have suddenly become very aware of litigation-related problems.

Having been interested for a long time in the logic of the law and the romance of legal research, I thought it would be useful to create a book that would result in the blending of great minds in law and medicine. It has been my long-standing observation and belief that the approach of professors of medicine, and that of learned members of the bar and bench, when put together, produce unique results. Putting these views together has been the real challenge in editing this book.

During the 52nd Scientific Session of the American College of Chest Physicians, I proposed the idea of producing a book on the subject of law and medicine to my distinguished friend and mentor Professor Roger Bone of Rush Medical College. After listening patiently to my ideas over lunch in a busy downtown San Francisco restaurant, he asked me what kind of legal help I was going to secure. I said, "I will try for the very best." He then graciously agreed to edit the book with me.

During that meeting of the college, I invited some of the most renowned chest physicians in the country to contribute to the book. I was honored by the large number of distinguished physicians who agreed to support the project and contribute their knowledge and experience to it. Dr. H.J.C. Swan, the innovator of the balloon-flotation catheter, agreed to describe in his own words how he conceived the idea of floating a catheter into the pulmonary artery (Chapter 14). Dr. Cyril Wecht, who is one of the pioneers in forensic investigation and in revealing the mysteries revealed by postmortem examination, also agreed to give the benefit of his years of expertise to our readers (Chapter 15).

A fortunate turn of events in the development of the book was the

acceptance of the joint editorship by the Honorable Justice Edwin Kassoff, Presiding Justice Appellate Term of Supreme Court of the State of New York. In turn, Justice Kassoff invited distinguished judges and attorneys to add that perspective that only legal minds can contribute.

How has the law impacted on medicine? New government laws and regulations have had a deep impact on medicine. Biomedical technology and research have created new questions that have not been considered before. Almost all of medicine is undergoing future shock. We accepted birth and deaths as normal incidents in our daily practice. Now, we can keep five 2-pound babies delivered together alive, yet to die in a United States hospital requires the whole retinue of doctors, nurses, and therapists, a minimum of an arterial line and ventilator, and the inevitable Swan floated in just before the moment of peace, and even then there may be questions (on which extensive monographs are written) as to whether death has occurred at the moment declared. A new area of medicine created by critical care specialists is when and how to "withhold and withdraw" life support systems that we hook our patients up to. Chapter 23 explores this topic.

The spread of the acquired immune deficiency syndrome (AIDS) has created new problems for doctors and law enforcement agencies. The criminal law is now involved with prostitutes and homosexuals who can spread the disease. Lawsuits from AIDS-related litigation are predicted to give away the courthouse. The legal aspects to this subject are covered in Chapter 28.

Yet another medicolegal problem is the devastation caused by asbestos years after exposure. As stated in the chapter on asbestos, the outcome from asbestos-related litigation is determined more by medical than legal points. The number of awards and their size has brought at least one giant corporation to its knees. Compensation for occupational lung diseases is in a state of flux and confusion and needs fresh legislative action. In Chapter 20, both legal and medical perspectives are discussed.

Has malpractice litigation caused the face of medicine to change? Definitely yes! At one time the welfare of the patient and his recovery were the only concerns of the doctor. Now, the doctor practices in the industrial-medical complex, and a much deeper concern occupies his mind. Even the most courageous doctor shudders at the thought of walking up those large steps of the local courthouse to confront his adversary, who will relentlessly pursue the case against him for large sums of money. Every doctor will be better equipped to deal with such problems by the insights given by the authors, and decisions of the highest courts of the land cited by them. Chapters 1 through 6 explore different facets of medical malpractice.

Where do we go from here? Certainly "risk management" programs have an important part to play, which is why I asked Michael S. Kaminski, the President and Chief Executive Officer of Flushing Hospital Medical Center, a major teaching affiliate of the Albert Einstein School of Medicine, to give us a chapter on the subject (Chapter 8).

I trust this book will be of interest to all who work in the fields of law and medicine, and particularly those who specialize in the fields of cardiology,

pulmonary, and critical care medicine. I believe that agencies analyzing and reporting such cases should find it a valuable reference. This book is also intended to cater to the needs of paralegals, nurse-attorneys, hospital risk managers, administrative personnel, and the intelligentia of the medical and legal communities. Finally, it is also my hope that by bridging some of the gaps between law and medicine, I would be able to generate further thinking and new legislation to replace the now antiquated tort system by a new and less traumatic system to compensate the injured and unfortunate quickly.

Most of all, every citizen ought to be aware of the working relationship between himself and the professions of law and medicine as relevant to medical care, and the special concerns of antitrust law and prescribed drug-induced illnesses.

I thank Rosemary Bone, who supported this book from the outset, and Phyllis Kassoff, whose ideas were instrumental in shaping the development of the book.

I owe a special thank you to my two efficient secretaries, Virginia Gallo and Anna Maneri, who gave so much of their time and energies to the book.

Finally, I sincerely thank all the eminent contributors for their useful and thought-provoking views.

Flushing and Great Neck, New York JAMES R. VEVAINA, MD

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Part I Law in Medicine: An Overview

1

The Evolution of Medical Malpractice Law

MELVIN M. BELLI, SR., JD

Medical malpractice laws can be traced back more than 4,000 years. The Code of King Hammurabi, 2030 BC, provided, "If the doctor has treated a gentleman with a lancet of bronze and has caused the gentleman to die, or has opened the abscess of the eye of a gentleman with a bronze lancet, and has caused the loss of the gentleman's eye, one shall cut off his hand." (If the patient were a mere slave and his life was lost because of the physician's treatment, the penalty was furnishing the master with another slave.)

The Code of Hammurabi imposed a much harsher standard than we now have. Today a doctor is not liable unless he was negligent or otherwise at fault in caring for or treating the patient; under the Code of Hammurabi, only the result mattered, not the doctor's conduct. Hence, a doctor was absolutely liable for deaths or injuries resulting from his actions, even if he did nothing wrong.

The Egyptians tempered the rule by exonerating a physician of liability for unfavorable results, so long as he had followed an established method of treatment for the disease. But even the Egyptian standard imposed severe sentences for errant doctors: for instance, if a doctor deviated from the standard accepted procedure and the patient had the misfortune to die, the doctor risked being beheaded. Roman rules were not unlike present-day standards; under their laws, a doctor was not responsible for malpractice without some type of fault.

The first recorded malpractice case in English law was the 1615 case of *Everad v. Hopkins,*[1] which involved a servant who received "unwholesome treatment" from a physician employed by the servant's master to treat the servant. The learned judge Sir Edward Coke (known as the father of "common law," and at the time Chief Justice of the Court) ruled that the master had the right to sue the physician based upon the contract, but the servant, not being a party to the contract, could not sue thereon. However, Chief Justice Coke stated that the servant, in his own right, had an action on the case for damages done by the treatment.

When I started practicing law in 1933 after graduating from Boalt Hall Law School at the University of California, Berkeley, medical malpractice lawsuits

were few and far between. Practitioners of the medical profession were effectively immune from civil lawsuits except in cases of gross misconduct. There were a number of reasons for this lack of medical malpractice lawsuits. It was not that doctors were not making mistakes back then; the biggest problem was simply finding a doctor to testify against another doctor.

Because medical issues ordinarily are outside the realm of the average layperson's experience, expert testimony (i.e., testimony of other doctors) is needed to establish both the standard of due care required under the circumstances and the breach of that standard. Without a doctor's favorable testimony, a plaintiff generally has little, if any, chance of winning a medical malpractice case. But doctors were unwilling to testify against their colleagues. They feared reprisal or ostracism from the medical community or an increase in their malpractice rates. They also feared what would happen if they were ever accused of malpractice. This led to the development of the well-documented "conspiracy of silence" among members of the medical profession.

In a 1903 opinion, the Supreme Court of Nebraska commented on the difficulty a plaintiff in a medical malpractice action had in obtaining a doctor to testify in his behalf: "We cannot overlook the well-known fact that in actions of this kind it is always difficult to obtain professional testimony at all. It will not do to lay down the rule that only professional witnesses can be heard on questions of this character, and then, in spite of the fact that they are often unwilling, apply the rules of evidence with such stringency that their testimony cannot be obtained against one of their own members."[2]

The Supreme Court of Kentucky likewise acknowledged this "conspiracy" in a 1956 case when it noted that "the notorious unwillingness of members of the medical profession to testify against one another may impose an insuperable handicap upon a plaintiff who cannot obtain professional proof."[3] In 1955, a California appellate court ruled that the trial judge did not err in remarking to the jury that the difficulty of securing a doctor's testimony was well known, as "[i]t was merely an open recognition of the truth of the popular legend that doctors are reluctant to testify to the negligence of their fellows of the same vicinity."[4]

Of the burden a plaintiff had of proving a medical malpractice case, a federal appellate court in 1956 stated: "Malpractice is hard to prove. The physician has all of the advantage of position. He is, presumably, an expert. The patient is a layman. The physician knows what is done and its significance. The patient may or may not know what is done. He seldom knows its significance. He judges chiefly by results. The physician has the patient in his confidence, disarmed against suspicion. Physicians, like lawyers, are loath to testify that a fellow craftsman has been negligent, especially when he is highly reputable in professional character, as are these defendants. In short, the physician has the advantage of knowledge and of proof."[5]

Similar sentiments were expressed in a 1957 California appellate decision: "[G]radually courts awoke to the so-called 'conspiracy of silence.' No matter how lacking in skill or how negligent the medical man might be, it was almost impossible to get other medical men to testify adversely to him in litigation

based on his alleged negligence. Not only would the guilty person thereby escape from civil liability for the wrong he had done, but his professional colleagues would take no steps to insure that the same results would not again occur at his hands. This fact, plus the fact that usually a patient is by reason of anesthesia or lack of medical knowledge in no position to know what occurred to him, forced the courts to attempt to equalize the situation by in some cases placing the burden on the doctor of explaining what occurred in order to overcome an inference of negligence."[6]

I remember the first medical malpractice case I handled: Jeanette Gluckstein was a handsome woman with an English accent that gave one the feeling that here was a woman of quality, and passion. She was a dress designer who had been working in San Francisco for 11 years before she walked into my office.

I asked her what the problem was. She tearfully replied, "I had plastic surgery on my breasts and now they're ruined." After a few more questions and answers, I called my secretary into the office. I asked Jeanette to show me the scars. She unbuttoned her blouse and removed her bra. (My secretary's mouth dropped wide open; she knew nothing about poor Jeanette's dilemma. Unusual happenings are often the rule than the exception in my office, but never before, or since, had I asked a woman to bare her breasts to see if I should take the case.)

The injury to Jeanette's breasts was the more horrendous I had ever seen: both breasts were almost square, one was quite larger than the other, the nipples had been sliced off and reattached inches higher than they should have been, and the nipples looked inward. Jeanette also had a large gash running from her breast to her pubes. I asked whether the good doctor had done that, too. She nodded affirmatively.

We sued for $250,000, an unheard of figure for the time. At trial I presented the only doctor I could get to testify. I called him "Clean Him Up" Smith because I had to clean and sober him up before I could put him on the stand. He had been a pariah in his profession, ostracized for being the only doctor around who dared testify against another physician. "Clean Him Up" testified that the doctor had "cut too much fat away," that he had cut the fat instead of "tearing it," and that this cutting process had created minute adhesions, perhaps as many as 500.

"It was simply not good plastic surgery on the abdomen," he testified, "and as for the breasts, nothing was accomplished. Right now all this woman has is a couple of bags of degenerative tissue and the cutting has shut off the circulation of the nervous system."

"What effect does that have on Miss Gluckstein?" I asked.

I was as surprised as the jury at the doctor's response: "It means there's no more titillation in the tits." It sounds funny now, but when the doctor said this on the stand, it was a quiet, somber moment, the staid jury carefully and thoughtfully weighing each word they heard.

During cross-examination, one of the first questions the defense lawyer asked "Clean Him Up" was, "How long have you been off probation?" The defense lawyer also asked Dr. Smith if it wasn't true that he had been testifying

in all types of malpractice cases against doctors for over 20 years. Dr. Smith wouldn't let himself be bullied. After all, he hadn't done anything wrong; the physicians who had committed malpractice and those who had covered up for them were the guilty ones. Dr. Smith replied, "Yes, we had one case in Stockton a little while ago—27 doctors in Stockton and the poor boy that lost his arm, and they couldn't get one doctor to say a good word for him, not one doctor. They were all told that if they testified their insurance would be cut off."

The case also presented an unusual problem in adequately demonstrating to the jury the bad result. I had some pictures of Jeanette's breasts, but the defense lawyer was claiming that she had fully recovered and looked "a lot better than in the pictures." I knew that if I could somehow get the jury to view Jeanette's breasts, they would see and appreciate the extent and permanency of her injuries. I asked the judge for a brief recess so counsel could confer with him back in his chambers. In chambers I asked the judge for permission to have my client bare her chest in open court, arguing that "a person has the right to show a jury what she suffers." The judge thought it over for a few minutes then said, "A jury maybe, but not an entire courtroom."

I looked at the judge and said, "Okay, just the jury then. In chambers." When I noticed the judge hesitating a bit, I quickly added, "One by one, with a lady bailiff in attendance."

The judge granted this request. Jeanette was brought into chambers, disrobed, and covered by a sheet. The jurors filed into the judge's chamber one by one, the bailiff pulling down the sheet for each one to see, then covering Jeanette again until the next juror came by to stand in front of her. Jeanette stood there like a statue, face scarlet, head down, her eyes filling with tears, the water running down onto the scars on her breasts. The jury awarded her $115,000, a sizable verdict for the time.

Has the law encroached too much upon the doctor's domain? I really do not think so. Stories are circulated of doctors retiring early because they cannot afford their malpractice premiums. One wonders whether the real reason might not be that the doctor has not kept up with all the changes in medicine since he graduated from medical school.

Today's doctor can expect sometime in his career to face a potential malpractice lawsuit. Fortunately, good lawyers will investigate a case thoroughly before filing suit to make sure there are sufficient legal, and medical, grounds for charging a doctor with malpractice. Doctors who have not committed any wrongdoing will be surprised to learn that their candid cooperation with the plaintiff's attorney during the preliminary investigation often will lead to a dropping of the suit before it is filed. When a doctor refuses to discuss in any way the procedure and the problem, the patient's lawyer usually assumes that the doctor has something to hide.

One thing that strikes doctors who find themselves in the courtroom, be it as a defendant, a plaintiff, or an expert witness, is the different emphasis of the legal profession from that of the medical profession. The American legal

system is an adversarial one. The lawyers for the opposing sides "put on the gloves" and fight it out before the judge and jury. When the judge reads the last instruction to the jury, the jury—12 (although many states now permit as few as six jurors in civil cases) people, ordinary men and women from all walks of life—decide which side has won the battle. Who has put on the better show? Who seems more sincere? Which expert impressed them the most?

It is by no means an exact or predictable process. Sometimes it is downright unfair. But overall, having visited courtrooms and talked with lawyers and judges in countless countries throughout the world, from London and Paris to Beijing and Cuba to name a few, I believe that ours is unequivocally the best system in the entire world. So long as we, the American people, maintain and exercise the right to a trial by jury, a trial by one's peers, I am confident our legal system will remain the paradigm for other countries to emulate.

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Editorial Comment

Internationally known for defending the "rights of individuals" and for representing the rights of victims of personal injuries, has earned for Melvin Belli the title "King of Torts," bestowed on him by *Life* magazine in 1954.

Admitted to the California bar in 1933, Belli began his career as counsel for the Catholic priests of San Quentin prison. Belli took up the challenge of defending men already condemned to die. Since the first case, Belli continues to make an impact in criminal and civil law.

Also known as attorney to the stars, Melvin Belli's famous clients include stars like Mae West, Erroll Flynn, Tony Curtis, and Lenny Bruce. One of his most famous trials included the trial of Jack Ruby for the murder of Lee Harvey Oswald.

Belli has also represented clients in spectacular mass disasters, such as the Korean jetliner disaster, the MGM Grand Hotel fire, the collapse of the Kansas City Hyatt, the Benedectin birth defect cases, and the Bhopal Union Carbide isocyanate gas disaster.

Author of 62 books on civil and criminal procedure, Belli is also the founder

and former president of the American Trial Lawyers Association. He is also on the board of directors of the Barristers Club, and provost of the Belli society. His most famous book is *Modern Trials,* a five-volume encyclopedia.

The name Melvin Belli is on the permanent list of this country's great attorneys. At the age of 80, when most men are content on reflecting on the past, Belli continues to make history.

2

A Judicial Overview of Medical Malpractice

HONORABLE IRA GAMMERMAN

For a period of five years beginning in 1981, I conferenced or tried most of the medical malpractice cases in the Supreme Court of New York County, perhaps the busiest trial court in the United States. The editors of this book have asked that I use that experience to discuss the issues most frequently raised by physicians in the troublesome area of medical malpractice litigaton—alleged excessive awards and meritless suits.

Sensational newspaper stories have created the impression that juries make wildly extravagant awards in cases that have no real merit. This is far from true. Newspapers report only the unusual and the sensational.

In reality, jurors in the vast majority of cases correctly assess both the liability and damage issues. Jurors are fair minded and reasonable. They are not swayed by emotion or sympathy. Time and again jurors have found for defendants in cases involving tragically devastating injuries suffered by children. Indeed, if jurors err, they usually err in favor of the defendant doctor or hospital. In the 6½-month period from January to mid-July 1987, 23 malpractice cases were tried to verdict before me. In all but two, the jury found in favor of the defendants. And my experience is not unique. In a recent study made in our court, it was determined that approximately 75% of the malpractice cases tried resulted in defendants' verdicts.

When a jury does find against the doctor and awards substantial damages, the question is not really what the jury awards but what the court allows. Thus, for example, a recent jury award of approximately $65,000,000 in the Bronx County New York State Supreme Court received widespread publicity. Very little attention was paid when the trial judge reduced that award by 95%. In many jurisdictions jury awards are subject to review by both the trial judge and the appellate courts. In those states, if doctors are unhappy with the size of the awards, their arguments are with the judges, not with the juries. When a jury awards substantial damages, it is usually in a case in which the injuries are severely disabling and the costs of maintaining the injured patient for the rest of his or her life are staggering. Projection of these expenses by an expert economist is customarily made on sound economic principles and is subject to review and verification or dispute by an equally qualified economist retained by the defendant.

Recent legislation enacted in a number of states (primarily in response to pressure from the medical profession and the insurance companies) will serve to further reduce jury awards or the impact of those awards on the medical and hospital defendants and their insurance carriers. In New York State, for example, all jury awards for future damages that exceed $250,000 must be structured, that is, reduced to the present value of an annuity to pay the award over a period to be set by the jury. It is estimated that this will reduce the cost of that part of the award by about 40%. This should, in turn, reduce the premiums for malpractice insurance.

Several states have enacted a cap on awards for pain and suffering in medical malpractice actions. Such legislation appears basically unfair. The pain and suffering that can be inflicted by negligent medical or hospital treatment is sometimes beyond calculation. Should the award for pain and suffering to a bright child trapped in a quadraparetic body because of the fault of another be limited to $250,000 (a figure often suggested)? Why should only the medical profession be insulated in this way? Doctors are not the only professionals who are held legally liable for their negligent acts. Malpractice lawsuits naming lawyers, architects, accountants, and others are on the rise. There is no evidence to support the claim that such a cap will have any impact at all on medical malpractice insurance premiums.

The general impression among physicians that most medical malpractice actions are frivolous is also erroneous. The action against *you* may be frivolous but there are, in fact, a number of doctors practicing bad medicine, negligent medicine who severely injure and, in some cases, kill their patients. The cost of medical malpractice litigation is so high and the chance of success for the plaintiff so low that most lawyers will take only those cases in which the negligence is quite clear and the injuries very severe. Nonmeritorious cases are not settled and are invariably won by the defense.

Legislative attempts to deal with frivolous medical malpractice suits have been either ineffective or counterproductive. Laws allowing damages to be imposed against the lawyer and/or the client who brings a nonmeritorious action have had no effect. Medical panel legislation enacted in a number of states (some of which have wisely abandoned such plans) have not reduced the number of suits instituted. Actually, the panels have delayed resolution of actions, increased the costs of litigation (and, presumably, the premiums charged by insurance carriers), and resulted in substantial prejudice to doctor defendants in a number of cases. For example, in a case involving two defendants, the panel may make a "no liability" finding with respect to only one and make no finding with respect to the second, creating an obviously unfavorable inference.

A panel finding of "no liability" rarely, if ever, induces a plaintiff to drop a lawsuit. A finding of "liability" certainly does not aid in the defense of the case. And, with respect to many defendant doctors, the panels make no findings at all, thus, without producing a result, consuming a good deal of time and costing the litigants perhaps $5,000 to $15,000 (depending on the number of parties participating). Panels have little effect on the outcome of the trial. A

skilled attorney (and both sides are usually represented by skillful counsel) can effectively negate the impact of an unfavorable panel determination. This is well understood by lawyers and insurance carriers. Thus, as a study in our court revealed, settlement patterns are unaffected by panel findings. There is general agreement among judges and lawyers representing both plaintiffs and defendants in the medical malpractice field that the panel scheme is a noble experiment that has long outlived its usefulness and should be eliminated.

What is the doctor to expect from his or her insurance carrier? Substantial premiums are paid. Indeed, it is the increase in premiums that has created most of the concern. The medical malpractice "crisis" is primarily the crisis created by the impact on the doctors' pocketbooks caused by an annual insurance premium that for some specialists approaches or exceeds $100,000. For that premium the insurance carrier, of course, provides insurance coverage up to the limits purchased by the doctor. The carrier also provides a legal defense consisting of attorneys, investigators, and expert witnesses.

The attorneys retained by the carriers are among the best. They are men and women of skill and experience. In some instances, however, conflicts arise between the insured doctors and the insurance carriers; for example, conflicts as to whether particular cases should be settled and conflicts of interest.

Most medical malpractice insurance policies provide that a case cannot be settled without the consent of the defendant doctor. Although no questionable or nonmeritorious case should be settled merely to avoid litigation, the doctor should remember that the insurance carrier and its lawyers have vast experience and are usually in the best position to decide whether a case should or should not be settled. Being sued is not only upsetting and unpleasant, but invariably affects the judgment of the defendant. As the insurance carrier and its lawyer are not personally involved, they can make dispassionate decisions.

There are, however, some cases that insurance carriers should settle and do not, either because the doctors are not sufficiently aggressive in urging settlement or because the carriers are more interested in protecting their funds than in protecting their insured doctors.

A recent example of this was a case involving a very prominent orthopedist and a well-known actress. The doctor, an outstanding specialist in the field of knee surgery (he had successfully operated on the knees of a number of famous athletes), planned arthroscopic surgery on the actress' right knee. He had advised her that there would be little discomfort and that the incision would be minute. When the actress awoke, she was indeed amazed. There was no bandage on her right knee, not even a bandaid. The dressing was on the left knee. Yes, the doctor had performed the procedure on the wrong knee and the patient sued.

The injury was not severe but the liability was clear. The actress' lawyer demanded a substantial sum in settlement and the insurance carrier offered 75% of the demand. The additional 25% was not a large amount. A settlement would have avoided a great deal of embarrassing publicity. The carrier refused to pay the additional 25% and the case proceeded to trial, a trial covered by all the daily papers and local television stations. The jury returned a substantial

verdict for the actress (she was a most persuasive witness), which was reduced as excessive. The actress appealed and the case was eventually settled for somewhat more than the original amount demanded. But the damage to the doctor from the resultant publicity was done, this time not by the plaintiff and her lawyer but by his own insurance carrier. When a doctor pays a large premium, the insurance carrier becomes obligated to act in good faith to protect the insured physician, an obligation not always appreciated by the carrier.

In many cases more than one doctor is sued. All may be insured by the same carrier. It will cost the insurance company less if it hires the same lawyer to represent all the doctors and in many cases that is just what is done. Little consideration is given at the initial stages of the lawsuit to the real possibility that there may be a conflict of interest among the doctors represented by the same lawyer. Occasionally, even after that conflict becomes crystal clear, the insurance carrier still does not take appropriate action to secure a different lawyer for each of its insureds.

One example of extremely questionable conduct on the part of an insurance carrier comes to mind. During relatively minor surgery a patient suffered a stroke and became quadraparetic. Both the surgeon and the anesthesiologist were insured by the same carrier and each had coverage of $1,000,000. For some reason the lawyer representing the injured patient sued only the surgeon within the period provided by the statute of limitations. He was late in suing the anesthesiologist and the action against that doctor was dismissed. The potential jury verdict, because of the very severe injury, certainly exceeded the coverage of the surgeon who was the sole defendant, exposing him to a judgment in excess of his coverage. Even though the plaintiff's lawyer had not brought timely suit against the anesthesiologist, the surgeon had the right to "implead" him as a third-party defendant, thus making an additional $1,000,000 of insurance coverage available and reducing the very real possibility of a recovery that would expose the surgeon to personal liability. An attorney representing only the doctor and not the insurance carrier would have done this immediately. The insurance company and the lawyer it hired to represent the surgeon chose, however, not to implead the other physician. This decision clearly indicated that the insurance carrier was prepared to expose its insured to personal liability rather than risk exposing its additional $1,000,000 coverage, a decision that graphically demonstrated the carrier's bad faith.

Although the above is a shocking example of insurance carrier bad faith, the issue of bad faith arises in almost every major case where the potential recovery exceeds the physician's policy limits *and* the plaintiff's attorney indicates a willingness to accept a settlement within the insurance coverage. Such a situation almost always creates a conflict of interest. The insurance company can lose no more than the policy limit (e.g., $500,000 in the case of some of the older policies). The doctor is at substantial risk of having to use personal funds to satisfy a judgment. The carrier has the legal obligation to act in good faith to protect the insured. To see that this is done, the doctor is well advised in such major cases to seek additional representation by an attorney unconnected with the insurance carrier.

Any professional subjected to criticism can well understand the reaction of a physician sued for malpractice. The institution of such a proceeding can only cause deep concern, anger, and resentment. Remember, however, that a claim of medical malpractice does not involve an attack on the general competence of the doctor sued. The claim relates only to an allegation that the physician defendant departed from accepted standards of medical conduct in one specific case with one specific patient. Indeed, in a number of cases no claim of negligence is asserted at all. A number of lawsuits are based solely on the charge that the doctor failed to provide appropriate information in relation to the risks of a particular procedure and its alternatives before obtaining the patient's consent to the procedure.

It is important, therefore, for the doctor to remain as objective as possible under the circumstances. The malpractice insurance carrier should be contacted immediately and guidance sought from it and the attorney it retains to defend the action. If more than one defendant is named, it is essential that each defendant be represented by separate counsel whose fees are paid by the insurance carrier, unless the interests of the defendants are truly identical: for example, one doctor is being sued only because he or she employed another who is alleged to have been negligent.

It is in the interests of both the medical and legal professions that medical malpractice lawsuits be decided on the merits. To this end, it is important that the doctor understand that his or her role is that of a party or witness. The doctor should not attempt advocacy. All witnesses and parties (be they plaintiffs or defendants) should be guided by the advice of experienced lawyers: Do not argue your case from the witness stand. Leave that to the lawyer. Answer questions without evasion using, whenever possible, terms that are understandable to the jurors. If an error has been made, admit it. For example, in a case involving a prominent neurosurgeon who had inadvertantly left a marking needle in a patient's cervical spine, the jury returned a relatively small verdict (one commensurate with the injury) because of the defendant doctor's candor and honesty. Do not equivocate about insignificant details. Do not dissemble or spar with the cross-examining attorney. Remember, your counsel will always have an opportunity to question you after you have been cross-examined. He or she will know what points to develop. Trust his or her judgment. As I indicated previously, you are being represented by a skilled attorney. You can play a role in advising the lawyer about the medical aspects of the case, but not the legal. And most important, never, never change or alter a record.

Although medical malpractice lawsuits are tried (as opposed to being settled) more often than other personal injury actions, most malpractice cases are settled rather than tried. Thus, it is more probable than not, on a statistical basis, that the defendant doctor will not testify in court. A concern about testifying, however, should not be the basis for settling. If the defendant doctor is convinced that the claim has no merit, it should be resisted. But if the defense is weak or if the trial appears to be going badly, there should be no reluctance to settle.

TABLE 2.1. Analysis of malpractice cases.

Obstetrics/Gynecology	62
Neurosurgery	4
General surgery	14
Orthopedics	28
Internal medicine	12
Cardiac surgery	6
Plastic surgery	16
Cardiologist	3
ENT (Ear, Nose, and Throat)	1
Endocrinologist	1
Podiatrist	6
Neurology	5
Anesthesia	3
Psychiatrist	1
Opthomology	3
Ophthalmology	3
Dermatology	4
Family practition	1
Vascular surgery	2
Urology	3

To be named in a medical malpractice lawsuit is not a disgrace. Many prominant physicians who are leaders in their fields have been sued. Doctors practicing in certain specialties are at a higher risk of suit. Table 2.1, drawn from records of the cases that came before me, reveals that specialists in the fields of obstetrics and orthopedics are more frequently named as defendants. To be sure, there are some doctors who are sued frequently because they practice bad medicine. During the past several years I have become well acquainted with several and, indeed, in one case sent the trial transcript to the state licensing authority. Perhaps the way to control these abuses is to make a hospital liable for the negligence of any attending physician on its staff. In this way, hospital administrators and chiefs of service would be encouraged, indeed required, to take appropriate action to ensure that good medicine is practiced by those doctors associated with the institution.

In the final analysis, the adversarial trial system is effective in resolving medical malpractice disputes. Arbitration or no-fault compensation (as suggested by some) would, in my view, not only be unworkable and unfair but would result in increased insurance costs. Assuming that medical malpractice insurance premiums are based on accurate actuarial assessments, they should be regarded as just another item of overhead. The task of the doctor is to practice good medicine and to deal with patients appropriately without concern or regard for possible litigation. Establish confidence and trust. The doctor who is respected and regarded with affection by the patient is rarely sued.

3

The Defense of a Malpractice Case

HERBERT DICKER, JD, AND JEFFREY D. ROBERTSON, JD

Hippocrates once admonished his physicians to "first, do no harm." But today a doctor who merely fulfills that prologue to the "Healers Oath" will not be immune to a malpractice suit. Nor will the plea that he did not depart from accepted medical standards of care guarantee a defendant's verdict. In an age where there are instant-paid professional experts eager to take the stand, much more is required than merely proof of good medicine. Although there are many meritorious cases that should be compensated, today's doctors must fight an uphill battle against the natural sympathy engendered by the injured plaintiff (patient).

The defense attorney and the defendant have to convey to the jurors both the majesty and the anguish of the practice of medicine. A surgical case, for example, involving complicated procedures and life and death decisions, should ideally not be tried in the courtroom. It should be tried in the operating theater. As that is impossible, counsel must recreate the antiseptic atmosphere of the surgical suite—the sights, the sounds, the deftness, to make the jurors really relate to the physician and his environment.

In this chapter, we explore the legal landmarks of pleadings, depositions, and the trial. We will also make the "grand rounds" of the basic law of malpractice. But to really understand how to defend a case, we must start with the most important body of evidence at our disposal: the defendant. What happens to this proud physician when the process server slaps him with the cold and impersonal stigma of the summons? What happens to his psyche? What happens to him as a witness, physician, and person, when he is suddenly branded a "defendant?" To understand the effects of the trauma of the summons, consider the following poignant words of one doctor sued for malpractice.

The Trauma of the Summons

The unfolded paper in her hand was a summons with an attached complaint that accused her of being a negligent doctor, of being a careless and indifferent physician who had

done grievious harm to Terry Walker. She was being sued for many millions . . . . The psychiatrist stared down at the summons, at the title that had so suddenly been given to her. For unrelieved months and years to come she would be known as the "defendant."[1]

The author is Dr. Sarah Charles, a psychiatrist who was sued for malpractice in a suicide case. Even though she was ultimately exonerated, the experience so traumatized her that she was moved to publish a research paper and a best-selling book on the psychologic effects of litigation on physicians.[2] A survey of 500 physicians was conducted assessing the impact of medical malpractice litigation on their professional practice and personal lives. Subjects were a sample of physicians in Cook County, Illinois, who had been sued during the years of 1977 to 1981. Although this random study cannot be used to generalize the total physician population, it does provide a fascinating and sobering insight for physicians, patients, and their counsel.

Another physician who is also an attorney has astutely observed that:

For the average physician, a malpractice suit is one of the most unsettling experiences in his professional career. From a legal viewpoint, the physician's dilemma and his response are out of proportion to the occasion. Nevertheless, the wound is deep and the physician's behavior throughout the suit is dictated by this pain. The legal community must be cognisant of this reaction. Lawyers realize that the plaintiff's attorney is simply "doing his thing" much as the surgeon "cuts" and the psychiatrist "shrinks" . . . . The surgeon feels he has done his best, his pride is hurt, his ego tarnished and, depending on the magnitude of the problem, resentment is all-consuming. It is within this fragile framework that the plaintiff's and defendant's attorneys encounter the physician. The defense lawyer must have the bedside manner of yesteryear to overcome his client's hostility and find a means of invoking cooperation.[3]

This initial trauma may cause the doctor to withdraw to such an extent that cooperation in his own defense becomes exceedingly difficult. The sensitive defense attorney must explain that this is not a criminal nor a disciplinary proceeding. Loss of license or punitive action is not involved. The accusations should not to be taken personally, but only "professionally." An objective approach will assure that at trial the doctor will be neither apologetic and obsequious, nor hostile and condescending. Neither anger nor guilt are appropriate emotional predicates for defending oneself. Many physicians become so incapacitated by their emotions that they subconsciously suppress important facts. If such facts come to light as "surprise" during a deposition or trial it may be difficult to remedy them.[4]

Some physicians internalize the lawsuit and blame themselves out of all proportion to the magnitude of the suit. This is the time that some fall prey to visions of "correcting" the record. This should never happen! *An altered record can never be justified.* Explanations are usually suspect and suggest an aura of an attempt to "cover up." For some defendants punishment appears as their only salvation. If hauled before a jury at this stage, this mea culpa attitude would guarantee an adverse verdict, despite the existence of a meritorious defense. Defense counsel should help to restore personal and professional

confidence and self-image. Not only will this improve the attorney-client relationship, but it will enable counsel to better implement his defense strategy. A catharsis of the negative emotions is the best prescription.

Sometimes this trauma has even led to tragedy. One physician was recently reported to have taken his life because of an impending trial.[5]

It is therefore not too trite, we trust, to recommend that dealing with the trauma of the summons be the first order of business between counsel and client.

Yet, there must be a quid pro quo between physician and counsel. That price is cooperation. The defendant physician's input is incalculably valuable. There is no substitute for total commitment and cooperation. The defense will be no better than the doctor is willing to let it be. He must be disabused of the notion that he need not be involved because "it's the insurance company's money," particularly in these days of multimillion dollar verdicts. The doctor must recognize that he is primarily responsible for his own defense and must assist in the medical aspects of the case. Ideally, he should provide medical books, review the records, and assist in preparing medical and panel briefs. Such involvement not only benefits counsel, but the doctor himself, for soon he will undergo the legal surgery that lawyers call "the deposition."

The Law

The fundamental concept underlying malpractice actions is *negligence*. Negligence on the part of any physician has been described as "doing something which he should not have done [commission] or omitting to do something which he should have done [omission] . . . ."[6] Although malpractice claims typically arise because of negligence, they may also result from breach of contract or an intentional tort.[7] The fact that a professional's act that causes injury to a patient is not willful but results instead from ignorance or carelessness does not excuse liability. The law presumes and holds all practitioners to a standard of reasonable care when dealing with patients. This standard of reasonableness has been described as follows:

> In the absence of a special contract, a physician or surgeon is not required to exercise extraordinary skill and care or the highest degree of skill and care possible; but as a general rule he is only required to possess and exercise that degree of skill and learning ordinarily possessed and exercised, under similar circumstances, by the members of his profession in good standing, and to use ordinary and reasonable care and diligence, and his best judgment, in the application of his skill to the case.[8]

Basically, a physician has a legal duty of ordinary and reasonable care to his clients once a doctor-patient relationship has been established. If he acts or fails to act in a way that is below standard, then the duty of care is said to be breached. As a proximate result of that breach of care, if a patient is injured, then an action for malpractice may be available.

The plaintiff must prove three basic things to succeed: 1) that a doctor-

patient relationship exists; 2) that there was a duty of care that was breached, a departure from accepted medical standards; and 3) that the breach lead to or was the "proximate cause" of the injury suffered by the patient. All these conditions must be met or there can be no legal recovery. Negligence alone is not malpractice. There must be an injury and there must be proximate cause.

The Complaint

The heart of the alleged malpractice is ostensibly contained in the four corners of the complaint. However, the physician should be advised that the Draconian window dressing of the complaint is often little more than boilerplate allegations used interchangeably from one lawsuit to another. Does the plaintiff seek recovery for negligence, lack of informed consent, wrongful death, breach of contract, assault, or defamation? What are the respective statutes of limitation? Have the elements for a prima facie case been set forth? Is a motion to dismiss for a pleading defect appropriate or will this educate your adversary too soon?[9] In reality, the allegations in these pleadings are only a framework that is fortified during the period of discovery. What about damages? Have specific monetary damages been sought? In some states plaintiffs cannot demand a specific monetary amount in the complaint because it might generate negative publicity against the physician, particularly in a small community. However, a special demand for damages may be served after issue is joined. Do you want to know the damages? Will the request only generate an unfounded multimillion dollar demand and unwanted publicity? On the other hand, is the doctor in danger of a verdict in excess of his policy limits? The answer to these questions will dictate whether or not the defendant may elect to *retain independent counsel* to monitor his interests.

The Deposition

The deposition or examination before trial is the most important part of pretrial discovery. Generally, it is taken in informal surroundings, in the attorney's office. The witness is sworn; testimony is given under oath and transcribed by a reporter. It is the defendant-physician's "dry run" of what he can expect at the trial.

There is a definite psychology to taking or surviving a depositon. Experts disagree on the appropriate approach, which varies from lawyer to lawyer and witness to witness. However, in general, the plaintiff's attorney wants to extract as much favorable evidence as possible from the witness, while defense counsel wants to restrict as much damaging testimony as is possible. Some plaintiff's counsel will try to intimidate the witness. Other will cajole and humor him to become a loquacious and cooperative witness. Whatever the technique, the defendant must control the pace of the questions and extent of the answers. *More cases are won or lost at deposition than at trial.* The doctor must be prepared relentlessly for it.

One of most important purposes of the deposition is its use at trial. A deposition is not an end in and of itself. It is a means to an end: victory at trial. Contradictions between the deposition and trial testimony can be dramatically presented to impeach the defendant. Admissions made during the deposition can be referred to in the plaintiff's opening statement with dramatic effect. It can be used with devastating effect at cross-examination. In one case during her deposition, a plaintiff testified about her lack of informed consent and then added, as she looked at her counsel, "Isn't that what I'm supposed to say?" This was revealed to the jury during the defendant's opening statement and used during cross-examination to impeach her credibility as well as that of opposing counsel.

The Trial

Most malpractice cases are tried before a jury. The applicable adage states that it is a trial by one's peers. However, there are no physicians allowed on the jury. It is really a trial by the plaintiff's peers. The jury is generally composed of citizens from all walks of life. Housewives, civil servants, businessmen, professionals, men, and women of all races and religions comprise the jury panel.

It is interesting and somewhat distressing to note the difference generally found in the attendance of the parties at the trial. From the very beginning, from the "voir dire" (jury selection) the plaintiff-patient is always in attendance, often with members of his or her family. More often than not, the defendant-physician is not present. There may be valid reasons why the doctor cannot be present at any particular point in the trial. The doctor may have appointments that could not be cancelled or broken or scheduled surgery that could not be postponed. However, barring unforeseen emergencies, *it is extremely important for the doctor to be present at the courthouse through the entire trial.* It is psychologically important for the jury to see the doctor present in the courtroom from the very beginning of the trial so that they will understand that he too cares about the result. It is important for the jury to know that the defendant-physician has a profound interest in the progress and outcome of the trial and that he is present to vindicate the propriety of his diagnosis and treatment and the soundness of his medical judgment.

His attendance is also important so that he may hear firsthand the testimony of his former patient and his or her witnesses, particularly in cases involving an alleged lack of informed consent. It is not uncommon for plaintiffs to lie or to fabricate conversations between themselves and the doctor that related to the discussions surrounding the risks and alternatives of the recommended treatment. Even if the plaintiff does not fabricate testimony or lie, his memory may be faulty and his recollection dimmed by the passage of time. Generally speaking, years elapse between the date of the alleged malpractice and the time when the case actually reaches trial. There is no one better qualified to pick apart the plaintiff's testimony in this regard than the doctor, especially where

his records were carefully documented regarding the risks and alternatives of treatment that were described to the plaintiff.

It is a recognized fact that many malpractice cases result not from the doctor's negligent treatment or misdiagnosis, but rather from an unhappy result from the patient's viewpoint. For example, congenital birth defects are often blamed on the negligence of the obstetrician and the pediatrician attending the patient; dissatisfaction with the results of plastic surgery are blamed upon the surgeon. Unfortunate but foreseeable consequences of treatment and/or surgery are often blamed on the physician's negligence no matter how skillfully the treatment or operation was performed, especially where there is no resultant cure.

One of the more critical times for the doctor to be present is when "the battle of the experts" takes place. The jurors, unlearned in the science of medicine, sit impassively through very long hours of direct and cross-examination of experts in the medical specialty field involved. They hear diametrically opposed opinions on the care rendered by the defendant-physician and the proximate cause of such negligent care that resulted in the plaintiff's injuries. The psychologic effect of the defendant-physician being present in the courtroom, looking the plaintiff in the eye as he or she testifies, cannot be overemphasized. The same applies to the testimony of the plaintiff's expert. The jury cannot help but take note of the doctor's presence in the courtroom. They must come to grips with the fact that the doctor cares about the result and is deeply concerned with the allegations leveled against him.

Often, the jury observes a female plaintiff sobbing or wiping her eyes as she listens to her expert testify. She may even break down as she testifies personally from the witness stand. Most jurors would be touched by such a scene, especially when an infant is involved. At least the jury ought to see that the doctor is there; that he has not gone on his merry way cavalierly leaving the defense of the case to his attorney and to his malpractice insurer. The summations at the end of the presentation of all testimony are the final acts on the part of the attorneys before the judge gives his instructions on the applicable law to the jury. Nothing should keep the doctor away from the courthouse at that fateful moment. The defendant-physican must see to it, by his presence, that when the jury retires to deliberate, they do so with the lingering memory of the defendant-physician anxiously sitting in the courtoom watching them rise as they prepare to leave the jury box. Let the jurors remember that there is also another human being, besides the plaintiff, waiting out in the courtoom, one who has sat through a lengthy trial and who only prays that justice be dispensed fairly. Let the jury remember the defendant as he testified during his direct examination and cross-examination in his own behalf with sincerity and dignity.

If the defendant is thoroughly prepared, if he has carefully reviewed the records, consulted with his experts, met with his counsel as the case progressed, and reviewed his deposition and the depositon of the other parties, statistics show that more often than not the physician will prevail.

As evidenced by the European medical schools of the 12th through 14th

centuries, physicians in those days had little worry about professional liability in the modern sense. But why? Do not think that those early healers were not actually conscious of being accountable to their patients. According to *The Astonishing History of the Medical Profession,* by E. S. Turner, physicians of that period were extremely canny in warding off problems of patient dissatisfaction. Perhaps we can still learn some lessons from these ancient healers. We call these rules "How to Make a House Call."[10]

1. Tell the patient that, with God's help you hope to cure him, but inform the relatives that the case is grave. Then, if he dies, you will have safeguarded yourself. If he recovers, it will be a testimony to your skill and wisdom.
2. When feeling for the patient's pulse, allow for the fact that he may be disturbed by your arrival and by the thought of the fee you are going to charge him.
3. Do not look lecherously on the patient's wife, daughters, or maidservants.
4. Do not disparage your fellow physicians. If you do not know them personally, say you have heard nothing but good of them.

According to our sources, by following these suggestions, no feudal physicians suffered any million-dollar verdicts. But times have changed. Although we recognize the patient's right to sue, we also look back nostalgically at the good old days of the "House Call" and wonder whether or not it is too late to bring them back today.

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4

Tort Law as It Applies to Medical Malpractice Litigation

TROYEN A. BRENNAN, MD, JD

Tort law is the law of compensation for accidents that involve damage to a person or property. Black's law dictionary defines a tort as a private or civil wrong or injury for which a court will provide a remedy in the form of an action for damages. Although sufficiently broad, this definition does little to inform the non-lawyer about the complex role played by tort law in our society. Indeed, whereas the task of tort law as defined by Fleming as "determining only whether a particular loss sustained by an individual should be left to lie where it fell or be shifted to someone else branded a tortfeasor"has remained the same over the past two centuries, the principles used by judges to determine the scope of tort law have changed dramatically. Thus, although tort law is simply that area of the law that deals with unintended injury, one can best understand its importance and significance only by examining its historical evolution.

Legal Concepts and Tort Law

Before turning to an historical analysis, however, it is important to become familiar with the basic elements of a tort suit. In Anglo-American law, judges and lawyers rely on the common-law tradition. The common-law tradition entails reliance on legal doctrines developed over centuries and evinced in judicial opinions. These earlier opinions, or precedent, define the parameters of any legal action and provide the doctrines on which judges rely. With regard to tort law, the common law states that the plaintiff, or injured person who brings a suit, must prove four elements in order to gain compensation from the person who injured him or his property, called the tortfeasor.

The first element that one must show is that the tortfeasor had a duty to conform to a certan standard of care. For instance, in a medical malpractice case, the plaintiff must prove that the doctor had a duty to fulfill a standard of care. Second, the plaintiff must prove that the tortfeasor failed to obtain the required standard of care. Third, the plaintiff must prove that there was an

actual injury. Finally, he must show or demonstrate a link between the failure to attain the standard of care and the injury. This link is referred to as a proximate cause.

In essence, tort law concerns a duty that is imposed by law and breached by the tortfeasor. The breach of the duty, also called negligence, must also be linked to an injury suffered by the plaintiff. This link is the proximate cause, which is best defined as that event without which, or but for, the injury would not have happened.

For example, a man enters a hospital to have elective gallbladder surgery. On the day of his operation, there is a confusion in the operating room, resulting in mistaken identification of two patients. The person who was to have his gallbladder removed instead has a below-knee amputation. He sues because he believes he ought to be compensated and the cost of his injury shifted to the hospital and doctors. He shows first that the hospital's standard of care was such that patients are not to be misidentified. Second, he shows he was misidentified. Third, he demonstrates his injury, the lost leg. Fourth, he proves he lost his leg because of the misidentification; the hospital's negligence with regard to patient identification was the proximate cause of his injury. The injury would not have happened for but the hospital's negligence. This is an example of tort law as we understand it today.

In medical malpractice litigation, the threshold question is usually the standard of care. Doctors have a duty to exercise a reasonable standard of care. Litigation occurs when patients believe that doctors have breached that duty. The court allows doctors themselves to set this standard. Thus, in a malpractice case, the plaintiff or patient must provide expert testimony that the standard of care was not met, and thus that the doctor was negligent. Negligence means only that the doctor breached his duty to attain a certain standard of care; it does not mean willful, deliberate, outrageous, or intentional conduct. The fact that a doctor was not paid does not relieve doctors of the duty to attain a reasonable standard of care.

All of this might seem foreign to doctors. The legal process relies on an adversarial system, in which truth emerges from argument. The art of persuasion is essential. Doctors sometimes try to think of law in terms of the scientific method. This is a mistake as legal logic is much different than scientific logic. Law must be understood in terms of its own process.

History of Tort Law

The doctrines of tort law were much different 150 years ago. At that time, tort law was much like criminal law in that it dealt with vengeance and deterrence. In fact, the major difference between criminal and tort law was the nature of the sanctions imposed. Tort law was imprecise and tort liability was often found without consideration of fault. The issue of a standard of care and a duty to conform to it was addressed only when courts dealt with carelessness by professionals such as innkeepers, doctors, or pharmacists.

With the industrial revolution, tort law began to evolve into a more comprehensive set of doctrines. Mechanization and transport created a greater potential for accidental injury. Courts were asked increasingly to hear cases brought by individuals injured by industrial concerns. Judges were, however, influenced by notions of social Darwinism and individualism. As a result, they were willing to let the injured bear the costs of injury unless the injured party could show fault on the part of the injurer. In short, proof of fault required demonstration of a standard of care that was not met, or intentional harm on the part of the injurer. Potential tortfeasors, or those accused of causing the injury, were protected by defenses of contributory negligency and assumption of risk. Thus, the plaintiff encountered large obstacles when bringing a tort suit.

In this century society in general, and judges in particular, have come to understand tort law as a method for spreading the losses caused by accidents, as well as a means for providing deterrence signals for those who cause accidents. Workers' compensation removed work place injury almost entirely from the realm of torts by providing an administrative, no-fault scheme for compensation of injury. Automobile accident litigation and product liability became the major paradigm of tort ligation. Lead by the progressive California Supreme Court, judges across the country overturned the traditional defenses of assumption of risk and contributory negligence. Judges began to focus on the spreading function of insurance and became more willing to shift the cost of accidents to tortfeasors. In addition, the concept of fault was dropped out of certain classes of cases as judges found defendants strictly liable, or liable without fault, especially in cases involving hazardous enterprises.

Tort Law Today

This reform of the rules of tort law has continued until today. Encouraged by academic characterizations of tort law as analogous to social insurance, judges have accepted innovative theories of causation and liability in litigation about hazardous substances. For instance, in drug product liability cases, judges have not required that plaintiffs prove which of several similar brands of the drug diethylstilbestrol (DES) actually caused an injury, but have instead said that the drug companies who produced brands of DES are liable according to the size of their market share. Thus, if a woman proves that she suffered injury as a result of her mother's consumption of DES, she need not prove which company provided the drug, but sues all of the companies who produce the drug and collects her award on a percentage basis from each company. In another case, the New Jersey Supreme Court has said that foreseeability is not a defense for asbestos manufacturers. This means the manufacturers are liable for injuries caused by asbestos even if the manufacturers could not have foreseen that the substance was dangerous at the time it was marketed.

With regard to medical malpractice, there have been many reforms in the past few years. Courts have increased the use of the concept of res ipsa locquitur. This is the doctine that "the thing speaks for itself" and it means

that if an injury occurred, and it is out of the ordinary, the standard of care must have been breached. For instance, when the patient admitted for gallbladder surgery has his leg cut off, he may claim that res ipsa locquitur applies; the mix-up leading to the unnecessary amputation must be negligence. Another issue is the statute of limitations. A plaintiff has only a few years after the discovery of an injury to bring a suit. After that time, his statute of limitations is said to have run. Courts have reinterpreted the meaning of statutes of limitations, and they are now timed not from the time of the injury, but from the time of discovery by the patient of an injury. Thus, doctors can be sued long after the injury occurred.

Other doctrines in medical malpractice have not changed as much. For example, doctors are free to treat those who they want to treat. However, if a doctor has embarked on a course of treatment for a patient, and then decides not to treat the patient any longer, the patient can sue him for abandonment. Thus, doctors must be careful once they start treating a patient. In accident or emergent situations outside hospitals, however, doctors are generally protected against suits by Good Samaritan laws. Nonetheless, many of the reforms of tort law in the 1950s and 1960s led to more, rather than fewer, suits.

In the past few years there has been some academic discomfort with these reforms. Coinciding with the perception by industry, physicians, and their insurers that tort litigation was growing out of control, some academics have urged new reforms. These reforms would be based on the proposition that tort law is a matter of economics and should be subject to economic analysis. If the administrative costs of tort litigation, the cost of hiring lawyers and litigating issues in courts are too high, then alternatives to litigation should be sought or the litigation restricted. In addition, these academics argue, tort law should be firmly tied to notions of fault. In some states, malpractice law has been reformed by caps on awards and changes in statutes of limitations.

It is too early to tell what the next phase of the evolution of tort law will be, but it will no doubt effect medical practice and so should be closely watched by doctors and all those interested in health policy.

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5

The Regulatory Law as It Affects Physicians

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The practice of medicine in the United States has traditionally been regulated by the individual states. Each state gradually adopted laws that first licensed physicians without attempting to regulate their professional conduct. Initially, states took a laisse-faire attitude and allowed physicians to practice with little outside supervision.

The Flexner Report, which was issued in the early 20th century, indicated that the education and training of physicians was often spotty and inadequate and hastened the movement to improve the quality of medical education and practice.

In the last decade, state legislatures have generally recognized that the practice of medicine needs to be more closely regulated to protect the public. Therefore, they have striven to increase their scrutiny of the professional competence and conduct of physicians.

The number of disciplinary actions taken against physicians in almost every state has increased substantially in the last decade.[1]

The *New York Times* in November 1986[2] reported, in an article on page one, that in 1985 state agencies revoked the licenses of a record number of physicians for incompetence and disciplined 60% more physicians than in the previous year. It is expected that this trend will accelerate during the next several years, primarily due to an increase in funding of state regulatory agencies.

Current estimates indicate that as many as 5% to 15% of doctors are not fully competent to practice medicine, either from a deficiency of medical skills or because of impairment from drugs, alcohol, or mental illness.[1] However, my experience as Director of Regulation in New York State is that actions are rarely brought against the deficient physician population and are often brought against physicians who are guilty, at most, of minor improprieties.

A recent trend, which has accelerated during the past 10 years, is for the state itself, rather than the medical establishment, to take over the supervision of the medical profession and to combine the licensing and regulatory function into one agency that is made responsible for the practice of all health

professions. That agency is often a state licensing agency, a health department, or a department of consumer affairs.

In many states the state agency that regulates the practice of medicine closely cooperates, and in some cases coordinates its activities, with governmental and private agencies that regulate professional practices or the fees charged by professionals under their programs. Thus, it is common for the state licensing agency to work with the Federal Drug Enforcement Administration and/or local narcotic control agencies that regulate the administration, dispensing, and prescribing of controlled substances. In many states the licensing and regulatory agency works with the Medical Assistance Program (Medicaid), Medicare, and other third-party reimbursement programs to insure that action taken by one agency is reported to the others.

New York State recently has adopted a law whereby actions taken by state or federal agencies are automatically considered to be unimpeachable proof of professional misconduct by the New York State regulatory agency that disciplines physicians.

Based on this law, findings of agencies that regulate payment of professionals, such as Medicaid and Medicare; by agencies that regulate drug use, such as the United States Drug Enforcement Administration; and by agencies that regulate the care provided to patients in various settings are now conclusively "professional misconduct." The professional charged under this law can now only present arguments in mitigation of the penalty to be imposed upon him.[3]

The right to practice medicine in any state of the United States has become a valuable commodity. It has now been estimated to be worth from $100,000 to several million dollars in court proceedings, which have valued medical licenses as an asset in divorce proceedings.[4]

Each of the agencies referred to, including the state licensing agency, employs investigators whose job it is to uncover substandard or fraudulent medical practices. The decision as to whether or not to press charges against a professional is often determined by information elicited by these investigators at interviews or from interrogation of the professional.

In my experience most professionals are unaware, at the time that they are first contacted by an investigator, of the jurisdiction and power of the agency that the investigator represents and of the rights of the professional in connection with the investigation.

As each state has its own agencies, which have slightly different jurisdiction and power, I will not attempt to describe the jurisdiction of each agency with specificity. However, no matter which agency conducts the investigation, it is likely that the investigative agency will refer any evidence of substandard or fraudulent practice to the regulatory agency in the state, which is capable of revoking a physician's license to practice medicine. Therefore, each contact with an investigator should be viewed as serious and potentially license threatening and treated with requisite care until the issues involved are resolved.

My experience has taught me that there are certain general procedures that

the professional should follow to best defend himself in the event his personal or professional practices are questioned.

As there are several potential sources of investigation (narcotic agencies, health insurance agencies, and professional standards groups), it is important to know the power and scope of jurisdiction of the agency that is interested in your practice.

Federal and state drug enforcement agencies are concerned with your administration, dispensing, and prescribing of controlled substances. They often exact monetary penalties or suspensions of a physician's right to order or write prescriptions for controlled substances. Although these agencies cannot take away a physician's right to practice medicine, they can interfere significantly with his practice of medicine and will refer their findings to the state agency or Board for Medicine that has the power to revoke or suspend a physician's medical license.

Investigators under the Medicaid or Medicare programs only have the power to remove a physician's right to bill under the particular program and to pay a fine or reimbursement to the government. Many times, these penalties involve double or treble damages and can be quite costly, often destroying a professional's ability to practice. In addition, their findings are often referred to the regulatory agency in the state.

Professional standards review organizations exist in each area of the country. They often examine admissions to hospitals, length of stay, and classification issues. Although their primary objective is to save money, they may refer their findings to the state regulatory agency for appropriate action.

No investigation is benign and should never be considered to be pro forma. It is unlikely that the investigator is making a routine check. Normally, investigators respond to complaints or inquiries about a professional's practice. Even in the event that the investigator is conducting a routine audit, only one of the many possible results of the audit can be considered favorable to the professional. Therefore, each investigation must be considered to be important and potentially license threatening until proven otherwise.

Investigators often use similar techniques. They often minimize the seriousness of their investigation and indicate that the professional may be able to clear up the problem and avoid further investigation if he will just answer a few questions at this time.

Investigators often drop in without warning or make a call to the professional's office, either to find out when the professional will be there or to make an appointment. They normally do not describe the specific areas of their intended inquiry before the office visit. Sometimes they do not describe the area of inquiry or reveal the specific area of complaint during the interview with the professional. At times, they may demand that the professional visit them at the office of the agency.

An alternate technique is for the investigator to frighten the professional. The investigator may arrive while the waiting room is filled with patients. The professional may be intimidated by this or be afraid that the investigator will speak to the patients or at least reveal to them that he is investigating their doctor.

Often, the investigator dresses so that he looks more like a policeman than a patient. The professional may fear that his patients will suspect that he is under investigation. At times, the investigator, particularly narcotic investigators, wear guns. Their jackets may open, particularly when they sit, revealing a gun attached to their belt. Such conduct often intimidates the professional.

At this point, a normally independent, self-confident professional becomes completely compliant and commences answering all questions and provides all documents requested. Although, as an attorney, I would expect the professional to require the investigator to produce any complaint against the professional and to explain the specific purpose of his visit before responding, such a reaction definitely does not appear to be the norm.

In many cases the professional turns over the original records to the investigator without first making a copy of the records or even requesting a receipt. The physician will often respond to questions about the matter and direct his staff to to the same. The cooperation of the professional and his staff, while it may appear laudable, may ultimately result in damage to the professional. Records may be lost or misplaced and are often not recoverable. Statements given "on the spur of the moment" may not be complete or entirely accurate and become detrimental to the physician. A confidential privilege may attach to certain patient records that may only be legally waived by the patient rather than the professional. Even a completely ethical practitioner may maintain incomplete records that cannot withstand the scrutiny of a government regulatory agency.

The professional would do well to consider the possible ramifications of his contact with the investigator before the meeting. If at all possible, he should postpone the meeting to allow himself time to consult with *an attorney who specializes in this area of law.*

It is not surprising that professionals wish to cooperate with investigators from government regulatory agencies. It is nonetheless astounding that they willingly turn over original patient records, often without making copies or obtaining a receipt and provide statements to investigators on the spot, without taking sufficient time to consult with an attorney or to consider the possible ramifications of their cooperation.

Professionals often consult with attorneys after they have severely compromised their case. To avoid this hazard, the professional should adhere to the following guidelines from the time that he is first contacted by a representative from a government regulatory agency:

1. Never turn over your original records to the investigator; submit only copies and receive a receipt for each document turned over.
2. Attempt to learn the specifics of the complaint from the investigator and note in writing any information that you are able to obtain, as well as all facts about the meeting.
3. Make no statement to an investigator before consulting with an attorney.
4. If you are not fully prepared at the first meeting, postpone the meeting to a more convenient time. Better yet, do not disclose any information to the investigator before consulting with an attorney.

5. Consult an attorney who is knowledgeable with resect to government regulatory matters, as well as professional matters.
6. Do not provide a written statement to the investigator or comply with a subpoena before consulting with an attorney.

You cannot be penalized for complying with the above rules and you may avoid much grief and retrospective analysis by seeking advice before a minor annoyance becomes a major problem.

The disciplinary process is particularly important to the hospital-based physician. Penalties other than actual revocation or suspension of license may have little or no effect upon a physician in private practice who does not accept third-party reimbursement. However, just being found guilty in a disciplinary proceeding without any further penalty may have serious consequences for the hospital-based physician, which will be discussed.

The state may impose penalties upon the professional less serious than revocation of license. States normally have the power to suspend licenses, to require public service, to require continuing education, to impose a censure and reprimand, and to place a professional on probation under certain terms and conditions.

Any action imposed by the state may be reported to third-party payers (such as Medicare, Medicaid, GHI, and Blue Cross), which may remove the professional from their list of participating physicians. Medical societies notified of such action may expel a member who has been disciplined by the state. Medical liability companies may, in turn, refuse to issue malpractice insurance or may do so only upon payment of an increased premium.

In addition, other consequences may befall the hospital-based physician. Hospitals and other facilities where physicians work may take such determinations into account and eliminate, reduce, or curtail a physician's privileges at that institution.

This effect on hospital privileges can cause great economic and personal hardship to the hospital-based physician. Conversely, hospitals and other facilities where physicians practice often report termination or curtailment of the privileges of a physician to the state for possible disciplinary action.

Therefore, it is apparent that the hospital-based physician should be aware of the connections between the state regulatory agencies and his hospital privileges and should use his collective influence in the hospital to cause rules and regulations to be promulgated by the hospital board and the medical board, which safeguard the rights of the physician.

At the present time, medical staff bylaws and hospital rules and regulations usually do not provide adequate protection to physicians who are faced with possible charges by the hospital. Courts, when faced with appeals from decisions of hospital boards, normally uphold the hospital's decision, holding a hospital to be a private agency and medical licensure not a right, so that due process rights are held not to have been required.

Because courts will not write due process rights into the rules and regulations

of hospitals, it is necessary that the professional attempt to insert these due process rights into the hospital's bylaws.

From my experience, I would suggest that the following terms, which are not normally part of the hospital's bylaws or regulations, should be proposed by the physicians group in the hospital that negotiates on behalf of staff physicians:

1. The professional must be given written notice of the specific charges against him.
2. The name of the witnesses, the dates of the specific incidents, and a narrative of the incidents referred to should be attached to the charges.
3. All incident reports prepared by the witnesses or other hospital personnel should be provided to the accused physician.
4. A written verbatim transcript of the proceeding should be made and furnished to the professional.
5. The accused should have some input into the compositon of the hearing panel.
6. Either side should have the right to review by a nonhospital-based committee or person appointed by an impartial source, such as the American Arbitration Association.
7. The accused physician must have the right to be represented by counsel of his choice at the hearing and at all other stages of the proceeding.

I believe that the suggested rules will not only provide a fairer hearing procedure to the physician accused but will serve to discourage proceedings based upon political considerations or those in which only top-level personnel would be expected to support the action contemplated.

Commentators on professional discipline proceedings often believe that the accused professional is provided with too many rights. An example is the following quote from the *New England Journal of Medicine,* one of the most prestigious journals published for physicians, "Everything works in favor of the accused, who always has the right to appeal."[1]

However, as an attorney who has headed the state agency in charge of professional regulation and who has also represented professionals in disciplinary proceedings, I believe that the scales of justice are overly weighted on the side of the state. Only through diligent action on the part of the professional can he protect himself against investigation and prosecution by state agencies for minor or, in some cases, nonexistent violations.

It is my opinion that physicians under investigation by state agencies have fewer rights than common criminals as they are not entitled to nor normally granted the *rights of due process of law granted to all citizens by the Constitution of the United States.*

It is never too early to protect oneself and one's license to practice medicine. All physicians are vulnerable to investigation and prosecution no matter how scrupulous their compliance with professional regulation may be. Physicians should prepare now to protect their license to practice medicine. As it states in an old adage, "an ounce of prevention is worth a pound of cure."

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The Expert Witness in Medical Malpractice Litigation

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The medical expert witness is one who by virtue of experience and training can offer "opinion testimony" before the court trying the case. Most experienced trial counsel consider it an art form. The best experts are not necessarily the best witnesses. To be an effective expert requires some experience with litigation.

To establish the necessary in-court foundation for the legal admissibility of evidence, the expert must be prepared to answer a series of questions put to him by the cross-examiner, the responses of which will provide the necessary legal foundation that can thereafter permit the opinion of the expert witness to be stated. The legal issue as to whether the foundation has been sufficiently established is one to be decided as a matter of law by the trial judge. Once the foundation is established, the jury is then charged with determining the weight it will attached to the testimony that is offered. In brief, the trial court will permit or refuse the testimony (question of law) and the jury will decide the weight to be given to it (issue of fact). This is how the role of the judge and jury is delineated.

In most jurisdictions, one need not be practicing the medical specialty at issue to qualify as an expert for furnishing expert testimony. For example, a general surgeon who is only familiar with thoracic surgery could conceivably meet the foundation of one who is offering expert testimony in a thoracic surgery case. The lack of specific board certification in thoracic surgery, however, might minimize the impact of such evidence.

Qualifying the Medical Expert

The following questions might generally be asked of the expert:

1. Doctor, are you a physician licensed to practice in the state of New York?
2. In what year were you licensed?
3. By way of education background, doctor, would you please tell the jury the

college you attended, the degree you received, and the year in which you received it.
4. What medical school did you attend?
5. Having received your medical degree what did you then do in pursuit of your medical career?
6. Doctor, what do you understand by board certification?
7. Having been board certified, did you then hold yourself out as a specialist in the field of cardiology?
8. During the period beginning with your entering the practice of medicine to the present time, how many patients have you treated in the specialty of cardiology?

Thereafter, there would be questions related to:

1. Teaching positions
2. Hospital affiliations
3. Books, chapters, and articles published
4. Membership in medical societies
5. Special honors (awards or grants for medical research)
6. Related activities that will further enhance the experience, reputation, and qualifications of the expert witness.

If the qualifications have been developed properly, the expert's opinion that will follow should have a persuasive impact on the jury. It is important, therefore, that the development of the expert's qualifications be discussed thoroughly during the preparatory session with the attorney. This is essential as the first impression that the jury will have of the expert witness will occur during the qualification stage. A clumsy, disjointed, or incomplete qualification procedure could taint the expert's entire testimony.

General Characteristics of the Expert

The following should be considered when selecting the medical expert:

1. Professional qualifications and expertise as documented by board certification and fellowships in numerous academic institutions.
2. Professional standing within the medical community.
3. The theory of liability or defense which is to be followed.
4. The type of analysis to be performed.
5. Understanding of the litigation process and the strategies to be used in the courtroom.
6. Ability to communicate with a jury and to be able to translate complex medical issues to understandable lay terms.
7. The ability to withstand rigorous cross-examination without appearing combative or adversarial.
8. Cooperation and accessibility for telephone and office consultations and court appearance.

Who Makes the Most Effective Expert Witness?

Qualification

The most important attributes that determines the effectiveness of the medical expert are the qualifications of such an expert. This takes into consideration the educational background, experience in the specific field of medicine, and overall knowledge including familiarity with the literature.

Special Expertise

The most impressive expert is one who has devoted a considerable percentage of professional time to the specialty that is the subject of litigation. The lack of such expertise can lead to vulnerability and destruction of the entire testimony by a seasoned cross-examiner.

Major Teaching or Hospital Institution

Being a member of the academic faculty of a major teaching institution is usually very impressive. If absent, the cross-examination by an astute lawyer can portray such a witness as one who has a local community practice, which can paint a parochial image in the minds of the jury, thereby limiting the impact of the opinions expressed.

Publications

One of the key questions asked of the witness either on direct or cross-examination, will address books, chapters, or articles published. It is self-evident that a medical expert who has been widely published has enormous appeal to a jury. Whereas the lack of publications might not by itself be damaging to the expert's total credibility, they could be damaging if the expert produced by the other side is an academic giant. The advantage of being a recognized author can be seized upon most effectively by an experienced attorney who can use the comparison to considerable advantage during summation.

Hired Gun

There are medical experts who spend more time in the courtroom and in the overall litigation process than they do in the practice of medicine. These experts are well known to both plaintiff and defense counsel with the result that they are usually confronted with transcripts of previous testimony that might contain inconsistent responses to questions asked at a former trial when used at the present trial. Even the most innocuous of inconsistencies can be seized upon by an adroit attorney with a chilling effect upon the witness. Aside from the inconsistency, the procedure for such confrontation by use of a prior

transcript usually rivets the jury's attention and often has a disquieting effect upon the witness, who after such encounter might appear perplexed before the jury. In the final analysis, a true expert's integrity, candor, sincerity, and honesty can win the day in court.

Materials for Review

The experienced cross-examiner will probe the expert as to all records reviewed for purposes of court testimony. As such, it is imperative that the expert reviews all hospital and office records of the case. In addition, the expert should review the pleadings, the bill of particulars, and the interrogatories, which set forth the theories of liability and the damages claimed. The expert should also read all depositions because depositions bring forth aspects of a case that are not apparent from reading the record.

Contracting with the Attorney

Physicians may not be aware that some attorneys decide the merits of a case based upon an initial telephone conference. Physicians should make it a policy not to render an opinion based upon such minimal information. Nothing can be more awkward than to render an opinion based on minimal information. It is advisable that the physician enter into a contractual relationship with the attorney who seeks his services. The purpose, scope, and extent of the work to be performed by the expert witness should be part of the agreement. The expert should not express an opinion until all significant hospital and medical records have been reviewed. The attorney will usually discuss the issues in detail in advance of requesting a written report. This provides the attorney with the choice of electing not to employ the physician as an expert witness, should the views expressed be adverse to the client's case.

The attorney may seek a consultation with the physician after a written report is received, to gauge the strengths and weaknesses of the medical issues involved. Often such dialogue demonstrates the differences in the logic of law and scientific thinking. A reputable attorney will not attempt to influence the expert's views, but will provide significant information that would impact on the physician's ultimate views and opinions.

Target Objective of the Expert Witness

It is the function of the expert to offer an opinion that reaches the ultimate or threshold issue that will be presented to the jury for its consideration and verdict. Having been accepted as an expert, his opinion will be admissible.

The manner and poise of an expert require much emphasis. Nothing is more impressive than an expert who keeps his dignity and is courteous even to a hostile cross-examiner. The true expert comes across as nonadversarial. He is

knowledgeable without being boastful. He is direct and not evasive. He is brief in making a significant point. His answers are germane to the questions posed.

The Hypothetical Question

The expert witness should be prepared in advance to answer a hypothetical question. Briefly, the hypothetical question is one that seeks an ultimate opinion from the expert after a series of hypothetical facts have been presented to the witness. For example, the expert will be asked to assume facts "A through D." Having assumed the facts that comprise the hypothesis, the expert will be asked if he has an opinion based upon the hypothetical facts presented. For example:

Q. Do you have an opinion with a reasonable degree of medical certainty as to whether defendant doctor departed from good and acceptable practice in the care of Mr. Jones?
A. I do have such an opinion.
Q. What is that opinion?
A. Defendant doctor X did not depart from good and acceptable medical practice in the care and treatment of Mr. _____.
Q. What is the basis of that opinion?
A. The basis of my opinion is _____.

The final answer in response to the hypothetical question is the most significant one that the expert witness will be called upon to render. Indeed, it is the expert's raison d'ètre in the case. This is an extremely significant opinion. The expert in answering should indicate that this is a "hypothetical response" to the questions asked. The success or failure in a given case may rest upon the answers given by the expert. The hypothetical question and its answer should be rehearsed in depth before appearance in court.

Financial Arrangements

The expert witness should in no case have a concealed financial interest in the case. At any point when he believes he cannot support a position, the physician should gracefully remove himself from the case. The best arrangement is to work for a fixed fee at an hourly rate.

Deposition

Some medical malpractice cases do not go beyond the deposition stage because they are settled out of court. The deposition is a very significant procedure, as it forms the parameters of in-court testimony of the witness. An in-depth conference with the attorney is essential before the taking of a deposition. The

golden rule is to be as brief as possible, giving "yes" or "no" answers when possible. An expansive response to a question will open the door to a series of new questions that could prove extremely troublesome.

Pitfalls

Advertisements can be found in most legal publications and Bar journals stating "doctors available to testify in medical malpractice cases." Physicians should be extremely cautious in dealing with such services. Opposing counsel often use such advertisements to depict an expert as one who is more involved in commercial litigation rather than the practice of medicine.

Why Do Experts Differ?

It is not unusual for two physicians with the same educational background, training, and board certification to have viewpoints that are diametrically opposed. Most physicians with similar knowledge and skills, however, do agree upon basic issues.

An adversarial courtroom atmosphere is created when two expert physicians present differing and strongly held opinions concerning the diagnosis and treatment of a given patient. Opinions may be widely disparate. One specialist may recommend a surgical procedure, claiming that the benefits derived far outweigh the risks of the operation. Another physician faced with the same clinical picture might recommend conservative treatment. It is not unusual for some physicians to recommend surgery, while others recommend conservative medical treatment. How does one explain these striking contrasts? Some physicians are attracted to quick operative modalities of treatment, whereas others, by virtue of their own preferences, require a high degree of diagnostic certainty before commencing treatment. Many medical investigators and diagnosticians may interpret the same data and reach opposite conclusions, but allowance must be made for the pertinent factors that led to a certain line of treatment.

Of late, more scientific expertise has been brought to the clinical decision-making process. What is described as "decision analysis" and "computer analysis" is emerging into a science that can be of assistance to physicians in arriving at the diagnosis of difficult conundrums. Approximately one sixth of such cases fall into a category of uncertainty. Translating such uncertainty into the litigation process, brings forth all of the prowess and talents of a physician. How this is accomplished is often the ultimate factor in whether a case is won or lost.

7

The Physician and Antitrust Law*

ARNOLD S. RELMAN, MD

For many years the learned professions enjoyed immunity from antitrust regulation. The basis for this immunity was that physicians were not thought to be engaged in the kind of commercial activity for which the Sherman Act and the Federal Trade Commission (FTC) Act were intended. In 1975, the US Supreme Court ended that immunity by declaring that the scope of antitrust law included the business activities of the professions. It gave no indication of exactly how antitrust regulation was to be applied to medicine. Since then numerous legal actions have been taken against physicians or physician groups to curb what government has perceived to be "anticompetitive" activities. These actions have been resisted by organized medicine in the courts and in the Congress, but to no avail.

Although the federal government now believes that at least some aspects of medical practice belong under antitrust surveillance, the laws enforced by the FTC do not prohibit medical associations from adopting ethical codes designed to protect the public—so long as such codes are not "anticompetitive." Thus, with respect to commercial conflicts of interest and ethical rules that simply requires physicians to disclose equity interests in health care facilities to which they refer their patients would probably not raise antitrust problems. L. Barry Costilo, a lawyer with the FTC, stated in 1985, "If an ethics rule prohibited physicians from having any ownership interest in a facility to which they referred patients, antitrust questions would be raised, since the rule would probably be overly broad as a means of preventing deceptive behavior or other abuses." This possibility may be worrying organized medicine's lawyers enough to cool whatever enthusiasm may have existed about taking stronger stands on the conflict of interest issue. The American Medical Association (AMA) has already had frustrating, expensive legal encounters with the FTC and clearly does not seek another antitrust confrontation at this time.

The underlying questions raised by the application of antitrust law to

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medicine cries out for public discussion and clarification. Does our society want to draw a line between the medical profession and the growing investor-owned health care industry, and if so, where? Should government encourage the profession to set its own ethical standards, even when the latter limit the freedom of physicians to make business arrangements in the medical marketplace? In the final analysis, where does the public interest lie—in strengthening the profession's fiduciary commitments to patients or in encouraging entrepreneurialism and commercial competition among physicians? It is clear that we cannot have it both ways. The kind of freewheeling business competition envisioned by antitrust law is simply not compatible with the ethical obligations of doctors to their patients. To quote Clark C. Havighurst, Professor of Law at Duke University, a leading authority on antitrust applications in health care, "Antitrust law does not, as a general rule, tolerate competitor collaboration simply because it serves worthy purposes, professional or otherwise. Instead the legal inquiry . . . focuses on whether a particular collaboration is compatible with the maintenance of competition in the market as a whole." According to Havighurst, federal policy today "starts from the proposition that the health care sector is a competitive industry to be guided, for better or worse, by market forces unless Congress declares otherwise. . . ."

Uncomfortable and costly though the process may be, organized medicine may have no choice but to pursue this issue in the courts and in state and federal legislative chambers. For if the free-market theoreticians and the antitrust enforcers have their way, the ethical foundations of our profession will be undermined, and the practice of medicine will come to be treated purely and simply as commerce. To avoid this, courts and legislatures will have to distinguish carefully between the collective activities of physicians that are appropriately subject to antitrust law and those that are not. In the former category, I suggest, belong such "anticompetitive" economic actions as boycotting, price fixing, unreasonable prohibitions on the dissemination of truthful information about the availability of medical services, and collusion to restrain the development of new types of practice organizations or the practice opportunities of competing but qualified physicians. Most of the FTC actions described by Mr. Costilo have been concerned with problems of this kind. In the off-limits category, however, should be all the self-regulating activities that defend the ethical integrity of the profession and the quality of its services, regardless of the effect on entrepreneurial activity. There are fundamental differences between medical care and the usual kinds of commerce, and the public interest requires that these differences be preserved, no matter what the consequences for "competition."

But even if we were to accept for the moment Havinghurst's description of health care as a competitive industry, "to be guided, for better or worse, by market forces," and even if we were to apply the yardstick suggested by Costilo, I find it hard to understand how an ethical ban on investments in facilities to which physicians refer their own patients could be regarded as a threat to competition. If anything, such an ethical rule would be procompetitive, for it would ensure that physicians' decisions to use facilities and

services were based on dispassionate medical judgments rather than vested financial interests. In most of the new health care businesses in which physicians are now investing, their contribution of venture capital is of far less importance to the success of the enterprise than is their patronage as purchasing agents for their patients. This is hardly the kind of competitive environment envisioned by antitrust law. In ordinary business relations, I believe, a purchasing agent employed by one firm would not be allowed to have vested interests in other firms from which he was purchasing supplies. Why should entrepreneurial physicians be an exception? Surely not because such arrangements would help the patient. The patient's (i.e., "consumer's") interest is best served by unbiased professional medical advice that can help guide him through the complex medical "market," but physicians who have strong economic ties to particular medical facilities, services, and products are not in the best position to give such advice.

Some would justify physician participation in medical businesses by arguing that this ensures quality of service and proper concern for patients' needs. This is an unpersuasive argument because it begs the question of whether such divided loyalty really allows physicians to do their best for patients. Furthermore, physicians can be managers of medical businesses without being in practice and thus can easily avoid conflicts of interest. Many physicians have, in fact, left practice to take up careers in the management of health care businesses, and I see nothing wrong with that. It is only when physicians act as "double agents" that ethical questions arise—when they serve as agents for their patients and as agents for businesses seeking to sell products and services to their patients. Because a competitive market works best when consumers and business firms are each independently pursuing their own interests, I should think that such a double role for physicians would pose problems for the FTC.

The underlying public policy issue needs to be resolved soon. Do we want our physicians to become even more entrepreneurial than they already are? If we do not, we shall have to seek appropriate means, judicial or legislative, to help the medical profession collectively avoid financial dealings with health care businesses and thus strengthen its traditional commitment to the ethics of service to the people of this nation.

8

Risk Management for the Physician

MICHAEL S. KAMINSKI, MPH, JEANNE H. PORES, MPA, AND ASHIFA BHAYANI, RRA

An Administrator's View of Risk Management

Risk management is an administrative function for controlling, predicting, and financing losses that cannot be assumed or avoided. In the hospital industry, risk management focuses on predicting the risk of patient harm and injury and implementing measures to prevent future losses from lawsuits against the hospital.

To accomplish this, hospital-based departments of risk management have evolved from clerically oriented legal or insurance departments into comprehensive programs for risk management. These programs identify sources of risks, offer solutions and alternatives, investigate patient injuries, and monitor physician compliance with procedures designed to minimize malpractice claims.

Most malpractice lawsuits originate from an incident in a hospital.[1] Even though a physician provided the treatment, the hospital is a likely codefendant. To address this, risk management departments often provide educational sessions and materials that are designed to capture the physician's attention and expand the knowledge of the medical staff in medicolegal subjects ranging from informed consent to do not resuscitate orders.

In the interest of brevity, we have selected a few topics that are key to the physician's understanding of risk management concepts in a hospital setting.

What Is the Significance of an Occurrence Report?

One of the basic, primary tools of any risk management program is the completion and collection of occurrence or incident reports. An occurrence report is a record, usually on a form preprinted by the hospital, that provides the description of any unusual event that takes place involving a patient. The form, at least in theory, is supposed to be used to record the circumstances surrounding the event, including person or persons involved, location and time

of the incident, and a brief narrative description of the incident without any judgment as to its cause.

In most hospitals, occurrence reports are sent immediately to the risk management department where they are reviewed and entered into a computerized data system so that appropriate recording and trending by nursing station and occurrence type can take place. Such trending should be generated to prevent future occurrences of the same nature.

Occurrence reports are, unfortunately, discoverable. Caution should be exercised before attempting to use it to blame someone for an injury, and no reference should be made in the patient's chart that an occurrence report was completed.

Recognizing the significant of these reports, the New York State Department of Health has implemented an incident reporting procedure that governs the reporting of certain incidents to the state within a 24-hour period. The section bearing most relevance for the physician reads as follows:

> Incidents to be reported include patient deaths or impairments of bodily function in circumstances other than those related to the natural course of illness, disease, or proper treatment in accordance with generally accepted medical standards.[2]

Problems associated with interpreting this regulation can best be illustrated with an example. Mrs. Smith, a 67-year-old patient, is admitted for an elective workup after her routine chest x-ray revealed a lesion in the left lung. A bronchoscopy and biopsy is performed. During the procedure, the patient sustains a pneumothorax requiring immediate transfer to the intensive care unit where a chest tube is inserted. Two days later, the patient falls out of bed and sustains a fractured hip. She subsequently develops pneumonia, deteriorates further, and dies due to respiratory arrest.

Technically, the pneumothorax can be considered a known risk of performing a bronchoscopy. However, can we relate the patient's death to her natural course of illness?

From a risk manager's perspective, this incident falls under the state guidelines for reporting occurrences. Hospitals found not to be reporting incidents are cited with deficiencies by the state regulatory agency, are often fined, and are subject to exposure in the press. The investigation into Andy Warhol's death at New York Hospital is an example of this process.

One additional requirement of the state reporting process is the need to include the name of the attending physician responsible for the care of this patient. The New York State Department of Health can pursue the incident and forward the case to the New York State Department of Professional Medical Conduct, a body with subpoena authority over physician credential files. If it is believed that the doctor acted inappropriately, they may pursue corrective action as they may deem it appropriate.

We recognize that most physicians view occurrence reports as a nuisance. because their importance and impact have escalated substantially with the advent of the new regulations and their accessibility by plaintiff attorneys, we

strongly recommend that physicians become familiar with hospital's incident reporting procedures and any related regulatory requirements governing the same.

Requirements of the New York State Medical Malpractice Law

On July 2, 1985, Governor Cuomo signed Chapter 294 of the Laws of 1985, the Medical Malpractice Law.

Among other things, the Medical Malpractice Law requires hospitals to implement credentialing procedures that include the review of data gleaned from infection rates, surgical case reviews, departmental morbidity and mortality reports, drug utilization studies, and patient complaints. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) also requires hospitals to demonstrate a linkage between the granting of and renewal of medical staff privileges and criteria for performing quality patient care.[3]

Due largely to the passage of this law, hospitals and health care organizations are steadfastly becoming more responsible for monitoring the competency and performance of its physicians. As hospital departments scramble to develop sophisticated information systems that track physician-specific data, so too do the federal and state regulatory agencies, thus creating an environment of intense scrutiny over the provision of patient care. From a risk management perspective, a physician's malpractice claims history is evaluated before either granting or renewing medical staff privileges. It is the physician's responsibility to provide complete disclosure to the facility on claims in which he or she is involved so that this process may be appropriately undertaken. The role of risk management in this is not only to limit the threat of future liability but to help to assure the credentialing of well-qualified medical staff.

Patients Access to Medical Records: An Added Exposure?

The growing interest of the individual's rights in the health care industry parallels the establishment of patient rights in gaining access to their health care information.

The State of New York recently enacted a law affording the consumer significant rights of access to their medical records. In adopting the new system, New York joins 14 other states that have similar access privileges for both doctors' and hospital patients' records.

As access laws become enacted in more states, curiosity about the content of health records may decline as in one midwest state where all patients are given their records upon discharge.

Unfortunately, available literature does not convincingly demonstrate that access either harms or helps consumers. Research supports the fact that physician's perceptions of harm because of access seem to vary with type of specialty and length of time in practice. In particular, pediatricians and

specialists in obstetrics and gynecology who have been practicing for several years seem less likely to fear harm to their patients as a result of record access than surgeons or interns and residents.[4] On the other hand, psychiatrists infer that psychiatric patients or medical patients with psychiatric problems do not always react positively to knowledge of record content, and they are probably right.

Research supports the statement that physicians who routinely provide access to records to their patients demonstrate an increased interest and involvement by the patient in the management of their care.

We can speculate that the increased interest in patient access to review records is another symptom of breakdown in physician-patient communications and trust. It would not be unfair to say that both hospitals and physicians characterize the request for record review as a potential threat for a lawsuit, rather than patient education. Because of this perception, we suspect that professional staff edit entries when a review is anticipated. Physicians with prior knowledge of review tend to document precise notes with thoughtful conclusions.

The owner of the record, be it the physician in his private office or the hospital, maintains total control over the integrity of record content. For this reason, policies and procedures to correctly handle requests for deletions or amendments are essential. Changes made after the completion of the record must preserve the "normal course of business" by accurately depicting the sequence of events.

Both the hospital and the health care practitioner are held ultimately responsible for preserving the integrity of the record content, both as a historical document and as a resource for continuing medical care.

Why Is Documentation in the Patient's Chart so Important?

Document it. If you haven't documented it, you didn't do it.

We agree with Dr. Mark E. Battista's premise that failure to document usually reflects negatively on the physician. According to Dr. Battista, a lawyer and malpractice consultant, although not a hard and fast rule, many physicians unfortunately learn the hard way that failing to document often makes an easier case for the plaintiff's attorney. Moreover, fighting in the patient's medical record is often a key factor that a plaintiff's attorney looks for before undertaking a malpractice case. According to Bernard D. Hirsh, MD, who served as general counsel of the American Medical Association for more than 2 years, at least 10% of all physicians do not keep thorough records and at least 20% of all physicians could stand some improvement in their record-keeping efforts. Hirsh says that where malpractice litigation is concerned, records can make or break a case. "Records have great importance in borderline cases. Frequently, good records will make the difference in a case that otherwise

might be lost. Likewise, poor records can make the difference where scales are tipped slightly in your favor. Sometimes even good records, if sloppy will make the critical difference."[5]

The most crucial advice any risk manager can give a physician who practices in a hospital is to not fight in the medical record. Just imagine the following scenario read out by a plaintiff's attorney in a court of law:

Attorney: Doctor, I see a note in here from a nurse that says. Dr. Smith 8:05 PM notified that the patient's condition has worsened. I see a note underneath it signed by you and timed 1:00 AM that seems to contradict this note. Doctor, would you please read this note out loud for the jury's benefit.

Doctor: The nurse who wrote the note indicating that I was notified at 8:05 PM was incorrect! I was not notified, nor was my answering service notified. This nurse has a habit of not following through as she should.

Obviously, this fighting in the medical record discredits both the nurse and the physician, and demonstrates unprofessional finger pointing. Although it is not particularly uncommon for doctors and nurses to have diverging opinions, the medical record is not the place to air differences.

The medical record is supposed to be a factual and objective record of the patient's course of treatment while in the hospital. Any notes that are not relevant should not be there.

Communicating with Patients

There are literally dozens of articles that speak to the importance of communication between the physician and patients. Why is this so important?

A study conducted by the Professional Competence Assurance Program at the University of California,[6] which focused on physician-patient communication, revealed that patients showed the most dissatisfaction with the lack of sufficient explanations concerning their conditions and alternative treatment, the side effects of medications, and how medications help their condition. Patients also expressed concern about the adequacy of discussion with their physician before surgery and also expected more reassurance from their surgeon as to how they were progressing postoperatively.

In an article written by Paul D. Rheingold,[7] the author shares his experiences with malpractice cases from a plaintiff's lawyer's perspective. In one case scenario that further illustrates our point about communication, Rheingold cites an example of a client who presented to his office wishing to sue his physicians. He indicates that the patient wanted to sue Doctors Green and Brown and not Dr. White because "I like him and he was nice to me while I was in the hospital." Rheingold goes on to say that this type of client sends shivers down his spine. He cites two reasons, first that such decisions as to who to sue are decisions that are ultimately for the lawyer to make. Secondly, leaving out one defendant will lead to the sued defendants ganging up on the unsued one after the statute of limitations has run. Since Rheingold feels that it

is essential to have control over the case, he probably would avoid taking this one on.

Clearly, communicating with your patients can only help, not hinder, your ability to limit liability.

The Doctrine of Informed Consent

Informed consent is a discussion that takes place between the physician and his or her patient that outlines the risks, benefits and alternatives to the procedure being recommended. Hospitals generally provide a cadre of forms designed to enhance the patient's understanding of the procedure, and ask that it be signed by the patient in the presence of a witness who, it is argued, may attest to its validity. Unfortunately, these forms are often abused, as they provide a false sense of security to both the physician and hospital staff who use them. Informed consent forms may be replete with useful information about the potential risks of any given procedure, but they do not replace the actual personal conversation that is supposed to take place between the patient and the physician. Although cases claiming lack of informed consent date back approximately 65 years, the frequency of such claims has increased substantially during the last 25 years.[8]

From a risk management perspective, it is far better for a patient to delay or refuse surgery based on their knowledge of the risks involved than to prompt a lawsuit due to an unanticipated, bad outcome. A patient who suffers blindness as a result of removing cataracts is perhaps less likely to sue if her physician informed her of the risk in advance. Either way, clear and concise documentation in the medical record reflecting the informed consent discussion, coupled with the informed consent form is the best approach to dealing with this issue.

Role of the Physician in Risk Management

Liability issues strain the relationship between physicians and hospitals. Hospitals are committed to providing the highest possible quality of care in a setting with the least risk to patients, visitors, employees, and staff. The main objective of risk management is the protection of the corporation's assets or resources.[9] Although the value of the assets is often expressed in financial terms, risk management seeks to preserve and upgrade the quality of care and minimize the physician's liability.

A hospital risk management program cannot succeed without the cooperation of the physicians who work there. The basic premise of any risk management program is that of concurrent reporting. Concurrent reporting means that the physician picks up the telephone and calls the risk manager when he suspects a patient will sue him for damages.

For every 10 malpractice suits against a hospital, 8 involve one or more physicians as codefendants.[10] According to an article appearing in *Michigan Hospitals*, the number of hospital personnel controllable claims (e.g., patient

falls), have been relatively stable while physician-controllable claims such as birth trauma have increased rapidly.[10] Protecting hospitals against culpable behavior by staff physicians through preventive strategies is a major risk management function. A great deal of time is being spent convincing physicians of their role in planning and implementing these strategies to prevent patient injuries from taking place.

Tips for Limiting Liability

The principles and practices of risk management are effective in limiting liability and should be incorporated into the daily practice of medicine. The following points in particular should be noted:

1. Do not fight in the hospital medical record.
2. Document fully, objectively, and comprehensively all medical facts in the patient's chart.
3. Use good communication techniques to avoid misunderstandings with patients concerning potential risks in their treatment or alternatives that are available.
4. Find out what statutes, if any, govern the practice of medicine in your state.
5. Ask your hospital for a list of factors that are considered when reapplying for privileges to practice there.
6. Visit your hospital's department of risk management, and inquire as to various policies or informational materials that are available to assist you in limiting your liability.

Hospitals are often in the position of "deep pocket," providing the majority of coverage for monetary damages accorded to the patient that cannot be covered by the underinsured physician. Because hospitals are held to a standard of corporate negligence, total commitment to patient care and a multidisciplinary approach that encourages physician participation in risk management is the only effective means to combat liability problems. The physician's role in this endeavor is a crucial one.

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A Physician's View of Risk Management

JOSEPH A. PENNISI

There are certain subspecialties in medicine that by their very nature carry a much greater risk than others. Neurosurgery, obstetrics, and orthopedics are the foremost examples. Obstetrics carries the added burden of an extended statute of limitations. These are the fields marked by a high incidence of results far short of perfect. Lowering the risk, or rate of risk, to an acceptable level is an impossibility. Despite scientific evidence to the contrary, an overwhelming number of cases are decided in favor of plaintiffs, merely on the basis of emotional appeal. These are frequently the most costly areas and prove most frustrating to those attempting to develop a mechanism by which risks can be reduced.

The challenge to professional leadership lies in the attempt to identify and isolate the individual cases manifesting trends or patterns of poor medical judgment from those cases which involve the highest risk per se. Complete involvement of the entire staff via hospital committees and departmental committees promotes the accumulation of pertinent information leading to corrective measures at the department level (i.e., CME, management protocols, etc.).

The physician's role in risk management is highlighted by the duties of the chairman of the clinical departments. In his mind there is very little distinction made between quality care rendered by his staff and risk management as perceived by the hospital. The two go hand in hand. The chairman must develop a system of ongoing evaluation of each physician as well as maintaining individual files enabling him to identify specific trends of practice. These problems of clinical practice may be department wide as well as specific and isolated. Early identification of untoward results may aid in addressing grievances brought on by patients' unrealistic expectations. The true cases of unacceptable practice comprises a small fraction of the cases brought to the attention of risk management.

Summary and Conclusion

The risk management structure within the hospital has been developed at great expense and in a short period to an efficiently managed organization. It has

accomplished the vital role of identifying, predicting, and controlling financial losses, while at the same time providing the impetus to quality care advancement.

Despite the time and expertise that has been expended in the hospital setting, the risk to the practitioner cannot be altered or reduced beyond a certain level. These are problems that cannot be alleviated by following good scientific medical practice.

An example is that of retrolental fibroplasia. As a consequence of measures taken to salvage severely premature babies, the very treatment produced blindness. Only after a number of years was the causal relationship discovered between high levels of oxygen needed to save the infant's life and the production of permanent change in the retina. The lawsuits that evolved before the expiration of the statute of limitations proved to be nothing but a mechanism of compensation to the unfortunate but living children.

Obviously, there is need for alternative approaches (social and legislative) to the satisfactory solution of the risk management/medical liability nightmare.

9

Protection of Research Subjects in Clinical Research

HAROLD M. GINZBURG, MD, JD

Introduction

There is an intrinsic difference between medical care and treatment and clinical research. Care and treatment are accepted therapeutic interventions; clinical research connotes an experimental or generally not accepted procedure or intervention. Whether the patient is going to be subjected to a treatment or clinical research procedure, the assent and cooperation of the patient or legal surrogate is required. The formal process of obtaining informed and educated consent is the critical issue in medical care, medical treatment, and medical research. However, there are a series of additional issues that must be recognized and addressed in conducting ethical (and legal) clinical research.

This chapter discusses issues relating to the historical development of the protection of human subjects, Institutional Review Boards (IRBs), informed consent, and the balance between the release (Freedom of Information Act) and withholding (Privacy Act and Confidentiality Regulations) of medical information.

Historical Perspective

The ethics and legal regulation of clinical research has been the subject of a number of textbooks.[1–3] The modern codification of ethical behavior for medical (human) clinical research was articulated, shortly after World War II, by the Nuremberg War Crime judges who presided over the trials of Nazi physicians. The 10 principles, known as "The Nuremberg Code," emphasized the absolute requirement for meaningful and voluntary consent of any human subject participating in research. This basic concept was restated in the Declaration of Helsinki, in 1964, by the World Medical Association.

Additionally, the declaration emphasized the concept that clinical research should be conducted only by medically qualified persons. Two years later, in 1966, the Surgeon General of the United States Public Health Service issued

the first United States federal policy statement requiring the establishment of a committee to review all research projects supported by the federal government. Six years later, in 1972, the Department of Health Education and Welfare, now the Department of Health and Human Services (HHS), published regulations requiring scientific and medical institutions to establish their own local committees to review those studies that would be funded by the department. Those committees, named Institutional Review Boards (IRBs), continue to be required to maintain the necessary expertise to review and monitor the ethical, legal, social, scientific, and medical aspects of the proposed research.[4]

As a result of the National Research Act of 1974, the Office for the Protection from Research Risks (OPRR), National Institutes of Health (NIH), was created to ensure that HHS regulations for the operation of IRBs are followed for all research funded by both NIH and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).[4] Before funds will be released to the research investigator, OPRR approval is necessary; OPRR has the authority to monitor the actual conduct of any given research project.

After having reviewed the extensive documentation required to initiate a research study, investigators may ask if all these formal protections are required when the research is being conducted by US investigators? The following two examples illustrate the necessity of IRBs and OPRR.

First, in 1932, the Unites State Public Health Service and the Tuskegee Institute and Hospital instituted a study to determine the pathophysiology of untreated syphilis in 600 poor black men living in a rural community. These men were never told that they were part of a medical experiment and they were never told that an effective treatment, penicillin, was available to them.[5]

Second, in 1963, at the Jewish Chronic Disease Hospital, in Brooklyn, New York, 22 weak and debilitated patients were injected with liver cancer cells. The researchers obtained consent from these patients; however, the informed consent did not indicate to the patients that they were actually being injected with "live" cancer cells.[6]

The present regulations for the protection of human subjects provide for administrative sanctions for research investigators found to violate them. Legal sanctions (prosecution) can occur if there is fraudulent (intentional) misrepresentation of the data or fraudulent conversion of funds. In these instances the Department of Justice is charged with conducting the litigation.

The individual research subject, however, also has the ability to sue for redress of injuries sustained in a clinical experiment. Medical malpractice ("malresearch") suits can be generated by research participants on the basis of negligence,[7] battery,[8] negligent misrepresentation,[9] deceit or fraudulent misrepresentation,[10] intentional infliction of emotional distress,[11] or invasion of privacy.[12] Thus, the failure of an investigator to abide by the rules, regulations, and law applicable to the conduct of human and animal research can result in civil and criminal litigation.

Protection of Human Subjects

Research

Research is defined, by HHS regulation, as the systematic investigation designed to develop or contribute to generalizable knowledge.[13] Demonstration, training, and service programs may find that they are actually conducting research within this definition, even if it is not the primary purpose of the interaction with the patient, client, or subject.[14] Research activities are generally grouped in terms of 1) interactions, 2) interventions, and 3) the gathering of identifiable private information. An interaction consists of communication or interpersonal contact between the researcher and the subject. An intervention may include a physical procedure or examination and an interview; either permits data to be gathered, generated, and analyzed. Identifiable private information refers to information about an individual's behavior, attitudes, and values which would not ordinarily be expected to be in the public domain and which are able to be linked with the individual (e.g., medical data found in a hospital chart or physician's record).

Human Subjects

Individuals participating in research supported by the United States Public Health Service (PHS) are protected by law.[15] The regulations, or interpretation of the law, define such a voluntary participant in a research protocol has a human subject. Specifically, a human subject is:

> a living individual about whom an investigator (whether professional or student) conducting research obtains [either] 1) data through intervention or interaction with the individual, or 2) identifiable private information.[16]

The regulation extends to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic (e.g., photographic and radiographic), written, or recorded information derived from individually identifiable human subjects. There are additional protections for certain classes of human research involving placentas, fetuses, pregnant women, human in vitro fertilization, and federal prisoners.

The regulation, however, does exempt certain categories of research involving human subjects that normally involve little or no risk (e.g., phlebotomy of adults). These limited exemptions are listed in the appropriate regulation.[17]

Further, those research designs that involve only the study of existing data, documents, records, or pathologic or diagnostic specimens, in which the subjects cannot be identified either directly or through codes, are not subject to this HHS regulation. Thus, it is permissible to analyze residual blood in a hospital laboratory for a purpose that the patient may not have given permission for, if before the analysis all identifying information about that specimen is destroyed. Once the identity of the specimen is destroyed, the research is no longer in a position to determine who provided the biologic specimen and

therefore cannot provide that individual with the results of the test. Thus, the test is anonymous. The key issue in these protective regulations focuses on researcher's ability to link the written or biologic data to a given individual. Confidentiality (even with a coding scheme that limits access to the actual names of the research participants) is not sufficient to guarantee the inability to link clinical data to an individual; complete anonymity is required.

Institutional Review Boards

Any human research covered by Federal regulation will not be funded unless it has been reviewed by an IRB.[18] The fundamental purpose of an IRB is to ensure that research activities are conducted in an ethical and legal manner. Specifically, IRBs are expected to ensure that each of the basic elements of informed consent, as defined by regulation, are included in the document presented to the research participant for signature (or verbal approval.)[19,20] All research documents may be reviewed by the federal government to ensure compliance with its regulations.[21] This reserved right of the government to conduct an "audit" of the research records must be clearly stated in the written informed consent forms that the research participants sign.

The deliberations of the IRB must determine that:

1. The risks to subjects are reasonable in relation to expected benefits, if any, to subjects; and, the importance of the knowledge that may reasonably be expected to result.
2. The selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.
3. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by the regulation.
4. Informed consent will be appropriately documented, in accordance with and to extent required by the regulation.
5. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
6. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When the IRB has special concerns about the vulnerability to coercion of some or all of the research participants, or the possibility of undue influence because of acute physical or mental illness, specific additional safeguards can be imposed on the researcher and his or her institution. In addition, special consideration can be given by the IRB for the inclusion of additional safeguards, when the research participants are educationally or economically disadvantaged. At a minimum, the IRB shall determine that all PHS requirements are satisfied before the research study being approved and implemented.

It is axiomatic that the IRB should ensure that the risks of participation in a research study should be minimized. The IRB must determine that this

objective is to be achieved by ensuring that investigators use procedures that are consistent with sound research design and that do not necessarily expose subjects to excessive risk. In addition, the IRB needs to ensure that the investigators, whenever appropriate, minimize risk and discomfort to the research participants by using, where possible, procedures already performed on the subjects as part of routine diagnosis or treatment (e.g., the results of clinically indicated lumbar puncture should be used by the investigator, instead of ignoring that data and specifically repeating the lumbar puncture as part of the research protocol).

Informed Consent

An informed consent is a contract between the research investigator and the research subject. It can be verbal or preferably written, and it must document what each party understands to be the limits of his or her responsibility to the other. The informed consent may be read to the research subject, but he or she must always be given the opportunity to actually read the document. There are instances where oral consent, without a written document, is sufficient. However, in all instances the informed consent should be documented;[22] In cases where a written informed consent is determined not to be required by the IRB, the IRB may require the investigator to provide research subjects with a written statement regarding the research.[23]

No informed consent, whether oral or written, may include any exculpatory language through which the subject or his or her representative is made to waive or appear to waive any of the subject's legal rights nor may it release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence. In short, the research subject cannot be placed in a position to give up his or her Constitutional right to sue, for negligence, the researcher or anyone connected with the research project.[24]

The elements of an informed consent for participation in a research protocol are provided by FDA regulation and include[25]:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental
2. A description of any reasonably foreseeable risks or discomforts to the subject
3. A description of any benefits to the subject or to others that may reasonably be expected from the research
4. A disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records
6. For research involving more than minimal risk, an explanation as to whether

any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or whether further information may be obtained
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following elements of information shall also be provided to each research subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable
2. Anticipated circumstances in which the subject's participation may be terminated by the investigator without regard to the subject's consent
3. Any additional costs to the subject that may result from participation in the research
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.

Investigators must realize that HHS informed consent requirements are not intended to preempt any applicable federal, state, or local laws which may require additional information to be disclosed for informed consent to be legally effective. Nothing in the FDA regulations is intended to limit the authority of a physician to provide emergency medical care to the extent that the physician is permitted to do so under applicable federal, state, or local law. Ultimately, it is the institution that receives the research funds or is accountable to HHS for these funds, that has the primary responsibility for safeguarding the rights and welfare of individual human subjects.

Office for Protection from Research Risks

There is an additional layer of administrative safeguard for the research participant. Before the actual award of federal funds for the support of research activities, the United States Public Health Service (PHS) is responsible for independently determining 1) whether human subjects are involved in the research activities, and 2) whether the protections for the research subject are adequate. This dual function is administratively managed by the Office for Protection from Research Risks (OPRR), at the National Institutes of Health

(NIH). Thus, OPRR is responsible for ensuring that the Food and Drug Administration (FDA) regulations, pertaining to informed consent[26,27] and the regulations pertaining to new drugs for investigational use[28] are observed.

Release of Information—Protection of Research Participants

Freedom of Information

The Freedom of Information Act (FOIA) as amended,[29] and associated public information regulations of HHS[30] require the release by PHS of certain information and documents to the public. Only information in the direct possession of PHS or its agencies can be released. If a FOIA request is made of the government, the principal investigator of the study in question will be notified as to who has generated the request, the action taken by the government, and the documents, if any, that were provided. Specific data about individual patients or experiments cannot be provided by the government if they are not in possession of such data. A FOIA request to the government cannot be used to force a government contractor or grantee to provide information to the initiator of the FOIA request.

The Privacy Act

The Privacy Act of 1974 provides certain safeguards for individuals against invasions of personal privacy.[31] Despite participation in a research study, a research participant does maintain the legitimate legal expectation that personal identifiable information will not become public information. The Privacy Act applies to all systems of records, not just to research records. There are two fundamental types of safeguards authorized in this act. First, there is the right of individuals to determine what information about them exists and is maintained in a Federal agency's files and to know how that information is used. These requests frequently occur when the research record is to be used to later document a medical event or verify a pre-existing medical condition. For instance, an individual participating in a research study may find that he or she wishes that his or her research data be linked with other medical records data, economic data, or laboratory or physical examination results to assist in an application to determine eligibility for an entitlement (e.g., social security, welfare, or Veteran's Administration) benefits. Copies of his or her file will be provided, upon written request of the concerned individual, to that individual.

Second, an individual has the right to have access to his or her records and to correct, amend, or request deletion of information in that record that is inaccurate, irrelevant, or outdated. These requests may occur when the individual determines that his or her data are incorrect and have been used, with negative effect, in a legal or administrative manner (e.g., the military service or Veteran's administration record wrongfully indicates that there is no

service-connected disability and the disability check has been discontinued). Requests may also occur merely because the individual is curious to know what is in his or her file. These types of requests are honored. However, any request must identify the specific study or data base A request for "all my records maintained by the Federal government" will be deemed to be too general and nonspecific as to warrant a response by the government.

Records maintained by grantees, because the data were not collected for the express purpose of the Federal government, are not subject to the Privacy Act requirements[32]; however, data generated by government contractors are often considered to be subject to the Privacy Act.[32]

Confidentiality

Third parties cannot request identifiable information about research subjects participating in grant-funded research without the permission of the individual in question unless they have obtained a court-ordered or administrative-ordered subpoena. In such an instance there is a balancing between the right of the requester to obtain information about projects that have been funded with tax dollars (the intent of FOIA) and the individual research subject's right to privacy (the intent of the Privacy Act).

The need to protect an individual's research records has been long recognized by the Public Health Service. The Centers for Disease Control (CDC) has statutory authority, in the Public Health Service Act, to protect research records pertaining to epidemiologic studies that they fund or actually conduct themselves.[33] This provision of the Public Health Service Act has been challenged in Federal court; the court has ruled that the identity of the individuals interviewed by CDC is protected.[34,35]

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) has statutory authority to grant a Certificate of Confidentiality, which precludes investigators from involuntarily providing any data on any research subject.[36] The research investigator, under a Certificate of Confidentiality, can provide any data on any of the research subjects to a third party as long as the researcher has received prior approval of the research subject in question (in the original informed consent or by a separate release of medical information). If the issue of transmission of the information collected in the research study to a third party is not addressed in the informed consent, then the research investigator can release the information to a third party, if the researcher independently determines it is appropriate to do so. However, there are other restrictions that may preclude the voluntary release of the information by the investigator.[37]

Summary

Today, conducting research in the United States is more complex than developing a satisfactory null hypothesis and designing a research protocol to

test that hypothesis. Historical events in this country and elsewhere have had a major impetus in forcing the Federal government to establish a set of legal principles and guidelines to protect the rights and well-being of human research subjects. Research investigators receiving federal funds must follow the policies of their respective IRBs and of the NIH OPRR. A research investigator who fails to comply with the existing local, state, and federal regulations and law can expect severe administrative and legal sanctions, including mal-research claims. In the final analysis, all the procedures, guidelines, rules, regulations, and laws have one purpose: to protect human subjects in the conduct of clinical research and thereby maintain the public's confidence in much needed clinical research.

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10

Informed Consent

CHARLES L. SPRUNG, MD, AND BRUCE J. WINICK, JD

Every human being of adult years and sound mind has a right to determine what shall be done with his own body and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages.[1]

With these words Judge Cardozo in 1914 expressed a patient's right to autonomy in medical decision making. Informed consent is currently an ethical, medical, and legal requirement. A physician must obtain informed consent before performing a procedure or treating a patient. Unfortunately, the legal requirements of informed consent have developed from atypical situations involving dissatisfied and injured patients rather than from the more usual occurrences of physicians helping patients with subsequent patient satisfaction. In addition, legal decisions have not set forth clear guidelines or rules for physicians to follow. It is therefore not surprising that the medical realities of informed consent sometimes clash with the legal requirements. This chapter reviews the elements of informed consent and summarizes the legal and medical realities. It is important for physicians and attorneys to be aware of state law on informed consent in their area,[2] as different courts may reach opposite conclusions based on the same facts.

The elements of informed consent include disclosure of information, competence, understanding, voluntariness, and decision making. A physician provides information to a competent person who after understanding the information makes a voluntary decision. In general, if no consent is obtained or if the performed procedure differs from the procedure consented to, a suit in battery may be brought. If some consent to the performed procedure is obtained but the consent is deficient or not informed, a suit in negligence is brought.

Disclosure of Information

Most courts require that physicians disclose to the patient the diagnosis, the nature of the proposed procedure, the benefits and risks of the procedure,

alternative procedures with their benefits and risks, and the consequences of not having the procedure.[3–6] A physician may not have to disclose risks that the patient knows or an average person would know.[4,6] There are two standards that courts have used to determine the physician's duty to disclose. The "professional" standard is based on the custom of other physicians practicing in the community.[3,7] Under this standard, the physician is not liable unless his omission of information deviates from the accepted medical practice in the community. Expert medical testimony is required to establish the accepted professional standard and to show that the defendant physician's disclosure deviated from this standard. The second is the "lay" or "material risk" standard, requiring the physician to disclose information that a reasonable person in the patient's position would consider material to the decision.[4–6] Expert medical testimony also may be used even if the lay standard is followed to note the risks and their frequency, alternatives, and the causal relationship between the lack of disclosure and the injury to the patient. Despite a trend in the courts to move away from the traditional professional standard toward the lay standard, many states have enacted statutes using the professional standard. Currently, a majority of states follow the professional standard.[2]

Whether a risk is material depends on its frequency and severity.[5] If the risk of injury is small, the physician informs the patient of the risks that are likely to occur. If, however, a serious injury might occur, the physician should inform the patient of all but the extremely remote risks. The definition of extremely remote varies with the court. Disclosure was required for a 3% risk of death or paralysis[8] and a 1% risk of hearing loss,[7] but was not required for a 1.5% risk of losing an eye.[9] The severity of risk required to be disclosed may range from death to less serious risks.[5]

If a physician does not disclose adequate information to a patient, the patient cannot recover for damages unless the patient suffered injury because of the nondisclosed risk. If it is shown that the patient would have agreed to the procedure or treatment had the risk been disclosed, there is no causation and hence no liability. Two standards have emerged to determine causal connection between the physician's nondisclosure and the patient's injury. The subjective test asks whether or not the individual patient would have agreed to the procedure if disclosure was given.[6] Because it is unlikely after an injury has occurred, however, that patient will admit that he would have agreed to the procedure has he been informed of the risks,[5] other courts have used an objective test. With this test the focus is on what a prudent person in the patient's position would decide if properly informed.[4] Most courts have used this latter objective test.

Informed consent forms have been used to document that informed consent occurred. Although a signed form provides evidence that consent was obtained, *it does not prove that the consent was informed.* Unfortunately, in many circumstances the consent form has become a means to avoid liability rather than a means to provide information to patients and has replaced the process it was designed to substantiate.

Competence

People are presumed to be competent and capable of decision making unless they have been formally judged to be incompetent.[10] If a patient is competent, a refusal of treatment must be respected,[11] whereas if a patient is incompetent, patient decisions are not valid and do not necessarily have to be obeyed.[12] Nevertheless the criteria used to determine competency vary and specific objective tests to establish competency have not been developed.[13]

Understanding

Requirements for understanding usually are that a reasonable person would understand the disclosed information. Courts have not usually required a demonstration that patients actually understand what is disclosed.

Voluntariness

Patient decisions must be voluntary and free from coercion or unfair persuasion. Involuntary treatment is rare in the United States today,[14] except perhaps in institutional psychiatry.

Decision Making

Finally, a patient must decide to accept or refuse the procedure or treatment. Consent can be expressed not only by words but by a person's actions, or implied from inaction or custom.[15]

In addition to the noted elements, there are also exceptions to the requirement of informed consent. These include emergency, incompetency, therapeutic privilege, and waiver.

Emergency

In an emergency it is assumed that the patient consents. Consent is implied without the patient's express statement.[15–17] Exactly what constitutes an emergency has not been clearly delineated, but emergencies may range from treatment necessary to preserve life or limb[16] to treatment that alleviates pain or suffering.[17]

Incompetency

Incompetent patients may be treated without permission. Nevertheless, an incompetent patient's assent to treatment does not necessarily allow the

physician to treat and an incompetent's refusal of treatment does not necessarily allow the physician not to treat. In general, incompetent patients are deemed unable to make important, rational decisions. This category typically includes patients who are unconscious, delirious, grossly psychotic, or senile. Physicians usually begin to consider a patient incompetent if he refuses therapy, is severely ill, or is incapable of communicating or understanding. When patients in intensive care units are treated without informed consent, it is based on an emergency and/or incompetency exception.

Therapeutic Privilege

Therapeutic privilege excuses a physician from the requirements of informed consent when disclosure of information could have a detrimental effect on the patient.[3] Controversy exists as to the specific criteria and degree of detrimental effect required for invoking this exception. Some courts use a professional standard based on medical judgment,[18] whereas others use a lay standard based on whether disclosure would have upset a reasonable patient.[5] The extent of this therapeutic privilege varies from a vague detrimental effect on the patient's best interest to a strict interpretation of detrimental effect.[4]

Waiver

The last exception allows a patient to waive his right to informed consent.[5] The patient may delegate to the physician or to a third party the right to make the decision for him.

If one of the exceptions to informed consent applies, the physician should document the exception. Under these circumstances it is unclear how disclosure and consent should occur. In an emergency, time may not permit disclosure or consent. If the patient is incompetent or therapeutic waiver is used, a surrogate should give informed consent for the patient. Parents are usually considered the legal guardians of their minor children, but children who are capable of understanding (such as adolescents) are increasingly taking part in decisions affecting their health care. Under most medical circumstances, however, a guardian has not been previously appointed by the court and such a procedure is not a realistic alternative. Exactly who should act as the patient's proxy has not been clearly delineated, but most courts and legal scholars consider a family member the legally authorized individual.[4,5] In fact, family members and intimate friends are routinely used by physicians in life and death decision making.[19]

Despite the legal requirements for informed consent, several studies have demonstrated that informed consent as envisioned by the law does not routinely occur.[20,21] There is a little disclosure of risks, benefits, or alternatives in routine hospital care.[20,21] Many physicians do not obtain consent or inform patients of major risks before radiographic procedures. Surveys have shown that most people desire information necessary for them to make medical decisions but studies have shown that many patients do not want to be

informed of the risks of hazardous procedures or anesthesia.[21,22] In fact, patients who ask questions usually do so for reassurance rather than for information.

Patient abilities to recall disclosed information or understand information necessary for a decision have been shown to be poor.[23] After 1 day, only 50% of patients understood the nature of a procedure to be performed, and only 55% could correctly list even one major risk or complication.[23] These findings could be secondary to an inadequate, initial disclosure of information and do not necessarily preclude an initial understanding of the information.

Despite the fact that involuntary treatment of patients is rare, large portions of routine medical care is performed without the explicit consent of patients.[14] It is as if the patient gives his consent if he does not refuse.[14] Even if a choice is available many patients do not believe they have a choice.

Patients rarely weigh risks, benefits, and alternatives in making a decision.[20,21] Many patients do not read informed consent forms appropriately, and make their decisions based on previous experiences or personal feelings.[20] In fact, in many instances physicians make recommendations for the proper medical care and patients do not make a decision but rather agree with the recommendation.[21]

Of the exceptions to informed consent, therapeutic privilege has received the most investigation. Anecdotal reports have noted patients developing myocardial infarctions after disclosure of information. Patients have suffered apprehension, anger, and anxiety after the disclosure of risks of anesthesia.[22] On the other hand, preoperative counseling has been shown to reduce anxiety and complications during convalescence and may even reduce hospitalization time.[24]

The visions of the law are very different than medical realities. This may be because medical decision making is not always a one time event with disclosure of benefits, risks, and alternatives. Rather, it is a process that occurs over time. Frequently patients are asked to consent to the standard medical therapy and no real accepted medical alternative exists. It is time for the courts and legislatures to tailor informed consent rules to the realities of patient-doctor relationships, decision-making processes, and medical practices. In the meantime, however, physicians should be cognizant of existing legal requirements of informed consent. Physicians who continue to act reasonably and communicate with their patients should not be at risk for legal problems.

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11

Improving and Refocusing the Medical–Legal System

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The use of risk-benefit analysis and risk assessment is widespread in a number of activities including engineering, actuarial analysis, investment brokering, military planning, and during the course of ordinary living.

It has long been recognized that most medical encounters involve potential risks as well as potential benefits. However, the use of risk-benefit analysis in medicine has not been extensive. It is surprising that few attempts have been made to analyze scientifically the nature and incidence of risks in medical practice. Such an analysis would be critical for an accurate assessment of the interaction of medicine and the law. Compensable violations during patient care should rationally be based on transgressions of risk-benefit balance resulting in harm to patients.

This chapter reviews the nature of medical risks faced by patients and the public and suggests modifications to current malpractice approaches designed to improve patient outcome or to protect the public welfare in the malpractice area. A patient and public-oriented approach should be central to the objectives of both the medical and legal systems. This approach is frequently overlooked.

Nature of Harm to Patients

Potentially compensable events during medical care (events that might eventuate in malpractice suits) usually arise by one of the following mechanisms.

Iatrogenic Accidents

These are the random accidents that happen to patients during medical care, which produce injury essentially unrelated to the natural history of their underlying disease.

There are three interesting aspects of iatrogenic accidents. One is that such accidents have a high prevalence. For example, in one retrospective series

about one third of hospitalized patients suffered minor or major complications during hospitalization as a result of errors; 8% suffered errors (defined as potentially life threatening), and in 2% of the patients the error was involved in the death of the patient.[1] Secondly, these accidents (with the exception of perhaps nosocomial infections) are seldom brought to the general attention of the medical staff of a given hospital. This eliminates an important source of learning; the ability to learn from our errors. Thirdly, it is even rarer that these errors are brought to the attention of the affected patient or the patient's family. As a result, the ratio of PCEs/Actual Compensated Events (ACE) is very high.

Gross Errors in Physician Judgment

There is mega-anecdotal evidence that such lapses in judgment do occur. For example, a 93-year-old woman, with diffuse carcinomatosis (liver, bone, brain, and lung) originating from the breast, enters a hospital terminally ill, primarily for the purpose of dying comfortably. A questionably new spot is observed on a routine chest x-ray and a pulmonologist is consulted. He subjects the patient to bronchoscopy and a transbronchial biopsy. This transgression of rational and compassionate medical care is not publicly recorded and would have escaped notice except for the intervention of a shocked respiratory therapist. We have no accurate "judgmentometer" to screen physicians in terms of judgment, so such travesties of medical care do take place.

Gross Defects in Physician Character

Physicians are drawn from the same pool of humans that make up the remainder of humanity. It is not surprising that there is an end of the spectrum of physicians that engages in antisocial activity directed against individual patients, groups of patients, or the public as a whole. Again, there is a rich anecdotal base that illustrates this source of patient risk.

The harm to patients coming from the previous two mechanisms occasionally spill over into the malpractice area.

Iatroepidemics

These are systematic errors introduced and widely accepted by the medical system. Being errors, these results in harm or death to masses of patients. In technical terms, these consist of practices that have unfavorable risk-benefit ratios, which are theoretically detectable before widespread acceptance. (The interested reader may consult references for details.[2–4]) In the present context, iatroepidemics are seldom involved in either individual lawsuits or class action suits. As a result, the failure to protect patients from these episodes constitutes a critically important blind spot in the law.

Potential Compensable Event/Compensated Events

Ratio

Careful retrospective analyses of medical records reveal a large number of PCEs.[5,6] Although no precise estimates are available, it is virtually certain that many of these are not brought to the attention of the involved patient or family. In fact, the record of some of these events may be deleted from the record. As a result, there is a high PCE/CE ratio that is not only a violation of fundamental patients' rights, but is an obvious source of injustice, however defined.

Proposed Changes

Flowing from these risks, a series of modifications of current law can be proposed that would tend to improve the efficacy of the law in dealing with torts involving patients and the public.

Standard of Practice *v* Prudent and Reasonable

Current criteria of medical malpractice are based on violations of standards of practice. This differs from the usual legal criterion involving nonmedical injuries, in which negligence is defined as the failure to act in a reasonable and prudent fashion.

The use of the prudent and reasonable criterion in medical malpractice issues would have several important beneficial effects on patient outcome. It would recognize systematic errors as an important source of preventable injury. It would provide compensation to victims of unacceptable medical practices whose general use was deleterious to patient care and whose deleterious effects could have been and should have been avoided (iatroepidemics). It would be useful to physicians who feel compelled to undertake certain practices that they feel are unwarranted in order to escape the possibility of lawsuits. Physicians could resist the standard of practice when they believed that 1) the standard was generally wrong, and 2) the application of the standard was wrong for a given patient. It would stimulate a much more careful evaluation of new technology and new management approaches before their widespread application. It would provide a consistency that is often lacking to legal decisions in the malpractice area. For example, it is now possible to be sued either for using or for not using hemodynamic monitoring.

Increasing the Flexibility of Statutes of Limitation

Most jurisdictions have strict limits defining the maximum period after the performance of a negligent act that a lawsuit can be entered. Strict limits, of course, do not provide for negligent acts whose consequences do not become apparent for many years afterward. For example, a current form of surgery for myopia, radial keratotomy (RK), has been performed on several hundreds of

thousands of patients. Radial keratotomy today is a less extensive form of surgery than the original variant performed in Japan in the 1950s. Twenty years after the Japanese operation, essentially 100% of the patients developed blindness as a result of bullous keratopathy. There is a risk that a similar sequence of events will take place in American patients undergoing the modern form of RK.[7] No legal provision is being made to provide for that contingency.

The association of clear cell carcinoma of the vagina to the subsequent development of congenital abnormalities in the offspring of women administered diethylstilbesterol while pregnant, required years to demonstrate. The legal problems confronted by those suffering from this iatroepidemic stem in part from the length of time required for these complications to become clinically apparent.

Because harm from negligent medical acts may not become apparent for years, a more reasonable and flexible approach to any statute of limitations would be in the public interest.

Mandated Disclosure of Significant Iatrogenic Accidents to the Family of Surrogates

A substantial number of grossly negligent acts almost certainly are never brought to the attention of the patient or the patient's family. In fact, a negligent act may not even be inserted into the medical records.

Two examples follow: A 59-year-old apparently healthy male, without any symptoms of disease, undergoes a "routine" stress test, which is positive. This leads to the performance of a coronary angiogram and the patient is found to have a single stenotic coronary artery lesion. The patient undergoes bypass surgery and, in the immediate postoperative period, develops a massive acute myocardial infarction and dies. At postmortem examination the cause of the acute myocardial infarction is found. The surgeon had (inadvertently) ligated the normal arterior descending coronary artery. As a result, an asymptomatic patient died needlessly. The family is not told of the accident.

A 35-year-old woman enters a hospital for an elective hysterectomy. During her postoperative care, she is administered a huge amount of salt-free fluids intravenously. As a result, she develops hyponatremia, cerebral edema, convulsions, coma, and she dies. Her family is told that the patient died of a stroke.

Episodes like these are, hopefully, extreme examples and rare. In terms of elementary concepts of justice, the patient or surrogate should be informed of significant iatrogenic accidents.

General *v* Specialist Experts

There is an increasing tendency for expert witnesses in medical malpractice suits to be narrowly based. Neurosurgeons testify about the standards of care by neurosurgeons, ophthalmologists about the standards of care by ophthalmologists, etc. This leads to three problems. There are general aspects of patient care that no physician should violate. Medical specialists are frequently

unfamiliar with these general aspects. Narrowly based experts frequently are subject to intrinsic biases within their specialty. These biases may not be in the best interests of patients. Highly specialized expert witnesses serve to enforce orthodoxy of views in a given field.

For example, there is overwhelming evidence that the use of electronic fetal monitoring (EFM) provides no statistical benefit to women during delivery and does pose some risks.[8] Obstetricians testifying during a malpractice suit would tend to enforce the view that the use of EFM is mandatory. A general expert might be expected to review the literature and testify about the unfavorable risk-benefit balance.

Removal of Favored Legal Status from Physicians Involved in Vanity Surgery

There is a proliferation of surgical procedures that are performed not because of medical indications, at least in the classical sense, but performed for essentially cosmetic reasons. Such procedures as radial keratotomy, liposuction, lipotransplantation, breast reduction, breast augmentation, and bilateral subcutaneous mastectomy fall into this category. Although the procedures are performed by physicians, their real intent is not therapeutic. Their major intent is to make money, and the physician is selling a service. Those performing the surgery are afforded the unusual privileges that society confers upon physicians. They do not have to guarantee the results. They brandish the impressive appurtenances that doctors possess, they are not required to be particularly reasonable and prudent, they usually are involved in a sharply limited temporal relation to the patient. Their fees are usually sharply elevated and arrangements for long-term follow-up are rare. Both the patient and the doctor have the right to engage in the procedure. The law should stipulate that these arrangements do not fall within the definition of a doctor-patient relationship. Given that neither their fundamental goal is therapeutic nor their patient interactions directed toward the best medical interests of the patients, it would seem reasonable to divest them of the privileged status that we physicians enjoy.

This is not to say that subjects would not be free to select these services nor that these physicians, acting in nonmedical mode, would not be free to offer them, but the relationship would be distinct from a patient-physician relationship.

Physicians as Officers of the Court

An adversarial basis for malpractice law is largely defended by most lawyers as an important and useful legal principle. I do not feel qualified to challenge this strongly held belief. However, it is apparent that the quality and veracity of information provided to juries and judges by adversarial experts results in a plethora of controversial and dubious testimony.

Patients and the legal system could benefit by the use of an impartial medical expert who provided expert analysis to the jury/judge. This expert would not

replace the use of experts hired by either the plaintiff or the defense, but would provide evidence free from any conflict of interest and from the pressures that arise from being hired by one side or the other. Many medical experts already function in this manner. Unfortunately, many do not.

Public Access to Information Having to do with Medical Outcomes and Professional Competence

Medicine operates relatively free from critical public scrutiny in a number of respects. One important respect is that the results of incompetency hearings on individual physicians are not made public. As a result, there is a population of recurrent malpractice-prone physicians who continue to practice submaximally. For the public good, the results of government administrative hearings should be made public. Although it is true that the outcome of these hearings is not always just and equitable, the usefulness of these data for improving medical care overweigh (in my opinion) the parochial benefits derived from hiding the data.

There are wide differences between different hospitals and different physicians in the outcomes of various surgical and other procedures.[9] Access of the public to data on comparative mortality, comparative morbidity, comparative rates of surgery, and comparative rates of various procedures would tend to improve selection of hospitals, selection of physicians, and selection of procedures by patients. Medicare has already taken steps in this direction.

Whereas crude data may be misleading in individual cases and these data may be misused by hospitals and physicians, I believe that these data belong in the public domain, and their publication would and should be coupled with educational analyses to make the information more relevant and useful.

What's in it for Medicine?

There are several common reactions among physicians to proposals of this kind because they are weighted so extensively in favor of the public and, by extrapolation, against physicians and medicine.

One reaction is that the proposals are idealistic and would require a world in which doctors were not faced with the problems of malpractice suits.

A second reaction is that patients and the public are not sophisticated enough to prevent harm and injustice to doctors and medicine should such proposals be implemented.

A third reaction is that the real world is too harsh and unsympathetic for doctors to expect fair treatment if the present legal system is modified substantially.

A fourth reaction is that, as is true of other professions, physicians should not be expected to be unduly honest and truthful.

Some of these reactions have some legitimate validity and many physicians have legitimate concerns about compromising their legal and social position even more than is currently the norm.

But there are several compelling reasons for opening medicine to a more intense scrutiny and holding medicine to higher standards than is currently the case.

One such reason is that it's the correct thing to do. The favored social and economic position of medicine arises partially from the impression that the main imperative for doctors is to protect the welfare of patients. So to speak, this imperative comes with the territory.

However, there is another compelling reason. There is a progressive crisis in confidence in medicine and in physicians by the public. To some extent this crisis of confidence stems from the (all too often accurate) perception that the goals of doctors are not primarily directed toward improved patient outcome. Modern medicine, with its new technology and science, increasingly deals with patients in an impersonal and dehumanized manner.

I submit that we can increase our valid use of science and technology without sacrificing our role as advocates for improved patient welfare. Supporting changes in the malpractice system that are good for patients would, I believe, play an important role in improving the general image of the doctor in society. There is little question that the image needs some improvement. Supporting what is good for patients may turn out to be good for doctors.

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12

Ethics, Medicine, and the Law

GEORGE A. KANOTI, STD

Ethics is like breathing. We do it all the time.

The achievements of pulmonary and critical care medicine have placed these disciplines in the spotlight of legal and ethical scrutiny about the use of life support and other forms of therapy. The landmark case of Karen Ann Quinlan[1] focused the attention of lawyers, judges, physicians, and ethicists on the implications of medical technology for choices in the treatment of acutely or chronically ill patients. Lawyers and judges addressed the legal precedents for instituting or withdrawing life support systems. Ethicists identified and developed moral principles that apply to the appropriateness of clinical judgments to institute or withdraw life support systems. The Karen Ann Quinlan case raised questions about the rights of individuals who face life-threatening situations, the legal and moral responsibilities of those physicians under whose care they come, and the moral principles justifying choices in such cases.

A decade of legal-ethical opinions, articles, and lawsuits concerning treatment of persons with chest trauma, chest diseases, or other illnesses with pulmonary complications has resulted both in clarity and confusion over the ethics of withdrawal of life support.[2] The clarity is seen both in the focus on the medical technology that has produced moral dilemmas, and the identity of the legal and ethical arguments about foregoing or withdrawing life-sustaining treatment.[3]

However, one of the unfortunate confusions has been the inability to distinguish moral, legal, and ethical sources of obligation that address practices and policies concerning the use of life-support technologies in the treatment of acute or chronic pulmonary trauma or other illnesses with cardiopulmonary complications. An inability to distinguish these sources of obligation confuses analysis and thwarts acceptance of well-grounded policies.

Law and Morality

Law can be defined as the collection of rules and regulations by which society is governed. It regulates social conduct in a formal binding way while it reflects society's needs, attitudes, and mores. Law is a dynamic concept that lives, grows and changes. It can be described as a composite of court decisions, regulations, and sanctioned procedures, by which laws are applied and disputes adjudicated.

Law sometimes reflects the mores of society but is not identical with it. The mores or the morality of society refers to moral norms that are accepted by society as standards of behavior between persons.[4] Moral norms are intended to assist judgment and to provide criteria for morally assessing behavior of individuals. The sources of moral knowledge are religious and/or cultural. Persons who act contrary to moral norms usually are sanctioned.

When physicians face a decision concerning life support for a patient, both legal and moral norms surface. These norms surface in practitioners' minds as well as in patients' and/or families' minds. Even the institutions where pulmonologists practice their art have a legal and moral awareness. Although it is important that pulmonologists know the legal norms in their community, pulmonologists also must be aware that moral norms may not be consistent with the legal norms. Further, their personal moral norms may differ from those of the patient. It is also important to note that in addition to the morality acquired by physicians through their own philosophical, religious, or cultural experience, physicians are also introduced to a professional morality, a code of expected professional behavior, through their training.[5]

In sum, when physicians face a moral question, for example, whether to institute or to withdraw ventilator support for a particular patient, at least three sources of obligation surface to direct and sometimes cause conflict in their judgment, namely: professional norms, legal requirements, and moral norms.

Ethics

Ethics is described as an organized body of knowledge that has a language and theories that address questions of conflict between law and morality, or between moral norms in clinical choices or policy questions.

Pluralism, namely culturally, religiously, or philosophically diverse moral obligations, creates conflicts. The challenge is to resolve conflicts between seemingly irreconcilable moral positions. Ethicists assist here because they address conflicts not through specific legal, moral, or professional norms but through value-based obligations that are not dependent on specific religions or cultures. Ethicists introduce into the resolution of conflict goals of behavior (called moral values) that are indicated as optimal conditions for human behavior and policy.[6] These moral values are both a goal, something to be striven for, and an attraction, something that appeals. Persons perceive moral values as essential to their personal and social well-being.

Moral Values

Four moral values provide a framework for decision making in a pluralistic setting.[7] The primary moral value is the value of life. This value emphasizes that life is good and important and must be protected. This moral value is self-evident. It indicates that without life there are no moral choices, there is nothing worth gaining or doing because there is nothing. This value is important to the moral tradition of medicine because medicine is dedicated to preserving life and staving off the illnesses that reduce the extension and/or quality of life.

The second moral value is freedom. The appreciation of this value is historically relatively recent, but it is identified as one of the most important of moral values. This moral value indicates respect must be given to persons because they are autonomous beings who ought to have the freedom to direct their own choices.

The third moral value, benefit, indicates actions should produce positive results rather than negative results on the person or persons toward whom the behavior is directed. The converse side of this value, do not harm, is found in the Hippocratic Oath, usually expressed as "at least do not harm the patient." This moral value means that all behaviors that affect patients should produce good results or a balance of good and bad results.

The final moral value is justice. The question of proper allocation of both benefits and burdens to persons is one of the concerns of the value of justice. To a large extent the gatekeepers of the allocation of resources to patients are physicians.

Ethical Dilemmas in the Treatment of Critically Ill Patients

Withdrawal of ventilator support to acutely or chronically ill patients raises serious legal and ethical dilemmas. The acquired immunodeficiency syndrome (AIDS) epidemic has reinforced the serious moral questions faced by pulmonologists. The obligation and the limits of obligation of physicians to perform invasive diagnostic or therapeutic procedures on these patients is another example. The choice to ventilate a terminally ill AIDS patient for whom no effective therapies exist raises further serious legal-moral questions.

Other issues that create dilemmas for pulmonologists are whether or when they should disclose terminal illness to patients, questions of confidentiality (especially for AIDS patients), truth telling, "whistle blowing" on toxic industrial or residential environments, and management of the chronically ill patient. The chronically ill patient raises issues such as commitment to the patient who is noncompliant, paternalism, etc. Further developments in critical care raise other questions such as the responsibilities of the physician to manage and to monitor home care ventilation.

Role of Ethicists and Ethics Committees

Pulmonary specialists face many serious legal and moral choices in their practice. They can profit from using the expert knowledge of ethics committees and/or ethicists in addressing these issues and avoid entering the court system where adversaries confront each other over the issues of responsibility and liability.

Most pulmonologists have not been trained to address ethical questions in a systematic way. They use their meager understanding of law, their sense of morality, and their sense of professional responsibilities as reflected in their codes to make decisions. Since approximately 1981 the introduction and development of institutional ethics committees, and the use of ethics consultants either on a part-time or full-time basis, has occurred. An ethicist is a person who has demonstrated mastery of ethical knowledge. A bioethicist or medical ethicist is a person who has demonstrated the ability to apply ethical knowledge to clinical choices.[8] Ethics committees, ideally, share both the mastery of ethics and the wisdom of each member's perspectives and judgment to address these conflicts. Although not all hospitals have ethics committees or ethics consultants available to them, the ethical dimensions of pulmonary practice are found in every hospital.

Ethics committees and ethics consultation are relatively new phenomena.[9] Initial reactions to this movement have been positive. Ethicists and ethics committees contribute to the quality of patient care by addressing the ethical dimensions of patient care decisions.

Ethics committees and ethics consultants provide opinions to the clinician. They do not police or monitor clinicians, nor do they intervene in the patient-physician relationship. What ethicists and ethics committees bring is a knowledge of ethics, an awareness of legal constraints and conditions, and an ability to communicate the ethical analysis of the options faced by the physician and the patient. Ethicists and ethics committees have contributed to resolving moral questions in medicine in two ways; by providing expert analyses for development of guidelines that can be used in the clinical setting and by providing bedside consultation when requested.

Moral Moment

When should a pulmonologist request the consultation of an ethics committee or an ethicist? Generally speaking, any time a "moral moment" is experienced in a patient-physician relationship an ethics consultation should be considered. The signs that a moral moment has occurred are psychologic, sociologic, intellectual, and moral.[10]

Psychologic indicators of a moral moment in medicine are heightened stress, discomfort, or even turmoil over the choices facing clinicians, patients, or families.

Sociological indicators of a moral moment are paradoxical: either the patient and/or choices are talked about by everyone and perhaps even vigorously or acrimoniously disputed, or the patient or options are not talked about by anyone. There can be a conspiracy of silence generated by frustration or fear.

The intellectual indicators of a moral moment are seen in the behavior and energy expended toward finding moral justification for choice. An awareness of personal uncertainty or ignorance may stimulate library searches for articles and/or documents, or formal or informal consults with colleagues for advice, wisdom, and knowledge.

Moral indication of a moral moment usually is the presence of entrenched opposing moral positions. For example when the need to reduce the patient's pain means using analgesics that will reduce already compromised lungs' capacity, one person insists that all must be done to keep this patient alive; the other person insists morally that the patient's pain must be managed. When a moral moment that produces indecision, conflict, or confusion is present, an ethical consultation is appropriate.

The value of an ethics consultation can be seen both prospectively and retrospectively. Every physician-patient relationship carries with it moral assumptions, expectations, and demands. Identifying and clarifying these moral assumptions helps the relationship proceed positively. This approach avoids the pitfalls of taking on the total responsibility for the patient's interests, or the pitfall of being totally dependent on the expressed wishes of the patient.

This author's experience shows that ethics consultation has definite advantages. Families have expressed their gratitude that no stone was left unturned in the management of the patient. The moral dimensions of clinical choices were addressed in a professional manner that gave assurances that what was being done was both medically and ethically justified. This increases patient and family confidence in the quality of care offered to patients and enhances the reputation of medicine as being not just a service industry, not a self-serving entrepreneurship, but a *humane profession* that responds to the medical and moral needs of patients and families.

How to Approach an Ethics Committee or Ethicist for Consultation

When moral dimensions of treatment options are either diametrically opposed or clouded, it is wise to obtain an ethical consultation. Unfortunately, not all hospitals have ethicists or ethics committees. Because ethics is intrinsic to the practice of medicine, this author suggests that in health care institutions without the services of ethical consultation, steps should be taken to develop properly educated and clinically astute ethics committees and/or to provide clinical ethicists to assist physicians address the moral questions of treatment.

Although procedures will differ from hospital to hospital,[11] generally speaking, the following information should be provided to the ethicist or ethics committee by the physician.

First, a description of the moral dilemma as perceived by the physician should be provided. The ability to articulate the problem is the first step toward solution. The process of articulating actually can resolve the problem; but, in any case, articulation focuses the problem.

Second, a description of the patient's diagnosis, current state, and the prognosis is important. Here the pulmonologist faces the challenge of communicating in accurate, nonprofessional language the prognosis, the current status, and the various conventional or experimental medical options that are available, as well as the potential benefits and/or risks that each of these options presents. Any information about patient or family wishes about treatment can be very helpful to the analysis of these problems. Unfortunately, very few physicians take "patient value histories" along with their history and physicals.[12] Value histories expose patient moral and ethical preferences and personal values. This value information frequently illuminates the problem and moves a moral dilemma into a moral choice.

Third, it is very important to indicate the urgency of the request.

The Ethical Process

The ethicist or ethics committee requires the above information to make an ethical analysis.[13] The analysis moves to identify the decision makers. It is a principle of medical ethics that the person who is most affected by medical choices has the greatest responsibility in making a choice. In all cases, this person is the patient or the patient's surrogate. But health care providers also have a role in decision making. The identification of that role is critical to the resolution of a problem. Health care providers must provide information, medical analyses, and prognoses as well as articulation of the personal and/or professional moralities that influence their judgment. The health care provider's role is to support and inform the decision analysis.

The next step in the ethical analysis is the identification of the options. All real, speculative, and even morally unacceptable options should be presented. Once options are identified, the analysis requires the systematic application of the moral values to these options. The moral values that normally apply to pulmonary care moral dilemmas are life, benefit, and freedom. The ethical analysis weighs the amount of benefit and quality of life to be achieved by certain options against the risks, untoward side effects, possibilities of death; and, finally, the patient's desires and wishes if they are available are introduced into the amalgam.

Conclusion

The purpose of ethics consultation is to illuminate and clarify the choices faced by the clinician and to give reasonable justification for his actions based on moral values. Clinical cases usually do not have only one acceptable ethical

solution. One of the challenges of the ethical analysis is to indicate clearly the relative moral force of all acceptable options. The ethics consultation does not remove decision making from the physician and the patient. Its intent is to assist that decision.

The value of an effective ethics consultation is psychological, sociological, intellectual, and moral.

Psychologically, even though a very difficult and stressful choice may have to be made, ethical consultation will increases personal confidence that the choice was made with the best available knowledge. Sociologically, tensions and divisions in medicine and teams in medicine usually occur over the moral propriety of choices and the handling of the moral dimensions of patient care. When all parties are involved in the decision process, acceptance of the choice can produce a sense of cohesion and coherence between patient, physician, family, and health care team. Intellectually, ethics consultation can be an educational opportunity. The pulmonologist can learn ethical analysis and gain experience and clarity about the application of moral principles to cases. Morally, ethics consultation can have great personal value because it may reinforce and clarify personal/professional moral principles or even challenge or reject some inappropriate personal/professional moral principles. Ethical consultation requires that persons unearth their moral assumptions, clarify them, and place them in a hierarchy of importance. This experience can be enriching because it can solidify personal moral commitments, sensitize perceptions of moral pluralism, and provide confidence in addressing moral dilemmas.

Two major purposes of medicine are served and assisted by ethics consultation. The physician can cure the moral ambiguity of clinical choices by ethics consultation, and can comfort patients and families by enhancing personal integrity through ethical consultation.

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Part II Legal Dimensions of Cardiology, Pulmonary Medicine, and Critical Care Medicine

13

Legal Problems in Critical Care Units

Medical Aspects of Critical Care Units

ROGER C. BONE, MD, AND JAMES R. VEVAINA, MD

Critical care medicine has rapidly developed into a flourishing discipline.[1] It has also engendered much scholarship in the legal and medical professions. The intensive care unit and the emergency room also have been the target of many legal sharpshooters.

Critical care medicine was defined[2] by a consensus development conference held at the National Institutes of Health in March of 1983 as a multidisciplinary and multiprofessional medical/nursing/paraprofessional field concerned with patients who have acute life-threatening illnesses or multiorgan failure due to disease or injury. The precursor of the critical care unit was the postoperative recovery room, where patients were monitored closely after surgery. Further experience in handling trauma victims was obtained during the Vietnam war. Trauma still remains the most common killer of people under the age of 40 in the United States.[3] It is responsible for more than 150 thousand deaths and 400 thousand disabling injuries in the United States every year.[3] Because trauma is primarily a disease of the younger population and because it can cause significant disability, it is responsible for greater economic loss to society than cancer and heart disease combined.

The advances in technology that have accompanied the interest in critical care have also brought along serious problems in terminating treatment for patients who can derive no benefit because their illness is terminal or those who are irreversibly comatose.[4] Very often in treating critically ill patients the question has been brought up, are we prolonging meaningful life, or are we prolonging the agony of dying[5,6]? Much of the therapeutic imperative in managing such patients has not resulted in a happier and more productive life. As suggested by Dr. Eugene Robin, the standard for evaluating the numerous interventions should be, "will diagnostic and therapeutic intervention hopefully result in a happier and more productive life for the patient?" Simplistic as this may sound, this goal is a more reasonable way to approach intensive care than any of the numerous interventions available.

Standards in the Intensive Care Unit

The lack of a clear and concise plan of treatment for the patient is one of the reasons for the numerous technical and medical misadventures that are known to occur in the intensive care unit.[7] These have been termed iatroepidemics.[7] The director of the intensive care unit should be responsible for establishing the chain of command and the standards for treatment of each individual patient. Currently, standards are being established for the credentialing of these positions. What would be extremely helpful would be the establishment of a national registry for collecting survival data and analyzing which subset of patients would benefit most from intensive care. In establishing standards for admitting patients to the intensive care unit (ICU), the director of the unit should also establish guidelines for the monitoring of patients.

Rationing of Intensive Care Unit Resources

With the advent of Diagnosis Related Groups (DRGs) numerous tertiary care centers have come to realize that taking care of seriously ill patients can be economically devastating.[8,9] In one major medical center taking care of patients on mechanical ventilators, the loss to the hospital was approximately $4.7 million below costs for 446 medicare patients, as reported by Butler et al.[9] This averaged out to a loss per discharge of $10,567. The evidence suggests that the federal government has provided strong financial disincentives for extended intensive care under the new DRG payment system. Increasingly, it is becoming apparent that the physician will have to provide services and technology consistent with what the taxpayer expects and is willing to pay for. It is also becoming apparent that most ICUs have limited resources and that some form of rationing of intensive care will be required in the near future. A 1985 review in the British journal the *Economist* stated that $15 billion is spent in the United States per year in critical care units for patients who cannot get well, the major portion of such expense occurring during the last 60 days of life.

Risk-Benefit Analysis

In evaluating critical care medicine, it is obvious from all of the patient data generated[6] that physicians not only do good but also have significant potential for doing harm. Accordingly an analysis of risk-benefit ratio should be made in every patient care decision. Harm can be seen in systematic errors perpetrated by some physicians who lack the critical judgment necessary to work in such areas. Harm also can be seen from life-threatening complications because of an overly aggressive approach. In one recent report of complications at a university hospital of 808 admissions, 35% had some minor or major complication, and 16% to 32% had major iatrogenic episodes.[10]

Nature of the Patients and Outcomes

Intensive care unit patient populations are heterogeneous. Many subgroups of patients emerge from studying an ICU population. One group of patients in whom ICU care is clearly not indicated is the group of terminally ill patients for whom intensive care simply means prolongation of the dying process. For this group of patients death with dignity seems to be a myth. Patients with terminal cancer, acquired immune deficiency syndrome (AIDS), brain death, irreversible coma, and fatal illnesses fall into this group. The size of this group can be enormous in certain hospitals.

A second group of patients include those whose admission to the ICU results in a happier and more productive life. This includes neonates with reversible illnesses, patients with drug overdose, patients with reversible trauma, and patients with chronic diseases that have a largely reversible component.

A third group of patients are those who will recover whether care is provided in the ICU or not. This group is at risk for iatrogenic complications.

A fourth group includes patients in whom excess morbidity and mortality lead to the conclusion that they would probably have been better off had they not been subjected to such intensive treatment. This group leads to the conclusion that there are no specific validated criteria for maximal benefits describe in any ICU. We require more exact data for admission and discharge from the ICU.

Teaching Aspects of the Intensive Care Unit

Undoubtedly, the last decade has seen technology leaping way ahead of its critical assessment. Many ICUs look like a space laboratory. The impression of some critics is that outcome in these ICUs is no better than that in simple ICUs. Obviously then, one should question those aspects of high intensity monitoring that can do harm to patients, and try to identify those aspects that are likely to do the most good. We do need more science, but we also need better science.[6] One aspect of critical care that perhaps has been most neglected is a closer coordination of nursing and medical services.

Standards in the Critical Care Unit

One observation[11] noted mostly in anesthesia is that most avoidable deaths occur not because of failure to manage exotic diseases or complications but because of failure to recognize common complications of diseases or equipment failure. One common example of equipment failure has been found in anesthesia machines where a mechanical valve was used to switch between manual and mechanical ventilation. It was possible to connect the ventilator hoses in the wrong order, thereby blocking the patient's exhalations during mechanical ventilation.

Authority in the Intensive Care Unit

Because care of the patient with critical illness is a multidisciplinary responsibility, a closely related problem is that of authority for and coordination of the patient's care. Writing orders and making patient care decisions are the responsibility of the attending physician. On a moment to moment basis decisions also have to be made by resident staff and nurses. No single person, however, has the authority to take care of the patient by himself. Whereas the law may view this as examples of "too many cooks," the legal liability when an injury occurs will rest with all the people involved in the patient's care. The court will ultimately sort out the tangle of overlapping authority and hold one or more persons liable. Telephone orders on critically ill patients should be discouraged. This often gives rise to conflicting orders with resultant poor patient care or mishap. Physician and nurse coverage should also be arranged so that there is smooth transition between the different physicians who assume responsibility for a patient's care.

Economic Considerations

Currently, there is pressure on physicians to prevent economic waste. In many hospitals the ICU is an area of financial drain and sometimes disaster.[10] The AIDS epidemic, expensive high technology, and the shortage of nurses have made intensive care a losing proposition for many hospitals. Despite this, many hospitals are building ICUs.[12] Balancing economic considerations against policies that jeopardize patient care and outcome is a matter of good judgment. The ICU director who can successfully do this balancing act is likely to come out a winner.[12] Although no strict guidelines exist, denying intensive care to patients with severe organic brain syndrome, persistent vegetative state, irreversible disease, and those who have come to the end of their lives seems like a reasonable guideline.

What is Quality Care in the Intensive Care Unit?

Quality of care is a difficult question to answer.[13] As stated by Dr. Otis Bowen, Secretary of Health and Human Services, to measure it we must first be able to recognize it when see we it. Some have defined it as the end result of treatment. However, as most critical care specialists know, the end result can be bad despite following the strictest scientific standards.

One fact, however, is clear. From all the studies on outcome from surgery and diagnostic procedures, there is an association between high volume rates and outcome from the procedure.[14] Through the study of a new field called the epidemiology of medical care, some answers are beginning to emerge on what hospital would be best equipped to do what procedure.[15] Directors of critical care units should also be aware of recently described[7] iatroepidemics.

An iatroepidemic is a systematic error introduced into patient care. It can produce severe harm or even death to large numbers of patients. Almost no specialty of medicine is immune. Iatroepidemics can be and should be prevented. It is an interesting fact about physicians that few (if any) in a specialty acknowledge the existence of an iatroepidemic in that specialty. Thus, cardiologists more easily acknowledge pulmonary iatroepidemics than they do epidemics in their own specialty.

Noninvasive Trends

"Big medicine" with its attendant high-powered technology also has been accompanied by numerous procedures.[16] Because of justifiable criticism of these highly invasive trends, many of which have not lead to a better end-product, numerous attempts have been made to perform noninvasive testing. Among these are the respiratory inductive plethysmograph, for noninvasive respiratory monitoring,[20] polysomnography for sleep apnea monitoring,[20] and the noninvasive evaluation of right ventricular function using nuclear cardiology techniques. Other noninvasive diagnostic tests that can be applied in the ICU are computed axial tomography (CAT) scanning, nuclear magnetic resonance (NMR) scanning, and echocardiography. The function of the diaphragm can be evaluated by the use of magnetometers or measuring its electrical activity. One of the latest noninvasive techniques is the use of DNA molecular biology in the diagnosis of pulmonary disease.[20]

Do Not Resuscitate Orders

Currently, there is pressure from administrators to reduce costs in ICUs.[17] Physician directors of ICUs are frequently in a difficult position because they are members of the medical staff and not the administrative staff. Their main aim is to protect the patients from policies that would jeopardize patient care. One way to reduce costs in the ICU is to write "do not resuscitate orders" on patients who are terminally ill or in whom there can be no reasonable hope of survival. However, there are inevitably legal consequences from writing such an order. These are discussed in another chapter (Chapter 23).

Summary and Conclusions

Care of the patient who is critically ill has developed into a recognized discipline.[1] A nationally recognized certification is available for intensivists practicing this discipline. In the changing economic climate of this nation, and medicine in particular, physicians will have to contain costs and provide intensive care only to those individuals who are mostly likely to benefit from it. Whereas this may deny access to care for certain groups of patients who are

hopelessly ill, limited resources dictate that such policies be implemented. There is dire legislative need for those with catastrophic illnesses who have no insurance coverage or in whom one illness can wipe out the resources of an entire family.

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Legal Aspects of Critical Care Units

SENATOR JOHN R. DUNNE

The legal aspects of medical treatment, particularly the critical care and intensive care areas of medicine, are probably far more complex than the legal considerations in any other medical discipline. Rare is the day when a critical care staff physician is not confronted with a case involving questions of life and death. These questions may present themselves both in situations of emergency and chronic critical care. In both instances, the physician is faced with a plethora of legal, and certainly moral, considerations.

The physician's dilemma is not only in addressing the conflict between an individual's right to choose his fate and the physician's oath, if not instinct, to do everything that is possible to save a life,[1] but also *knowing* the legal limits of a person's freedom of individual choice, and the physician's responsibility to preserve the life. Furthermore, physicians and hospital administrators must resolve these dilemmas in a context of scarce resources. The law of life and death, ever changing and expanding, simply exacerbates those problems, making it almost impossible for physicians to address critical care cases with any sense of unequivocal decisiveness.

In critical care medicine, time is a luxury that is usually not afforded the physician, the patient's family, or hospital administrators. The emergency critical care and chronic critical care scenarios force the involved parties to acutely consider questions of life and death. Little time is usually afforded so as to engage in lengthy philosophical or legal discourse over the rights and intentions of patients or their physicians to terminate treatment or withhold life supports.

The physicians involved in a critical care situation in which life and death are in issue is necessarily faced with the task of determining his rights and liabilities as they have been established in several developing areas of the law: do not resuscitate orders, the right to die, and living wills. Each of these concepts has been the focus of an enormous amount of attention during the past 15 years, in large part because of the celebrated case of *In Re Quinlan*[2] and its progeny. Generally, "do not resuscitate orders" (DNR) are contained in hospital records and prohibit the application of routine resuscitative techniques, such as cardiopulmonary resuscitation, in situations of cardiac distress or arrest. The "right to die" issue revolves around the extent of an individual's right to self-determinism in the course and conduct of life-sustaining medical treatment. Finally, "living wills" are documents expressing an individual's intentions and desires regarding DNR and the right to die.

Physicians, while faced with the enormous task of keeping abreast of constantly changing legal and medical developments, must remember that it is not a failure of the law to provide a more definitive sense of direction to follow when faced with life and death decisions. The states through their legislatures and courts, have continued to define and redefine the parameters of proper

behavior for a physician, vis-à-vis an individual's right to select or forego treatment, as these issues are presented in varying factual situations. The judicial and legislative branches, however, cannot simply impose new dictates, but, rather, must respect and acknowledge certain long-standing common law precepts and constitutional rights while giving direction to the gradual evolution of rights for terminally or critically ill patients.[3]

New York's highest court, the Court of Appeals, established the common law foundation upon which most, if not all, discussions of a patient's rights versus a physician's duty have been developed. In *Schloendorff v. Society of New York Hospital*,[4] the Court of Appeals determined that competent adults have a common law right to do with their persons as they see fit. This right also protects them against unwanted intrusions. The Schloendorff decision has long been seen by courts throughout the country as establishing a right to determine whether treatment will be accepted or refused.

The New York Court of Appeals, however, has greatly limited the common law right to choose either a course of treatment or the withdrawal of treatment. *Eichner v. Dillon*[5] and *In Re Storar*[6] collectively stand for the proposition that the individual is the only person who may determine his course of treatment; substituted judgment and the inferring of an individual's intent were specifically rejected.[7]

The development of "living wills," "right to die," and "do not resuscitate" laws, now in 37 states and the District of Columbia,[8] have in many instances specifically limited physician liability for failure to treat.[9] It is important for physician fraternal groups, medical societies, and hospital organizations to thoroughly digest the applicable local law to determine exact rights and liabilities of physicians, a measure that will require a closer cooperative effort between attorneys and physicians.

The life and death question that inevitably will confront any physician who routinely practices in critical care medicine should provide ample initiative to the physician or hospital administrator to understand the rights of patients, the rights and obligations of physicians, and the rights of the hospital or institution in which he practices. The earnest physician also should determine if his institution has an established procedure for dealing with life and death situations and the procedure for obtaining consent. The physician's failure to adequately acquaint himself with the local law and practice may, indeed, pose as much of a legal problem as does the actual decision of whether to terminate treatment.

Physicians, and hospital administrators in particular, will also be placed in the unenviable position of conducting risk-benefit analyses as financial resources continue to strain under an ever-growing demand for critical and intensive care treatment, and under the reality that as the general population ages, the benefit of critical medical care decreases. These considerations should be analyzed as soon as possible, for the projections indicate that by the end of this century, 49% of all elderly persons will be over the age of 75.[10] Additionally, studies indicate that the longer a patient remains in critical care units, the greater the chance is that the patient will die.[11] This begs the

questions of whether it is feasible to employ and devote scarce resources to irreversibly ill patients.

The risk-benefit analysis goes not only to the preservation of resources, but to the proportional benefit received by the patient. In *Matter of Beth Israel Hospital,* a New York trial judge in state Supreme Court ruled that a terminally ill patient would incur greater burden than benefit by having her leg amputated, and thus blocked the hospital from performing the procedure.[12] The court said that the action by the hospital had no curative effect, but would simply prolong the dying process. The court specifically involved a risk-benefit analysis, considering within that context the best interest of the patient.

Another situation in which physicians and patient (or patient's representative) are at odds over the course of treatment, with neither party knowing for certain the scope of their rights, is found in the following case study.

Case Study *Brophy v. New England Sinai Hospital, Inc.*[13]

Hospitals and physicians never know when a critically injured individual or the intensive care treatment rendered on behalf of that individual will present a clear-cut question of life and death. The physicians at New England Sinai Hospital were faced with this very question in dealing with the case of Paul Brophy, victim of a cerebrovascular accident, the rupture of an aneurysm. He presented at the hospital unconscious, and surgery to correct the damage from the CVA was not successful. The hospital, however, with a patient in critical condition, did not know how to proceed from that point (i.e., there was great uncertainty of the hospital's and physician's rights and liabilities when faced with the patient's wife's request for a withdrawal of nutritional support.)

The opinion rendered in *Brophy,* provides a "blueprint" analysis that all hospitals and physicians should perform when facing a controversy of this nature. The court, in addressing Mrs. Brophy's request, considered the state's interests in preserving life, preventing suicide, protecting innocent third parties and maintaining the ethics of the profession. The court also took into account the local practice of using substituted judgment.[14] The court concluded, with Solomonesque wisdom, that the individual, through his representatives, did have a right to forego support, but that the institution, New England Sinai, and its physicians could maintain their ethical principles by not being forced to withdraw support. The patient's representatives were allowed to transfer the patient to a facility that would satisfy the request for termination.

The Brophy case represents an all too common problem of institutions and physicians being sued over their refusal to withhold treatment primarily because those parties are unaware of the extent of the legal and ethical parameters in which they can operate. This is rather ironic when one thinks that it is usually the failure to provide treatment that proves to be the focus of litigation. This reasserts the necessity to know, from the outset of development of the physician-patient relationship, the rights of an institution and the individual physician.

The special considerations to be made in situations of life and death are not the only medicolegal issues facing the critical care physician. The physician must also be cognizant of the traditional legal rules of medical malpractice that apply to his actions. In light of the strict time constraints imposed in most critical care cases, the physician is required to be particularly adroit in his diagnostic and treatment procedures, for the legal consequences could be significant. Additionally, the critical care physician is, in most instances, a specialist. Thus, he will be held to the standard of care becoming of members of that speciality, and not simply the local or community standard of care that is afforded general practitioners.

Because time is of the essence in most instances in which a patient requires critical medical care, the physician must quickly weigh his options. This can be problematic if, as is often the case, the physician providing the critical care is not the patient's attending physician. The physician in this situation, therefore, must bear in mind that he should approach the medical problem in a logical way by exploring his options, and choosing from among those options what he considers in his professional judgment to be the most advantageous course of action for that situation. If this regimen is followed, the physician will usually not be held liable for any unforeseen or unfavorable outcome.[15] The courts of New York have provided wide latitude to the exercise of professional judgment, and will in many instances give a charge to the jury that a physician cannot be found to have committed malpractice upon a mistake in judgment.[16]

In the defense of a medical malpractice action generally, and those situations involving critical care treatment, the most pressing issue is that of proximate cause. This element of the "chain of tortious liability" (i.e., the duty owed by virtue of the physician-patient relationship, the breach of that duty, the existence of an injury, the breach of duty representing the proximate cause of the injury, and damages incurred as a result of the injury), is the most difficult component of a plaintiff's burden of proof. This burden dictates that the plaintiff provide evidence not merely illustrating a departure from good and accepted standards of medical practice, but also that this departure proximately led to the injury complained of by the plaintiff.[17] The physician providing critical medical care, in many instances of alleged malpractice, will not be held liable for damages if it is seen that the injuries related to the underlying ailment and not to the malpractice.[18]

In most critical care litigation, expert testimony will be the order of the day. Generally, expert proof is necessary to establish:

1. The standard of skill or care ordinarily possessed by the medical profession at the locality where the diagnosis or treatment occurred (or in the speciality, if one is in issue)
2. The fact that the defendant-physician has not complied with the applicable standards of skill and care
3. Proximate cause[19]

Each of these elements will vary from case to case, depending upon its factual foundation, the speciality involved, and the nature and scope of the injury. Thus, it is difficult to discern in the abstract what methods of procedures in critical care will be deemed adequate and which actions will in fact constitute malpractice. These determinations depend upon the state of medical care at the time an alleged incident occurs, the condition of the patient, and the good and accepted standard of applying that care to a patient in that condition. For example, the failure to proceed with cardiopulmonary resuscitation on a patient whose condition indicates this procedure will not constitute malpractice where written consents have been obtained and a DNR order has been duly placed in the hospital chart. This is one way in which statutory law determines good and accepted practice; however, much of the responsibility for establishing good and accepted practice remains with the medical profession.

In most cases involving complex medical concepts or difficult medical situations, the plaintiff will be required to present expert proof as part of his case in chief.[20] "Ordinarily, expert medical opinion evidence, based on suitable hypotheses, is required, when the subject matter to be inquired about is presumed not to be within common knowledge and experience and when legal inference predominates over statement of fact, to furnish the basis for a determination by a jury of unskillful practice and medical treatment by physicians."[21] Expert medical proof is also necessary for the plaintiff to withstand a defense motion for summary judgment.[22]

The essential element of a critical care physician's regimen of medical judgment and treatment, aside from his knowledge of the law or his rights and liabilities, is his caring for the total patient; that is, caring not exclusively for the injury, but rather the entire patient and the ramifications the specific illness has on his psychological well-being and emotional state. Physicians should also remember that the family of the critically ill patient comes part and parcel with the patient. The physician must treat the family crisis as well as the illness, for that not only impacts upon the patient's ability, and desire, to recover, but it could very well reduce the tensions and resentment that so often develop in times of serious personal trauma. Despite his limited role, the specialist is not to be exempted from dealing with the patient or their family. He must coordinate with the primary attending physician to assure that the diagnosis, prognosis, and course of treatment is known and understood by the parties. Addressing the needs of the family by simply extending understanding and concern is a quick but invaluable way of diminishing the potential for litigation.

Summary and Conclusion

Critical care medicine, because of its need for emergency responses and use of life-saving treatment, presents unique questions of legal rights and liabilities. The physician and hospital administrator must understand that the days of paternalism are over, that they must encourage partnerships with their patients and their families, and that their actions, in either preserving a patient's life or

withholding treatment, will come under close scrutiny by the courts if there is any uncertainty as to the rights and liabilities of physicians in dealing with critically ill patients.

The burden upon physicians is admittedly intense, for they must not only deal with lofty issues of life and death, but also the traditional laws of medical malpractice. They must bear in mind that, as specialists, they are to be held to a higher degree of care. Protections from malpractice can be a reality if the physician knows that which is expected in his performance and the limits upon that performance.

References

1. The "instinct" that motivates physicians to protect a patient, despite the latter's protestations against further treatment or artificial support, has been identified by a commentator as the physician's paternalistic view of the physician-patient relationship. See Annas and Densberger, "Competence to Refuse Medical Treatment: Autonomy vs. Paternalism," 15 U. Toledo L. Rev. 561 (1983) (paternalism dictates a limited view of a person's competence to understand and decide between medical treatment and allowing a disease to take its natural course). Richards and Rathburn also suggest that the current "underlying paradigm of critical care medicine is the technological imperative, "the desire of physicians to do everything that they have been trained to do." It has been this devotion to high-technology medicine, the authors suggest, that has led to certain other treatment realities, including the obfuscation of the rationale for treatment by the technology, the use of high technology to keep a patient comfortable, as opposed to having any creative benefit, the desire to see on the side of greater, not less treatment, and the inability of a patient to have his wishes known. Most alarming, however, is the use of high technology as a weapon in defensive medicine—see Richards and Rathburn "Legal Issues in Critical Care Medicine," *J Intensive Care Med* 1986;1:101–110.
2. *In Re Quinlan,* 70 N.J. 10, 355 A.2d 647 (1976), *cert. denied sub. nom. Garger v. N.J.,* 429 v.s. 922 (1976).
3. Issues as weighty as those under consideration here will *always* be subject to analysis, review and critique. Public policy makers have already gone to significant lengths to define rights and liabilities of patients and physicians, implementing natural death and living wills legislation in thirty-seven states and the District of Columbia. It is well recognized, though, that many questions are still unanswered. See Greenfield, "Recent Amendments to the Texas Natural Death Act: Implications for Health Care Providers," 17 St. Mary's Law Journal 1003, 1005 (1986). For an excellent treatment of the burgeoning case law and statutory enactments, see note, "To Die or Not to Die: The New York Legislature Ponders a Natural Death Act," 13 Ford. Urb. L.J. 639 (1984–1985).
4. 211 N.Y. 125, 105 N.E. 92 (1914). While the New York courts have developed the right to withdraw treatment from a common law perspective, the court in *In Re Quinlan,* 70 N.J. at __, 355 A.2d at 663, has determined that there is a constitutional right of privacy for competent adults to decline medical treatment.
5. 73 A.D. 2d 431, 426 N.Y.S.2d 517 (2d Dept. 1980), *modified sub nom.* In Re Storar, 52 N.Y.2d 363, 420 N.E. 2d 64 (1981).
6. 52 N.Y. 2d 363, 438 N.Y.S.2d 266, *cert. denied* 454 U.S. 858 (1981).
7. But *cf. Superintendent of Belchertown State School v. Sarkewitz, 373 Mass. 728,*

370 N.E. 2d 417 (1977). (substituted judgment permitted); In Re Quinlan, supra n. 2. Additionally, the New York Legislature, in 1987, buffered the impact of *Eichner* and *Storar* to a certain extent by adopting a substituted judgment provision relating to DNR orders. See Chapter 818 of the Laws of 1987.

8. See note 3, supra.
9. Chapter 818 of the Laws of 1987. The New York law provides civil and criminal liability protections to physicians who obtain the consent of patients to insert DNR orders in their hospital charts. These are specific provisions regarding procedures and the compilation of written requests before an order can be effectuated.
10. *Hospitals,* Dec. 20, 1986, p. 72.
11. Robin, "A Critical Look at Critical Care," *Critical Care Medicine* (1983) 11:144–147.
12. *New York Law Journal,* Sept. 15, 1987, p. 1.
13. 398 Mass. 417, 497 N.E. 2d 626 (1986).
14. Massachusetts recognizes substitute judgment. Supra, n. 7. New York, in contrast, recognizes an individual's rights when his intent has been explicitly stated. See *Eichner,* supra, n. 5 and *Storar,* note 6, supra.
15. *See Spadaccini v. Dolan,* 63 A.D. 2d 110 (1st Dept. 1978).
16. *Id.;* see also Pattern Jury Instructions.
17. *Pike v. Honsinger,* 155 N.Y. (1898); see also Pattern Jury Instructions.
18. This is not meant to suggest that a physician will escape culpability in those instances where malpractice has been found, but that the patient would have died or suffered an injury in any event. As the court in *Jones v. City of New York,* 57 A.D. 2d 429, 430 (1st Dept. 1977) indicated, "[t]hat the patient may well have died soon because of his generally debilitated condition . . . cannot exculpate defendant [physician] from responsibility for neglecting caused death at an earlier moment . . ."

    It is interesting to note that in *Jones,* which involved the development of a bilateral pneumothorax, in an individual with acute viral hepatitis and in a hepatic coma, resulting from the insertion of chest tubes found to be thin, soft and inadequate, the damages awarded by a jury were dramatically reduced by the appellate court. A verdict of $450,000 was reduced to $25,000 because, despite the obvious malpractice, there was a question as to how much conscious pain and suffering could actually have been attributed to the malpractice, or how long the decedent would have survived, given the critical condition he was in when the malpractice occurred.
19. See *Warren's Negligence,* Section 13.02 (1978).
20. *Id.*
21. See also *Ledogar v. Giordano,* 505 NYS2d 899 (2d Dept. 1986); *Fileccia v. Massapequa General Hospital,* 99 A.D. 2d 796 (2d Dept. 1984)
22. *Fiore v. Galang,* 64 N.Y.2d 999 (1985) (expert proof needed in analyzing allegations of failure to diagnose cancer and properly conduct abdominal surgery).

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Legal Aspects of Medical Inventions

HAROLD J.C. SWAN, MD, PHD

INTRODUCTION BY JAMES R. VEVAINA, MD

The 1956 Nobel Prize in medicine was awarded to a German physician Werner Forssman for an intriguing experiment that he had conducted on himself 27 years before that time.

In 1929, Forssman graduated from Berlin University, and according to his own account his dreams of becoming an internist were shattered when his application to work with Dr. Georg Klemperer at Moabit Hospital in Berlin was declined. 3 weeks later Forssman found a position in a small hospital in Eberswalde and there he found a friend and mentor in Dr. Richard Schneider, to whom he proposed his plans for introducing a ureteral catheter "via an antecubital vein which would inevitably find its way to the heart."

Dr. Schneider denied Forssman permission to try the experiment on patients, but he could not deter him from trying the experiment on himself. In the summer of 1929 Forssman decided to proceed and after persuading the surgical scrub nurse to let him tie her up so he could get sterile instruments, he anesthetized the antecubital fossa and advanced the catheter into the right atrium. He then ran down several flights of steps to the x-ray department to document his achievement. His idea was published in *Klinische Wochenschrift*.

Forssman's excitement was not shared by the German medical community. In fact, at the Charite Hospital he encountered hostility, antagonism, and questioning of his claim to the idea. Over the next 2 years he made several attempts at imaging the right side of the heart with inadequate results.

Forssman turned to surgery and urology. During World War II he served as an army surgeon in Germany, Norway, and Russia. He returned home "embittered and half starved." When the Nobel committee awarded him the Nobel Prize, Forssman is reported to have commented, "I feel like a village parson who has just learnt that he has been made bishop!"

G. Liljestrand who presented the Nobel Prize to Forssman stated, "Even in our enlightened times, a valuable suggestion may remain unexploited on the grounds of a preconceived opinion." Presumably, he was working in a milieu that did not clearly grasp the great value of his idea.

Because we were curious to know what kind of legal advice a modern-day

investigator had obtained, I asked Dr. Bone to write to Dr. Jeremy Swan, the innovator of the balloon-tipped flow-directed pulmonary artery catheter, a device that virtually brought cardiac catheterization to the bedside.

Dr. Swan did not feel that he could write an entire chapter; however, his letter to Dr. Bone was so sparkling with originality that I requested Dr. Swan's permission to publish his letter as his contribution to the book. Dr. Swan kindly consented.

Should a physician obtain legal advice and a patent if he believes his invention has merit? Our answer is definitely, yes.

CEDARS-SINAI MEDICAL CENTER

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Roger Bone, M.D., F.C.C.P.
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Dear Dr. Bone:

I have received your letter of February 9, 1987 concerning the book you are co-editing on Medico-Legal Aspects of Chest Disease. I am most flattered and honored.

I really don't believe that I could put together a meaningful chapter that would have relevance to present day situations and conditions. However, for what it's worth, I offer the following account in regard to the balloon-tipped, flow-directed catheter.

I have to confess a certain amusement at the naivete at which my colleagues, Willie Ganz, George Diamond, Jim Forrester, and I entered into the floatation catheter development. That was in 1967, when life was much less complicated. At that time, I had been thinking of a steerable guidance device for right heart catheterization but the notion of patent protection never occurred to me. The development was entirely informal. Having experienced enormous frustration the evening before on trying to float one of the soft, so-called soft Bradley Catheters (a 0.9 mm outer diameter soft tubing attached to a transducer), the idea came to me one sunny fall weekend while watching a sailboat catching the wind. If one had a guidance device attached to the tip of a catheter it would "sail" into the pulmonary artery.

Our motivation was to know more about the hemodynamics of acute myocardial infarction, a topic characterized by near complete ignorance at that time. Previously, (1959-1965) I had been Director of the Diagnostic Catheterization Lab at the Mayo Clinic (St. Mary's Hospital), Rochester, Minnesota. The heterogeneity of patient coronary disease presentation and the frequently unpredicted outcomes strongly suggested that few physicians really knew what they were doing and that a major deficiency existed in regard to an understanding of hemodynamic performance and factors which might modify it. Our motivation was to understand the fundamental physiological processes better, and thereby improve clinical decision making. Wider application of hemodynamic monitoring was predicted in our original article in the New England Journal of Medicine in 1970. At the time of this writing, 16 years later, it is perhaps gratifying that the original device has been modified only by incorporation of additional sensors. Frankly, the notion of persona. profit from broad application of hemodynamic monitoring to routine clinical care - in contrast to the attainment of greater knowledge and understanding of biological process - never occurred to us. Several years later (and considerably better informed), we did obtain a patent on the multi-electrode

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catheter for sensing electrical signals within the right atrium and right ventricle.

It so happened that in 1967 I was consultant on new devices to the then fledgling Edwards Laboratories, which had been acquired by the American Hospital Supply Corporation. I spoke with Dave Chonette and Will Perrie of American Edwards regarding the concept and they evidenced an interest in the notion that a sail or parachute could improve one's ability to rapidly and easily catheterize the pulmonary artery. We did not research the matter much further and they came up with the practical solution from their standpoint - to take a balloon of the Fogerty type, which they had already developed, and attaching it on a length of extremely flexible catheter material. This they did and I received those catheters in the fall of 1968. At that time, Willie Ganz was working with a dog for another experiment. At its conclusion, I took over the animal and immediately demonstrated consistent and easy passage from the superior vena cava into the right pulmonary artery. Subsequently, we did little further animal testing or research. The concept worked eminently. The next batch of catheters were taken to the cardiac catheterization laboratory, and once again, they demonstrated consistency and we used them to simplify right heart catheterization. Indeed, the director of the laboratory suggested they should be banned from a training experience because they made right heart catheterization "too easy". Without any human subjects review or any of the other now current aspects of institutional review, we took them to the the infant coronary care unit and George Diamond, Jim Forrester and myself carried out the initial catheterizations. At that time, Willie Ganz in the laboratory made most important technical improvements.

At the time I inquired of Cedars-Sinai Medical Center as to whether they had any interest in pursuing the patentability of this device. They had no objection to me doing it on my own money (of which I had none), but were not interested in supporting any type of patent search. Later, when American Edwards looked into the matter, it was found that the use of the balloon as a guidance mechanism had been suggested previously, although in a secondary context. Therefore, it was not possible to obtain a patent. The concept of a parachute-sail, however, might have been successful.

So, although subsequently several process patents were obtained, we did not seek legal protection for our device. Dr. Ganz and I receive a fee and other benefits from American Edwards Labs for the use of our names with the catheter. If it was nunk pro tunk (now as if then) obviously, we would have proceeded in a different manner.

I certainly look forward to seeing your book when it is published. I think it is a most important and worthy project. I wish to thank your co-editors, Dr. Vevaina and the Hon. Justice Kassoff, for their kind invitation to participate. Keep up the good work. With best wishes.

Most cordially yours,

Jeremy J. Swan.

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15

Mysteries Unravelled by Postmortem Examination

CYRIL H. WECHT, MD, JD

History and Development

Dissection of the human body was performed as long ago as the 3rd century BC to obtain medical knowledge. A postmortem examination conducted on Julius Caesar concluded that only one of 23 stab wounds inflicted by his fellow Roman senators was fatal. In 1247 AD, the Chinese compiled a fascinating tome, *The Washing Away of Wrongs,* which set forth guidelines for medical investigators called upon to determine whether an individual found dead unexpectedly had died from unnatural causes. This remains today as one of the oldest classics on forensic medicine.

After the Dark Ages, autopsies were done for medicolegal purposes in several European cities. An extensive and detailed tome on forensic medicine was written by Zacchia, an eminent Papal physician, in the 16th century.

Modern concepts of forensic pathology and toxicology applied to death investigation evolved in the latter part of the 18th and 19th centuries with the evolution of pathology into a true medical science. Morgagni and Rokitansky performed thousands of autopsies in which they correlated clinical signs and symptoms with postmortem findings, categorized various pathologic diagnoses, and established the importance of the autopsy to academic medicine and research.

Significance

There are many important and significant reasons why autopsies should be undertaken to the greatest extent possible. These include a variety of benefits to the family of the deceased, such as identifying familial disorders and assisting in genetic counselling, providing information for insurance purposes and death benefits, and indirectly helping in grief assuagement; benefits for the public welfare, such as discovering contagious diseases and environmental hazards, providing a source of organs and tissues for transplantation and

scientific research, and furnishing essential data for quality control and risk assessment programs in hospitals and other health care facilities; benefits to the overall field of medicine, such as the teaching of medical students and residents, the discovery and elucidation of new diseases (Legionnaire's disease and AIDS), and the ongoing education of surgeons and other physicians regarding the efficacy of particular operations and medications; and benefits to the legal and judicial systems, such as determining when an unnatural death (accident, suicide, or homicide) has occurred, and enabling trial attorneys and judges to make valid decisions pertaining to the disposition of civil and criminal cases.

In light of all the significant contributions and substantial data that are derived directly and indirectly from postmortem examinations, it is rather incredible that the Joint Commission on Accreditation of Hospitals in 1970 dropped its long-standing requirement that hospitals perform autopsies in a certain percentage of patient deaths to maintain JCAH certification (teaching hospitals, 25%; other, 20%). Moreover, when one keeps in mind the increasing numbers of wrongful death cases involving medical malpractice and other personal injury and products liability claims, as well as thousands of homicides, suicides, and drug deaths each year, all of which require definitive and complete autopsy findings to pursue legitimate objectives within the civil and criminal justice systems, it is an amazing paradox that the JCAH adopted such a regressive policy revision.

Areas of Concern

A surprising percentage of clinicians, hospital administrators, and even pathologists have expressed a general reticence toward any new, concerned effort to increase the number of hospital autopsies. The reasons usually given are economic, educational, and legal.

Hospital executives and their nonmedical administrative personnel are constantly seeking ways to cut costs and increase income. Autopsies cost money: pathologist, technician, toxicology, chemistry, bacteriology tests on tissues and fluids obtained at postmortem, and supplies. Pathologists are busy with all their other responsibilities and do not get paid extra for autopsies. Attending physicians and house staff rarely attend and do not even bother to seek information concerning the postmortem later. Both clinicians and hospital administrative chiefs are concerned that autopsies may reveal evidence of malpractice in certain instances, and generally provide more data for plaintiffs' attorneys in professional negligence lawsuits brought against doctors and hospitals. The reasoning is that in the absence of pathologic evidence, the plaintiff will have a difficult or even impossible task in proving the death was in any way directly and causally related to errors of omission or commission in the diagnosis and treatment of the patient; that is, that there was any deviation from acceptable and expected standards of care on the part of the attending physicians or nurses.

The truth is that in the great majority of cases, autopsy findings clearly demonstrate that there was no medical negligence in the patient's treatment. The objective, scientific documentation of the cause and mechanism of death, will be the single most important factor in dissuading a patient's family and their attorney from initiating a malpractice action, or if a lawsuit has been filed, in providing the defendant-doctors and/or hospital with tangible evidence of an advantageous nature. Speculation and conjecture will help plaintiffs more often than physicians in medical malpractice cases.

The idea that new technology and improved diagnostic skills have made autopsies obsolete is incorrect and naive at best, and intellectually arrogant and dangerous at worst. Although it is true that certain cases are so well understood and unequivocally documented that it is not necessary to perform an autopsy, there are many clinical questions to be asked and answered in a majority of deaths. No matter how competent and experienced the treating physician may be, and despite highly sophisticated equipment like computed tomography (CT) scans and magnetic nuclear resonance (MNR), there can be no substitute for actually examining organs and tissues at autopsy, insofar as definite and accurate diagnoses are concerned.

Infectious Diseases

Numerous postmortem surveys have demonstrated that a significant percentage of infections are not correctly diagnosed, and hence, not properly treated. In addition to the obvious adverse clinical ramifications to the patient and potential legal consequences for the doctor in such instances, there are other important considerations, such as the need to protect family members, fellow employees, and hospital personnel in those cases in which the infection may be of a communicable and contagious nature. Infection Control Committees, required by the JCAH, cannot be effective if they do not obtain necessary information concerning infections, including nosocomial and iatrogenic processes, from postmortem examinations.

Statutes

Laws and various governmental regulations pertaining to postmortem examinations have been adopted in response to the public's general ignorance and abhorrence of autopsies, so that at the present time, most countries require consent from the next of kin to proceed with a postmortem examination. However, in the United States, such permission is not required in those instances in which the coroner or medical examiner has assumed jurisdiction.

The laws of the 50 states and the District of Columbia vary considerably with regard to the circumstances under which a coroner or medical examiner may be called in to investigate a death and perform an autopsy. The Model Medical Examiner's Act compiled a half century ago by the National Municipal League has served as a basis for several statutes.

The Oregon Statute sets forth the circumstances under which a medicolegal autopsy may be authorized:

> Where death was or apparently caused by external force, including but not limited to the following causes: homicide, and suicide; criminal abortion, including one self-induced; accident; thermal, chemical, electrical or irradiation injury; and in the following situations: where death was caused or apparently caused by a disease which is of a hazardous or highly communicable nature as specified by the board; where death was or apparently cased by deceased's employment or accident while employed, including diseases relating to injury; where a person who is found dead or has died suddenly has not been under the care of a person licensed to practice one or more of the healing arts during the period immediately previous to death; where deceased was admitted to a public or private institution for less than 24 hours and is not known by the medical investigator to have been under the care of a person licensed to practice one or more of the healing arts during the period immediately previous to admittance; where a death certificate has been signed, but circumstances indicate that further investigation may be necessary to determine the cause of death; where death occurred under suspicious or unknown circumstances, the medical investigator or coroner shall make an investigation.

This is an example of a good, broad law that fairly well ensures review of those deaths requiring medicolegal investigation. If the statute is firmly, consistently, and universally adhered to, and if competent forensic pathologists are used, there should be no suspicious cases that evade professional scrutiny.

Investigation of Sudden Unexpected Deaths

The abrupt onset of cardiac arrest should be analyzed from both clinical and pathologic perspectives to understand why an individual collapsed and died unexpectedly. The autopsy may reveal dramatic and clear-cut findings, such as an acute myocardial infarction, severe atherosclerosis of the coronary arteries with a recent thrombus, or hemopericardium. However, a substantial number of apparent cardiac deaths reveal very little from an anatomic standpoint, and a thorough clinicopathologic correlation must be made to conclude with reasonable medical certainty that the cause and mechanism of death can be attributed to the cardiovascular system. These deaths are essentially due to the development of a cardiac arrhythmia with dysfunction that leads to acute heart failure and cerebral hypoxia. Cerebral edema usually develops, causing the swollen brain to impinge upon the vital cardiac and respiratory centers in the brainstem, and the heart is further compromised. If this vicious cycle is not reversed within a few minutes, generally through effective cardiopulmonary resuscitative measures, death will ensue, and the postmortem will demonstrate no changes in the heart. These limitations, frustrating as they may be, must be borne in mind and appreciated by the forensic pathologist in signing out the cause and manner of death.

Other pathologic processes must be diligently searched for, also, including interstitial myocarditis (a microscopic finding that requires dissection of the cardiac conduction system with several dozen serial slides); prolapse or

TABLE 15.1. Suggested outline for analyzing clinicopathologic correlations.

- Cardiovascular and pulmonary diseases
  - Determination of nature and extent
    - Etiology
    - Time of onset (period of development)
    - Relationship to other disease processes
    - Aggravation and exacerbation by external factors
      - Precipitating factors
      - Psychological factors
  - Sudden unexpected death
    - Atherosclerosis of coronary arteries
    - Cardiac arrhythmia
      - Precipitating factors
      - Clinicopathologic correlation
    - Myocardial infarction
      - Special histochemical techniques
      - Microscopic determination of time of occurrence
    - CVAs
    - Other causes
  - Chronic obstructive pulmonary disease
    - Pneumoconiosis
      - Anthracosilicosis (CWP or black lung disease)
      - Other chronic lung diseases—asthma, emphysema, bronchitis, and bronchiectasis
      - Cor pulmonale
    - Special stains
    - Microincineration and other special techniques
  - Environmental considerations
    - Smoking
    - Ethanol
    - Normal urban, industrial exposure
    - Employment activities—physical and emotional stress
      - Usual, "normal" duties
      - Atypical, "extra heavy" endeavors
  - Abestosis
    - Pulmonary disease
    - Mesothelioma
    - Undifferentiated carcinoma
    - Adenocarcinoma, lungs and other organs
    - Special stains
  - Lung cancer
    - Incidence among steelworkers; employees exposed to asbestos
    - Role of various chemical and physical compounds
  - Cardiotoxicity
    - Prescription drugs
    - Adverse reaction or idiosyncrasy
    - Drug and food interactions

rupture of a valve, a previously undiagnosed congenital anomaly; or a pulmonary thromboembolism.

Clinicopathologic studies have revealed that as many as 40% of cases involving pulmonary emboli are misdiagnosed during the patient's life. This is an astounding figure and has obvious medicolegal implications of a serious and

TABLE 15.1. *(Continued.)*

Cardiovascular injuries
Blunt force trauma
Acute
Delayed
Penetrating injuries
Toxic exposure
Ingestion
Inhalation
Occupational relationship
Iatrogenic
Cardiac catheterization
Pericardial and thoracic taps
Surgical procedures
Pacemaker deaths
FDA investigations
Products liability lawsuits
Role of Pathologist
Clinical laboratory tests
Surgical specimens
Autopsies
Correlation with clinical data, occupational environment, and social factors
Preparation of laboratory reports
Postmortem protocols

extensive nature. At autopsy, it is often difficult for the pathologist to differentiate between an antemortem embolus and a postmortem clot. Careful dissection and microscopic examination of appropriate representative sections are required to distinguish between intravitam process and a postmortem artefact. The pulmonary artery should be opened in situ so that a very recent embolus, which has not yet become adherent to the internal surface, is not dislodged and overlooked in the subsequent dissection of the heart, lungs, and great vessels.

Role of Pathologist in Evaluation of Medicolegal Issues Involved in Cardiac and Pulmonary Deaths—Coal Workers and Other Pneumoconiosis Cases, Lung Cancer, Heart Attacks

In the review and evaluation of fundamental medicolegal issues encountered in the litigation of coal workers' pneumoconiosis (CWP) claims, particularly in death cases where an autopsy has been performed, the pathologist frequently plays a major role. The postmortem findings must be correlated with the clinical data, as well as the patient's occupational, medical, and social history to analyze the nature and extent of all the pathological processes, with particular emphasis on the pulmonary and cardiovascular systems. Careful and thorough gross and microscopic examination of all the vital organs will usually be sufficient to determine whether CWP is present and to what extent.

Polarized light microscopy should always be done in these cases, and in some instances, special stains and physicochemical studies (e.g., microincineration and ashing) are indicated. Weighing the significance of the lung findings in relationship to other disease processes for the purpose of determining the exact mechanism of death, as well as the sequence and relative importance of antemortem clinical events, will be critical to the disposition of the black lung claim.

The evidentiary burdens confronting the claimant's attorney require the pathologist to express expert opinions with a reasonable degree of medical certainty or probability. In most cases, chronic obstructive pulmonary disease (COPD) will not be the sole or principal cause of death. Furthermore, questions relating to the decedent's smoking habit, ordinary and ubiquitous exposure to nonoccupational carbonaceous and silicaceous materials, and other environmental factors should be considered by the pathologist to evaluate the role of CWP as either the principal or major concomitant cause, or as a substantial contributing factor, in the patient's death.

To thoroughly evaluate the various environmental, social, and medical factors, and correlate all the known antemortem clinical facts and circumstances with the gross anatomic and microscopic autopsy findings, it is helpful to take into consideration any and all known disease processes and injuries that the patient may have suffered. Table 15.1 suggests an outline format that can be used in analyzing such clinicopathologic correlations.

While disability is a medical question to be evaluated and determined by the clinician, the role of CWP as a causative factor in the patient's death is a matter that falls within the special purview and expertise of the pathologist.

Paternity Suits and Blood Typing

Dramatic advancements have occurred in the field of blood typing. These have revolutionized the legal approach in disputed parentage cases and in criminal cases involving the identification of possible assailants in homicide and rape cases. Of course, these studies are used routinely in organ and tissue transplant cases to match donors with recipients, and also for blood product transfusions.

The following is a typical report in a paternity case, which illustrates the degree of sophistication of clinical pathology laboratories that perform these studies.

Conclusions. Paternity cannot be excluded. For this mother-child combination, our blood test results would have excluded 98.84% of falsely accused men as the true biological father. As no paternal exclusion was found, we have calculated the cumulative paternity index, which represents an odds ratio of the alleged father and a random male producing a sperm carrying the paternal genes observed in the child. For this case, the cumulative paternity index is 84. The probability of paternity was also calculated from the paternity index on the basis of a prior probability of 0.50. The probability of paternity may vary from

Re: Paternity test results.

	Race	Blood drawn
Mother	W	27 Apr 87
Child		27 Apr 87
Alleged father	W	28 Apr 87
Case number		

System	Mother	Child	Alleged father	Paternity index
ABO	Al	Al	0	0.93
Rh	dce	DcEe	DCcEe	3.23
MNSs	MSs	Ms	MNs	1.62
Kell	K−k+	K−k+	K−k+	1.04
Duffy	a+b+	a+b+	a−b+	0.98
Kidd	a+b−	a+b+	a+b+	1.03
HLA	A 2,x	A 2,3	A 3,32	16.43
	B 15,40	B	B 15,35	
		15,35		
			Cumulative paternity index: 84	

100% (proof of paternity) to 0% (proof of nonpaternity). For this case, the probability of paternity is 98.83%.

Physicians should be aware of the nature of these reports and appreciate their applicability and relevance to particular clinical, medicolegal, and forensic scientific investigations.

Limitations of Autopsy

Physicians, pathologists more so than others, are aware of the fact that in a small percentage of cases, there will be few or no findings of a substantial nature at autopsy to satisfactorily provide an explanation for the individual's death. Forensic pathologists encounter this frustrating dilemma much more often than hospital-based pathologists because sudden, unexpected, unexplained, and medically unattended deaths fall within the jurisdiction of coroners or medical examiners and usually become the subject of a medicolegal inquiry, thereby leading to the withdrawal of the hospital pathologist.

In a significant number of these puzzling cases, the answer is found in the postmortem toxicologic analyses. There are many more prescription drug-related deaths than most people realize, often because of the synergistic CNS depressant effect of ethanol, and sometimes because of interactions with other drugs. (These cases are in addition to all the illicit drug-related fatalities occurring among drug abusers and addicts.)

Among the categories of cases in which substantial gross and microscopic anatomic evidence is lacking at postmortem, the two most frequently encountered are so-called crib deaths (SIDS, sudden infant death syndrome) and those apparently attributable to epileptogenic or other convulsive disorders. In these

cases, a detailed medical and social history is essential to appreciate the patient's background and arrive at a logical conclusion after a clinicopathologic analysis of all the facts and circumstances surrounding the death.

Laryngospasm, sometimes associated with a hypersensitive or idiosyncratic reaction to a medication or other allergenic compound, cannot be determined at autopsy, although there usually are some gross and microscopic findings that enable the pathologists to conclude that such a mechanism most probably caused the patient's death. This kind of evaluation is exceedingly important in those instances in which a drug, food, or other substance was inadvertently given to patient with a known allergic history to that particular compound.

Anesthetic-related deaths are exceedingly difficult to evaluate, also, and thereby present serious medicolegal problems for everyone concerned: patient's family, surgeon, anesthesiologist, pathologist, hospital, and attorneys. All perioperative fatalities should be reported to the medical examiner or coroner immediately, and no tubes or other detachable instrumentalities or pieces of equipment should be removed or altered before the postmortem examination. A meticulous analysis of the anesthetic record and operative note ideally should precede a thorough autopsy, in which appropriate body fluids and tissues are taken for biochemical analysis as well as for pathologic study.

Conclusion

Postmortem examinations continue to play an important and necessary role in the advancement of medical science. Frequently, they provide definitive answers in all kinds of medicolegal situations and may prove to be dispositive of the key issues involved in various civil, criminal, and worker's compensation lawsuits.

The requirements of any civilized society and the best interests of justice mandate the performance of autopsies whenever feasible and in compliance with existing statutes and regulations. Current negative attitudes prevailing among many physicians and hospital administrative personnel, as well as among many nonmedical and nonpathologist coroners, must be recognized and revised to accomplish this goal. It is not realistic to expect that the public at large will ever become sufficiently informed to appreciate what must be done when a member of their family dies and spontaneously overcome their adverse visceral reaction to the idea of an autopsy. If physicians and other health care professionals, attorneys, courts, legislators, and other governmental officials do not provide the intellectual influence and emotional guidance in society's approach to death investigation, nobody else can be expected to do so.

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16

Legal Implications of Adverse Drug Reactions

EDWARD C. ROSENOW III, MD, AND
SCOTT E. ROSENOW, JD

Americans are a drug-taking society. They take 2 to 10 times more prescription and over-the-counter drugs than a comparable population anywhere else in the world. The hospitalized patient takes an average of 6 to 13 drugs. The risk-benefit ratio of this many medications is unknown. However, there is no question that medications have saved and prolonged many lives. As there is no mandatory reporting of adverse drug reactions (ADR) in this county, we have no way of knowing what percent of drugs taken produces adverse side effects.[1] More than 1.6 billion prescriptions for more than 30,000 different drugs are written each year in the United States,[1] with about 200 new drugs approved each year. The estimates of significant side effects, meaning adverse drug reactions, range from tens of thousands to several million per year!

There are a number of studies reporting various estimates of adverse drug reactions. The University of Florida reported that 2.9% of admissions to a medical service were due to drug-induced illness and that more than 6% of these patients died. They pointed out that 82% of these reactions were due to prescription medications.[2] Another study from the Boston Collaborative Drug Surveillance Program noted in that 3.7% of 7,017 patients an ADR either caused or strongly influenced the admission of the patient to the hospital.[3] In another study of 6,199 consecutively monitored medical patients, it was estimated that death due to drugs administered in the hospitals caused 27 deaths (0.44%) and 3.6% of all deaths in the hospital.[4] Shapiro et al[4] summarize other reports of estimates of deaths in the hospital from ADRs ranging from 1.0% to 2.3%. Up to 18% of hospitalized patients experience a drug reaction before discharge.[5] The Boston Collaborative Drug Surveillance study estimated that 0.9 patients per 1,000 monitored in patients died as a result of an ADR.[6]

At one point there was an estimate by Senator Ted Kennedy of up to 140,000 ADR deaths per year in this country![7,8] Stettler[8] explains how this number was blown out of proportion and estimates 2,000 to 3,000 deaths associated with drug reactions in patients suffering from apparently nonlethal diseases. Ballin[9] says if we would accept the figure promoted by Senator Kennedy, that

iatrogenic drug reactions would account for 8.4% of all deaths and would rank as the fourth cause of death exceeded only by heart disease, cancer, and stroke!

Dr. Koch-Weser[10] tries to put this into some perspective. He says that legislation is not the answer and that the best chances of reversing some of these ADRs is through greater national effort in research and training of clinical pharmacology.

To get a better understanding of ADR numbers, it is important to know a little about the Food and Drug Administration (FDA). Congress directed the appointment of the FDA in the late 1950s as a result of a number of cases of aplastic anemia due to chloramphenicol.[1] In 1962 the revision of the Food and Drug Act required the pharmaceutical industry to report all adverse reactions to the FDA, and since 1969 nearly 300,000 reports have accumulated. More specifically, in 1984 there were 26,753 spontaneous ADR reports from individuals or manufacturers in the United States.[1] Twenty-four percent were classified as serious because they involved hospitalization (18%) or death (6%). The 6% deaths would amount to a total of 1,605 deaths in 1984 from ADR. (All of this was reviewed and summarized by Karch and Lasagna.[11]) This may be the tip of the iceberg, when one realizes that the reports are submitted voluntarily. However, 90% of the total reports come through the manufacturer, probably as a report to the manufacturer from the physician. The physician has fear of reporting a serious and fatal reaction because of the possible subsequent lawsuit that this might engender. However, the FDA reassures the physician that no suit would come from this kind of report. Four to six times a year all physicians receive the *FDA Drug Bulletin,* in the back of which is a single sheet to report the reactions (FDA form 1639). It is estimated that in only 19% all details are included, such that most reports are incomplete and it is difficult to abstract appropriate data from these reports. There is one estimate that only 2% of ADRs are reported to the FDA.[12] Many physicians do not even know of the FDA ADR report forms and their availability in the back of the *FDA Drug Bulletin* or, if they do, they do not keep it on hand to report a reaction when it does occur.

Clearly we have a problem, but how many of these patients with ADRs required this medication for significant and even life-threatening illness? It is unknown what underlying factors such as drug interactions, systemic debility and extrasensitivity to medications may have brought about their ADR and even death. The public demands the best of medical care and realizes that this cannot come about without medication.

Yet there is no medication that is without side effects. Table 16.1 lists the classification of drug reactions.[13] Table 16.2 lists the majority of the drugs that we know will potentially produce adverse drug reactions affecting the lungs and airways.

More is known about the incidence of adverse reactions on the lung produced by nitrofurantoin than almost any of the other drugs, with the possible exception of bleomycin. In regard to nitrofurantoin, the incidence varies from 0.001% to 0.26%![14–17] D'Arcy[16] reviewed the manufacturers'

TABLE 16.1 Classifications of drug reactions.

Predictable reactions
Overdosage: (toxic effects): the untoward effects directly related to absolute overaccumulation which prevents breakdown or excretion of drug at normal rate. Can occur with any drug.
Side effects: the undesirable but unavoidable pharmacologic actions of the drug (e.g., sedative effect of antihistamines).
Secondary effects: indirect consequences of the primary action of the drug (e.g., disturbance of normal bacteriologic balance while on antibiotics).
Drug interactions: the alteration of metabolism of certain drugs by another drug(s) (e.g., cimetidine impairing the metabolism of theophylline).
Unpredictable reactions
Intolerance: untoward effect represents a qualitatively normal pharmacologic effect of the drug which, however, is quantitatively increased.
Idiosyncrasy: the reaction to the drug is qualitatively abnormal and does not correspond to its usual pharmacologic actions (e.g., slow acetylator of isoniazid).
Allergy or hypersensitivity: a result of an immune response of the organism (or organ) leading to the formation of specific antibodies or of sensitized lymphocytes or both to the medication, in turn releasing toxic substances with adverse effects on various parts of the body (e.g., penicillin reactions).

records in which they estimated that there were 120 million courses of the drug given during a 30-year period and found an incidence of 0.001%. Koch-Weser et al,[17] on the other hand, found 1 in nearly 400 (0.26%) patients experienced an adverse pleuropulmonary reaction to nitrofurantoin! This is more than a 250-fold difference. The physician does not really know how great a risk he is subjecting the patient to as a result of this variability in statistics, and this can have an influence on his prescribing a drug. The details of these adverse reactions have been reported by a number of different authors and will not be given here.[18,19]

There are no tests available to diagnose an adverse drug reaction affecting the lungs, except in the rare cases of drug-induced systemic lupus erythematosus, and no specific chest roentgenogram change or blood test. The best test is a "high index of suspicion." Treatment consists of discontinuing the medication and, in some instances, adding corticosteroids. Most ADRs affecting the lung do not progress to death if the reaction is recognized early enough by the physician (or the patient) and the drug is stopped. Confirming the cause and effect relationship between the drug and the disease is not always easy, but it is very likely that the entity has been described in the medical literature.[18,19] We do not advocate rechallenging the patient with the drug. If the clinician believes that it is absolutely necessary to rechallenge a patient for whatever reason, then this must be fully explained to the patient (preferably in writing along with a signed consent form), the risk-benefit ratio fully explained to the patient, and the rechallenge, if necessary, carried out in the hospital setting.

The court has now made it clear that the FDA listing of adverse reactions is held up by the court system, meaning the physician must know all of the potential side effects of the 30,000 available drugs![20] He is expected to be familiar with the data listed on the package insert which, for the most part, is

TABLE 16.2. Drugs inducing lung disease.

Cardiovascular	Illicit drugs
Amiodarone	Heroin
Protamine sulfate	Methadone
Beta blockers	Propoxyphene
Propafenone	Anti-inflammatory
Angiotensin-converting-enzyme anhibitors	Acetylsalicylic acid
Tocainide	Nonsteroidal anti-inflammatory agents
Hydrochlorothiazide	Gold
Chemotherapeutic drugs	Penicillamine
Bleomycin	Miscellaneous
Cyclophosphamide	Blood products
Busulfan	Tocolytic agents
Azathioprine	Oxygen
Mitomycin	Streptokinase
Vinblastine	Dilantin
Procarbazine	Amphotericin B
Melphalan	Inhaled beclomethasone
Chlorambucil	Ethiodized oil
Nitrosoureas	Ehanolamine oleate
Methotrexate	Drugs inducing SLE (more than 30)
Cytosine arabinoside	Methysergide
Antibiotics	
Nitrofurantoin	
Azulfidine	
Sulfonamides	
INH	
Gentamicin	
Polymyxin	
Colistin	
Neomycin	
Streptomycin	

the same data available in the *Physician's Desk Reference* (PDR). No longer is the patient in the dark regarding the potential adverse side effects of drugs. The PDR is available in any bookstore for a reasonable price and, by law, the patient is to be given a package insert describing all the potential side effects. The FDA regards the package insert as an extension of the labeling of the drug. Information on the package insert begins with the manufacturer's New Drug Application (NDA). For an indication to be listed in the package insert, it must be proved that the drug is safe and effective for that purpose. The package insert follows the regulation of "full disclosure" requiring that information of the indications, effects, dosages, routes, frequency and duration of administration, side effects, contraindications, and other precautions must be listed.

However, there is concern that so much will be written into the package inserts that no one will read it. There have been a number of legal cases now tried in court concerning the manufacturers' package insert. The manufacturers engender their own legal culpability if insufficient warning is not included on the package insert.

The lack of knowledge about drugs is no excuse, and failure to know the

possible universal reactions to prescribed drugs can be interpreted as negligence.[21] Prescribing drugs without a diagnosis makes the physician even more prone to future problems. If the physician deviates from the prescribing recommendations contained in the package insert, this can be recognized as negligence. These recommendations are supplied by the manufacturer after extensive trials and then approval by the FDA and serve as a legal notice to the prescribing physician that any deviation from this is negligence. There is little recourse if there is death or disability from the drug and the reaction is listed in the package insert. If it is not listed, then the manufacturer may be at fault.

The liability for a patient's adverse reaction to a prescribed medication is determined by general standards of due care.[21] If the physician uses a degree of skill, knowledge, and care that prevails in his state in prescribing drugs as well as recognizing the ADR and managing the reactive symptoms, he is not usually liable. A patient cannot necessarily infer negligence simply because results of treatment were unsatisfactory. However, it is important that he be aware of the side effects of any medication prescribed. The patient should be informed of the risk and given a chance to refuse to take the medication. Again, ignorance of the possibility of a reaction is evidence of negligence. Continuing to prescribe a drug with adverse reactions can result in physician culpability.[22] If, according to the standard of due care, the medication given was not the proper one for the disease diagnosed, negligence can also be imputed even though the adverse reaction that occurred could not have been prevented.[23] If, indeed, the physician is certain that the drug being used is the proper one from the therapeutic standpoint as an appropriate treatment of the presumably correctly diagnosed disease and knows the possibility of adverse reaction is present, yet believes it is necessary to take the risk, he must then inform the patient of his decision and receive the patient's consent to proceed with the drug administration, in order to be legally protected. This is keeping in mind that the physician does not guarantee a cure of any disease nor is he an insurer of the patient's welfare. But the patient should be involved in the decision of the administration of drugs.[24]

Before prescribing any medication that has the possibility of causing an adverse reaction (and this is essentially almost every medication prescribed), the physician is legally bound to make a reasonable effort to determine if an adverse reaction is likely to occur.[25,26] The use of a thorough history can often lessen the problems of drug reactions. For example, knowing a patient's history of alcoholism can alter the availability of the use of some medications. The physician is liable if he does not warn the patient of side effects that can occur while taking a medication.[27,28] After the principle of "informed consent," the physician is required to discuss the possibilities of permanent adverse effects by medication with the patient.[29,30] This is frequently not done when medications are prescribed by phone, a practice that should be avoided. If there is any doubt, then for full protection a properly signed and witnessed informed consent should be obtained.

In conclusion, maintaining an active dialogue with your patient on the possibility of ADRs will limit the risks that physicians subject themselves to

when unexpected results occur. Patients should be placed in the position of active participation in their care.

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17

Chest Trauma: Differing Medical and Legal Perspectives

A Surgical Perspective

KENNETH L. MATTOX, MD

Scope of Potential Legal Issues Resulting from Thoracic Trauma

According to the Centers for Disease Control in Atlanta, trauma is the leading cause of premature death in America for persons 65 years of age and under. There are more than 4 million patient encounters per year for nonmilitary trauma. From this number, approximately 150 thousand deaths will result, including suicides, homicides, burns, and accidents. Chest injury directly accounts for at least 25% of these deaths; and in another 25% a chest injury or a thoracic complication contributes to the death.

The physician taking care of the patient with a chest injury may be an emergency room physician, general surgeon, thoracic surgeon, or a consultant in critical care medicine, pulmonary medicine, cardiology, pediatrics, radiology, or anesthesiology. These physicians may encounter legal issues involving these patients in at least three potential areas:

1. Contagious diseases and acts of social violence fall into the category of "reportable diseases and conditions" that must be reported to legal or public authorities. In this area, the health care team initiates legal notification and is liable only if appropriate authorities are not notified.
2. For chest injuries secondary to industrial mishaps or involving third parties, including the state (i.e., in instances of attempted murder or persons injured while committing a crime), often the physician will be asked to prepare briefs, reports, letters, or statements regarding cause/effect and prognosis. In this area, the physician may be asked to appear in court for the purpose of introducing matters of clinical record into evidence.
3. Professional liability lawsuits against a physician for alleged malpractice may be filed for any of a large number of thoracic injuries. Certain types of chest injury, however, are among the most litigious in America. Cited reasons for such suits being charged against the physician stem from at least three problem areas: 1) Patient dissatisfaction with a result. Although the result may be acceptable to and even expected by the physician and the medical community at large, if the patient and his or her family believe a

"better" result could or should have been achieved, consultation with a lawyer usually occurs; 2) incomplete, inappropriate, inaccurate, or delayed medical record maintenance. Although a patient's care may have been exemplary, the written record is what endures and what is relied upon by insurance companies, attorneys, consultants, experts, and all others in judging the quality of care rendered. The importance of complete and accurate records cannot be overemphasized. Comments concerning apparent conflict between nursing notes, consultant notes, and the primary physician notes must be concise and reflective of the true course of treatment. Operative notes and documentation of complications must be dictated or written in a timely manner, not days or weeks later; and 3) informed consent. Although much has been written about informed consent and its importance, it is highly probably that no patient fully comprehends all aspects of his injury and treatment. Furthermore, several months after an event it is likely that both the patient and his or her family will not recall all of the ramifications of the "informed consent session," even if the form is signed, notarized, or even videotaped. Nevertheless, again, as in the area of medical record maintenance, specific informed consent with complete documentation and appropriate signatures are imperative.

General Factors Contributing to Litigation

Currently, controversy is evolving with regard to techniques and devices used in thoracic trauma. Those not directly involved in patient care tend to espouse only the side of the controversy that supports their bias. Academic discussions continue on use and nonuse of synthetic vascular grafts, appropriate monitoring techniques, protection of distal circulation when aortic clamping is necessary, and the length of time the spinal cord, kidneys, and liver can endure hypoperfusion. Valid arguments for both sides of each issue exist, and dogmatically repeating only one biased view for the benefit of a jury will, in the long run, benefit no one, neither physicians nor patients. The end result of this tactic will be fewer and fewer physicians willing to treat patients with high-risk (high potential for lawsuit) injuries and limitation on research into new and innovative approaches to managing these injuries.

Trauma is a surgical disease. From the prehospital phase through rehabilitation, the surgeon must direct the care of the patient with thoracic trauma. Surgery is the only specialty that trains its residents to be involved in the total continuum of care. Within the trauma center structure, invasive acts such as tube thoracostomy and emergency room thoracotomy, as well as decisions with regard to arteriograms, surgery, and necessity of invasive monitoring, *must* be under the control of the surgeon. Emergency physicians, intensivists, and other consultants must never be primarily responsible for triage, decision making, or specific treatment schemas. The surgeon may become a victim of transferred liability for actions taken by another physician before transferring a patient. Transferring patient care responsibilities to other disciplines when

treating the patient with chest trauma is asking for complications and delays in diagnosis and therapy. The emergency room physician should call the trauma surgeon, who is then in the emergency room when the patient arrives. It is unacceptable for the emergency room physician or the intensivist to perform procedures such as tube thoracostomy, emergency center thoracotomy, tracheostomy, crycothyroidotomy, insertion of a Swan–Ganz catheter, or other procedures on the chest trauma patient without the knowledge and direction of the surgeon. Significant numbers of lawsuits against surgeons taking care of patients with thoracic trauma have been "transferred" to the surgeon because of delays or iatrogenic complications created by nonsurgeons. The surgeon, not the radiologist or other consultant, decides the need for arteriography in the patient with chest trauma. Angiography, not computed tomography (CT) or magnetic resonance imaging (MRI), is the standard for determining the presence of vascular injury requiring operative repair. Computed tomography and MRI create further delay and only document the presence of mediastinal hematomata rather than the specifics of a great vessel injury. At present, nonsurgical intensivists have neither surgical nor operative training. The patient with a chest injury in the intensive care unit has multisystem problems, including cardiac, fluid and electrolyte, infectious, renal, hepatic, pulmonary, metabolic, immunologic, wound, nutritional, and many others. Nonsurgical intensivists are not trained in all of the disciplines and ramifications of the post-traumatic surgical problems. Therefore, the surgeon must directly manage the primary care of the patient, using any consultants he deems necessary. Especially in the chest trauma patient, it is important that only one physician write orders and orchestrate the treatment program. Consultants (with their sometimes controversial and conflicting advice) must *not* a priori impose their orders, but rather cite their opinions as progress notes.

Specific Complications Often Associated with Legal Issues

Paralysis is the most common condition following thoracic injury that results in a lawsuit. The factors that lead to paralysis after blunt trauma are exceedingly multifactoral and complex. Considerable debate exists as to the exact cause of paraplegia and how to prevent it. Indeed, in patients with major aortic injury, no treatment schema has reduced paraplegia to zero. The patient with severe injury requires longer and more extensive repair and has more associated injuries. In such a patient, all complications, including respiratory insufficiency and paralysis, are not uncommon. Debates about clamp times, monitoring techniques, shunt *vs* clamp/repair *vs* pump, and others are diversionary tactics and ignore the more important issues of early diagnosis and location and timing of operating on a critically injured patient who may not be in any condition for transfer and meticulous evaluation of multisystem injury.

Currently, it is estimated that when paraplegia occurs after surgery for acute injury to the descending thoracic aorta, a malpractice lawsuit is filed against the surgeon, the hospital, the emergency room physician, and others in at least 25% of the cases. These cases occur regardless of appropriate informed

consent and use of standard operative techniques on a documented critically injured patient in a life-threatening situation. The obvious result of this trend is for emergency facilities to refuse to accept patients with complex, obviously "litigious-prone" injuries. Society then trades a paraplegia rate of 8% in such lesions for a mortality rate of greater than 75% because of nonavailability of surgeons and/or hospitals willing to accept the associated legal risks. We have already seen this situation develop in the specialty of obstetrics, where many physicians limit their practice to gynecology. In many communities a pregnant woman may find it almost impossible to find an obstetrician, especially if the pregnancy is high risk or she is new to that community.

Iatrogenic and missed thoracic injuries pose potential for lawsuit. At times, such misadventures are not possible to avoid. Aggressive therapy is mandatory, and the time for a "fishing expedition" workup is simply not available.

Summary

In a recently published textbook on trauma, Professor Charles Weigel points out that the surgeon treating the victim of trauma usually *begins* with an undesirable result and a patient looking for someone to blame his injury and suffering. He further points out that a less than perfect result does not infer malpractice, but rather most frequently reflects the extent and severity of the initial chest injury. If an undesirable result did infer malpractice, 50% of all attorneys involved in court cases would be guilty, because one side in all lawsuits will be unhappy with the outcome.

Trauma is the leading cause of premature death in America. Thoracic trauma produces significant death and complications. Both the injuries and techniques of treatment are complex. The surgeon interfaces with medical legal facets in almost every patient with thoracic injury. There must be understanding on the part of the patient, the family, insurance companies, attorneys, juries, and the general public that the complexities of thoracic injury are multifactoral. The "villain" of the undesirable outcome may not be identifiable, may be a combination of many factors and circumstances, or may be entities impervious to litigation, such as alcohol, drugs, and excessive speeds.

A Legal Perspective

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Physician-Patient Relationship

The physician who undertakes the care of a patient with chest trauma is confronted by a number of medical dilemmas and potential legal liabilities. All of the legal, as well as medical implications as to the physician, arise as a result of the physician-patient relationship.[1] The relationship is generally considered to be a contractual one, although the contract is usually implied from the actions of the parties and is not often expressed in contract terms. This is

usually the case in a chest trauma situation, when the patient is brought to the emergency room or trauma center.

Protecting Patients' Legal Status

If the thoracic trauma is due to an accident, the physician has the duty to acquire information that will help determine the causal relationship of the event to the trauma or injury to the patient, whether it be a worker's compensation situation, an environmental accident, or personal injury. The physician has the duty to acquire and preserve all the facts to protect the patient's legal status. Documentation and recordkeeping are necessary to comply with the requirement that the patient be protected in any claim for compensation as a result of the chest trauma.

Successive Tortfeasor

The physician is also faced with the specter of being a successive tortfeasor.[2] Under the law, the initial wrongdoer is usually responsible for all damages to the victim, including losses due to negligent medical care. However, the original wrongdoer is entitled to seek indemnification from a negligent physician for the amount of damages caused by the negligence, even though the victim selected the physician. In a recent case, an automobile driver who accidentally injured an individual was allowed to seek indemnity from the physician who negligently treated the injured individual and aggravated the patient's injuries. This is a situation in which physicians have been held liable to a third party which involves the patient or the negligent professional treatment of a patient injured by a previous wrongdoer or tortfeasor.

Negligence

The physician who is involved in the case of a chest trauma patient has to recognize that because of the nature of the trauma, he is vulnerable to committing an act of negligence that may later make him a defendant. He must comply with the standard of care for the treatment of this problem. It is likely that he will be judged according to a national standard. Negligence by the physician/surgeon in this type of situation can be defined as the failure to do something that a reasonable specialist in the field, guided by those considerations that ordinarily regulate the conduct of a reasonably prudent specialist, would have done. It may also be a failure to do an act that is necessary for the protection of the patient.[3] If the physician did not possess the knowledge and skill ordinarily expected of such a specialist, or failed to exercise the care and skill ordinarily used in like situations, he may be liable. In a thoracic trauma case the question is, "Does the physician have the expertise to properly manage the patient?"

Standard of Care—National Standards

The more specialized a physician becomes, the more likely he will be held legally liable for professional acts based on national standards. Thus, a specialist needs to be aware of the standards established by his or her professional organizations and organized specialty groups.[4]

In the past courts recognize a standard of care as applying to practices in the same or similar locality or community. However, national standards recently have been invoked for health professionals and hospitals. Increasingly, specialists are being held to a national standard of care, defined as that ordinarily exercised by reputable members of their specialty under similar circumstances.[5] Legally, "doing the best you can" is not a plausible defense.

A professional source for the standards of care may be a publication of the American College of Surgeons (ACS). During the last 10 years the college has developed a course for general surgeons and others as well. The purpose of the course is to instruct practicing physicians in trauma management. The course is entitled Advanced Trauma Life Support (ATLS). A certification of completion is awarded if the course is passed. Frequently, possession of such a certification may be a prerequisite to employment at a trauma center. Many states, such as Pennsylvania, have included possession of such a certificate by staff members as a requirement for state authorized trauma center designation. This is one way of establishing a minimum level of competence.

Competence of Physician

One of the first decisions the physician must make is whether he is capable of and competent to treat the patient. This is a judgment each physician must make for himself, although later this judgment may be called into question. The law does not state that the physician must be a trauma specialist, a chest surgeon, or even have specific qualifications, expertise, and training except as set up by the medical profession itself. If the physician believes he is competent by training and experience according to these medical standards, the law supports his professional right to proceed.

Consultation and Referral

If, on the other hand, the physician has questionable expertise, then he should refer the patient to a physician with the necessary expertise, or seek consultation depending on the circumstances.[6] This is a legal duty that may have legal consequences for the physician if he ignores his need for help and the physician suffers harm. This includes the duty to know when help is needed and who can best supply it.

Managing the Patient

The ATLS manual also describes in detail the management of a patient with trauma. In general, patients with thoracic trauma have multiple injuries, and

although the manual is cautious and describes the system of trauma management as one of many possible techniques, the ATLS way is fast becoming a standard of care. The obligation in time to come will increasingly rest on the physician to prove that deviation from the ATLS standards was actually an improvement. This is especially true in those situations where things have gone wrong. The doctor will have a difficult row to hoe if he fails to follow ATLS guidelines. Thus, ATLS is similar to the PDR (Physicians Desk Reference) in that it provides a notice to physicians about an acceptable mode of clinical practice, deviations from which require considered judgment on the part of the physician.[7]

The Team Approach

Organization and a team approach are crucial in trauma management, whether the trauma team consists of a physician and nurse in a small rural hospital, or a host of emergency room physicians, surgeons, thoracic surgeons, and critical care nurses in a regional trauma center. Team members must know their responsibilities and be prepared to carry them out with skill. The overall goal is to stabilize the patient while simultaneously evaluating injuries sufficiently to allow his or her transfer from the emergency department to the appropriate site for definitive care, usually the operating room.

Timely Critical Interventions

The initial management of the patient, according to ATLS, is to maintain the stability of the cervical spine. Current statistics indicate that up to 10% of patients who enter the emergency department after major trauma may have fractures of the cervical spine.

In the primary survey of the patient, the critical considerations are whether the patient's airway is patent, whether he is breathing, and whether circulation is normal. A number of procedures are available to preserve the trauma patient's airway. Another critical part of the initial assessment in ATLS is restoring the circulation. Another dilemma is whether the patient can and should be moved for diagnosis and treatment.

Patients who are confused, disoriented, and agitated must be controlled according to circumstances. The JCAH manual requires the emergency department to have a specific policy on the management of the belligerent patient with altered mental status. Frequently, the etiology behind the abnormal behavior of a patient involved in trauma cannot be ascertained. The physician's first obligation is to be certain that this "altered" mental state is not due to a life-threatening medical problem. Treatment of potential etiologies precedes diagnosis, especially where that treatment has a minimal risk of causing harm. Belligerence and refusal to accept medical therapy are most often due to a head injury, drug or medication abuse, alcoholism, electrolyte imbalance, hypoxic state, and drug overdose. Which of these are present can be determined easily by the laboratory predicated on a high degree of suspicion on the part of the physician. In these situations, acquiescence by the physician to the patient's

refusal of care may result in death of the patient with all its legal consequences, particularly an action for wrongful death discussed elsewhere.

All of these actions fall within the accepted and required standards of care. If there is a deviation from these standards that caused the patient harm, a successful lawsuit may follow. It must be stressed that the physician must document his actions, to that end he can then show that he merely made a mistake or an error in judgment which is a human frailty and not reckless disregard of the standard of care.

Specific Treatment

The standards for treating specific chest injuries of the patient have been established by the medical profession. Some do happen to be controversial. As soon as the patient has achieved cardiopulmonary stability, it is critical to attempt to get a thorough medical history, paying particular attention to the factors that determine the type and severity of the patient's injury. The physician must also find out as much as he can about the accident. The details of the accident may be a tipoff to associated injuries, such as blunt abdominal trauma that may otherwise go unrecognized in all the excitement. Family, friends, and the emergency crew are all helpful sources. An outreach effort may be necessary to seek and search for people who may provide valuable facts.

In the physical examination the first priority is to assess the level of consciousness. Determining the baseline neurologic functions heads the list, because if the patient survives the ultimate concern is whether the physician is going to be left with a patient in a chronic vegetative state. Because hypothermia affects the body's response to resuscitation and supportive measures, a special low-reading thermometer may be required. The accepted standards for history taking, doing a physical examination, and ordering appropriate tests have been discussed in the chapter on the "Medical and Legal Issues of Lung Cancer" (Chapter 21). They are appropriate here as well.

Benefits Versus Risk Rule

Concomitantly, the physician must determine as best he can the nature, severity, and the extent of the chest injury. With the trauma patient, time is precious and the evaluation must be performed as rapidly as possible. Under any circumstances, lifesaving treatment and stabilizing measures must be initiated as soon as problems are recognized, and often before they are completely understood.

This is frequently fraught with great difficulty because of the nature, extent, and severity of the chest injury, which makes their evaluation difficult. Time may be of the essence, and yet the physician needs some time to make the evaluation. Therefore, the extent of evaluation must be made on the basis of the benefit-risk rule (i.e., an evaluation of the path that was taken and why, is critical).

The Golden Hour

The physician must always remember that complacency sometimes kills. When the physician thinks he is aware of all the injuries present, he should reevaluate and think again. What else could be hidden away in the battered body? There are plenty of surprises to go around.

The early and rapid team management of trauma produces better results. If this "golden hour" is lost without effective resuscitative and stabilizing efforts, the patient is unlikely to respond to similar efforts undertaken at a later time.

Keeping Abreast—Keeping Up

The law and medicine have imposed a duty on all physicians to be aware of changing concepts and new developments.[8] It is not the physician's duty to implement new techniques merely because they are new; usefulness must be reasonably established. What may be accepted as the most advanced practice of trauma medicine one time in a physician's career may be swiftly outdated by new discoveries and advances, and it is his obligation to render treatment to his patients based on adequate understanding of those new developments. But a specialist who is ignorant of the recent developments that are known to, and accepted by, the profession may be liable if the use of an outmoded method results in harm to the patient. Although adherence to the usual practice by which the local medical community deals with a problem is ordinarily a good defense to a charge of negligence, "everybody does it" is not an excuse if it is in fact a sloppy or careless practice, or contrary to national standards.

Consent

Giving informed consent to medical care is the absolute right of every patient.[9] This issue is discussed in detail in the chapter on informed consent. The mere signing of an operative permit is not informed consent. It is merely a license to treat.

Informed Refusal

Both the medical and the legal professions have accepted that the physician has a duty, as they say, to lead the patient to the water, but not to make him drink. This may no longer be completely accurate. Recent rulings render the physician liable for any injury legally resulting from the patient's refusal to take treatment, diagnostic or therapeutic, predicated on the duty that the physician has to inform the patient of the perils and pitfalls of declining the care and management in a discreet, human, ethical, moral, and professional manner, and that he failed to do so. It is not very likely that a patient with severe trauma to the chest will refuse treatment, but truth is sometimes stranger than fiction. The physician is best advised to know the law under these circumstances.

Assumption of Risk

The doctrine of "assumption of risk" means that the patient understand the possibility of all risks of untoward, unpreventable results of either treatment or no treatment, and knowingly consents to the course selected.[10] Where it applies, this is usually a good defense to an action for negligence on the part of the physician. It should be noted that this doctrine is related to the doctrine of informed consent and refusal. If all risks that in fact occur have not been carefully explained to the patient, as a matter of law the doctrine of assumption of risk is not applicable.

Assault and Battery

Assault and battery are two torts and two words we often hear together, but they have separate meanings. Assault is the unjustifiable attempt to touch another person or the threat to do so in such circumstances as to cause the other reasonably to believe that the threat will be carried out.[9] The tort of battery involves an intentional act that is a harmful or offensive touching of another without that person's consent. Medical care and treatment that involves the touching of another person has been held to constitute a battery if the person touched has not consented to the treatment.

The lack of consent or privilege is an important part of the meaning of battery. Consent is a defense to an action for battery. If a physician goes beyond the limits to which a patient consented, he may be liable. Also, if the person who does consent is known to be a person incapable of giving consent, that consent is not a valid defense. At times, physicians have learned "the hard way" that the fact that treatment is desirable does not allow them to go ahead without the consent of the patient or someone entitled to give consent. In an emergency one may do what they can to save life and limb, even in cases in which they have no consent or can obtain none.

Emergencies—Good Samaritan Statutes

A physician has no legal duty to treat someone who is in an emergency situation. Good Samaritan statutes, however, provide immunity from civil liability for doctors who render aid in an emergency. The statute does not apply if a prior physician-patient relationship existed, or if the physician acts with gross negligence. The statute does not apply to treatment in a health care facility, under the circumstances under discussion.[12]

Duty to Report

Every jurisdiction has a list of diseases that must be reported to authorities.[13] These include injuries sustained in accidents, violent crimes, occupational diseases, or environmental problems. It is incumbent on the physician to do so. In these cases, he not only has the right to disclose the information to proper

authorities, he has the duty. The physician should be knowledgeable as to what conditions are reportable. Failure to report may lead to civil, criminal, and administrative sanctions.

Epilogue. I have presented an overview of the law as it applies to the care and management of patients with chest injuries.

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18

Assessing and Presenting the Medical Evidence in a Case of Occupational Lung Disease

Introduction by W.K.C. Morgan, MD

If lawyer's hand is fee'd, Sir, He steals your whole estate.

John Gay, *The Beggar's Opera*

Mr. Richman gives a lucid and objective account of how to present medical evidence in litigation concerning occupational lung disease. His advice is excellent and his own record as counsel for defendants in litigation of this nature has been second to none. His chapter would seem to suggest, however, that right and justice always prevail, but this is far from the case. Unfortunately, being both plausible and a good witness cannot necessarily be equated with knowledge, objectivity, or even honesty. Moreover, even the Bench has its preconceived ideas and prejudices. The plain fact of the matter is that salesmen are seldom honest, invariably embroider the facts, constantly spew forth hyperbole, and, moreover, are to be found both in the medical and legal professions. Whereas some physicians who appear as expert witnesses are mendacious and intelligent, others are mendacious and stupid, but even gross stupidity is not always revealed for what it is. A minority is both honest and well informed, but many of the confreres will not appear in court because of unpleasantness involved. Particularly dangerous to the administration of justice are those medical expert witnesses who cast themselves in the role of social reformers or avengers for past injustices, and who believe with compelling fervor that their main role in life is to punish the successors of industry's robber barons of 40 to 60 years ago. It is the prerogative of the Lord thy God only "to visit the sins of the fathers upon the children, even unto the third or fourth generation." It is in the light of these facts that the present situation needs to be judged.

Compensation for occupational lung disease in the United States is in a state of flux and also in dire need of reform. As the system now operates, there is a lack of uniformity, an absence of fairness, and a surfeit of illogicality in regard to legislation for industrial disease and accidents. Although a selected few profit, more often and in contrast, many suffer and certain industries and large companies have been put out of business or rendered unprofitable. That the present system will continue, albeit with some minor modifications, for sometime is all too evident, but the recurrent attempt to cobble the more glaring defects can only prolong the agony. Complete reorganization is

desirable and inevitable. The present modus operandi has contributed to a reduction in the work forces in both the steel industry and in coal mining, to the migration of industry to the southern states where Workers' Compensation benefits are less "florid," and it is now causing an exodus of many companies to the Third World countries.

The present mess, and this term is an euphemism, evolved slowly in an uncontrolled manner as a result of a number of interested parties all seeking an extension of their power and dominance, a higher standard of living, and remuneration for themselves. Thus, the labor unions, unwilling to face the fact that their lifestyle and habits, in particular cigarette smoking, excessive alcohol intake, and overeating, are responsible for the vast majority of illnesses and death in the work force, have given tacit assent to the concept that most illnesses in the work force are induced by occupational exposures. They have lobbied effectively for expensive programs of medical surveillance, most of which are futile, some of which are actively harmful and create anxiety and thereby illness, and all of which are expensive and a burden to industry and to the consumer. In this they have been aided and abetted by the US government agencies such as EPA, NIEHS, and NIOSH, all of which have endorsed the same viewpoint to maintain themselves in the limelight. These agencies realize full well that the US public, the media, and Congress do not want to hear about chemicals that do no harm (the vast majority), they want to hear about any agent that has dreadful effects, be they real or imaginary. There exists a continuing need for hyperbole if these agencies are going to maintain or increase their appropriations. The military-industrial complex has been superseded by the government-labor union complex; a lobby for the perpetuation of mythology and irrationality. Certain members of legal and medical professions also have contributed to the emergence of the present system.

However well intentioned those of the legal profession might have been when they initiated the contingency fee, there is no doubt that this now has a deleterious effect upon the administration of justice. When single awards for industrial disease often amount to $2 to 3 million, and with the plaintiff's lawyer receiving 25% to 60% of the award, objectivity goes by the board. Cupidity becomes the prime motivation and the desire to win at all costs leads inevitably to excesses and misrepresentation. About 10 years ago, an award of more than $1 million was made to the family of a subject who had died from amyotrophic lateral sclerosis. The award was made on the basis that the disease was a consequence of exposure to heavy metals during welding. No reputable member of the medical profession subscribes to this outlandish hypothesis, yet the company, the insurance companies, and indirectly the general public had to foot the bill. Moreover, nowadays virtually every disease is being attributed to occupational exposure.

Clearly, what is needed is a nationwide system that awards equal compensation for equal disability, whether the latter is related to occupation or naturally occurring disease. The system would need to be devised in such a way as to eliminate the present tedious, time-consuming, expensive, and unjust litigation that presently takes place. Mr. Richman, whose chapter follows, is a most

gifted and persuasive lawyer, who is only too aware of the present defects. He has fought long, hard, and successfully to right some of them, with, I might add, a fair measure of success. He is one of the authors of the Franklin Report.[32] I recommend this to the reader as an example of an enlightened, disinterested, and yet a constructive proposed solution to the ne plus ultra of legislative faux pas—the Black Lung Acts. He does not share my enthusiasm for radical reorganization, but then we see the situation from different vantage points.

Assessing Medical Evidence*

STEPHEN I. RICHMAN, JD

The Labor Department has estimated that at least 260 thousand American workers are "severely or partially disabled" from occupational lung disease.[1] Senator Gary Hart claims that, from asbestos-related causes alone, as many as 5,000 asbestos workers will become disabled or die *each year* until the end of the century.[2] The National Institute of Occupational Safety and Health (NIOSH) has identified occupational lung disease as the number one cause of work-related "injury."[3] Yet, Morgan and associates[4] have written that even among coal miners who are claimants for black lung compensation, "substantial and disabling impairment is distinctly uncommon."

According to the Labor Department, ". . . [m]any occupational diseases, particularly respiratory illness, exhibit clinical symptoms indistinguishable from 'ordinary diseases of life.' "[1] Indeed, when compared with lifestyles and social behavior patterns, the etiologic role of the workplace may be very small.[5] Even in the dusty industries, writes the distinguished British scientist, Dr. P.C. Elmes, "stopping smoking would have a far greater effect on the burden of disease than the complete suppression of all the dusts and fumes."[6] Consequently, 90% of respiratory disease claims are litigated.[7] Issues of causation (whether the occupational disease caused the personal injury or death) and etiology (whether occupation caused the disease) are controverted in over 75% of the litigated cases.[8] Respiratory disability is also a much disputed issue.

In the litigation of occupational lung disease claims, the principal controverted issues, both in number and in complexity, are medical and not legal. "Those lawyers who have chosen to devote some or all of their professional time to working in the area of the law dealing with the compensation of the victims of . . . [occupational lung disease] must have an intimate understanding of its medical aspects."[9] Because the ability to assess and present rhetorically the medical proof will often determine the result, the litigator of an occupational disease case must know how to obtain, organize, and interpret

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these types of evidence: 1) the clinical history, including toxic exposures, smoking habits, and symptoms; 2) the clinical and pathologic findings, including physical, radiologic, physiologic, and histologic; 3) the epidemiologic and hygienic data; 4) the standard criteria for diagnoses and measurements of impairment; and 5) the relationship between impairment and "disability." After it is gathered and analyzed, this evidence will be presented by the medical expert through a report, and through testimony subject to cross-examination. The purpose of my chapter is to acquaint the attorney with basic information and references that will help in performing these essentially medical tasks.

Clinical History—Occupation, Smoking, and Symptoms

A careful occupational history is very important, and it is always wise to inquire specifically about work with asbestos or in any particularly dusty jobs.[10] A smoking history, which includes data about duration and quantity adequate for conversion to "pack years," is also very important. A detailed medical history, to include past illnesses, symptoms, and treatments should be obtained. To confirm or contradict the smoking and medical histories that have been elicited from the claimant, all available medical records or reports, including office progress notes of treating physicians and records of hospitalizations, should be obtained and examined by the attorney and his medical consultant. The existence of any relationship between the history of symptoms and the work and smoking histories should be investigated for clues to the etiology of the symptoms.

The most frequently encountered respiratory symptoms are dyspnea, productive cough, and adventitious breath sounds.

"Abnormal shortness of breath is almost always the result of either cardiac disease or of obstructive or restrictive lung disease."[11] Equally important, exertional dyspnea is almost never due to simple pneumoconiosis.[11] In the setting of a claim for compensation benefits, as distinguished from the treatment setting, complaints of shortness of breath are often exaggerated and should be regarded skeptically.[12,13]

The symptom of cough and phlegm is common in cigarette smokers[14,15] and also in nonsmoking workers exposed to industrial dusts or fumes.[16,17] "It is most often due to cigarette smoking."[18]

Wheezing is a symptom of obstructive lung disease,[19] but it can also be due to cardiac disease.[20] If it is intermittent, the wheezing is probably from asthma, which may or may not be work related.[21] Crackles (rales) is a symptom of asbestosis[22]; it can also be due to nonoccupational lung diseases[23] or even to heart disease.[24]

Clinical and Pathologic Findings

The occupational, smoking, and clinical histories are supplemented with findings that are obtained by physical examination and by radiologic, physiologic, and pathologic studies. These findings are initially presented through the reports of experts trained within the appropriate medical specialties.

Persons who have occupational lung disease often do not have any signs of it on physical examination.[11] In advance stages of some occupational lung diseases (e.g., asbestosis), clubbing of the fingers and basilar rales may be observed.[22] Signs of overinflation, diminished breath sounds, and hyperresonance may be seen in advanced emphysema,[21] a condition which is almost always due to cigarette smoking.[15,17,25] The adventitious sound of wheezing was previously discussed.

The chest x-ray "is the best currently available clinical method of diagnosing pneumoconiosis."[26] However, it has limitations: in the early stage of the disease, when the lesions are small and sparse, the film may be falsely normal[26]; and many nonpneumoconiotic diseases falsely project the radiographic appearance of pneumoconiosis.[27] The films should be interpreted according to the standardized scheme of the International Labor Office.[28] The chest x-ray is usually not helpful for diagnosing the diseases that result largely from airway reactivity (e.g., chronic bronchitis, asthma, byssinosis)[29,30]; furthermore, even in pneumoconiosis there is often no relationship between radiographic changes and pulmonary impairment.[31] Some, therefore, hold that the chest radiograph "is an unreliable method of diagnosing impairment and disability."[31] Others, however, point out that, at least in pneumoconiosis, roentgenographic findings "*do* strongly suggest the degree of impairment—and even the degree of disability . . . [because simple pneumoconiosis] causes few if any clinical manifestations and little or no decline in pulmonary function."[32] When films taken at different times over an extended period are available, the attorney should get them all to make a serial, comparative study that will reveal the static or progressive character of the x-ray changes and thereby provide valuable diagnostic information.[33] For radiologic consult, the recommendation is to employ a "B" reader,[34] whose impressions are entitled to greater weight.[35]

Assessments of lung function and exercise capability are based on laboratory studies of respiratory physiology, which measure functional impairment and exercise tolerance. ". . . [I]mpairment of pulmonary function is broadly categorized into airflow obstruction, ventilatory restriction, and diffusion defects."[36]

". . . [A]ny measurable level of respiratory or pulmonary functions which significantly deviates from normal shall be sufficient to establish impairment."[37] "Normal" is determined by comparing the value observed in the test actually performed by a claimant, with the value predicted for a person like the claimant according to published tables of normal values. Respiratory impairments of airflow obstruction and ventilatory restriction are measured by spirometry, and impairments of diffusion function (gas exchange) defects by studies of diffusion capacity and arterial blood gases. Ergometric studies (e.g., treadmill) measure exercise tolerance. Because these kinds of tests are well described in the literature,[9,38,39,40] a description of them is not repeated here. A few appropriate practice tips will be given. That class of impairments which are detectable by sensitive laboratory tests but are too mild to cause symptoms, should not be used for assessing disability; these include impairments of the small airways[38,40] and of the alveolo-arterial oxygen gradient.[38] Because the

TABLE 18.1 Comparison of ventilatory studies.

	Dr. Rhurdy 1/17/74	Dr. Rhurdy 5/19/75	Charleston Med. Cen. 8/5/75	Dr. Renn 10/18/79	Harron Clinic 12/3/79	Monongalia Gen'l. Hosp. 1/24/80	United Hospital Center 9/23/80	CAMC-McMillan 8/11/81	Dr. Alpern 4/11/86	Dr. Silverman 5/3/86	W.V.U.H. 8/8/86	Dr. Silverman 9/6/86
FVC (Observed)	4.70–4.62	4.80–4.80	4.86	4.30–4.34	4.23	4.51–4.24	4.68	4.61	3.48–3.92	3.39	4.51	3.87
FVC (% of Pred.)	101%–100%	104%–104%	106%	98%–99%		111%–104%	127%	110%	85%–96%	79%	110%	94%
FEV-1 (Observed)	2.40–3.30	3.12–3.12	3.57	2.99–2.98	3.22	2.97–2.98	3.48	2.98	2.62–2.31	2.74	3.09	2.87
FEV-1/FVC Ratio	74%–71%	65%–65%	73%	69%–69%	76%	63%–70%	74%	64%	75%–69%	91%	69%	98%
MVV (Observed)	111–114	148–135	135	143–149	115	129–120	144		46–63	79	127	87
MVV (% of Pred.)	98%–100%	128%–117%	88%	100%–104%		95%–88%	131%		35%–48%	60%	100%	68%
Height	68-1/2″	68-1/2″	67-1/2″	69″	69″	67″	68″	67-1/2″	68″	68″	67-1/2″	67″
Weight	165#	178-1/2#	165#		178#		179#	182#	201#	202#	194#	194#
Age	50	51	51	56	56	57	57	58	62	62	62	62

Claimant's vital data: date of birth, October 11, 1923; date of retirement, October 28, 1981 (age 62)

maximum voluntary ventilation (MVV) test is difficult and effort-dependent, a normal performance of it practically excludes significant obstructive or restrictive impairment[41]; but an abnormal performance of it, when other tests are normal, should be given little weight.[38,40,42] When several tests have been done over time with intervals between them, a serial and comparative study of them will provide valuable information about whether the condition(s) causing impairment are acute and transient, static, or progressive. An effective litigation technique is to prepare a chart of the serial studies (Table 18.1). It becomes introduced into the case as an exhibit by the medical expert, who will refer to it in the testimony which he gives. The most suitable medical expert is the internist who is board certified in the subspecialty of pulmonary disease (a pulmonologist), especially if he is also a B reader.

Because open lung biopsy is rarely indicated in the evaluation of workers for compensation purposes, the diagnosis of occupational lung disease, in the usual clinical setting, is made in the absence of pathological findings.[22] Nevertheless, pathological findings, often the surest evidence for correct diagnosis, may become importantly involved in the case. If a postmortem autopsy was performed, the pathological findings may be decisive; they must be obtained and studied. Surgical biopsy material can often confirm or rule out clinical findings and diagnoses. Indeed, pathological studies may be the only way to decipher enigmatic clinical evidence.[27] The attorney's pathological consultant may have become involved in the law case because he had been the surgical pathologist or the autopsy prosector, or because he had been asked to review materials prepared by other pathologists. Regardless, the pathological consultant should describe in his report all significant pathological findings.

Microscopic slides, paraffin blocks, and even body organs are routinely indexed and stored to maintain their diagnostic value.[43] They are available for study by the attorney's pathological consultant. When a pathologist identifies a structure of particular diagnostic importance (i.e., asbestos bodies in a case of asbestosis or a rare granuloma in a case of suspected beryliosis), he should delineate the lesion with an indelible marker so that the identity of the structure can be observed by other pathologists. Microphotographs can be effective demonstrative evidence to prove a diagnosis. Both the attorney and his pathological consultant should be aware of the value of microanalytical studies and their interpretation and when they should be performed in support of a diagnosis.

Histologic sections should be of a size and number from sites which are fairly representative of all gross conditions, both healthy and pathologic. The tendency of pathologists to sample the "worst" areas they see at autopsy may mislead the consulting pathologist and attorney to the conclusion that the pathology is more severe than is actually the case; if there are also physiologic data available, this sampling error can often be identified.[44]

The consulting pathologist should study and consider the antemortem histories and clinical findings, which should be provided to him by the referring attorney. If he considers his understanding of the clinical data wanting, he

should ask the referring attorney to arrange for additional consultations with appropriate medical specialists. In cases of survivor claims brought under the federal black lung law, where entitlement may be based either on death or disability due to pneumoconiosis, my own law firm retains as medicolegal consultants both a pathologist and a pulmonologist, and we request their mutual consultation.

Epidemiologic Data

"Decisions regarding [diagnosis, etiology, and] causation shall utilize all available scientific data including the results of appropriate epidemiologic studies."[45] Therefore, both the attorney and his medical consultant should be informed about the prevalences and etiologic associations of diseases established by the science of epidemiology. They should also comprehend the importance of relevant exposures to toxic substance pollution which have been identified in a claimant's occupational and environmental history, for which consultation with a chemist, toxicologist or industrial hygienist may be required.

However, the traditional legal formulations may not harmonize with the new formulations of epidemiology. The point is well illustrated where lung cancer is diagnosed in a smoking asbestos worker who had been exposed to other carcinogens. Unresolved scientific questions may preclude an expression of opinion as to etiology with "reasonable medical certainty.[46]" According to Enterline,[47] an opinion about the tumor's etiology *cannot* be stated *with certainty,* because to attribute lung cancer to asbestos with *certainty* would falsely imply that the asbestos exposure somehow blocked the possible effects of the other cancer-causing agents; *but* an opinion *can* be expressed *relatively* as a mathematical *probability* for each carcinogenic agent to which the worker had become exposed. At what point medicine's *probability* becomes equivalent to law's *reasonable medical certainty* is yet to be addressed by the courts.[48] Until it is, the problem will certainly perplex the informed and conscientious medical expert.

Some contend that, in a case like the one given by illustration, *any* asbestos exposure (no matter how trivial) should by law be etiologically *presumed* unless a contrary etiology is proven with reasonable medical certainty. According to Weill,[49] ". . . [i]t is not possible . . . to conclude that any . . . [asbestos] exposure, no matter how trivial, is causally associated with the development of [lung cancer] . . . ." A presumption, like this, could therefore be grossly unjust.

Diagnosis, Etiology, Causation, and Disability

After analysis of all of the collected information, the medical consultant prepares his opinions as to diagnosis, etiology, causation, and disability.

"Diagnoses . . . should be expressed in acceptable terminology of a recog-

nized disease nomenclature.[44]'' This requirement is especially important in the litigation setting. Lawyers and adjudicators are very likely to be confused by the babel which occurs when standard diagnostic criteria and nomenclature (e.g., as exists in coal workers' pneumoconiosis[26,32] and in asbestos-related diseases[22]) are not used. In my practice, I have frequently seen medical experts ignore or reject the published standards, and instead employ peculiar nomenclatures and diagnostic criteria in a regrettable litigation tactic calculated to confuse. According to Naeye,[44] the consulting physician, when expressing his opinions, either should follow the published medical criteria and nomenclatures for making the diagnosis, or else provide justification based on his own independent research.[44]

In formulating opinions the consulting physician must also take into account the legal criteria as provided to him by the referring attorney. The legal criteria and the medical criteria may conflict. Examples of conflict between medicine and law are found in definitions of the terms ''pneumoconiosis,'' ''anthracosis,'' ''macule,'' and ''bronchogenic carcinoma.''[51]

The medical consultant must be made aware of the applicable legal standard of causation, and his opinion must conform to it. If he is asked his opinion as to the cause of disability or death when multiple dread diseases are present concomitantly, and only one of the diseases is occupational, the question is difficult. When *is* the contribution by the lone *compensable* disease large enough to permit the finding that it had *caused* the disability of death? In cases of workers's compensation, the issue is far from settled.[52] Depending on the jurisdiction within which the case arises, federal black lung law interpreting the Part 727 regulations[53] is variable. It can require that death or disability had been due to pneumoconiosis ''*in and of itself*''; or that, pneumoconiosis had been a ''*significant cause*;'' or that pneumoconiosis had been merely ''*a contributing cause*'',[51] For an occupational lung disease to be compensable in Pennsylvania, it must be a ''*substantial contributing cause*''.[54] All these criteria are overly subjective and indefinable.[55]

''Disability'' generally means wage loss caused by a physical impairment which prevents an employee from performing his former work,[56] although mere ''reduced ability'' to work is enough for disability under federal black lung law.[57] Proof of disability is given by the opinion of a medical expert, who will compare work demands with functional capacity. Usually, this opinion is a mostly subjective assessment. However, the disability opinion can be given with relative objectivity by comparing measured oxygen consumption during maximal exercise with the demands of a particular job.[58–60]

In some jurisdictions, a fully functioning worker can be compensated for disability because he has an asymptomatic disease that might cause future functional impairment upon further workplace exposure to dust or fumes.[56,61] Examples are the diseases of simple pneumoconiosis, asthma, or hypersensitivity pneumonia. Evidence as to air quality, including the efficacy of available respiratory protection equipment, should be presented in this type of case in order that the medical expert can express an opinion about what risks of future impairment actually do follow from continued employment.[62,63]

Presenting the Proof

The expert opinions of the medical consultant are expressed in his report and his testimony. These opinions may be based upon any reliable source, including such hearsay sources as hospital records, reports of other physicians, statements elicited from the claimant, and acknowledged learned treatises.[64,65] (However, an expert's opinion which is based upon false facts is not competent or substantial evidence.[66]) To have the report identify the records and materials which had been studied, and cite references of authorities which support the conclusions, is an effective way to demonstrate the expert's intellectual command of the evidence and the issues.

The report is usually available to all parties to the proceeding.[67] It may become admitted into evidence and, unsupplemented by oral testimony, constitute the plenary statement of the medical expert. If its author does give oral testimony, ambiguities or errors in the report will be used to discredit the testimony. Therefore, a referring attorney should not be reluctant to request and obtain needed clarifications, amplifications, or corrections. The attorney should explain to his consultant that such requests are common and should not be regarded as slighting or offensive.

The ultimate conclusions of the medical expert should be expressed with "reasonable medical certainty."[68] The conclusions should be based upon facts or data of a type reasonably relied upon by experts in the particular field.[65] They should be reached by standard methodologic principles from the data available and a comparison with the known literature on the subject.[69,70] Unless these evidentiary criteria are achieved, the conclusions are not "substantial evidence" and are incapable of supporting an adjudicator's finding of fact.[55]

References to learned treatises are often invoked to corroborate or to impeach the expert's opinions. "To the extent called to the attention of an expert witness upon cross-examination or relied upon him in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine or other science of art, established as a reliable authority by the testimony or admission of the witness . . . , may be read into evidence. . . ."[72] Skillful use of learned treatises can be a very effective way to demonstrate that the opinions expressed by your expert reflect positions and views which are well established and correct, and that the contrary views of the opposing expert are not.

The late Dr. C.L. Anderson, formerly a pulmonologist from Pittsburgh, had offered some advice that can be used in preparing your own medical expert to testify. On cross-examination, do not be misled by hypotheticals; stick to what is known medically, be not persuaded by "what might be" or "what could be," stay with "what is," avoid being led by the cunning cross-examiner down the path to an improbable disease state.[73]

Conclusion

The outcome of occupational lung disease litigation is determined more by medical points than by legal points.

Indeed, a decision in a case is often reached by adopting the opinion of a particular medical expert. Therefore, tell your expert this: in giving testimony, keep in mind the specific medicolegal issues, avoid digression, remain relevant, and explicate the points comprehensibly. And be convincing! "However learned the person may be, it must always be remembered that it is not just what the expert knows, it is also what the . . . [adjudicator] understands and believes the expert knows."[64]

In an occupational disease case, the decisive medical points are difficult even for physicians who do not specialize in diseases of the lungs. It is the task of the attorney and his medical expert to present sophisticated and complex medical information in a way that can be understood by an adjudicator who is not a physician. If both are informed and prepared, the attorney and his expert enhance their chance of persuading the adjudicator to decide for their client.

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19

Impairment Evaluation for Disability Determination

RICHARD E. KANNER, MD

The physician plays an essential role in the decision-making process that determines whether or not a claimant is awarded disability benefits. This is a very important part of medical practice. Social Security and Supplemental Security Income Disability programs in 1985 cost about $25 billion,[1] and in addition to this are the costs of other government disability programs such as the Black Lung Act, the Veteran's Administration, the Military, State Industrial Commissions, as well as the private sector. Although most of the money spent goes to the disabled, in 1986 the Social Security Administration planned to spend more than $225 million to obtain medical evidence, which includes about $200 million for consultative examinations.[1] The respiratory system accounts for approximately 6% of all claims, being exceeded only by mental and neurologic disorders, cardiovascular disease, and musculoskeletal problems.[2]

Evaluating individuals for impairment and disability purposes is more of an art than a science. In the area of pulmonology there is little scientific data to justify the various guidelines in effect.[3] However, society demands that impairment and disability criteria be established. Thus, physicians and others must develop reasonable methodology based on the best available existing evidence. One aspect of disability determination involves occupational causation of the impairment. This includes the pneumoconioses and occupational asthma and, except for illustrative purposes, will be covered elsewhere.

In the United States usage has defined the terms impairment and disability and the American terms and definitions are different from what has been proposed by the World Health Organization. In the United States impairment has been defined as

> purely a medical condition. Most impairments result from a functional abnormality, which may or may not be stable at the time the evaluation is made, and may be temporary or permanent. . . . Impairments of lung function may be of varying degrees of severity, ranging from those that preclude some types of labor to those that ordinarily preclude any gainful employment.
>
> Some impairments are not dependent on lung function and result from an environ-

mentally related diagnosis (e.g., occupational asthma warrants proscription of continuing exposure to the inciting agents), from the prognosis (e.g. unresectable lung cancer), or from public health considerations (e.g., tuberculosis).[4]

Physicians have the obligation to evaluate the subject for the presence or absence of an impairment and, if one is present, to quantitate it. Impairment evaluation is primarily the role of the physician in impairment/disability determination.

Disability is "a term that indicates the total effect of impairment on a patient's life. It is effected by such diverse factors as age, gender, education, economic and social environment, and energy requirements of the occupation."[4] Disability is an administrative decision that requires a combination of medical and nonmedical considerations. Two people with identical impairments may have very different disabilities. A simple example would be the loss of the fifth finger on the nondominant hand of a physician practicing internal medicine or a similar injury to an attorney and the same impairment in a concert pianist. The physician and attorney will have no disability; yet the pianist would be unable to continue to perform with the same skill on the stage and would have to find another and possibly less financially rewarding aspect of his or her art.

In Europe the terms often used are those developed by the World Health Organization.[5] These definitions take into consideration the lack of a strong correlation between the function of a single or individual organ system and the overall function of the person. Thus, impairment of the respiratory system describes a loss of lung function as is usually measured by tests such as spirometry or the diffusing capacity. Disablement due to lung disease is the resultant loss in exercise capacity as would be measured on a treadmill or cycle ergometer. Handicap is the total effect of the disablement on a subject's life and corresponds to the American use of disability.

In evaluating subjects for impairment/disability purposes, the physician is usually dealing with the Social Security Administration (SSA) or with private insurance companies. The physician may be their own patient's advocate or may be a third party asked to provide an independent assessment. In general the physician, in preparing the report, should provide as much objective quantifiable data as possible. Subjective impressions and testimonials regarding the claimant's character are of little value.

Subjects having an impairment/disability evaluation should have a thorough medical workup and a diagnosis should be made. Even methods as described by the American Medical Association (AMA)[6] and the American Thoracic Society (ATS)[4], which categorize impairment on the basis of pulmonary function values, require this. A subject may have impairments of other body systems and the sum of these additional problems combined with the respiratory abnormalities may have an effect on disability awards. The SSA has different tables for determining total impairment for subjects with obstructive airway problems than are used for restrictive lung disease. The AMA and ATS schemes do not distinguish between these two categories of disorders with

respect to quantitating the impairment by physiologic measurements. Some diseases may show little impairment by pulmonary function studies yet result in a significant disability.[4] Examples include hypersensitivity pneumonitis and occupational asthma, which only occur as a result of specific workplace exposures. Social Security Administration and private insurance companies may request that only a specific test or tests be performed as that is all they will pay for. Obviously, the physician should comply with that request.

Pulmonary function studies are used in all guidelines for determining impairment due to respiratory disease. Thus, spirometry pre- and, when indicated, post-bronchodilator should be performed. The single breath carbon monoxide diffusing capacity is used in many schemes and is especially helpful in cases of interstitial lung disease. In general, measurements of lung volume are less helpful. Some guidelines require rest and/or exercise arterial blood gas studies. Exercise studies on a treadmill or cycle ergometer may be helpful as oxygen uptake ($\dot{V}O_2$) can be determined. $\dot{V}O_2$, in general, is correlated with spirometric and diffusing capacity studies, but there are many situations where the results of the more routine tests do not agree with exercise testing. The "gold standard" for respiratory impairment remains to be established. Exercise testing does have the advantage of detecting nonpulmonary problems such as poor conditioning or cardiac disease as the cause of the subject's complaint of dyspnea. At present there is no concensus as to what are the best physiologic tests to use. However, the particular guidelines used in evaluating a specific subject usually state what methodology they favor.

The SSA, ATS, and other guidelines usually require some quality control for the studies. Most agencies that award disability benefits want the spirometric tracings to be certain they were optimally performed. Also, evidence the spirometer was properly calibrated may be required. Specifics for quality control of arterial blood gas measurements also may be requested, if not at this time, then certainly in the future. As more and more laboratory studies become standardized, the criteria for standardization will be provided by the guidelines and the agencies will be demanding that these criteria be met. If a laboratory has a spirometer they should have a calibrating syringe and a copy of the most current ATS or other standards for spirometry.

In preparation of the report, the physician should document all abnormalities noted in the workup and arrive at a diagnosis. Then the degree of impairment should be stated using the guidelines appropriate for that evaluation (AMA, ATS, SSA, etc). In some studies the physician may be requested to state an opinion on the cause of the impairment. This would apply to situations where the claimant believes the abnormality is work related such as coal worker's pneumoconiosis (CWP), occupational asthma, and so on. If the evaluating physician concludes that the impairment is totally, partially, or not at all related to the claimant's occupation, it should be so stated with as much documentation as possible. Examples would be evidence that an individual developed asthma only after exposure to western red cedar wood dust and that challenge testing using this substance or plicatic acid (which is in western red cedar) brings on symptoms. A coal miner claiming CWP may have a normal chest

radiograph and a work history of not being in the dusty areas of the mine, but has a history of smoking two packs of cigarettes per day for 30 years. Such an individual would be more apt to have airway obstruction from smoking than from coal dust inhalation. The report should say that "with a reasonable degree of medical certainty" the condition is or is not of a particular cause and why the physician believes this to be the case. The legal profession prefers that physicians not use terms like "believe" or "think." They prefer that testimony be given in unequivocal terms. Thus, as an example a report or testimony should say "with a reasonable degree of medical certainty it can be stated that John Doe has occupational asthma on the basis of inhaling toluene diisocyante fumes even though the level of these fumes are within the accepted safe levels."

In writing a report for a specific condition strictly defined by a law or federal regulations the wording should try to be consistent with the wording in the law. An example would be the Black Lung Regulations.

> For purposes of the Act, "pneumoconiosis" means a chronic dust disease of the lung and its sequelae, including respiratory and pulmonary impairments, arising out of coal mine employment. This definition includes, but is not limited to, coal workers' pneumoconiosis, anthracosilicosis, anthracosis, anthrosilicosis, massive pulmonary fibrosis, progressive massive fibrosis, silicosis, or silicotuberculosis arising out of coal mine employment. For purposes of this definition a disease "arising out of coal mine employment" includes any chronic pulmonary disease resulting in respiratory or pulmonary impairment significantly related to, or substantially aggravated by, dust exposure in coal mine employment.[7]

The physician's report should thus read the claimant has or does not have a "chronic dust disease of the lung" giving the definition as written and he or she has or does not have chronic pulmonary disease resulting in impairment significantly related to or substantially aggravated by dust exposure in coal mine employment. The wording of the regulations may not be what a physician would prefer, but it is the basis which a judge or panel would use to come to a final decision and they usually adhere fairly closely to the written definition. Thus, use the wording of the law as closely as possible.

There will be occasions where different physicians serve as experts on opposite sides. An example is where a coal miner and his or her lawyer might hire a physician to provide evidence to support the claim, whereas the coal mine operator uses the services of another physician with expertise in the field. When this occurs the judge has to decide which line of reasoning to accept. The wording of the report and/or testimony becomes important because the judge tries to relate the information presented to the regulations. Thus, a well-worded report can give one side an advantage. A competent lawyer will make sure the physician uses language consistent with the law or regulations.

In some situations the physician may wish to justify the presence of total disability even though the pulmonary function values would not qualify. For instance, SSA guidelines only list criteria for severe impairment that would qualify for total disability.[8] However, SSA also has provisions for awarding total disability benefits when a nonsevere impairment is present. This informa-

tion is available in the Programs Operation Manual System (POMS),[9] and the appropriate chapters can be obtained from the local Disability Determination Service (DDS). The local DDS manages SSA disability for its particular region, and its location varies from state to state or region to region. Physicians performing evaluations for SSA should learn where their local DDS is located and should obtain a copy of the appropriate section of POMS and the most recent copy of "Disability Evaluation Under Social Security".[8] (POMS is a very long manual which goes far beyond what a physician or lawyer needs for impairment/disability evaluation. Thus, one only would need the Disability Insurance Section.) The POMS takes into consideration many situations. This includes the ability to do past relevant work and to do other types of work which is determined by mental capacity, education, age, previous work experience, ability to be retrained, and medical factors. This must be documented. An example is a 59-year-old woman with asthma and airway obstruction that does not meet the pulmonary function criteria for total disability. With optimal medical management she does not meet the total disability guidelines for the frequency of exacerbations requiring therapy in an emergency room or hospitalization. However, she has only worked as a housewife, has less than a high school education, is a widow, cares for a 30-year-old son who has Down's syndrome, and she suffers from side effects due to having to take between 10 and 50 mg of prednisone per day. The side effects of steroid therapy are by themselves not qualifying as her cataracts have been surgically corrected and her osteopenia is not sufficient to meet SSA guidelines under that organ system. However, with documentation of all of the above SSA awarded her total disability.

Private insurance companies do not have guidelines for determining impairment. They may request that the evaluating physician use a particular approach such as the AMA or ATS proposals or they may leave it up to the physician. They may or may not state what tests they want performed. In situations where specific studies are requested, the physician should perform these and, if it is believed other measurements would be helpful, should contact the company referring the patient to negotiate the additional evaluations. When AMA or ATS guidelines are used the directions for their application are readily available.[4,6] Again objective evidence is necessary and there should be documentation for any opinions expressed. An example would be a 43-year-old male electrician who has recent onset asthma. He was exposed to unspecified fumes as a result of a fire that occurred while he was at work and dates his symptomatology to that fire. However, the medical history and records from other physicians indicate he stopped smoking two months before the fire, as he was experiencing respiratory symptoms. The records indicate his symptomatology was mild and easily controlled before the occupational incident but became worse subsequent to the fire. Although the evidence is not 100% conclusive, it strongly suggests this man developed mild asthma which became worse as a result of inhaling irritating fumes. Thus, the report stated he had symptoms before the incident but the fire did have an adverse effect on his condition and did contribute to his inability to again work in an environment

containing atmospheric irritants. Adjudicators for the insurance company will then decide how to apply this information regarding impairment for purposes of disability awards or for job retraining.

Often a claimant may not be satisfied with the outcome of a disability hearing. In the SSA system the local DDS makes the initial determination, and the individual may appeal the verdict if they believe they did not get fair treatment. This initial appeal is usually considered by the same DDS that initially handled the claim. The claimant should try to present additional evidence to convince the DDS of the merits of his or her case, and the physician and/or lawyer may be asked to assist. The reasons for the initial DDS decision should be carefully considered and then it should be determined what other data need to be collected and documented. The DDS usually uses the guidelines for severe disability but may consider the less stringent regulations listed in POMS. Should the appeal to the local DDS not satisfy the claimant, they can then appeal again, this time to an Administrative Law Judge (ALJ). The ALJ has a little more latitude than the local DDS, but to deal fairly with the appeal needs a maximum of objective data. The physician's report is vital, and all opinions should be supported carefully with evidence.

There are situations in which impairment may not be directly related to a reduction in lung function. Patients with asthma may suffer from acute exacerbations of their bronchospasm due either to sensitization to substances in the working environment or from the nonspecific irritant effect on the airway of nonsensitizing agents. Testing such an individual in a clean hospital laboratory may fail to demonstrate the subject's problem. Thus, pre- and post-workshift studies may be in order.

Hypersensitivity pneumonia early in its course may not result in measurable abnormalities in lung function. However, a subject experiencing this type of disorder should not be subjected to recurring episodes. This group of disorders can be documented with appropriate challenge testing, and the subject may require a change in the work environment.

Sleep disorders now are included as a respiratory impairment. Subjects with sleep disordered breathing who may not have a good night's rest may have daytime hypersomnolence. This can be dangerous if their occupation requires constant vigilance such as driving a truck or running other types of machinery. Cough syncope also can be a dangerous condition if the worker's occupation requires constant vigilance.

Bullous lung disease is hazardous in occupations where barotrauma may occur. This would include aviation and underwater work. Recurrent hemoptysis or pneumothorax may require being near adequate medical facilities. All of the above conditions plus others that may not be disabling on the basis of physiologic measurements can in fact be very disabling to certain individuals. The data should be collected, documented, and applied to the specific situation. As many workers are candidates for retraining, the physician's report should state what types of occupation would be suitable or unsuitable for the specific claimant.

In evaluating subjects for impairment and disability purposes it becomes

easy to focus on what function has been lost, and not enough attention is paid to what remains. The SSA uses the term residual functional capacity (a poor choice of terms for the pulmonologist). The amount of residual function is extremely important as it will help those determining disability decide whether or not the subject can be retrained to perform other work. Many factors influence the ability to retrain a person, but the residual function is the point at which the disability panel will start. The physician measuring impairment should give this residual function at least as much emphasis as is given to what has been lost. With respect to the previously described electrician with asthma described it was pointed out that in the relatively clean environment of the hospital his obstructive defect would be considered mild. In the absence of cold air, irritating fumes, or strenuous exertion he could perform useful work. We proscribed his doing any welding, soldering, working outdoors in winter, working in an environment with irritants known to exacerbate his problem, or doing work which would cause exercise-induced bronchospasm. However, we pointed out that this 43-year-old man probably could perform useful work for the next 20 or more years despite his limitations if he was properly retrained. We also pointed out he had one year of a college education so lack of intellectual ability was not a significant problem for most types of work. Such information is a vital part of the physician's report.

Most impairment/disability cases that do not involve a claim of negligence or wrongful action on the part of the defendant are determined by a panel or by an administrative law judge. Usually the physician's evidence is presented in the form of a written report. However, should the physician give live testimony, the court environment is a little less formal than in a jury trial and the expert witness has a little more latitude in being able to explain his or her views. However, the witness is still under oath.

When physicians and lawyers work together on behalf of a patient/client, each must become somewhat familiar with the role and jargon of the other. Physicians usually have no interest reading what to them seem to be long dull legal decisions, bureaucratic regulations, or enacted laws. Thus, the lawyer must tell us what these documents say and how we should word our reports to comply with these regulations. At the same time lawyers would not be expected to know respiratory physiology or such obscure terms as FEV_2, $\dot{V}o_2$, Pao_2, and so on. The physician should clearly explain to the attorney the terms and what they mean with respect to impairment evaluation. Often we will perform spirometry on the lawyer explaining what the test is about and what the numbers represent and mean. This interchange can help coordinate the medical with the legal aspects of this case.

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20

The Asbestos Connection: The Differing Perspectives of Medicine and the Law

A Medical Perspective

ALBERT MILLER, MD

Introduction

The magnitude of the problem of asbestos-related disease was brought to public attention in 1978 by an advisory of Health, Education, and Welfare Secretary Joseph A. Califano, Jr.: "The total number of workers exposed to asbestos since the beginning of World War II is estimated at between 8 and 11 million . . . including 4.5 million who worked in shipyards." These workers, whose occupational exposure often was long past and incidental, are frequently unaware of their risk of disease.

Nothing in the decade since this advisory was issued has reduced the magnitude of the risk. Indeed, more scrutiny is now being directed at occupations with little obvious asbestos exposure: maintenance workers, custodians, the entire range of construction tradesmen, including sheet metal, iron work, boilermaking, dry wall construction, carpentry, plastering; friction (brake) products, and a wide range of maritime and railroad jobs. A more recent estimate[1] is that 27,5000,000 individuals were exposed to asbestos at work in the period 1940 to 1979, placing their families at potential risk as well.

Medical Considerations

THE SPECTRUM OF ASBESTOS-RELATED DISEASE

Asbestos is unique in causing a wide variety of nonmalignant and malignant diseases of various organs of the body; many of these diseases involve the lungs.

Asbestosis

This was the first disease whose cause was attributed to the inhalation of asbestos fibers. The term was coined by Cooke in 1927 in reporting a female asbestos textile worker who died of pulmonary fibrosis.[2] Epidemiologic studies in the 1930s began to bring home the magnitude of the problem in American mines and factories. By 1965,[3] Dr. Irving J. Selikoff of the Mount Sinai School

of Medicine in New York, whose investigations were to dominate the epidemiology of asbestos-induced disease for the next two decades, reported a 50% prevalence of radiographic asbestosis in insulators and noted the correlations of radiographic findings with length of time from onset of exposure and with the most important clinical symptom, dyspnea.

Asbestosis is one form of interstitial lung disease (ILD), a large category of relatively uncommon disorders of diverse and often obscure etiology. The term *pneumonitis* emphasizes the inflammatory process (initiated and maintained by the asbestos fibers), the term *fibrosis* stresses the end result of this process, namely, scarring of the lung.

Asbestosis can be of any degree of clinical severity ranging from absence of symptoms and normal pulmonary function to respiratory failure with resultant heart failure. The latter is called cor pulmonale, literally meaning "pulmonary heart." Radiographic involvement is quantitated by the International Labour Office (ILO) coding system[4]; see "Is the radiograph positive or negative for asbestosis?" below.

Asbestosis is dose-related. Its severity is directly related and its latency is inversely related to the cumulative exposure.[5] Latency is the interval before the disease is detectable by clinical, radiographic, or standard physiologic examinations. The research of Dr. Raymond Bégin in Sherbrooke, Canada, has begun to elucidate the processes of small airways disease and alveolitis (pneumonitis) during this interval.[6]

By the time physicians encounter it clinically, asbestosis is a chronic diffuse interstitial fibrosis (DIF). Although little change is seen in examinations made 6 months or a year apart, asbestosis is generally progressive, as the fibers continue to interact with the cells of the lung.

Pleural Thickening or Fibrosis

After the ILO code, pleural thickening is classified either as circumscribed (areas of circumscribed thickening are called plaques) or as diffuse. In general, circumscribed thickening is on the parietal pleura and diffuse on the visceral. Although "circumscribed," plaques may be extensive and virtually continuous. Pleural fibrosis is related to peak exposures, and pleural fibrosis and calcification are both related to the residence time of dust in the lung.[5] That pleural fibrosis may or may not co-exist with detectable DIF raises an important question: Can the lung remain unaffected by the asbestos fibers as they must traverse its tissues (or its lymphatics) to reach the pleura?

Pleural plaques may be considered evidence of inhalation, retention, and biologic effect of asbestos fibers. This is almost as true of unilateral as of bilateral plaques, as little else can cause these lesions. Detection of plaques is increased by additional radiographic views (lateral and obliques) and especially by computed tomographic (CT) scanning.

Unlike plaques, diffuse thickening can be caused by many conditions. However, the etiology can usually be arrived at by the following clinical guidelines: 1) diffuse pleural thickening of other cause is unlikely to be bilateral, and 2) many causes of diffuse pleural thickening are major illnesses

(pneumothorax therapy of tuberculosis, empyema, traumatic hemothorax) which are well known to the patient.

Pleural fibrosis can cause measurable decrement in lung function.[7] This may be minor but may also cause respiratory impairment and dyspnea. At the extreme, I have reported ventilatory failure and death in 5 patients as a result of asbestos-induced pleural thickening.[8] Impairment is more likely to result from the diffuse thickening which follows inflammatory asbestos pleural effusions (see below).

Although a large part of the ILO report sheet is occupied by codes for different aspects of pleural thickening, the distinctions are arbitrary (e.g., between diffuse and circumscribed, between tangential and en face) and are markedly affected by minor changes in positioning or radiographic technique.

Inflammatory Asbestos Pleural Effusion

This is an outpouring of exudative (often bloody) fluid secondary to an intense inflammatory process in the pleura.[9,10] It is called benign to set it apart from similar effusions secondary to mesothelioma. It is often the earliest clinical manifestation of asbestos inhalation and may be asymptomatic or result in a major, painful, febrile illness the diagnosis of which is difficult, depending on the exclusion of other specific causes. It is frequently recurrent and/or bilateral.

Chronic Pleuritic Pain

In my clinical experience, I have noted several patients with continuing or recurrent pleuritic pain who have no explanation after many years of observation other than an asbestos-induced chronic active pleurisy.

Bronchogenic Carcinoma

This is the most common cause of death in asbestos-exposed populations, which include a high proportion of cigarette smokers. Case reports of bronchogenic carcinoma in asbestos workers in the United States and Great Britain began appearing in 1935. The Chief Inspector of Factories for Great Britain reported in 1947[11] that 13% of workers who died with asbestosis also had bronchogenic carcinoma. An editorial in the *Journal of the American Medical Association* in 1949 cited these reports as well as animal experiments to call for "increased attention to this probable occupational hazard."[12] By 1955, Dr. Richard Doll[13] demonstrated a greater risk of this disease in British asbestos workers. Dr. Selikoff reported a similar increase in risk in American insulators in 1964,[14] and described synergistic effects of asbestos exposure and cigarette smoking in 1968.[15]

A dose-response relationship with asbestos is demonstrable in a greater incidence of carcinoma and a shortening in its latency with greater fiber burden; the relationship is less clear at low burdens. Asbestos is thought to act as a co-carcinogen, most often with cigarette smoke. A useful generalization deducible from the findings of Hammond and Selikoff[16] is that asbestos

multiplies the existing risk of bronchogenic carcinoma by a factor of 5; if this risk is already 10 to 20 times greater because of cigarette smoking, the final risk is 50 to 100 times that of a nonsmoking, nonasbestos-exposed group.

Laryngeal and Gastrointestinal Carcinomas

Observations on large cohorts have shown roughly greater rates of laryngeal[16–19] and gastrointestinal (especially colorectal)[16,19,20] carcinomas.

Mesothelioma

This malignancy is a unique biologic effect of asbestos inhalation, even though it occurs in a tissue (the serosa or mesothelial cell lining of the major body cavities, namely, the pleura in the thoracic cavity and the peritoneum in the abdominal), which is not the site where asbestos is first inhaled or ingested. Until the widespread use of asbestos in the middle of this century, mesothelioma was an extremely rare disease which was not coded in standard classifications of disease. The epidemiologic association with asbestos was established in 1960 by the publication of 33 cases from South Africa by J. C. Wagner and colleagues.[21] In 1979,[16] Hammond and Selikoff reported 170 deaths from mesothelioma (61 pleural, 109 peritoneal) in American insulators, or 9% of the total of 1946 deaths.

Because of its unique etiologic relationship with asbestos, mesothelioma is considered a biologic marker of exposure. Risk is not related to smoking status.

Causality

The asbestos-related diseases are a good example of how causality is demonstrated in medicine. Causality was first suggested by individual case reports; the clustering of these cases in occupations with a common exposure was apparent next. (Indeed, now the process has reversed; the recognition of radiographic DIF or pleural thickening or of cases of mesothelioma identifies more and more occupations as sources of asbestos exposure, as noted in the introduction.) The presence of the causative agent was recognized by conventional histologic techniques (in the form of the asbestos body) early in the history of asbestosis, and then by increasingly sophisticated mineralogic and electron microscopic methods.

Once an association with asbestos was suggested, epidemiologic surveys were undertaken and have provided much of our practical knowledge of these diseases. Both cross-sectional surveys of defined occupational groups and longitudinal surveys of these cohorts during and after their occupational exposures have provided information on the prevalence and incidence of the various asbestos-related diseases, on dose-duration-response relationships, on the role of other etiologic factors such as smoking, and on the correlation of various findings such as radiographic opacities, functional impairment, symptoms, and disability.

Mortality studies of defined groups have added new diseases to the spectrum (e.g., laryngeal and gastrointestinal carcinomas), whereas autopsies have

provided more information on fiber burden and the frequency and severity of various biological effects.

Once the association of a causative agent (asbestos) with various disease processes was identified by case reports and/or epidemiologic studies, these diseases were investigated experimentally using intact animals (e.g., small airways disease, alveolitis and DIF in sheep; mesothelioma in the pleural and peritoneal cavities of various species). Work with tissue cultures and cell lines has begun to elucidate the molecular mechanisms by which asbestos fibers bring about their inflammatory, fibrogenic, and neoplastic effects.

Scientific Questions

1. The Definition of Asbestosis

This question is not as simple as it appears to be. Is asbestosis a combination of findings, some of which must be present and others of which are optional? The Canadian Task Force on Occupational Respiratory Disease, in its 1979 report,[22] required that the two essential criteria listed below be present plus either two of the confirmatory criteria or the pathologic criterion: 1) essential criteria, significant exposure and ILO reading $\geq 1/0$; 2) confirmatory criteria, restrictive or gas exchange abnormality, progressive dyspnea, bibasal rales on physical examination, clubbing on physical examination (Bégin added neutrophilia on bronchoalveolar lavage [BAL] as a confirmatory criterion[23]); and 3) pathologic criterion: Interstitial fibrosis with a "sufficient number" of fibers or asbestos bodies. What is a "sufficient number?" The "Pathology Standards for the Diagnosis of Asbestos-Related Diseases"[24] recommended that at least two asbestos bodies be seen in routine sections. Dr. Andrew Churg[25] concluded that this criterion is too stringent. A single asbestos body suffices, as a single body would be seen in no more than one in 100 sections from someone with only background (non-occupational) exposure to asbestos. Additionally, asbestos bodies are not uniformly present in lung tissue and may not be seen in any one area.

If disease is defined as "an interruption or perversion of function of any organ or a morbid change [in anatomy] in any tissue," then such a dysfunction or anatomic alteration must be demonstrated. A pulmonologist has three standard noninvasive methods for demonstrating asbestosis:

1. Physical examination, that is, signs of ILD such as rales or clubbing. These are the least sensitive signs, present usually in more severe disease.
2. Radiographic findings of ILD. The sensitivity of radiography depends on the boundary between normal and abnormal. The report sheets of the Centers for Disease Control—National Institute of Occupational Safety and Health score profusion of irregular opacities 1/0 and greater as abnormal, as does the Canadian Task Force[22] (see above), while an American Thoracic Society committee, in a controversial statement,[1] "regard[s]" $\geq 1/1$ "to be of recognized value." Murphy et al[26] used 2/1 as their radiographic criterion, although they listed 1/0, 1/1, and 1/2 as "slight *asbestosis*." Requiring higher grades of profusion (e.g., 1/1 or 2/1) as evidence for asbestosis is

based on a concern for greater specificity. This concern may not be necessary for the following reasons: a) readings of 1/0 and greater are rare (under 5%) in nonexposed populations. It should be noted that several earlier "control" populations were likely exposed, for example, Murphy's shipfitters and shipyard pipefitters, 14% of whom had readings $\geq 1/0$.[26] The 1/0 boundary is discussed below, "Fixing a boundary on a continuum, 0/1 vs. 1/0." b) Asbestosis tends to progress. Someone who has severe disease has reached this stage through progressive increments in profusion of radiographic opacities. As the ATS statement[1] put it, "It is likely that an individual who develops asbestosis moves more or less uniformly from the normal roentgenologic appearances (−/0, 0/0, 0/1) to the abnormal (1/2, 2/1, 2/2, etc.)." The reader should note the absence of 1/0 and 1/1 on this continuum, making uniform movement impossible! Thus, on follow-up, a patient with 1/0 is likely to become 1/1.

3. Physiologic evidence of ILD. In addition to spirometry, testing may include diffusing capacity, full lung volumes, arterial blood gases, and exercise evaluation. Pulmonary function tests can be clearly abnormal in ILD including asbestosis when the radiograph does not show DIF,[27] and, additionally, the diffusing capacity can be clearly abnormal when both the radiograph and spirometry do not show changes of DIF.

In my view, one of the three methods outlined above (clinical, radiographic, or physiologic) must yield an abnormality in order to diagnose asbestosis. Radiographic DIF is not mandatory. Although conventional radiography is probably the most sensitive of the standard evaluators of asbestosis, it sometimes does not show DIF when physiologic abnormalities are evident (as stated above) or when DIF is demonstrated histologically. In the absence of an abnormality by at least one of these methods, a dyspneic asbestos worker would not be said to have asbestosis. An important exception is:

4. Histologic evidence of asbestosis obtained coincidentally (removal of lung tissue for carcinoma), on biopsy or at autopsy. Important questions are how much (or how little) fibrosis must be present and in what distribution, and whether transbronchial biopsy through a fiberoptic bronchoscope can be sufficient to make the diagnosis.

As stated above, methods 1 to 3 provide evidence of ILD in the absence of lung tissue. How can we say this is asbestosis?

5. Exposure to asbestos. This is generally occupational but may be avocational (home repairs), household, or neighborhood.
6. Appropriate latency. Carcinoma does not occur in less than 5 years after the start of occupational exposure, nor does clinical asbestosis. It is unclear whether latencies between 5 and 15 years are "appropriate" for carcinoma.
7. Specificity. Clinically, asbestos can be considered the cause of demonstrated ILD if considerations 5 and 6 are present unless the course is inconsistent with asbestosis (rapid progression, waxing and waning, response to corticosteroid therapy) or there is evidence for another cause of ILD. The following two findings may incriminate asbestos as the cause even if exposure is

unclear: a) pathognomonic pleural changes—on conventional radiographs or CT scans of the thorax, and b) greater than background numbers of asbestos bodies on conventional microscopic examination or of asbestos fibers on mineralogic or electron microscopic examination of lung tissue.

Does the histologic finding of DIF in the absence of asbestos bodies mean that an asbestos-exposed individual has asbestosis? Animal studies show that asbestos bodies fragment with time[28] and therefore they may not be seen in patients with remote exposures. Asbestos bodies are not uniformly distributed in lung tissue and might be missed in a biopsy sample. Here the clinical (and if available, pathologic) findings may provide the answers. Pleural thickening may be characteristic of asbestos disease. If there is no evidence of another disease capable of causing DIF and if the exposure, latency, and progression are consistent with asbestosis, it would be appropriate to ascribe the DIF to asbestos in the absence of asbestos bodies. If questions remain, the tissues can be examined by electron microscopy and mineralogic analysis to demonstrate asbestos fibers too small to elicit the formation of asbestos bodies or to be seen with the light microscope.[29]

Asbestos bodies also may be found in sputum or bronchial washings. Churg[25] states that although asbestos bodies are a "good indication" of exposure, they are not by themselves "manifestations of disease." Of course, asbestos bodies indicate retention of fibers as well as exposure, and in addition, interaction with the inflammatory cascades of the lung.

2. Restrictive Impairment: The Limitations of Spirometry

Much time during pretrial discovery and in court is consumed in a stultifying, soul-wearying disputation about whether restrictive impairment is present. This is because restrictive impairment is characteristic of ILD, whereas obstructive impairment is characteristic of chronic obstructive pulmonary disease (COPD). Chronic obstructive pulmonary disease is most often caused by smoking. Unfortunately, patients do not come in neat diagnostic packages and a smoker exposed to asbestos may have COPD as well as asbestosis.

I have defined restrictive and obstructive impairments in a recent book[30] and given guidelines for their evaluation. Put as simply as possible, restrictive impairment is a reduction in lung volumes. In pure restrictive impairment, the vital capacity (VC) is reduced and airflow is maintained. Thus, a reduced VC and normal airflow (e.g., FEV_1/FVC ratio) may be considered evidence of restrictive impairment. Unfortunately, the VC can be reduced in obstructive impairment as well, as a result of air trapping. Measurement of full lung volumes, including functional residual capacity (FRC), residual volume (RV), and total lung capacity (TLC) would permit the physician to say whether restrictive impairment is or is not present when the VC is decreased, as obstructive impairment is associated with an increase or at least a maintenance of these volumes. A decrease in TLC implies restrictive impairment whether or not obstructive impairment is present. However, full lung volumes are not available on many patients.

3. Pulmonary Fibrosis and Cigarette Smoking

Several epidemiologic studies have shown greater frequency of radiographic DIF in asbestos workers who have smoked.[31–33] Because this is true at all intervals from onset of exposure, it may be said that the latency of asbestosis is decreased by smoking. The interaction is thought to be additive rather than synergistic and to be caused by interference with clearance mechanisms by smoking, leading to an increase in retained fiber burden.[34]

Although Auberbach's autopsy studies[35] have shown a relationship between smoking and microscopic foci of interstitial fibrosis in the general population, smoking does not cause the clinically diagnosable or progressive disease variously called idiopathic pulmonary fibrosis, usual interstitial pneumonitis, or fibrosing alveolitis. Control populations almost invariably show prevalences of ILO readings $\geq 1/0$ that are substantially below 5%.[36,37]

Weiss' 1969 series[38] showed frequencies of radiographic "fibrosis" of 2.3% for exsmokers, 2.2% for current smokers of 10 to 19 cigarettes a day, and 1.7% for current smokers of 20+ cigarettes a day. The overall prevalence of diffuse pulmonary fibrosis (DPF) was 40 out of 2,825 subjects (1.4%). Several points should be borne in mind:

1. These rates are low and inconsistent with a dose–response relationship.
2. Miniature (70 mm) films were used. The author noted that in "10 subjects whose 70 mm photofluorograms were read as showing DPF, concurrent 14 × 17-inch roentgenograms were considered abnormal in only 5."
3. Films were read by a single reader.
4. The definition of DPF was nonspecific ("prominent" bronchovascular markings). Neither standardized coding nor standard films were used.
5. Unlike clinical ILD, the DPF described in the paper was associated with "ventilatory abnormalities characteristic of COPD."

4. Small Airways Dysfunction (SAD) Due to Asbestos

Small airways dysfunction is a decrease in flow through bronchioles of diameter ≤ 2 mm. Cigarette smoking is the predominant cause of SAD in the general population. Although a much larger percentage of smokers show evidence of SAD than of COPD, it is thought that COPD develops in those with SAD. In most cases, SAD does not cause dyspnea or disability.

Small airways dysfunction has been described in asymptomatic asbestos workers, often young, after brief durations of exposure and with normal chest radiographs.[39,40] As cigarette smoking is the predominant cause of SAD in the overall population, it is generally not possible to attribute findings of SAD to asbestos if an asbestos worker also smokes. Small airways dysfunction is the physiologic counterpart of lesions in and/or surrounding the small airways caused by either of these exposures. In a nonsmoking asbestos worker, SAD may be attributed to asbestos. However, the research of Dr. Bégin has clearly demonstrated that the physiologic findings of SAD are no longer detectable when diffuse pulmonary fibrosis supervenes and that obstructive impairment does not develop in patients with asbestos.[41]

5. *Effect of Asbestosis on Life Expectancy*

A mortality study of asbestosis patients certified by British Pneumoconiosis Panels[42] provides an estimate of the effect on life expectancy of this illness. Of 383 deaths, 39% were from lung cancer (9.1 times the expected rate), 9% from mesothelioma, and 20% from asbestosis. After 10 years from certification, half the workers had died compared with an expected mortality of one quarter. Excessive death rates were apparent as early as 1 year after certification. Reduction in life expectancy was related to extent of disease (assessed as percentage of disability awarded) and ranged from 3 years for 10% disability to 8 years for 30% and 12 years for 50% or more.

Is the Radiograph Positive or Negative for Asbestosis (0/1 *v* 1/0)?

This is the most elemental question: yes or no, positive or negative, diseased or normal?

To standardize readings by physicians around the world and to overcome the use of nonspecific terminology like "increased markings," the International Labour Office has devised (and revised) a scheme for reading DIF based on size, shape, and profusion of opacities.[4] In the United States, the National Institute of Occupational Safety and Health (NIOSH) and the American College of Radiology train physicians in the use of the ILO codes and conduct arduous examinations. These certify "expert" readers, who are designated B readers (to the mystification of all those familiar with the Latin, or even Phoenician, alphabet).

Asbestosis opacities are linear, irregular, or streaky (as opposed to rounded). They can be of various diameters, designated s, t, and u. Severity of asbestosis depends on the profusion score or number of opacities in each area of the film. This is read by comparing each posteroanterior (PA) film with standard films showing profusions of 0/0, 1/1, 2/2, and 3/3. The irregular, linear, and streaky shadows cast by the normal bronchi and blood vessels of the lung, and by their associated connective tissue, are encompassed in the 0/0 standard; anything greater must be so coded after adjustment for radiographic technique, body muscularity and adiposity, and other disease.

The full ILO scale marks 12 specific positions on a continuum from "starkly normal" (0/−) through "unquestionably normal" (0/0), and "probably normal" (0/1) through "probably fibrotic" (1/0) to "unquestionably fibrotic but slight" (1/1), on to "greatest profusion for which a standard film exists" (3/3) and "even more than that" (3/+). (The descriptions in quotation marks are my characterizations of these scores, not official definitions!) As must be true of any continuum, there is no sharp separation between adjacent positions on the scale and no clearcut distinction between prominent but normal bronchovascular markings (0/1) and slight interstitial fibrosis superimposed on normal (or prominent) markings (1/0). Yet, the NIOSH report sheet and many physicians and public health officials consider 0/1 "normal" and 1/0 "asbestosis." It is within the definition of these categories that the same expert reader may read

the same film 0/1 one day and 1/0 another day, or that two expert readers will arrive at these different readings. Despite much interest for it to do so, the ILO has yet to provide standard films for these two all-important boundary categories.

A pulmonologist who encounters patients with all types and degrees of lung disease in his daily practice will often look at a 1/0 film and report it as "normal." By this he means that if he comes across such a film in a clinical setting (review of hospital admission films), he would not respond by making a diagnosis of ILD. This is not ILD as he sees it in his clinical practice because he does not see patients with the counterpart of a 1/0 film in his clinical practice. His patients are generally much sicker!

The ILO classification cannot overcome difficulty in reading films of an individual patient who is at a boundary. It was not devised for this purpose. It does fulfill the epidemiologic purposes for which it was created by allowing quantification of disease (as it presents radiographically) in large numbers of exposed subjects and correlations with duration and dose of asbestos exposure, with symptoms, with effort intolerance and loss of pulmonary function, and with mortality.

Extensive pleural thickening, especially en face, superimposes shadows upon the lung fields. These may mask DIF that is present or may be interpreted as DIF when the latter is not present.

Summary

This chapter has described the various asbestos-related diseases and illustrated how causality was attributed. I have attempted to answer frequently raised questions concerning the definition of asbestosis, the meaning of restrictive impairment, the relationship between cigarette smoking and pulmonary fibrosis in asbestos-exposed and general populations, the significance of small airways dysfunction, and the effect of asbestosis on life expectancy. The differing perspectives of medicine and the law on the various asbestos-related diseases have been explored.

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A Legal Perspective

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General Standards of Liability

Understanding the litigation of claims on behalf of the countless victims of asbestos disease requires a familiarity with the basic concepts of product liability law, which governs all product liability cases. The foundation of product liability law in the majority of jurisdictions[1] today is the Doctrine of Strict Liability in Tort, which is codified in the Second Restatement of Torts and provides as follows:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby

caused the ultimate user or consumer . . . if
(a) the seller is engaged in the business of selling such a product, and
(b) it is expected and does reach the user or consumer without substantial change in the condition in which it was sold.
(2) The Rule stated in Subsection (1) applies although:
(a) The seller has exercised all possible care in the preparation and sale of his product, and
(b) The user or consumer has not bought the product from or entered into any contractual relation with the seller.

Justice Schreiber of the New Jersey Supreme Court provided the following precis of the standard by which a manufacturer's product is to be measured:

If at the time the seller distributed a product, it is not reasonably fit, suitable and safe for its intended or reasonably foreseeable purposes so that the users of others who may be expected to come into contact with the products are injured as a result thereof, then the seller shall be responsible for the ensuing damages.[2]

A manufacturer's obligation to market a reasonably safe product is a nondelegable duty.[3]

A manufacturer is under a legal obligation to provide with its products warnings about the dangers posed by the product and instructions on its safe use. An adequate product warning is "one that include the directions, communications, and information essential to make the use of the product safe."[4] A warning is legally adequate only if it is of a character "reasonably calculated to bring home to the reasonably prudent person the nature and extent of the danger."[5] The requirement that a manufacturer warn of the hazards of its product is limited in the majority of jurisdictions to those dangers of which it has knowledge or could have acquired knowledge through the application of "reasonable, developed skill and foresight."[6]

The trial of a strict liability claim requires that the factfinder focus solely on the safety of the product without regard to the conduct of its manufacturer or the trade customs of the industry. Manufacturers are deemed to know of the hazards of their products and plaintiffs are relieved of the burden of proving that a defendant knew that its products were dangerous. This is the basic distinction between strict liability and negligence in a products case. Negligence requires proof that the manufacturers knew or should have known of the dangers of its products.[7] A fundamental premise of these common law principles of strict liability is that it is the judicial system, not the commercial system that is the appropriate forum for determining whether or not a product has been manufactured in a reasonably safe condition.[8]

To make out a prima facie case, a plaintiff must prove by a preponderance of the credible evidence that:

1. The product was defective
2. The defect existed when the product was distributed into the stream of commerce
3. The defect caused injury to a reasonably foreseeable use
4. The product was being used in a reasonably foreseeable manner[9]

The exact nature of a plaintiff's proofs in a products liability action is dependent upon whether he alleges a product is defective because of manufacturing defects or design defects. Although a failure to warn adequately is a form of design defect, generally it is considered a third category of defect for purposes of strict liability analysis.[10]

A finished product contains a manufacturing defect when it varies from its intended design, for example, a mass-produced product that comes off the assembly line missing a part. Proving a defect in this situation is accomplished by comparing the product with its prototype. An incongruity would establish prima facie liability for injuries caused thereby.[11] In failure to warn cases, a plaintiff must prove what the hazards of a product are and that the defendant failed to provide information about these potential dangers and how to avoid them.[12]

The difficult analytical problems in the product liability field have arisen in those cases where plaintiffs allege that a product conforms to its specifications and cannot be adjudged to be defective by comparing it with the manufacturer's design.[14]

Whether a product is defectively designed has required the judicial formulation of a standard against which the design of the product can be compared. The mode of analysis the courts use in design defect cases is the risk-utility test.[15] Under this test, a product may be found to be defective if a jury determines that "the magnitude of the scientifically perceivable danger as it is proved to be at the time of trial outweighed the benefits of the way the product was so designed and marketed."[16] Risk-utility analysis requires that the parties present evidence addressing the key factors listed below so that juries will analyze a product's safety in a prescribed manner:

1. The usefulness and desirability of the product)—its utility to the user and to the public as a whole
2. The safety aspect of the product—the likelihood that it will cause injury and probably seriousness of the injury.
3. The availability of a substitute product that would meet the same need and not be as unsafe
4. The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
5. The user's ability to avoid danger by the exercise of care in the use of the product
6. The user's anticipated awareness of the dangers inherent in the product and his knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions
7. The feasibility on the part of the manufacturer of spreading the loss by setting the price of the product or carrying the liability insurance[17]

Proponents of the risk-utility test envision that it can be applied at three different times during the course of a trial: by the trial judge before the case is

given to a jury, to determine whether liability should be precluded or imposed as a matter of law; when the case is given to a jury the trial judge instructs the jury on those factors of the tests for which the parties have presented specific evidence; and after a jury has rendered its verdict, to review the sufficiency of the evidence upon a motion for a new trial or a judgment notwithstanding the verdict.[18]

Courts sometimes use the consumer-expectation test in which a product's safety is considered in light of the user's reasonable expectation that it will "safely do the job for which it was built."[19]

A plaintiff may theoretically establish liability in a product liability action even though he cannot demonstrate that the product could have been designed in a safer fashion by the use of then existing technology if he can prove by a preponderance of the evidence that the risks of the product outweigh its benefits to society.[20]

Although there are no published appellate decisions where this theoretical application of the law has been employed, it has been thought by judges and commentators to be appropriately used in situations such as childrens' toys, handguns, and tobacco.

Defenses

A seller of a product may shift the responsibility of an accident with a defective product to the plaintiff if it can demonstrate that the plaintiff voluntarily and unreasonably proceeded to use the product knowing of the dangers that caused his injury. The defenses of plaintiff's conduct cannot be used when the plaintiff's actions were merely careless or if he failed to discover the defect.[21]

Manufacturers of products frequently use "the state-of-the-art" defense to the allegation that its product is defective. "State-of-the-art" has been defined as "the existing level of technology, expertise, and scientific knowledge relevant to a particular industry at the time a product is designed."[22] The term "state-of-the-art" is a label applied to two different types of defenses in product liability actions. In design defect cases, the manufacturers use the state-of-the-art defense to demonstrate that it was not technologically feasible to have eliminated the danger of a particular product at the time it was manufactured.[23] In failure to warn or instruct cases, the manufacturers invoke the state-of-the-art defense to provide that their failure to warn was a consequence of the fact that the danger of the product was unknown or scientifically undiscoverable at the time to product was manufactured.[24] The state-of-the-art defense is not an absolute one under the doctrine of strict liability in tort. A product may comply with the state of the art but may be found to be defective if a jury finds that its risks outweighed its ability.[25]

Conceptual confusion arises when the term "state-of-the-art" is misused in strict liability cases. "State-of-the-art" has been a term used in negligence cases to describe common practice and standards in a particular industry. The appropriate label to use when describing this species of negligence proofs is "trade custom" not state-of-the-art. Trade custom is not a defense in a strict

liability action.[26] Where a manufacturer has a legal responsibility to sell a reasonably safe product regardless of whether others in industry are doing so. Thus, although state-of-the-art is a defense in a design defect case when the evidence under discussion refers to technological and engineering feasibility and in a failure to warn case when the evidence pertains to knowledge known and discoverable by the scientific community, it never includes trade custom.

Asbestos Litigation and Strict Liability: A Development of the Law

Plaintiffs in asbestos litigation have generally sought to recover under strict liability principles in product liability cases based upon the allegations that sellers of these products have failed to provide adequate warnings on the potential health hazards of asbestos exposure or adequate instructions on how to eliminate or minimize the risks of working with asbestos.[27] No discussion of these issues can begin without reference to the seminal decision of *Borel v. Fibreboard Paper Products Corporation*.[28] Although numerous asbestos cases have been tried since *Borel* was decided, its application of strict liability principles to the facts of asbestos litigation have provided the blueprint for all the cases that have followed. The plaintiff, Clarence Borel, was an insulation worker, who became afflicted with asbestosis and mesothelioma, after a working career of occupational exposure to asbestos. Borel finally succumbed to mesothelioma and his widow proceeded with this legal action against the defendants who were manufacturers of asbestos products that decedent had worked with in his trade. Plaintiff claimed that the defendants were legally responsible under strict liability because they had not provided adequate information with their products on the dangers of asbestos. The defendants argued that they had not supplied warnings in years past because medical science had not identified the risks to finished product users. Some manufacturers argued that the warnings they provided in later years were sufficient to relieve them of liability. A jury verdict in favor of the plaintiff was returned and then appealed by the defendants.

The Circuit Court of Appeals reviewed the extensive proofs on the issue of "state-of-the-art" at the trial and found that the plaintiff had produced sufficient evidence on scienter to sustain the verdict. The summary of evidence on this issue published in the case is a classic history of the state of medical knowledge on the issue of when the scientific and medical communities knew of the hazards of asbestos exposure.[29] Some manufacturers had adduced evidence that they began placing warnings on their asbestos products in 1964 and these defendants argued to the appellate court that their warnings absolved them of liability as a matter of law.[29]

The Court of Appeals reviewed the language of these warnings and found that their content lacked specific information on the hazards of asbestos or adequate instructions on how to avoid the dangers. The manufacturer's admonition to avoid breathing the dust was described as "black humor."[30] Another issue the appellate court had to face was whether or not the plaintiff's conduct should have precluded his recovery. The factual background for this

issue was the plaintiff's admission that "(he) knew the dust was bad, although you never know how dangerous it was." The Court noted that the legal standard against which plaintiff's conduct had to be measured was whether or not he had "voluntarily and unreasonably proceed(ed) to encounter a known danger,"[31] and found ample support for the jury's decision that plaintiff's conduct had not been negligent.

A final issue that was explored in the appeal was whether the plaintiff's proofs were inadequate because they failed to pinpoint the degree to which each plaintiff's exposure to each of defendant's products has caused his illness and death. The decedent had used many different asbestos products at different times in his career and no medical expert could apportion the illness among each of the defendant's different products. The Court found that this procedural shortcoming was not fatal to the viability of plaintiff's claim because of the technical inability of medical science to accomplish this task.[32] The Court of Appeals eloquently summarized what they perceived the impact of their holding was in this case:

> If in reaching our decision in the case at bar, we recognize that the question of the applicability of Section 402A of the Restatement to cases involving "occupational diseases" is one of the first impression. But though the application is novel, the underlying principle is ancient. Under the law of torts, a person has long been liable for the foreseeable harm caused by his own negligence. This principle applies to the manufacture of products as it does to almost every other area of human endeavor. It implies a duty to warn of foreseeable dangers associated with those products. This duty to warn extends to all users and consumers, including the common worker in the shop or in the field. Where the law has imposed a duty, courts stand ready in proper cases to enforce the rights so created. Here, there was a duty to speak, but the defendants remained silent. The district court's judgment does not more than hold the defendants liable for the foreseeable consequences of their own inaction.[33]

Courts have adhered to the *Borel* prescription that strict liability principles apply to sellers of asbestos products[33] and asbestos fibers.[34]

Product Identification

The most critical issue in a product liability action involving exposure to asbestos is whether or not the plaintiff has adduced sufficient evidence to identify the culpable manufacturers of asbestos products that were the source of exposure causing the plaintiff's illness. Evidence on the issue of product identification is usually supplied by a plaintiff or co-worker or employer who is able to remember and describe the specific manufacturer's asbestos products that the injured party was exposed to.[35] Evidential problems arise when a plaintiff does not have a sufficient recollection of which asbestos products he was exposed to over periods of many years or in instances where the plaintiff is a bystander who cannot pinpoint the source of his exposure because asbestos products were used by other trademen working the same areas. This procedural problem has sometimes been overcome by plaintiffs through the application of principles of "circumstantial evidence" to the facts of a case.

If a plaintiff can establish that he has an asbestos-related disease; that he worked in the vicinity of tradesmen who were using asbestos products which entailed the creation of asbestos dust and fibers; and he can elicit testimony from the tradesmen regarding the identify of the manufacturers whose products were being used at that time and place; this is usually sufficient to make out a prima facie case.[36] A plaintiff does not meet his burden of proof on the issue of product identification simply by establishing that a manufacturer's product was being used at the plaintiff's worksite unless he is able to show a direct link between the plaintiff and the asbestos dust and fibers from specific products being used by others in the area.[37] Many plaintiffs have sought to overcome their inability to identify the culpable manufacturers by attempting to use enterprise or market share liability. These efforts have generally been unsuccessful.[40]

Proof of Defect

Like any other product liability action, a plaintiff must establish that the asbestos-containing products he was exposed to were dangerous and that the defendants failed to provide adequate warnings or instructions regarding these hazards. Plaintiffs generally establish the dangers of asbestos through the use of state-of-the-art experts and/or their experts on medical causation. This testimony coupled with proofs submitted by the plaintiff of the absence of adequate warnings on the products are generally sufficient to make out a prima facie case.

Experts are required on both the issues of state-of-the-art and medical causation because of the obvious reason that discussion of these issues required specialized medical knowledge that can be communicated to juries only by those who are adequately trained in the fields of medicine and epidemiology (see chapter on expert witness, Chapter 6). Defendants generally defend their clients on liability by arguing the state-of-the-art defense and the adequacy of the warnings that their manufacturers may have placed on asbestos-containing products beginning in the mid- to late 1960s.

In those cases where manufacturers defend their products based upon warnings they placed on their products in the 1960s or 1970s, the issue is drawn as to whether or not the warnings given were adequate. Expert testimony is not essential but is helpful on the issue of whether or not warnings were sufficient. The issue of defect is more complicated in those cases where plaintiffs are alleged to be exposed to products where asbestos is an ingredient encapsulated with the product. Defendants generally produce engineering testimony to demonstrate that asbestos emissions from the products are either de minimus or nonexistent. Plaintiffs must rebut such testimony with expert testimony of their own if the case is to survive a motion to dismiss.

State-of-the-Art

The issue of the state-of-the-art defense in asbestos cases has commanded considerable attention from the Courts and the parties who litigate these cases.

A major development on this issue was the case of *Beshada, et al. v. Johns-Manville, et al.*,[39] in which the New Jersey Supreme Court held in an asbestos case that the state-of-the-art defense was not available in a strict liability case. The Court offered the following rationale for its decision:

> Essentially, state-of-the-art is a negligence defense. It seeks to explain why defendants are not culpable for failing to provide a warning. They assert, in effect, that because they could not have known the product was dangerous, they acted reasonably in marketing without a warning but in strict liability cases, culpability is irrelevant. The product was unsafe. That it was unsafe because of the state of technology does not change the fact that it was unsafe. Strict liability focuses on the product, not the fault of the manufacturer.[40]

This decision was widely criticized in the academic literature. Some jurisdictions have declined to follow the ruling, whereas others have adopted the holding.[41]

Proximate Cause

The issue of proximate cause is applied to two different sets of issues that must be resolved by the Trial Court. The first issue is whether or not exposure to a particular defendant's product was a substantial contributing factor to the development of asbestos-related disease in a plaintiff. A plaintiff establishes a prima facie case if he can prove that he was exposed to the defendant's products on at least one occasion which in conjunction with other asbestos exposures resulted in the development of an asbestos-related disease.[42]

Medical causation is the battleground on which asbestos litigation is fought today. Many asbestos-exposed workers also have histories of cigarette smoking which complicate the art of diagnosing occupational pulmonary disease. Plaintiffs with alleged asbestosis also may have been diagnosed with chronic obstructive pulmonary disease, which raises difficult issues among the parties as to which disease or the extent to which each disease is causing plaintiff's resultant disability. Patients who are suffering from lung cancer who have both histories of smoking and asbestos exposure are alleged in asbestos cases to have developed their disease as a consequence of a synergistic reaction between asbestos and cigarette smoke.

Asbestos manufacturers defend many of these claims by arguing that cigarette smoking is the sole cause of the lung cancer or that the lung cancer would not have occurred but for the patient's history of cigarette smoking. This defense is especially poignant in lung cancer cases because the defense can effectively argue that plaintiff's conduct was a substantial cause of the plaintiff's medical problem. Although these factual situations are new and complex, the established precepts of proximate cause are flexible enough to provide an analytical framework for resolving the issue of causation. It is the plaintiff's burden of proof to establish by a preponderance of the evidence within a reasonable degree of medical certainty that asbestos was a cause of an injury to the plaintiff as well as to establish the extent to which it has effected his overall pulmonary health.[43] A defendant in an asbestos case will not be

legally responsible for a separate and distinct pulmonary injury which is not caused by asbestos exposure. Under established principles of proximate cause, an asbestos defendant will only be responsible for a lung disability that contributed to by both smoking and asbestos if it can be proven that the asbestos exposure aggravated the plaintiff's underlying lung pathology. If a plaintiff can demonstrate that the asbestos exposure did aggravate this underlying pulmonary condition, then the defendants will be legally responsible for all of the sequela of the ensuing disability.[44]

A plaintiff with histories of smoking and asbestos exposure need not prove that asbestos was the only or even the dominant cause of his disease. Under the law of "concurrent causation" there may be two more directly cooperative and efficient proximate causes of an injury. To recover, a plaintiff need only establish that asbestos exposure was a substantial contributing factor to the development of the cancer.[45] If a jury accepts the postulation of synergism in the facts of a given lung cancer case, there is no legal obstacle to a finding of proximate cause.

Some jurisdictions allow jurors to apportion damages between asbestos exposure and cigarette smoking if there is sufficient credible evidence to allow the jury to make the apportionment.

Proximate cause also must be evaluated on the issue of whether or not the defect of the product was a cause of the plaintiff's injuries. In the factual setting of an asbestos case, a plaintiff must show that had an adequate warning been supplied with the products that he would have read the warning and changed his conduct in response to the information supplied. Some jurisdictions dispensed with this requirement and give the plaintiff the benefit of a rebuttable presumption that had the warning been given the plaintiff would have read and heeded it.[46]

Damages

A plaintiff suffering from an asbestos disease is entitled to recover compensatory damages for any and all of the medical and financial consequences which the plaintiff can establish will proximately result from asbestos disease. The courts have had considerable difficulty in applying this simple law of damages to asbestos cases because of the myriad of medical consequences that can befall an individual who has been exposed to asbestos. The medical community generally recognizes that a plaintiff who is afflicted with asbestosis is statistically at risk of developing an asbestos-related carcinoma, but it is impossible for physicians to prognosticate whether or not the asbestotic will actually develop into cancer (within a reasonable degree of medical certainty). Most jurisdictions do not permit recovery for "statistical injuries," proof of which falls short of the generally recognized barometer of reasonable medical certainty.[47] Given these legal constraints, a plaintiff with asbestosis is likely to be able to make out a claim only for the future course of the disease he is afflicted with but not for other diseases for which he is at risk. Jurisdictions deal with this issue of future risk in different fashions.

Some states follow "the single cause of action," rule which allows only one claim for all injuries that are caused by asbestos exposure.[48] In these venues, a plaintiff with asbestosis can recover only for this condition no matter what happens to him in the future. Even if he subsequently develops bronchogenic carcinoma or malignant mesothelioma, he will not be permitted to file a new claim. This same plaintiff cannot elect to forego his claim for asbestosis in order to wait and see what his future holds because applicable statutes of limitation bar any action not commenced with a period of time after as any injury at all is diagnosed. The dilemma these plaintiffs face was succinctly described by a superior court judge in New Jersey:

1. A plaintiff who fails to sue within 2 years after he is diagnosed with asbestosis or later sues when a malignancy develops is barred by reason of the statute of limitations.
2. Alternatively, a plaintiff who sues within 2 years after asbestosis is diagnosed and cannot then prove that future malignancy is probable cannot later sue if a malignancy develops because such a suit is barred by the entire controversy doctrine.[49]

Many jurisdictions that have faced this "catch-22" situation have held that plaintiffs may file separate causes of action for each separate and distinct form of asbestos-related disease.[50] A plaintiff who is pursuing a claim for asbestosis may recover for fear of developing asbestosis-related cancer if he meets the following evidential criteria:

1. Plaintiff is currently suffering from serious fear or emotional distress for a clinically diagnosed phobia of cancer
2. The fear was proximately caused by exposure to asbestos
3. Plaintiffs' fear of getting cancer due to their exposure to asbestos is reasonable
4. Defendants are legally responsible for plaintiffs' exposure to asbestos[51]

Punitive Damages

Many plaintiffs have sought punitive damages from a number of manufacturers of asbestos-containing products based upon an allegation that the defendant knowingly marketed a dangerous product without informing the public of the dangers of asbestos exposure. The proofs that plaintiffs product at trial must make a showing that a manufacturer is "aware of or culpably indifferent to an unnecessary risk of injury and refuses to take steps to reduce that danger to an acceptable level."[52]

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Medical and Legal Issues in Lung Cancer

Medical Perspectives

JAMES R. VEVAINA, MD

Lung Cancer

Lung cancer is an enormous topic and accordingly, no pretense will be made to cover the topic in its entirety. This chapter will touch up on those aspects of lung cancer that have legal significance. Readers are referred to the larger treatises in the medical literature of which there is no dearth.[1-3] Lung cancer is the predominant fatal neoplasm of our times. In 1987, approximately 155,000 cases of lung cancer will be diagnosed in the United States. Whereas advances in the clinical management of lung cancer have been stymied, our understanding of cancer in the laboratory has accelerated dramatically. This is largely due to our understanding of cell cytogenetics and molecular alterations, which distinguish the malignant cell from its normal counterpart.

Although these are interesting scientific advances, the progress against cancer has been called a medical and political scandal. Despite the expenditure of literally billions of dollars in research for cures for cancer, at least on a statistical basis, we are losing the so-called "war against cancer." A report by John C. Bailar and Elaine M. Smith summarized the cancer mortality data from 1950 to 1982. These data confirmed the ugly fact that cancer mortality continues a yearly upward rise. This report[4,5] from the Harvard School of Public Health concluded, "A cancer program that does not reduce overall death rates is not a success, whatever its other accomplishments."

In diagnosing and treating lung cancer, therefore, physicians must understand that mortality from the disease is the serious health care issue. Carcinoma of the lung is a super-aggressive form of cancer. It is the leading cause of cancer deaths in men, and in recent years, it is rapidly assuming a similar status in women.[6] As Joseph Califano, exsecretary of Health, Education, and Welfare, stated, "Women who smoke die like men who smoke."

Medicolegal Issues in Lung Cancer

Medicolegal issues in lung cancer relate mainly to:

1. Failure to diagnosis lung cancer
2. Wrongful death during a diagnostic procedure or surgery

3. Pathologic misdiagnosis
4. Fruitless thoracotomy
5. Occupational carcinomas—the latest being radon
6. Unproven and quack therapies for cancer; for example, Laetrile
7. Informed consent issues

Diagnosis of Lung Cancer

The diagnosis of lung cancer is fairly straight forward. It rests upon the time honored and traditional test of a complete history, a detailed physical examination, and chest x-rays. These are supplemented by sputum cytology, computed axial tomography, and bronchoscopy (rigid or flexible). The reason that a lot of lung cancers are missed is because of a lack of a strong degree of suspicion and the lack of periodic x-rays and sputum cytologies. Further, it has been well documented in recent studies that lung cancer has a higher prevalence in patients with chronic airflow obstruction.

The medical history is an important part of the diagnostic workup of any cancer patient. There are numerous lawsuits based just on this fact. An incomplete medical history may be a significant factor in failure to diagnose lung cancer. A physician may also fail to include cancer in the differential diagnosis of a new patient with lung disease. Family and racial history is important in certain cancers, especially those related to asbestos and small cell lung cancer. Specific questions should include: a history of smoking, exposure to asbestos and other carcinogens, previous radiation therapy, the use of certain drugs, especially cytotoxic medications. Failure to perform a proper physical examination, over-reliance on a negative examination, and failure to perform a follow-up examination have all been the basis for lawsuits.

In an effort to diagnose the disease early, numerous studies attempting to make an early diagnosis of lung cancer have been carried out. Studies done at Johns Hopkins University, the Mayo Clinic, and Memorial Sloane-Kettering Hospital[8] have all concluded that the early detection of lung cancer is a difficult and expensive proposition. Each of these programs enrolled approximately 10-thousand cigarette smoking individuals over 45 years of age and evaluated them with chest x-rays and sputum cytology. On initial screening, 211 lung cancers were detected in approximately 30,000 patients screened, an incidence of 7 per 100,000 patients. The logical conclusion to all these studies is that there is only one way to fight lung cancer and that is cessation of smoking. Numerous proposals to raise the tax on cigarettes have found defeat in the legislatures.

Solitary Pulmonary Nodules

For a detailed description of the management of the solitary pulmonary nodule, the reader is referred to *Recent Advances in Lung Cancer,* edited by Richard Matthay.[1] Briefly, a solitary pulmonary nodule is an intrapulmonary lesion that is spherical in contour and has fairly well demarcated margins in all projections. Nodules often show up as unexpected findings on a routine chest x-ray.

Nodules less than 8 mm in diameter are almost always benign. Forty-five percent of all nodules are found to be malignant at surgery. In the diagnosis of pulmonary nodules, computed axial tomography and needle aspiration biopsy have revolutionized the workup of lung nodules. The growth rate is also important in differentiating benign from malignant nodules. Seventeen percent of patients who undergo surgery for a lung carcinoma will later develop a secondary primary.[12]

We recommend in patients with suspected lung cancer who have normal chest x-rays and positive sputum cytologies that a thorough nasopharyngoscopy and bronchoscopy be done.[13] Bronchoscopy has the advantage of visualizing the larynx, vocal cords, and the main stem bronchi. At the same time, a tissue diagnosis is possible. The disadvantage of bronchoscopy is that the yield gets less as the lesion gets smaller and smaller. If the carcinoma is not found in the chest, it is almost always found in the head or neck.[14]

Skinny or thin needle aspiration biopsy using either fluoroscopy or computed axial tomography has gained increasing popularity in American hospitals. The procedure is easy to do with the proviso that one knows the segmental anatomy of the lung. In most good hands the yield is over 90% of positive biopsies, and this is an advantage over bronchoscopy in that even as the lesion gets smaller a positive biopsy is possible. In some cases mediastinoscopy will provide a diagnosis and a stage for a lung carcinoma without doing a formal thoracotomy.[15] The final diagnostic modality is a formal thoracotomy.

Pathologic Misdiagnosis

In 1977 the World Health Organization (WHO) adopted a nomenclature for malignant tumors of the lung. For practical purposes, lung carcinoma can be classified histologically into small cell or nonsmall cell carcinoma, although the WHO classifies lung tumors as follows:

Benign tumors	Squamous cell papilloma
	Adenomas
	Carcinoma in situ
Malignant	Squamous cell carcinoma
	Small cell carcinoma
	Adenocarcinoma
	Bronchiolo-alveolar carcinoma
	Large cell carcinoma
	Carcinoid tumor
Soft tissue tumors	
Mesothelial tumors	Benign mesothelioma
	Malignant mesothelioma
Miscellaneous tumors	Carcinosarcoma
	Pulmonary blastoma
	Malignant melanoma
	Malignant lymphoma
Secondary tumors	

Mesothelioma is a distinct type of lung carcinoma which is a rare tumor that arises from either the visceral or parietal pleura. The solitary benign mesothelioma is a localized growth in the pleural space that does not usually produce a pleural effusion and that may be cured by surgical removal. The diffuse malignant mesothelioma spreads widely in the pleural space and usually is associated with an extensive pleural effusion. Direct invasion of thoracic structures usually prevents surgical cure.

Accuracy of diagnosis is of paramount importance in the treatment of lung carcinoma. The treatment of small cell lung carcinoma is distinctly different from that of nonsmall cell carcinoma. It is often misdiagnosed when it does not have classic histologic features. When the diagnosis is in doubt it is reasonable to request a second opinion from a more experienced pathologist. We are aware of at least one nationally known institution where a patient with pneumonia was misdiagnosed as having lung carcinoma and underwent unnecessary surgery. This was followed by a lawsuit.

Small cell carcinoma has rapid growth rate, early wide spread metastasis, and frequent central endobronchial location. Further regional nodes are often involved, and the tumor is characterized by the production of hormones and paraneoplastic syndromes. It is responsive to chemotherapy and radiation. In managing small cell lung cancer, the major question is whether the patient has localized or extensive disease.

Surgical Aspects

Resection is generally accepted as the treatment of choice for lung cancer.[16] Once the primary tumor has been removed, death of the host is usually attributed to metastasis disseminated before surgery.

One legal problem that surgeons often face is the question of unnecessary surgery.[17] Unnecessary surgery or fruitless thoracotomy is difficult to define, but to use an extreme example it is clearly unnecessary to do surgery on a patient who already has distant metastasis. I, for one, have never gotten over the outrage that there are some thoracic surgeons who do perform operations primarily for the fee involved and not in the best interests of the patient.[18] We can leave behind many pulmonary cripples if we do not make surgeons adhere to strict guidelines for pneumonectomy[18] and other procedures[19] as recommended by the American Thoracic Society and the American College of Surgeons. Seeking a second opinion on behalf of the patient can only be deemed good surgical practice, and more and more insurance carriers are willing to pay for these opinions.

Staging of Lung Cancer

Staging a lung cancer is the estimation of the anatomic extent of the primary tumor, and the absence or presence of spread to the regional lymph nodes. It also assesses more distant metastasis. The American Joint Committee for cancer staging and end result reporting was developed in 1973 based on the retrospective analysis of more than 2,000 cases of lung cancer.[20]

Patients in this staging system are divided into stages:

T primary tumor	
TxNoMo	Positive cytology, negative chest x-ray, and bronchoscopy
T1	Tumor 3 cm, surrounded by lung
T2	Tumor more than 3 cm, or any tumor invading pleura or having obstructive atelectasis. Must be 2 cm distal to carina
T3	Tumor any size, with direct extension to pleura, diaphragm, chest wall, or mediastinum
N regional lymph nodes	
No	No lymph node metastases
N1	Regional lymph node metastases
N2	Mediastinal lymph node metastases
M distant metastases	
Mo	No distant metastases
M1	Metastases outside the thorax

Using this system patients are divided into three stages, which reflect anatomic extent, resectability, and prognosis. The system generally uses the TNM classification. T describes the size and local extent of the tumor. N describes involvement of regional lymph nodes, and M describes the presence or absence of metastases. Accordingly the stages are:

stage I	T1NoMo
	T1N1Mo
	T2NoMo
stage II	T2N1Mo
stage III	T3 with any N or M
	N2 with any T or M
	M1 with any T or N

Staging is important because it helps in evaluating individual patients as well as large cancer treatment protocols under the auspices of the American Cancer Society. It also separates heterogenous patients into homogenous groups. Computerized Axial Tomographic scanning is usually done as a prelude to surgical staging of the mediastinum. A relatively new procedure for assessing resectability is the Wang transbronchial biopsy needle.[21] With this, needle biopsy of mediastinal nodes is possible by penetrating the wall of the bronchus.

Mediastinoscopy was developed by Carlens.[15] It is the most direct way of sampling lymph nodes and assessing resectability. On the left side, an anterior mediastinostomy or Chamberlain procedure involves an incision through the second intercostal space to reach lymph nodes.

Preoperative Evaluation for Surgery

Clearly, one of the roles of a pulmonary specialist in the management of carcinoma is to assess to the best of his ability and within the limitations of

pulmonary function testing, a patient for surgery. This evaluation is geared toward assessing whether the patient can or cannot tolerate surgery. The standard test[18] is to use the FEV_1 as a screen. A forced expiratory volume of less than 1 L is associated with a high mortality. It is now also possible to estimate the perfusion that each lung contributes to total lung perfusion.[19] This can be done by the quantitative perfusion lung scan. In normal people, 55% of perfusion is provided by the right lung, and 45% by the left lung. The importance of preoperative pulmonary function testing is that it might prevent unnecessary surgery.[17]

Occupational Carcinomas

There is increasing evidence that a wide variety of occupational exposures can lead to the development of lung carcinoma. Some of these agents have been known for at least a century when radiation-induced lung cancer was described in the mountains of Joachimsthal in Czechoslovakia. Asbestos is perhaps the most widely studied of all occupational carcinomas. In addition to producing parenchymal and pleural asbestosis, exposure to asbestos can result in lung cancer and the rare lung tumor mesothelioma.[22] Other carcinogenic agents that clearly should be elicited in the history are cigarette smoke, arsenic, chloromethylether, isopropyl oil, mustard gas, nickel, beryllium, and perhaps the most important new carcinogen, radon.

Adjuvant Therapy

Adjuvant therapy is therapy that is instituted in addition to primary resection. The goal being to alter the growth of remaining tumor at the site of the primary lesion. Radiotherapy, chemotherapy, and immunotherapy are all forms of adjuvant therapy. To date, none can be considered proven[1] or capable of increasing survival, which is the goal of all therapy for carcinoma.

Chemotherapy

Whereas great strides have been made in chemotherapy for other carcinomas, small cell carcinoma of the lung is the only tumor where chemotherapy is of some generally accepted value. Clearly, 1-year survival has been improved with combination chemotherapy. The most encouraging combinations include the use of cyclophosphamide and vincristine, with or without doxorubicin.[2] Other agents used are methotrexate, VP-16, CCNU, and mechlorethamine. Chemotherapy for nonsmall cell carcinoma of the lung is practically worthless, in my opinion.

Radiotherapy

Radiation is currently considered only palliative for lung carcinoma. An interesting study on Radiotherapy alone for patients with inoperable lung carcinoma was reported by Cooper.[23] He treated 72 patients who had a carcinoma that was operable but in whom the patient had refused surgery. All the patients had nonsmall cell carcinoma without evidence of spread. They also

had a negative staging mediastinoscopy. It was evident that the results of radiotherapy were disappointing. Cooper recommended on the basis of this study that resection should be tried even in patients who are marginal in terms of operable risk.

Laser Therapy

The role of laser surgery in the management of lung cancer is still evolving.[24] Lasers are devices that generate electromagnetic radiation (for simplicity, light). Light is generated when a quantum system (atoms, molecules) undergoes a transition from a higher to a lower energy level. The most commonly used laser in the bronchial tree is a Neodymium-YAG laser, which has been developed for use with the fiberoptic bronchoscope or the rigid bronchoscope. YAG lasers are used principally for treatment of obstruction of central airways in patients who are inoperable. A limitation of the system is that the depth of penetration is only approximately 2 cm. Laser treatment has been complicated by fires when inhalation anesthetics have been used. There are also complications of massive hemorrhage and perforation of airways. The cost effectiveness of this form of treatment remains to be proven.

Research Aspects

Whereas there have been few advances in the clinical care of cancer patients, our understanding of lung cancer in the laboratory has dramatically accelerated. This is, in large part, due to our understanding of cytogenetic and molecular alterations which distinguish the malignant cell from the normal cell. For example, a specific chromosomal abnormality of the short arm of chromosome 3 has been described in small cell lung cancer. These abnormalities are thought to play a role in the pathogenesis of malignancies and are not just markers thereof.[25] Finally, another development in molecular biology has been the development of oncogenes.[26] These are genes whose expression or mutation is important in malignant transformation of cells. These insights in the laboratory will hopefully direct further research into the management of lung cancer in humans.

Some Practical Pointers

We think it worthwhile to recommend to our readers an office procedure to visualize individually all x-ray reports and laboratory data on patients. These should be initialed before they are entered in the patient's file. We cannot emphasize enough, that even if the treating physician is a pulmonary specialist, a radiologist reviews all abnormal x-rays. We recently read about a case where a pulmonologist was performing chest x-rays in his office, and reading them himself. He missed a small cancer in the upper lobe. He was found liable not only for missing the cancer but also for failing to have a radiologist review the films.

Conclusion

Lung cancer is a complex multifaceted disease. Liability in treating this disease occurs mainly from a failure to diagnose. Physicians can protect themselves by adhering to strict procedures for diagnosis, referral, and treatment.

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Legal Perspectives

HAROLD L. HIRSH, MD, JD

The oncology patient presents particular medical and surgical as well as legal problems for the physician. Lawsuits primarily involve misdiagnosis or, more often, late diagnosis. Plaintiff patients alleging misdiagnosis are basically complaining of a "loss of chance." Almost always there is the question of whether the misdiagnosis caused the patient's injury to a reasonable medical certainty or probability, or whether the natural course of events were unchanged.

There are also legal actions involving proper treatment and invariably the question of the statute of limitations. Because patients with cancer are often desperate, a physician must address the legal consequences of administering unorthodox treatment, particularly if the patient insists upon it. The use of radiation therapy is frequently the source of medicolegal problems. Basic to the resolution of these problems involves invoking risk-benefit judgment, comparing the anticipated benefits from therapy with its risks, and weighing the consequences of no treatment.

Lesser legal problems involve patients' failure to comply. It often becomes necessary to invoke as a defense the patients' contributing or comparative negligence.

Chemotherapy is fraught with complications. For oncology patients, informed consent, or informed refusal if care and management are refused, are very important. The physician may choose to use therapeutic professional discretion to keep medical facts from the patient when the physician believes disclosure would be harmful, dangerous, or injurious to the patient.

Standard of Care

There are now recognized specialties in medical and surgical oncology. Consequently, any physician treating a patient with cancer would best be advised to review his care of a cancer patient with someone practicing in the recognized specialty of medical and/or surgical oncology for the simple reason that once a lawsuit is filed, the treating physician, in most jurisdictions, will be

held to the standard of care or standard of practice exercised by a reasonably prudent physician, depending upon the care that is at issue. The physician should consider the need to offer the patient a consultation or referral, depending upon the expertise of the treating physician.

It is critical, therefore, that a physician be mindful of the need to confer with cancer specialists when taking on the primary care of a cancer patient to assure that the patient receives treatment consistent with the standard of care. This is especially necessary when medical information regarding the cancer patient is evolving at such a rapid rate. There are recognized tumor boards associated with hospitals or cancer centers and teaching institutions with specialty areas in various aspects of cancer care. Physicians at these centers will not only be consulted if there is litigation, but better still they can well advise the treating physician and safeguard against a medical malpractice suit based on the allegation that the physician's care fell below the acceptable standard of practice. Consultation with a specialist may be more cost effective than defending against a lawsuit for failure to consult or refer.

A physician should also be mindful of the fact that university centers may treat cancer patients as part of a study. Such treatment will not necessarily coincide with that which is recognized and accepted as the standard of care for cancer patients outside of the study. Ultimately, the standard of care is best defined as that care exercised by the majority of reasonably prudent medical specialists treating cancer patients with the same or similar type of cancer. Generally, the standard of care will be that standard that is practiced by the reasonably prudent physician practicing nationwide for a patient in like or similar circumstances. The "locality rule" in determining standard of care has been abandoned. This is particularly true in areas of medical specialty such as cancer; a physician's care will not be compared just with other physicians in the immediate community. The failure to diagnose cancer or a delay in the diagnosis of cancer can be devastating to a patient and the family. It may result in a patient having to undergo more extensive treatment, reduce his chances of survival, lead to earlier or unnecessary death, and cause physical and emotional burdens that more timely diagnosis could have avoided. Liability may be based on a physician's own negligent action or inaction, or both.[3]

Medical History

As has been noted, the medical history is an important part of the diagnostic workup of cancer. The failure to appropriately consider the history may be negligent.[4–6]

Family and racial history particularly in certain cancers is an important criteria in evaluating patients for cancer screening, as well as for obtaining the proper, indicated tests in certain symptomatic patients.

Physical Examination

Failure to perform a physical examination, performing an inadequate examination, over-reliance on a negative examination, or failure to perform a follow-up examination may contribute to suits for failure to diagnose cancer.[6] Failure to

perform an examination, particularly when there is a significant symptom found, figures prominently in many failures to diagnose cancer cases, as does failure to perform follow-up examinations.

Testing

A physician has an affirmative duty to obtain or perform appropriate tests in the diagnosis of a suspected cancer. Failure to appropriately or properly test resulting in injury is very likely to result in liability. However, ordering a test in lieu of a physical examination will not necessarily protect the physician. On the other hand, an error in the evaluation of a test which results in a serious or unnecessary operation, or an incorrect diagnosis that an inoperable malignancy exists, also virtually guarantees large damages for the plaintiff. There usually are serious physical and emotional consequences to the patient after being told incorrectly that a cancer is present. Although presumably it is better to diagnose a malignancy that does not exist than it is to fail to discover one that actually does exist, in either case the patient undoubtedly has been harmed by the error.

A physician may also be likely to be found negligent if he performs radical surgery for a suspected malignancy without ordering appropriate tests first, except in an emergency situation. If his opinion is wrong and the surgery later proves to have been unnecessary, he will undoubtedly be found negligent. In an emergency situation, misdiagnosis that leads to the conclusion that surgery is not required also may result in liability.

Various tests also may be necessary in some cases to make a proper diagnosis, including those that are invasive. Where the test carries serious inherent risk, it becomes a matter of medical judgment whether or not the patient, whose condition is best known by the physician, should be subjected to the procedure. Therefore, the more complicated and dangerous the test may be, the less likely it is that a court will find that a physician was negligent in failing to perform it. If, however, the patient's condition is serious, a physician would be much more likely to be held liable for failing to have ordered a dangerous test than if the condition was no more serious, at worst, than the test itself.

Even where a report is negative, over-reliance on that report may be negligent when clinical suspicion should be high. Mere reliance on a test performed by a consultant does not always mean negligence, however. Failure of a physician to read the test report or consultant's recommendation or communicate the report or recommendations to the patient may be negligent. Failure to repeat a test or perform additional studies when an initial test is negative may be negligent when clinical suspicion is, or should be, high that cancer may still be present. Negligence during the performance of a test that damages the patient, apart from the accuracy of the report, may impose liability.

Failure to Follow Recommended Protocols

The American Cancer Society and various professional specialty organizations have for a number of years published guidelines for physicians suggesting

schedules or protocols for early cancer detection. Although not legally binding in any way, these recommendations are wisely disseminated via the mass media and are common public knowledge.

Failure to follow these protocols is not necessarily evidence of negligent failure to diagnose cancer. In fact, many practicing physicians do not follow these protocols, either due to ignorance or because they disagree with the guidelines. However, the success of the American Cancer Society's educational program emphasizing the importance of early cancer detection may make a delay in diagnosis more difficult to defend.

Referral and Consultation

Failure of a physician to refer to another physician or specialist for a suspected cancer may also be a negligent act of omission. Generally, because of the imposing consequences of treatment, for example, if chemotherapy or radiotherapy is proposed, the patient should be offered the benefit of a consultation to assure adequate exposure to alternative modalities. This is one of the most effective ways to avoid a later allegation of undue influence or pressure. Once the offer of a consultation or second opinion is recorded in the chart, there is significantly less chance for a patient to allege he was railroaded into a particular cause of action.

Causation

Although a physician negligently acted or failed to act and has failed to fulfill the standard of care owed the patient, a successful lawsuit cannot be maintained unless the negligence caused some calculable harm to the patient.[8]

Loss of Chance

Loss of a chance caused by the negligence of another, a physician, has been recognized. The question of how to weigh diminished prospects for a plaintiff whose statistical future expectations are already severely impaired has caused many courts to re-examine the issue: should liability be imposed for negligence that merely increased the probability of an already probable negative outcome?

The majority of US jurisdictions retain the "but for" test, that is, a negligently injured patient must prove that the chance for recovery or survival was probable, was more likely than not, or was better than even. The rationale for this all-or-nothing approach is that less-than-probable losses are speculative and unfairly impose liability based on unquantified possibilities. The majority position is that what the measure "might have caused" is insufficient quantum of evidence.

Negligence

Negligence is grounded in the fundamental principles of tort law. Duty, breach of duty, and proximate causation resulting in injury and damage must be established. Specifically, there must be a person who owed a duty of care to the

decedent, who breached that duty by a negligent act or omission, and that breach caused the injury and damage without which the death would not have occurred.[9]

As to health care providers these elements are basic to malpractice. Although the relationship is created by a contract, hospitals and physicians are deemed to owe a duty of care to their patients because of superior knowledge. When the care provided falls below certain prescribed standards of care and that is the proximate cause of harm or an injury that results in damages, the practitioner is considered to be negligent.

Wrongful Death

A wrongful death is a death earlier than it would have ordinarily occurred. If negligence is the legal causation of the patient's death, then his statutory survivors or his personal estate may bring an action in "wrongful death." Its rationale is to benefit the survivors. The action is considered to be a derivative one, it cannot be brought unless the decedent would have had a cause of action had he survived. The action is thus a creature of statute, and allows the decedents survivors to maintain civil actions. Recovery includes pecuniary damages, or that amount which the decedent could reasonably have been expected to contribute if his death had not ensued, plus damages for emotional injury. Wrongful death is a common source of malpractice lawsuits after an alleged failed treatment.

Damages

In failure to diagnose cancer cases damages are meant to compensate a patient for physical pain and suffering and emotional distress due to the requirement for additional treatment, loss of life, or loss of chance of survival due to the delay in diagnosis and treatment. Monetary damages also may be awarded to the patient's family for harm done to them.

Delay in diagnosis and treatment of cancer, however, are generally not compensable if the delay did not materially affect the ultimate treatment and outcome of the disease. A long delay in the diagnosis of a uniformly fatal type of cancer or a very short delay in a potentially curable cancer may more likely result in a judgment against a physician, especially if the patient presents with a later stage of that cancer at the time of the delayed diagnosis and treatment.

Loss of Consortium

Consortium is that conjugal fellowship of husband and wife, and the right of each to the company, cooperation, affection, and aid of the other in every conjugal relation. Traditionally, only husbands were entitled to recover for the loss of their wives' services. Damages for loss of consortium are now being awarded to wives, female partners, parents, and children. This development is due to the legal recognition of the fact that all family members suffer emotional injury when one is injured. Similarly, the law now recognizes that children have

a compensable consortium damage when parents are injured or lost. Until recently, parents were not compensated for grief because the law did not recognize that the loss of consortium was more than merely a loss of services. Rather, it includes the loss of companionship, security, society, aid, comfort, love, affection, solace, and guidance. It is no more difficult to determine the worth of the loss of such intangibles than it is to determine damages in general.

Contributory and Comparative Negligence

Contributory negligence is conduct on the part of the patient that is a contributory cause to his or her own injuries, that falls below the standard one owes oneself to avoid one's own injury at the hands of another. At common law, a plaintiff patient's contributory negligence was an absolute and complete bar to any recovery for the negligence of the patient as compared with the negligence of the physician.

Because contributory negligence acts as a complete bar to a plaintiff patient's recovery, causing many harsh results, the majority of states by statute or judicially have adopted the doctrine of comparative negligence.

Under comparative negligence, malpractise recovery places the economic loss on the parties in proportion to their fault. In pure comparative negligence states the plaintiff can recover a percentage of his damages where his own negligence exceeds that of the defendant.

Informed Consent

The law in all states requires a physician to obtain the consent of a patient before rendering treatment. In the absence of that consent, the physician may be held liable for battery, assault, and professional negligence. This concept is discussed separately in another chapter (Chapter 10). When the question is raised as to whether or not the consent was an informed one, it is as to whether or not that adult person understood to what it was he or she was consenting to.[12] There are times when an informed consent need not be obtained:

1. An emergency situation
2. Physician exercises "therapeutic professional discretion"
3. Patient rejects disclosure and wants to remain ignorant
4. Patient has already had a similar medical experience

Unorthodox Cancer Treatments

Cancer victims, particularly those who are terminally ill, are vulnerable to exploitation because of their predicament. Desperate for any glimmer of hope, they are easy prey for charlatans and the insatiably greedy intent on financial gain. Traditionally, the law has protected those unable to protect themselves, most frequently applied to juveniles and the mentally ill, on the basis of parens patriae.

However, the state's interest in protecting its citizen must be balanced against an individual's right to have control over his body and to make decisions regarding their medical care. Most cancer patients are adults in full control of their mental faculties, which distinguishes them from other citizens the state seeks to protect under the parens patriae rationale.

It is this basic conflict between the state's interest in the health and welfare of its citizen and the right of the individual to make decisions affecting his health that has confronted legislatures and courts attempting to deal with the problem of unorthodox cancer treatments.

This conflict has not been resolved uniformly; considerable variation presently exists among the various states with regard to regulation of unorthodox cancer treatment. Interestingly, where there has been legislative action, most legislatures have granted the individual a measure of freedom in selecting cancer treatment that is unproven. In most states that have acted legislatively, this freedom is not unlimited. When courts have considered the subject of unorthodox cancer treatment, they have focused more on the state's right to regulate the lives of its citizens under the police power.

Many of the states that require a licensed physician's prescription of the unorthodox treatment also require that the patient first sign a consent form indicating that the physician has explained that the treatment has not been proved to be effective in the treatment of cancer, has not been approved by the Food and Drug Administration for the treatment of cancer, that alternative therapies exist, and that the patient requests treatment with that medication.

Several states have attempted to maintain a precarious balance between its police power and individual rights by reserving the right to prohibit unconventional cancer treatment when it is found to be harmful as prescribed or administered in a formal hearing before the appropriate state board.

The most sweeping exercise of police power has been enacted in California, where it is a crime to sell, deliver, prescribe, or administer any drug or device to be used in the diagnosis, treatment, alleviation, or cure of cancer that has not been approved by the designated federal agency or by the state board. The statute has been upheld by the California Supreme Court against a constitutional challenge based upon the right of privacy.

It appears that a competent cancer patient, or the next of kin for an incompetent patient, may decide to receive unorthodox treatment. His only legal protection is that he be given all the information, and if he does not, he can sue for lack of informed consent.

The balance weighs heavily in favor of allowing cancer patients to obtain the treatment of their choice. The state's interest in protecting the health of its citizens can be adequately protected in this context by requiring an informed consent by the patient following disclosure of the nature of the proposed treatment.

Worker's Compensation

Under our law an employee who is injured, that is, develops lung cancer while at work, has only one recourse to seek redress; he must go through the state's

workers' compensation process. His next of kin, however, may have an independent cause of action against the employer.[13,14]

An employee, who is injured on the job by the negligence of an independent contractor, may have a cause of action against that peripheral tortfeasor.[15]

Environmental Aspects

Certainly the effect of pollutants as causative factors of disease processes, such as lung cancer, is a medicolegal problem. The victim may seek legal redress from the polluter.

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22

Brain Death and the Law

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I have a rendezvous with death at some disputed barricade.
Alan Seeger

When the poet penned those words over 70 years ago little could he imagine that the definition of death itself would be at some "disputed boundary" today.

In recent years, the two most natural human experiences of birth and death have become problematic. Not long ago, it was accepted that when a severely handicapped infant was born, or when death approached the elderly, nature took its course. Today we can engineer changes in life; we can sustain life that, hitherto, could not be sustained. Even the definition of death is in dispute. Merely possessing the ability to do something, be it genetic engineering or organ transplants, does not, of course, require us to do it. But having the ability requires us to choose.

Death is as old as history, but scientific definition of the exact moment of death is, of course, subject to the precision and accuracy of our scientific tools and accumulation of our knowledge.

The commonlaw definition of death generally was defined as cessation of life, ceasing to exist, total stoppage of circulation, or cessation of vital functions such as respiration.[1]

It later became apparent that such a definition did not fulfill the needs of modern society. As one expert observed:

> Indeed it is clear that a person is not dead unless his brain is dead. The time honored criteria of stoppage of the heartbeat and circulation are indicative of death only when they persist long enough for the brain to die.[2]

In 1968 an ad hoc committee of the Harvard Medical School developed a new definition of brain death based upon:

1. unreceptivity and unresponsiveness to external stimuli
2. no spontaneous breathing or movement
3. no reflexes
4. a flat electroencephalogram (EEG) reconfirmed within 24 hours

Historically, the definition of death has been debated in scientific literature.[3] Although the old classic definition of cessation of cardiac and respiratory functions is still valid in instances where death occurs in an environment where

life support systems are not available, it is quite a different story if death occurs in an institution. Most often Americans can expect to go through the tortures of the damned before they are allowed to die of cancer, heart or lung failure, or pure senile decay. Not so many years ago a diagnosis of terminal illness was followed within a relatively short period by the patient's death. Now, however, an average of 30 months passes between the time of diagnosis and the time of death. Furthermore, 80% of patient deaths now occur in hospitals or chronic care facilities rather than at home, and during the final year of life an average of 80 days of hospitalization has been documented.[4]

Dying then is no longer a private event involving the patient, family, a few friends, and the physician. It has become a process with tremendous socio-economic, mediocolegal, religious, and ethical overtones. The problems do not go away, cannot be ignored, and must be faced by all individuals who are involved. Several authors have suggested that brain death be used as an additional criterion of death. However, there are those who disagree with the concept of brain death on moral and scientific grounds.[5–8]

Since 1970 the majority of states have enacted legislation based on either the American Bar Association's proposed definition of death or the Capron-Kass models.[9,10] Although the wording differs to some extent, as does the interpretation from one state to another, the following is more or less representative:

> A person will be considered dead if in the opinion of a physician, based on ordinary standards of approved medical practice, the person has experienced an irreversible cessation of spontaneous respiratory and circulatory function. In the event that artificial means of support preclude a determination that these functions have ceased, a person will be considered dead if in the announced opinion of a physician, based upon ordinary standards of approved medical practice, the person has experienced an irreversible cessation of brain function. Death will have occurred at the time when the relevant functions ceased. In any case, when organs are to be used in a transplant, an additional physician, not a member of the transplant team, must make the pronouncement of death.

Many reasons can be cited which led to the enactment of such legislation, including a desire to reduce the cost of care of hopeless cases, the need to free intensive care beds for other patients with a reasonable chance of survival, and the maintenance of the supply of transplant organs. Although such legislation has been generally regarded as enlightened, objections have been raised. The problem, according to Byrne et al[11] is the equating of loss of brain function with the death of the brain in the person. They suggest that this approach of legislating death is misguided.

Brain death has often been seen as a radical departure from our traditional idea of death, and in addition has been held to be highly suspect since its adoption is believed to have been motivated in part by the desire to get healthy organs for use in transplantation. It is reasonable, however, to view brain death as a conservative revision necessitated by our modern medical technology.

The reason why heart and lung function became the legal and social standard to determine the time of death, we might argue, is that when one either stopped

breathing or suffered cardiac arrest, irreversible loss of total brain function invariably followed within minutes. Today, however, mechanical devices have made it possible to artificially maintain heart and lung function, even in the presence of brain death. If we have other tools (Table 22.1), such as the Harvard criteria, to tell us what is actually going on with the brain, we should rely on those, and not the artificially maintained heart and lungs, to determine death.

This argument assumes that heart and lung function are important, not for themselves but as signs of brain activity. And this assumption seems quite plausible. When surgeons stop the heartbeat for an hour or more during open-heart surgery, and a bypass pump is used to prevent any brain damage, we do not normally say that the person has died and then been reborn, unless we are speaking metaphorically.

TABLE 22.1. Summary of sets of criteria used by different investigations and clinicians.

Harvard criteria[33]	1. Unresponsive coma
	2. Apnea
	3. Absence of cephalic reflexes
	4. Absence of spinal reflexes
	5. Isoelectric EEG
	6. Persistence of conditions for at least 24 hrs
	7. Absence of drug intoxication or hypothermia
Minnesota criteria[34]	1. Basic prerequisite—diagnosis of irreparable cerebral lesion
	2. No spontaneous movements
	3. No spontaneous respiration
	4. Absence of brainstem reflexes
	5. Persistence of condition unchanged for 12 hrs
Japanese criteria[35]	1. Basic prerequisite—diagnosis of primary cerebral lesion
	2. Deep coma
	3. Respiratory arrest
	4. Bilateral dilated pupils and absent pupillary and corneal reflexes
	5. Flat EEG
	6. Abrubt fall in blood pressure of 40 mm Hg with hypotension
	7. Persistence of condition for at least 6 hrs
Swedish criteria[36]	1. Unresponsive coma
	2. Apnea
	3. Absent brainstem reflexes
	4. Isoelectric EEG
	5. Nonfilling of cerebral vessels on two aortacranial injections of contrast media 25 min apart
Cerebral survival criteria[37,38]	1. Basic prerequisite—completion of all appropriate diagnostic and therapeutic procedures
	2. Unresponsive coma
	3. Apnea
	4. Absent cephalic reflexes with dilated, fixed pupils
	5. Isoelectric EEG
	6. Persistence of the above for 30 min to 1 hr, and 6 hrs after onset of coma and apnea
	7. Confirmatory test indicating absence of cerebral circulation

To understand brain death correctly, however, we have to sort out its empirical and ethical elements. Whether irreversible loss of spontaneous brain function has occurred when the Harvard criteria are present is an empirical question. But whether irreversible loss of spontaneous brain function is to be equated with death is an ethical question.

In 1970 Kansas became the first state to adopt a statutory definition of brain death.[12] Thereafter, a Uniform Brain Death Act was passed that defined brain death as an irreversible cessation of all functioning of the brain including the brainstem, such determination to be made in accordance with medical standards.

Before statutory recognition, the medical community came to a critically unanimous consensus that when the whole brain no longer functions an individual is dead.

Twenty-nine states have enacted statutes that define death incorporting some aspect of brain death. They can be categorized as follows:

1. Statutes defining death as total brain death (Arkansas, Montana, Nevada, North Carolina, Oklahoma, West Virginia, and Wyoming).
2. Statutes defining death as either total brain death or cardiopulmonary death.[13]
3. Statutes defining death as brain death if traditional means of death cannot be determined because of life supports (Alabama, Alaska, Florida, Hawaii, Iowa, Louisiana, Michigan, and Texas).

Thirty-four states have either legislatively or judicially recognized brain death. Several other states recognize brain death for anatomic gift acts.[14]

In *Loyola v. Haymer*[15] the Illinois Court sanctioned the definition of brain death when Loyola University sought a declaratory judgment to declare a 7-month-old child dead to permit withdrawal of life support.

The court cited the acceptance of brain death in many states judicially or statutorily as well and the fact that under Illinois Anatomical Gift Act, death was defined as irreversible cessation of total brain function.[16]

In *Lovato v. District court,*[17] it was held that an individual is dead when he sustains irreversible cessation of all functioning of the total brain:

> We recognize the authority of, and indeed encourage the General Assembly to pronounce statutorily the standards by which death is to be determined in Colorado. We do not however believe that in the absence of legislative action we are precluded from forcing and resolving the legal issue of whether irretrievable loss of brain function can be used as a means of detecting the condition of death. Under the circumstances of this case we are not only entitled to resolve the question but have a duty to do so. To act otherwise would be to close our eyes to the scientific and medical advances made in the past 2 or 3 decades.[18]

Other decisions judicially recognizing brain death include the following: *State v. Fierro;*[19] *Snafford v. State,*[20] *State v. Meints;*[21] and *New York City Health and Hospitals v. Subena* (1975).[22] Although state laws are not uniform regarding brain death, generally speaking, the country has accepted brain death as an adequate criteria for death.

Life support systems are now routinely shut off when individuals are brain dead and virtually no court that has adjudicated the issue has ever rejected the concept of brain death. It is now generally accepted that any extraordinary life support measures may be terminated when an individual is declared brain dead. This appears to be the criteria in almost all of the states.

In 1980 the Uniform Determination of Death Act,[23] superceded the previous act. This is a model statute which was approved by the National Conference of Commissioners on Uniform State Laws and has been endorsed by many organizations. The statute defines death as:

> Where an individual has sustained either irreversible cessation of circulation and respiratory function or irreversible cessaton of all function of the entire brain, including the brain stem a determination of death must be made in accordance with accepted medical standards.

Nevertheless, despite the nearly universal acceptance of brain death, its application has caused controversy in the prosecution of criminal cases, organ transplantation situations, and the termination of life support.

In *Dority v. Superior Court of Bernadino County,*[24] the court was called upon to determine the propriety of judicial intervention regarding the termination of life support in the bodily functions of a brain dead minor. After observation of a seizure disorder, a 19-day-old infant was admitted to the emergency room of a local hospital and transferred to the Loma Linda University Medical Center. The physician upon examination found that the baby had increased intracranial pressure and placed him on a respirator. After 1 week the child failed to respond to any stimulation. Physicians ordered an EEG and a cerebral blood flow determination. The results of this test showed that there was very little electrical activity in the brain, if any. The physicians concluded that the child was brain dead. The hospital defined brain death as total and irreversible cessation of brain function, although there was no written policy of how that diagnosis was to be made.

As a result of the diagnosis, the physicians recommended the removal of the life support device. In prior situations the hospital had deferred to the desires of the parents concerning the life support even in the presence of brain death to ensure emotional well-being. The parents, however, chose to withhold consent to the withdrawal of the child's support. The parents were charged with child abuse and a guardian was appointed for the child. The guardian gave the consent to the health care providers to withdraw the life support system being used to maintain the respiration of the child. The parents petitioned the court for a writ of prohibition against removing the life support device. Before this case was decided, the life support system was removed and the infant died. However, because of the importance of this issue, the court agreed to determine the ultimate issue, stating:

> The novel medical, legal, and ethical issues presented in this case are no doubt capable of repetition and, therefore, should not be ignored by relying on the Mootness Doctrine. This requires us to set forth a framework in which medical and legal professions can deal with similar situations.

The court found that often the prolongation of biologic existence brought about by life support devices only prolong suffering, adding economical and emotional burdens to everyone. They did recognize that the termination of such life support, however, also could cause emotional damage.

The Dority court specifically found that the medical profession did not need to go into court every time it declared an individual brain dead when the diagnostic test results were irrefutable. The court pointed out that this did not mean that parents or guardians could not request an additional medical opinion. It simply failed to mandate that physicians must be at the mercy of the court when making determinations of brain death.

In evaluating this case further, the court found that once brain death has been determined by medical diagnosis under statutory provisions effective in California, no criminal or civil liability could result from disconnecting life support devices.[25] Furthermore, the court found that no judicial intervention is necessary where both health care provider and the party representing the person allegedly declared to be brain dead agreed that brain death has occurred. The court's jurisdiction should only be invoked where it is alleged that an error has been made in the diagnosis of brain death. The court did endorse, however, participation of the parents or guardians when reaching the decision as to the termination of life support and in fact, commended the policy of the Loma Linda Medical Center, which granted the parents' wishes not to terminate life support until the initial shock of the diagnosis of the infant's brain death had passed. The Court thus articulated the principle that health care providers generally have an absolute right to terminate life support from brain dead individuals without the need for any judicial intervention and without fear of any liability.

The Definition of Brain Death in Criminal Law

The courts have generally found in homicide cases that even in the absence of the statutory definition of death, a conviction will be upheld where a victim died after life support systems were terminated. These decisions generally have been upheld on the basis of the judicial recognition of brain death or an analysis under traditional causation doctrine.

In *Arizona v. Fierro,*[26] the Arizona Supreme Court traditionally recognized brain death. At that time Arizona did not have a statute defining death. The defendant in this criminal appeal of a murder conviction argued that the termination of life support 3 days after brain death diagnosis was the actual cause of the victim's death.

The court found that under the common law definition of death, the victim would not have been officially dead before life support termination as he was breathing and his blood was circulating.

However, under the Harvard criteria the victim would have been dead before the life support systems were withdrawn. The court recognized the test proposed by the Harvard committee to be a valid one and relying on *New York City Health and Hospital Corporation v. Sulsona,*[27] stated that:

The victim had suffered irreversible brain death before life supports have been withdrawn. In fact, the doctors were just passively stepping aside to let the natural cause of events lead from brain death to common law death. In either case the victim was legally dead for the purposes of the statute.

In *United States v. Gomez*[28] the court affirmed a premeditated murder conviction under the brain death standard. In this case a soldier had bludgeoned his victim into a comatose state. The defendant argued that the doctor had erroneously applied a brain death standard of death and a removal of the patient's life support killed the victim, not the initial action by the defendant. No prior cases had defined when death occurred and Hawaii's brain death statute was not controlling under federal military law.

The court adopted the definition of the Uniform Determination of Death Act, and decided that in a military homicide case an individual was dead when he sustained either irreversible cessation of circulatory and respiratory function of irreversible cessation of total brain function. Such determination was to be made in accordance with acceptable medical standards.

An example of how the traditional causation analysis was invoked to uphold a murder conviction was illustrated in *State v. Inger*.[29] In that case, the victim's condition had deteriorated after a beating by the defendant. A test performed by the attending physician disclosed no brain activity and the life support system was disconnected. The court refused to rule whether there had been compliance with the brain death statute effective in Iowa at the time. Rather than address that issue, the court stated that the trauma inflicted was still the proximate cause of death and that the removal of life support did not act as a superseding cause. Similar holdings have been held in other cases.[30]

It therefore appears that the courts will use available brain death criteria, where warranted to uphold homicide convictions. The defense that the removal of the life support system constitutes an intervening act has apparently been dealt a fatal blow.

Some ethical ramifications of revising criteria for death are illustrated in the following hypothetical case adapted from Brody.[31]

The year is 1988; Michigan's brain death statute has been in effect for 15 years, and a law to allow mercy killing in terminally ill patients at their request or at the request of the next of kin was passed by the legislature last session. None of this is of much help to you as you try to figure out what to do with Mr. L. Mr. L. has been in a coma and maintained on a respirator for 26 days, ever since the auto crash in which his wife was killed. For 3 weeks you still had some hope that the 58-year-old patient might be brought back to consciousness; now you have pretty much given up, but the state of his reflexes and movements are too equivocal to allow you to pronounce him dead by the Harvard criteria. You have told Mr. L.'s two grown children that it seems as if there is nothing to be gained; and if no dramatic change for the better occurs within 24 to 48 hours, you will disconnect the respirator.

This morning you have a visitor—a lawyer for the Great Atlantic and Pacific Life Insurance Company. He tells you that Mr. L. is protected by a six-figure

insurance policy that pays double indemnity in cases of accidental death. However, to qualify under that clause of the policy, the death must take place within 30 days of the accident.

The lawyer says that his company has developed a fear that you are plotting in concert with Mr. L.'s children to turn off the respirator inside the magic 30-day limit, "despite the fact that he is obviously still alive." To guard itself against this course, the company has authorized the lawyer to inform you that you will be sued for the amount of the insurance policy should the respirator be turned off, in the absence of clear signs of death, within the 30-day period.

No sooner has this gentleman left than you are visited by the attorney newly retained by Mr. L.'s children. He reminds you that proper regard for the best interests of your patient's family would require that the respirator be turned off immediately, "since he is obviously already dead. Anyway, he should have a right to death with dignity, without all sorts of tubes stuck in him." In case you need encouragement to consider these interests more closely, the lawyer notes that should you cause the family to lose the double indemnity sum, they plan to sue you for that amount.

Conclusion

Brody does not offer an answer to this rather fanciful case. It is included to remind us that defining and pronouncing death are in no sense isolated medical functions. Death triggers important legal consequencs. A determination of death ends marriage and business partnerships; it begins the process of disposing of a deceased's property, and may signal the obligation of a life insurance company to pay death benefits or a hospital's right to remove the deceased's organs for transplantation. Given the significance of death as a condition precedent to a wide array of legal rights and results, one would think it desirable for law and medicine to formulate a precise conception of when death occurs and what the term "death" means.[32] No medical approach to death can be viewed apart from its impact on these other social and legal considerations; a new concept such as brain death must be judged for its impact on the entire social structure, not just on narrow medical grounds. All indications are that brain death will meet these tests well, so that we are justified in adopting it.

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Withholding and Withdrawing Life Support

Medical Aspects

THOMAS A. RAFFIN, MD

Introduction

Intensive care units have become a routine part of modern American medicine during the past 3 decades. Presently, it is estimated there are more than 60,000 intensive care unit (ICU) beds in America, and these beds account for approximately 35 billion dollars in health care costs per year. Because of the widespread availability of mechanical ventilators, dialysis machines, and cardiovascular support technique extraordinary life support is commonplace. Furthermore, the lay public is quite aware of the struggle for life and death which takes places in intensive care units. Along with the development of life support techniques have come the perplexing ethical issues dealing with whether or not to withhold or withdraw life support. Many patient cases have been adjudicated in courts of law and thus there is now a significant body of law that deals with withholding and withdrawing life support. This chapter addresses the medicolegal aspects of withholding and withdrawing life support. Initially, we review recent legal trends and precedents involving life support. Following this we suggest general and specific principles to promote effective decision making. Finally, we use these principles to examine four common clinical situations dealing with life support: initiating basic life support, initiating advanced life support, withdrawing advanced life support, and withdrawing basic life support.

Legal Precedents

It is critical to establish the following ethical and legal underlying principle in the practice of medicine: it is the right of competent adults to consent to or refuse medical treatment based on full information. This is defined as informed consent and its precedent can be dated back to 1872.[1] Competent adult patients with incurable but not immediately terminal illnesses can refuse treatment over the objection of physicians and hospitals. This was affirmed by the California Court of Appeal's of 1984 decision in *Bartling v. Superior Court*.[2] In 1986, the

decision in *Bouvia v. Superior Court*[3] established the right to refuse nourishment and hydration. However, this decision like the Bartling decision were in California courts and such issues may be treated differently in other state jurisdictions.[4]

Important legal parameters for the withdrawal of life support were identified in a 1983 criminal prosecution of two physicians in *Barber v. Superior Court* in the State of California.[5] Murder charges were made against two physicians who, with the informed consent of the patients' spouse and children, withdrew intravenous nourishment and hydration from an irreversibly comatose man. The Court dismissed the charges and relied on the vital concept of proportionality as the key criterion to be used in deciding whether or not to withdraw life support. The Court stated, ". . . proportionate treatment is that which, in the view of the patient, has at least a reasonable chance of providing benefits to the patient which outweigh the burdens attendant to the treatment." The *Barber* court went on to address the central question of a definition of such terms as "benefits" and "burdens." It relied in part on the *Quinlan* decision of more than a decade ago which examined". . . the reasonable possibility of return to cognitive and sapient life as distinguished from . . . biologic vegetative existence."[6] The *Barber* court suggested that a benefit exists when a life-sustaining treatment contemplates "at very least, a remission of symptoms enabling a return toward a normal functioning, integrated existence."

In 1986 the Massachusetts case of *Brophy v. New England Sinai Hospital*[7] emphasized the outcome of proposed treatment. The Court authorized the withholding of nutrition and hydration, although they might have sustained the patient in a persisitent vegetative state. It noted that this measure was appropriate because the patient would never "regain cognitive behavior, the ability to communicate, or the capability of interacting purposefully with his environment."

The *Barber* court attempted to identify who could help make decisions for incompetent patients. In such cases, they pointed out that physicians must identify a surrogate to make a "substituted judgment" on behalf of the patient. The Court believed that it was legal and reasonable to bypass formal conservatorship proceedings. It supported the concept that the spouse and children are the most appropriate surrogates because they: "a) are in the best position to know the patient's feelings and desires regarding treatment, b) would be most affected by the treatment decision, c) are concerned for the patient's comfort and welfare, and d) have expressed an interest in the patient by visits or inquiries to the patient's physician or hospital staff."

Numerous cases are now being heard by courts in many states. As yet, no significant case over the past 3 decades has been heard by the Supreme Court of the United States. Thus, state precedents will continue to exert the most influence in their respective states.

Besides court decisions, living wills are beginning to play a more important role in assisting with decision making concerning withholding or withdrawing life support. The living will[8] is a nationally distributed document that expresses patient's wishes regarding medical care should they become incompetent to

decide. Some legislation in certain states that deals with this area also has fallen under the rubric of living will. A generic living will document that has not been passed by state legislature has no binding force in that particular state.[9] However, it still stands as a clear expression of the patient's wishes and can be helpful in decision making. At the present time, a total of 38 states have enacted Living Will or natural death act legislation.[10] The more recent California Durable Power of Attorney for Health Care,[11] which was developed in 1984, has created an effective and legally protected procedure whereby individuals can indicate whatever treatment preference they prefer and can identify an "attorney in fact" who will be able to make medical decisions if the patient becomes legally incompetent. At the present time, many state legislatures are attempting to pass even more sophisticated documents which will optimize decision making for patients who are legally incompetent and in which decisions concerning withholding and withdrawing life support become paramount.

General Ethical Principles

As vital ethical issues concerning withholding and withdrawing life support must arise, it is important to identify the general ethical principles underlying decision making. Furthermore, ethical principles underly the legal principles when withholding or withdrawing life support. A variety of texts thoroughly discuss these general ethical principles.[12] At least five principles should be identified: 1) the preservation of life; 2) the alleviation of suffering; 3) "first do no harm" (primum non nocere); 4) the autonomy of the individual patient; and 5) the concept of justice (e.g., fair allocation of medical resources).[13]

Practical Principles

After identifying general ethical principles it is important to go on to analyze four key practical principles that are used in decision making concerning withholding and withdrawing life support. First, one must establish the source of authority for decision making. All health care professionals must be constantly aware that the true source of authority resides with the patient. Patients alone, or their legal surrogates, have the right to control what happens to them. Many of the ethical dilemmas arising in critical care situations derive from overt or tacit violations of this principle.

Second, it is vital to have effective communication with patients (when possible) and families. The skill of effective communication is one of the most important attributes of the physician. This is especially true in critical care situations where patients and families are under maximal stress, are fearful, and are often intimidated. In essence, health professionals are responsible not merely for attempting to communicate, but for ensuring that effective communication takes place. Clearly, some physicians can communicate better than others. If it appears there is a problem with communication which might be due to the health care professional or the patient and family, then a proven

facilitator should be called in. Such a communication facilitator might be a social worker, chaplain (and denomination), psychotherapist, etc. Oftentimes communication in the setting of the intensive care unit is extremely difficult for physicians. There are at least three reasons for this: 1) each case is stressful and emotionally wrenching, taking a major physical and psychological toll on professionals; 2) the cumulation of many such cases exacts a more chronic price from physicians; and 3) effective communication requires quite a bit of time and usually physicians do not have time to meet on a daily basis for an extended period with patients or families. Therefore, outside facilitators can be extremely valuable on the health care team because they have the communication skills and the time to exercise them.

To optimize communication and therefore minimize legal difficulties in the intensive care unit setting one can identify a list of guidelines for effective communication which would include: 1) create an environment that fosters communication, minimize rushed, impersonal discussions in the hospital setting; 2) due to the stress of the situation attempt to keep communication simple but truthful until it is clear that more detail will be helpful rather than overwhelming; 3) encourage patients and families to ask questions and express feelings; 4) present information in the language and at the level of detail that best enables patients or surrogates to decide, it is not useful to intimidate laypersons with an esoteric vocabulary; and 5) after talking to patients and families ask them to summarize what has been said to check the accuracy of vital communications. Usually, it is remarkable how little information has been transmitted even if all involved have tried their best. All physicians should do this when dealing with the complex medicolegal issues surrounding withholding and withdrawing life support.

The third practical principle is that there should be early determination and an ongoing review of patients' decisions concerning withholding and withdrawing life support. Individual patients or their surrogates are the only ones who can make decisions concerning withholding and withdrawing life support as they are the ones who understand what the quality of life issues are. It is important for professionals to avoid making assumptions about quality of life, especially with patients of differing religious or ethnic backgrounds. It is extremely important to provide rigorous informed consent to patients or their surrogates if this type of decision making is to be effective. Candor about the level of discomfort associated with any anticipated treatment is essential, but emotional coldness or brutal abruptness should obviously be avoided. At a minimum, every significant change in the patient's condition demands re-evaluation of proportionality decisions. As is evident to any professional working in an intensive care unit, there is a critical point beyond which medical interventions may act less to prolong acceptable life than to extend a miserable dying process.[14]

The fourth practical principle has to do with the health professionals' recognition of the rights of a patient. The American Hospital Association has clearly identified the rights of patients and in many states these have been enacted into law.[15] Of interest to many health professionals, in some states

these patient rights are required by law to be posted in appropriate places within every hospital. There are five key rights: 1) the right to considerate and respectful care; 2) the right to receive information about the illness; 3) the right to receive as much information about any proposed treatment or procedure as is necessary to make an informed consent decision; 4) the right to participate actively in decisions regarding medical care; and 5) the right to have all patient's rights applied to the person who may have legal responsibility to make decisions regarding medical care on behalf of the patient.

Specific Applications to Initiating and Withdrawing Life Support

Initiating Basic Life Support Measures

Basic life support measures such as food, water, and supplementary oxygen are among the most difficult to forego in medical practice because of their emotional significance. Few of us know what it feels like to undergo cardiopulmonary resuscitation (CPR) or an organ transplant but all of us know what it is like to be hungry, thirsty, or short of breath. Health care professionals provide the basic life support measures as a reflex act. In critical illness when one might consider withholding basic life support, then a careful decision-making process should take place which includes the following points: 1) every medical intervention should be undertaken after obtaining informed consent from the patient or his surrogate; 2) it is wise to include close family members in the decision-making process as this will enlist the family on the side of the eventual treatment course, this act can minimize the possibility for conflict, 3) physicians should anticipate the eventual medical outcome and should attempt to identify in advance the specific choices the patient would wish to make; 4) once a medical intervention is initiated, its withdrawal, not to prolong a miserable dying process, is a direct action that may result in the death of the patient, even though such an action is ethically and legally appropriate it is important to realize that those who take the action are invitably left with disturbing feelings; 5) medications need to be evaluated carefully because some can prolong a miserable dying process and were not initially indicated, examples would be the use of antibiotics or steroids to treat infections or cerebral edema; 6) physicians need to clarify the purpose of placing intravenous lines, once an intravenous line is in place it becomes difficult not to treat infections and chemical imbalances, a lack of treatment might provide a humane end to a miserable situation; and 7) similar cautions apply to the placement of nasogastric feeding tubes, especially in patients who are in a chronic vegetative state.

Initiating Advanced Life Support Measures

If a patient undergoes a cardiopulmonary arrest, then the health professional must initiate cardiopulmonary resuscitation (CPR) unless it is clearly understood that the patient did not wish to have CPR performed.

During the past several years there have been a variety of new studies

concerning CPR. A 1983 study of all the resuscitations at a major center in 1 year showed that only 14% of those receiving CPR survived to leave the hospital.[16] Only 19% discussed CPR with their physicians, and in only 33% of the cases was the family consulted about resuscitation, even though more than 95% of the physicians claimed to believe that such consultations were appropriate.

Another study involving "do not resuscitate" (DNR) orders revealed that 22% of patients and 86% of families were involved in decisions not to resuscitate.[17] The families identified the attending physician as the best source of help with their decisions.

These studies help to highlight the ethical problems surrounding CPR. Because the outcome of CPR is poor particularly in the setting of chronic, severely debilitating, or terminal conditions it is important to make sure the patient desires this procedure. This relates back to the third practical principle which underscored the importance of early determination and ongoing review of patient wishes with regard to withholding and withdrawing life support. Several points should be taken into account concerning the institution of advanced life support measures: 1) CPR should be discussed in advance in hospitalized patients or ill patients who remain at home or in nursing homes, code status should officially be conveyed to patients, families, and all health care providers, prominent signs affixed to the front of medical charts or records are useful; 2) physicians should take the lead in bringing up the issue of whether or not to write a DNR order, if there is a communication problem, then a facilitator should be used; and 3) it is important to point out that CPR usually results in the admission of a patient to an intensive care unit or a cardiac care unit. This should be communicated to the patient or the patient's surrogate. Certain subpopulations of patients have a very high mortality rate cared for in the intensive care unit. For example, patients with hematologic malignancies who are admitted to intensive care units have an average survival rate of 10% to 20%.[18] Special precautions should be used in decisions to either intubate or resuscitate such subgroups.

Withdrawing Advanced Life Support

One of the most difficult decisions to confront health care professionals is that to withdraw advanced life support. If the physician has already established effective communication with the patient or the patient's surrogate, then these issues would already have been discussed when discussing potential DNR orders. However, it is unusual for guidelines concerning the withdrawal of life support to have been clearly defined by patients or surrogates. Several points can be of assistance when considering the withdrawal of advanced life support. It is important to identify the medical benefit from further treatment in patients on life support. Studies such as APACHE (Acute Physiological Assessment and Chronic Health Evaluation) II provide valuable prognostic guidelines.[19] It is important to make sure the patient is legally competent. The majority of patients who have been in intensive care units for several days and are on

mechanical ventilation are not legally competent. If the question of legal competence cannot be decided then a psychiatric consultation should be sought. Seek unanimity among health care team members. Severe problems can arise if any one professional or group of professionals feel excluded from the decision-making process. It is a fact that nurses provide the real intensive care and often have information about patients and families that is available only to those who have spent hours at the bedside. There is no excuse for not attempting to obtain a patient's judgment even though the patient might be on mechanical ventilation. Some patients on mechanical ventilation are clearly legally competent. The physican or health care team, when the patient is legally incompetent, should work with the family or legal surrogate, toward a unanimous decision regarding the withdrawal of life support. If communication is a problem then a facilitator should be called in. Earlier would be much better than later. If there is not agreement on the withdrawal of life support then attempt to establish time-limited goals based on clinical judgment and information such as APACHE II data. An effective way of telling patients or families that you believe life support should be withdrawn is to state, "It is my best judgment, along with the other doctors and nurses, that your relative has essentially no chance to regain a reasonable quality of life. We believe that life support should be withdrawn, which means that your relative will probably die." There are two important components to this statement. First, the statement is realistically qualified or hedged, which implies that the decision must be shared. Second, it is made clear that death is the probable result of the recommended course. Without this knowledge, there has been no true informed consent, and potential liability (both emotional and legal) is enhanced. Grief-stricken or guilty family members may attempt to relieve their distress at the patient's expense by advocating disproportionate treatment. Such problems are usually eliminated once the underlying feelings are acknowledged and understood. If a health care professional is involved with a case that he believes is inconsistent with their ethical principles, then should attempt to be transferred to another case. If such involvement cannot be avoided, frequent discussion of one's feelings with understanding colleagues will make optimal care more likely. If patients are legally incompetent and there is no clear understanding of what the patient would have wanted, then the health care team and the family or friends must explore the quality of life values previously held by the patient. Once a family or friends have agreed that a patient would not have wanted to go on, consent to stop usually follows. If no one knows the patient well enough to provide information about his or her quality of life values, professionals can establish a group composed of physicians, nurses, family or friends, and two patient advocates (at least one of whom is a representative of organized religion, preferably that of the patient). This group identifies what they believe to be the most thoughtful "substituted judgment." Decisions in most cases should be made by family, friends, health care providers, and facilitators. Only rarely is legal assistance necessary.

Withdrawal of Basic Life Support

The withdrawal of basic life support is a topic of much current interest and is ethically controversial and complex. The usual mode of withdrawal of basis life support is to discontinue hydration or nutrition by intravenous lines or feeding tubes. No one feels comfortable that a loved one might "die of thirst" or "starve to death." Regardless, in many states, nutrition and hydration are considered no different from any other medical treatments for purpose of informed consent. At least three states (California, New Jersey, and New York) at the writing of this chapter support the withdrawal of hydration and feeding for patients in chronic vegetative states. However, numerous cases are being adjudicated and judicial support will probably expand for withdrawal of these treatments when they are not clearly benefitting patients.

It is vital to have a clear understanding of the patient's interests when considering withdrawing basic life support. One must have truly informed consent and through this most painful ambiguities can be avoided. It is helpful to detail in writing the patient's wishes regarding the withdrawal of basic life support. Families need assurance that comfort and caring will be maintained and that doctors will not abandon them.

Conclusions

Withholding and withdrawing life support have become daily events in most of the hospitals and intensive care units throughout the country. These are legal and ethical dilemmas about which the laypublic are becoming quite well informed and which challenge the practitioners of modern day medicine. There are a variety of legal precedents that have developed and are evolving. They help guide us in decision making to withhold and withdraw life support. Furthermore, fundamental ethical principles help to support these legal decisions. Most medico-legal problems surrounding withholding and withdrawing life support can be avoided with careful attention to the following points: 1) understanding that authority regarding medical care rests with patients or their legal surrogates; 2) support patient rights, especially to informed consent; 3) emphasize effective communication; 4) if communication is not optimal then rapidly obtain a proven facilitator (chaplain, social worker, etc.); 5) decision making concerning withholding and withdrawing life support should be performed early in each treatment course or with each change in clinical status; and 6) once an intervention is initiated its withdrawal can be quite problematic. However, in many settings life support should be thoughtfully withdrawn.

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Legal Aspects

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Landmark Decisions

The heart-wrenching problems inherent in the withdrawal of life support systems have frequently caused families, institutions and conservators of patients to resort to judicial fiat for resolution.

To begin with, we must recognize the commonlaw right of a patient to decline medical treatment no matter what the consequences may be. The individual's right to decline life-sustaining treatment must, however, under certain circumstances, yield to the limitations imposed by the state upon the exercise of a person's right to refuse treatment.

Incompetent Persons

The extension of the right to refuse life-sustaining treatment to incompetent patients, however, is more complex.[1]

In one of the early landmark cases, the parents of Karen Ann Quinlan petitioned the New Jersey Superior Court to remove the respirator from their 21-year-old daughter who was in a chronic vegetative state and could not breathe spontaneously. In its decision, the court ordered the discontinuance of

the respirator and extended the right to refuse medical treatment to incompetent patients based upon the patient's constitutional right of privacy. Karen Ann continued to be fed by artificial means and died several years later.[2]

In the Eichner case,[3] Brother Fox, an 83-year-old clergyman, was sustained on a respirator. He had lapsed into a coma during a hernia operation and, as a result of cardiac arrest with loss of oxygen to the brain, sustained substantial brain damage. He was in a chronic vegetative state with no reasonable chance of recovery. The head of his religious order, Father Eichner, applied to be appointed Brother Fox's committee to obtain an order to disconnect the respirator. There was testimony during the hearings that Brother Fox personally had expressed a desire not to have his life prolonged by life-sustaining procedures if his condition were hopeless.

The New York State Court of Appeals held that an incompetent person has the right to terminate life-sustaining medical treatment, for example, a respirator, where it is established by clear and convincing proof that when competent, he expressed a desire to invoke that right and where there are no countervailing compelling state interests present.

The court held that the desire of Brother Fox to die with dignity outweighed the state's interest in the preservation of life, reasoning that "the patient in a permanent vegetative coma has no hope of recovery and merely lies trapped in a technological limbo awaiting the inevitable." Accordingly, the court ordered the mechanical respirator to be disconnected. The withdrawal of feeding tubes, however, was not addressed by the court at this time.

The Appellate Division of the New York State Supreme Court recently decided the *DeLio* case which involved the withdrawal of basic life support (nutrition and hydration).[4] Daniel DeLio, a married 33-year-old exercise physiologist, existed in a chronic vegetative state with no cognitive awareness and no hope for improvement as a result of complications from a routine surgicial procedure. DeLio had been diagnosed as neocortically dead. He breathed spontaneously without the need of a respirator. He could not chew food or swallow. Nutrition and hydration were provided by gastrostomy and jejunostomy tubes.

DeLio's wife applied for an order, as his conservator, to discontinue all medical treatment, including removal of the tubes. The medical center where DeLio was hospitalized opposed the application on the ground that withdrawal of the feeding tubes would constitute a deliberate act, causing his death contrary to its mission to preserve life.

After extensive hearings, a Supreme Court Justice found the evidence to be clear and convincing that DeLio, while competent, had expressed his desire not to have his life sustained by artificial means if he were in a chronic vegetative state with no hope for recovery. Nevertheless, Justice Cerrato denied the application stating:

> Placing a judicial imprimatur on a decision to terminate the care in this case, in the absence of clear legislative or judicial guidance is fraught with danger.[5]

Justice Cerrato concluded in a thoughtful opinion that, "judicial activism in cases such as this could only involve the courts in a yet unsanctioned broad scale policy of euthanasia." Nevertheless, in a unanimous reversal, the New York Appellate Division authorized DeLio's conservator to act in accordance with the clearly expressed wishes of her now incompetent husband. Medical testimony conclusively established that DeLio had no hope of recovery because of severe brain damage, but could live indefinitiely through the feeding tubes. The court stated:

> Clearly, there is no benefit to the State in prolonging DiLio's existence under circumstances he would have found demeaning and degrading to his humanity and which would serve merely to lessen the value of his life by denying him the right to choose the course of his medical treatment.

The Appellate Court wisely, to avoid the intrusion upon the physician/hospital's ethical integrity, offered an alternative to the hospital, to wit, the opportunity to transfer the patient to another institution or to his home, in the event that it could not ethically comply with the order to discontinue the life support.

Matter of Conroy

Clare Conroy, an 84-year-old nursing home patient, was severely senile. She was neither comatose nor in a chronic vegetative state. She was marginally aware of her environment. Her only relative, a nephew who was appointed her guardian, sought leave to remove a nasogastric feeding tube. The medical prognosis was that with the tube she would survive for 1 year, but would die within 1 week without it.

The New Jersey Supreme Court held that life-sustaining treatment, including nourishment and hydration by artificial means, may be withheld from an incompetent, institutionalized elderly patient with severe and permanent mental/physical impairments with a limited life expectancy. The value of this decision lies in the court's analysis of the patient's desires and her experiences of pain and pleasure rather than on the type of treatment involved.[6] The court rejected any distinction between feeding by artificial means and other forms of medical treatment, stating:

> Analytically, artificial feeding by means of a nasogastric tube or intravenous infusion can be seen as equivalent to artificial breathing by means of a respirator. Both prolong life through mechanical means when the body is no longer able to perform a vital bodily function on its own.

The Massachusetts court adopted the Conroy and Eichner rationale in the Brophy case in authorizing the discontinuance of nutrition and hydration through a gastrostomy tube to a patient in a persistent vegetative state who had previously expressed a desire not to have life prolonged by artificial means.[7]

The court would not differentiate between "extraordinary" or "ordinary" treatment. In accord are the following cases: *Bouvia v. Superior Court; Barber v. Superior Court;* and *Corbett v. D'Alessandro.*[8]

The Storar case decided by the New York State Court of Appeals involved a profoundly retarded 52-year-old man suffering from terminal cancer of the bladder.[9] He was receiving chemotherapy treatments and blood transfusions. His 77-year-old mother requested that the transfusions be stopped because her son found the procedure to be disagreeable. With the transfusions, his estimated life span was 3 to 6 months. The argument for discontinuing the transfusions was that it only prolonged the patient's suffering. However, an official at the state facility where the patient was confined sought an order to continue the transfusions to keep the patient alive. The New York State Court of Appeals held that "it is unrealistic to attempt to determine whether the patient would want to continue potentially life-prolonging treatment if he were competent and that the only realistic approach was to treat him as an infant."

The court held that the state's interests as "parens patraie" (parental protection, the role of the state as guardian of persons under legal disability) to protect the welfare of a child prohibited the courts from permitting a parent to deny a child all treatment for a condition that threatens his life.

The Storar decision hinged on the absence of any past expressions of intent concerning life-sustaining treatment and evidenced the court's unwillingness to judge the quality of the remainder of a patient's life.

In contrast to the *Storar* decision, the Supreme Court of Massachusetts, under a similar fact pattern, in an earlier case, came to an opposite conclusion.[10] Joseph Saikewicz, a 67-year-old mentally retarded patient, had been a resident of mental institutions for 54 years. In 1976, he was diagnosed as suffering from leukemia. He could not communicate verbally; he could not respond intelligibly as to whether or not he was experiencing pain.

The superintendent of the facility where Saikewicz was confined petitioned the court for the appointment of a guardian ad litem for Saikewicz with authority to make the necessary decisions concerning his care and treatment. The petition alleged that Saikewicz was in urgent need of medical treatment and was incapable of giving informed consent. Chemotherapy was medically recommended to treat Saikewicz's condition.

An important facet of the chemotherapy process was the problem of serious adverse side effects caused by the treating drugs, such as, severe nausea, bladder irritation, numbness and tingling of the extremities, and loss of hair. The probate judge who heard testimony concluded that the following considerations weighed against administering chemotherapy to Saikewicz: 1) his age; 2) his inability to cooperate with the treatment; 3) probable adverse side effects of treatment; 4) low chance of producing remission; 5) the certainty that treatment would cause immediate suffering; and 6) the quality of life possible for him even if the treatment did bring about remission.

The Supreme Court of Massachusetts affirmed the determination not to provide chemotherapy to Saikewicz. The court, to a great degree, relied upon the patient's unwritten, constitutional right of privacy found in the penumbra of specific guarantees of the Bill of Rights. "This guarantee encompasses the right of a patient to preserve his right to privacy against unwanted infringements of bodily integrity in appropriate circumstances. The recognition of that right

must extend to the case of an incompetent, as well as a competent patient, because the value of human dignity extends to both."

Despite numerous state court decisions, no significant case during the past 3 decades has yet been heard by the Supreme Court of the United States. Thus, state precedents will continue to exert the most influence in their respective states.

Decisional law confirms that desires of the young generally healthy person to refuse treatment are entitled to the same protection as those of an elderly terminally ill individual.[11]

States' Interests

The common law right to refuse medical treatment is not absolute and may yield to a compelling state interest. There are four identified compelling state interests in medical treatment decisions:

1. Preservation of life
2. Prevention of suicide
3. Protection of innocent third parties
4. The maintenance of ethical integrity of the medical profession

The most significant state interest appears to be the preservation of life. Courts have stated, in balancing the state's interests against the individual's right not to be kept alive in a chronic vegetatie state,

> The state's interest . . . weakens and the individual's right to privacy grows as the degree of bodily invasion increases and the prognosis dims.[12]

Proposed Right-to-Die Legislation

The pendulum on the right-to-die issue which is synonymous with the withdrawal or withholding of life support systems has taken a dramatic swing in California. A voter-initiated referendum that would give terminally will patients the right to choose a time to die is being proposed for the California ballot next year. This measure would change state law to allow doctors to accede to the request of an incurably ill patient to administer a lethal dose of drugs. Two qualified medical opinions would be required, certifying that the patient involved was likely to die within 6 months. This proposal is one more example of how the debate over the right to die has spread from the secrecy of hospital rooms to the public domain.[13]

Even many people in the right-to-die movement who support a patient's absolute right to determine what medical attention he can receive or refuse, cringe at the thought of actively causing a death.

While some states have formally released medical personnel from legal liability for allowing a terminally ill patient to die, in the United States the doctor who actively helps a terminally ill patient to die risks prosecution for murder or assisting a suicide, a felony.

Conclusion

The sequential chronology of the right to die appears to have progressed and to be progressing from the following evolutionary stages:

1. The right of every patient to refuse medical treatment.
2. The right of a competent terminally ill patient to refuse extraordinary life support systems.
3. The right of a competent terminally ill patient to refuse ordinary life support systems.
4. The right of an incompetent patient to have life support systems withdrawn where there is a clear and convincing proof that when competent the patient had expressed a rejection of life support assistance.
5. The right of an incompetent patient through a surrogate to reject both extraordinary and ordinary life support systems to continue life.
6. The overriding compelling state interest as "parens patriae" to continue the use of support systems to incompetent persons under certain circumstances.
7. The escalating drastic trend of legislative enactment that would authorize and legalize euthanasia to competent terminally ill patients to choose the time to die.

In some instances, because of the importance of the questions raised, the courts have rendered opinions despite the fact that the patients involved had already died. We must remember that the cases that come to the attention of the courts are not run-of-the-mill cases, as they pose issues for judicial resolution in a field of the most far-reaching and solemn implications.[14]

All of the courts recognize the right of a competent adult to make decisions with respect to his own medical or surgical care, even if the consequence is to hasten death. A more complex question is whether, and under what circumstances, a surrogate decision can be made on behalf of the patient when he is incompetent to make it himself, where he has been diagnosed as incurably ill and where the decision relates to the withholding or withdrawal of extraordinary life support medical procedures. As Judge Jones stated in his dissenting opinion in the *Storar* case, the subject deals with irreversible decisions affecting life and death and some may feel that judicial intervention seeks to trespass on the domain of Providence.

Few areas of judicial activity present such awesome questions or demand greater judicial wisdom or restraint. Judge Jones conceded that the courts can claim no particular competence to reach the difficult ultimate decision, depending as it necessarily must not only on medical data, but on theologic tenets and perception of human values which defy classification and calibration.

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Airway Management and Mechanical Ventilation

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Acute respiratory failure is defined as severe impairment of the lung's capacity to oxygenate blood and eliminate carbon dioxide thereby generating tissue hypoxia and life-threatening acidosis. Endoctracheal intubation and mechanical ventilation provide life support until the acute insult resolves. If progress is satisfactory, the patient is weaned from mechanical ventilation and the endotracheal tube is removed. Because these patients are critically ill, often with multisystem disease, any untoward event that occurs during this process, whether spontaneous or iatrogenic, can result in morbidity or death and place the physician at risk for litigation. Physicians caring for postsurgical patients, many who were previously healthy, would appear to be at greater risk of litigation than physicians caring for patients with multiple organ system failure should an adverse event occur. An acute unfavorable event in the former would be identified easily by the patient, family, or lawyer; whereas in the latter circumstance, it may be masked by overwhelming multisystem illness.

In this chapter, we discuss the specific aspects relating to mechanical ventilation that present medicolegal risk to the pulmonary physician if a "bad result" occurs. These issues include informed consent, endotracheal tube placement, prolonged intubation, complications of mechanical ventilation, and weaning from mechanical ventilation (Table 24.1).

Informed Consent

To protect the patient's right to personal autonomy, an ideal medical doctrine would prohibit therapeutic intervention until the patient understood all potential risks and complications and subsequently provided informed consent. In the critical care setting, however, this doctrine is often difficult to uphold. The rapid and often unpredictable onset of respiratory failure and the urgency of intubation and mechanical ventilation may prevent the critical care specialist from including the patient or family in informed consent. The courts have addressed this issue by emphasizing that informed consent is required from all

TABLE 24.1. Complications of mechanical ventilation (N = 354).

Complication	% Incidence	Associated with decreased survival
Endotracheal tube		
Prolonged intubation attempt	30	No
Right main stem intubation	10	Yes
Self-extubation	9	No
Premature extubation	7	No
Tube malfunction	6	Yes
Ventilator		
Inadequate humidification	13	No
Alarm found off	9	No
Alarm failure	4	No
Machine failure	2	No
Medical complications		
Hyperventilation	11	No
Hypoventilation	10	Yes
Atelectasis	5	No
Hypotension	5	No
Pneumothorax	4	No
Pneumonia	4	No
Massive gastric distention	1	No

Modified from Zwillich et al: Complications of assisted ventilation. *Am J Med* 1974;57:161.

patients of "sound mind."[1] As this landmark decision is presently interpreted, victims of medical emergencies are exceptions to the informed consent doctrine if obtaining consent would delay therapy and result in clinical deterioration.[2]

Unfortunately, there are no clear definitions of "medical emergency" to protect the physician in all situations where tracheal intubation and mechanical ventilation are required.[3] Clearly, extreme clinical situations such as cardiac arrest relieve the physician from an obligation to obtain informed consent before intubation. Other less uncontestable emergencies, such as slowly progressive respiratory failure, must be determined by medical judgment, which can be reviewed by the courts and overruled. The courts have generally considered that unconscious patients may be treated if there is potential harm from a failure to treat,[4] and other decisions have extended these judgments to include emergency treatment that would alleviate pain and suffering even in the absence of a threat to life.[5] A practical approach in many instances of respiratory insufficiency is to obtain partial consent from the family or conscious patient if time allows even though communication of risks and alternative therapies are not possible. This approach has been supported by the courts in emergency situations less extreme than respiratory failure.[6]

Complications of Endotracheal Tube Placement

Emergency intubation via the oral or nasal route results in successful tracheal cannulation in 95% of patients.[7,8] An unsuccessful intubation attempt most commonly results from operator inexperience in correct technique or inadequate patient preparation.[9] Occasionally, however, patients will have anatomic or functional abnormalities that present difficulties in intubation even to the most experienced personnel. In these situations, knowledge of specialized devices and techniques, such as fiberoptic bronchoscopy or directable intubation guides, improves the likelihood of succesful tube placement. Physicians responsible for intubating critically ill patients should be adept at these techniques and also be able to perform emergency cricothyroidotomy if translaryngeal intubation proves impossible.

Multiple unsuccessful intubation attempts may provoke cerebral hypoxia with seizures, bradycardia, and gastric distension with aspiration. Prolonged intubation attempts frequently occur in the "crash" situation but can be minimized by having the procedure performed by the most skilled operator present. The Louisiana Court of Appeals [*Hughes v. St. Paul Fire and Marine Insurance Company* (1981)] affirmed that the person performing endotracheal intubation is at risk of litigation in the event of unsuccessful intubation.[10] A 59-year-old patient with status asthmaticus suddenly became unresponsive. On instructions from the physician, the certified nurse anesthetist attempted nasal intubation, which was unsuccessful; the physician ultimately performed a tracheotomy and ventilated the patient. However, shortly afterward the patient died of "acute respiratory failure." A judgment was rendered against the nurse anesthetist for failure to intubate; the doctor was not found negligent.

Failure to perform a successful intubation places the operator at obvious risk of litigation. Intubation is a procedure that a trained pulmonologist should be able to perform in almost all circumstances. In 1987, endotracheal intubation is one of the procedures in which proficiency is required by the Pulmonary Disease Subspecialty Board of the American Board of Internal Medicine. In our opinion, the pulmonologist is responsible for the intubation even if he or she is in a supervisory capacity; anticipated difficult intubations should not be delegated to less skilled operators. If the pulmonologist feels uncertain of his competence in such a situation, a more skilled operator should be called immediately.

Inadvertent intubation of the right main stem bronchus is a potentially serious complication causing alveolar hyperventilation, pneumothorax, and atelectasis of the contralateral lung (Table 24.1).[11] Diminished breath sounds in the left chest after intubation demand immediate withdrawal of the endotracheal tube until breath sounds improve. As breath sounds may be "normal" when occlusion of the left main stem bronchus is incomplete or when the tip of the endotracheal tube is just below the carina, a chest radiograph should be examined immediately after all endotracheal intubations. Prolonged right main stem intubation leads to atelectasis and impaired removal of secretions from

the left lung, predisposing the patient to pneumonia. Securing the endotracheal tube at the mouth or nose after proper placement should avoid "delayed" right main stem intubation. Despite the potential for serious complications, right main stem intubation has not been subject to court decisions probably because it is a subtle finding leading to a subacute problem.

Complications of Prolonged Intubation

Despite adequate restraints, patients manage to remove their endotracheal tubes with an alarming frequency of 9%.[11] Self-extubation and reintubation not only lead to increased risk of laryngeal damage but cause an increased chance of pneumonia. If patient alertness and cooperation cannot be assured, restraints and/or sedation are indicated to prevent self-extubation. Although reversed on appeal, in *Allen v. Mobile Infirmary* (1982),[12] the attending physician and the hospital initially were successfully sued because they "allowed a respirator tube to be pulled from the throat of the patient" allegedly causing postoperative distress leading to death. Self-extubation is a dramatic event that could potentially lead to a disastrous outcome if laryngospasm occurs and reintubation is not accomplished expeditiously. The physician is potentially at risk if he does not specifically address measures designed to minimize the possibility of self-extubation.

Endotracheal tube malfunction can occur after a difficult intubation attempt or prolonged mechanical ventilation or when intubation is performed with a defective endotracheal tube. An endotracheal tube cuff leak should be suspected by noting an increasing discrepancy between the delivered and expired tidal volume. A rare, but potentially lethal, complication is herniation of the cuff over the end of the endotracheal tube; this should be suspected when there is difficulty passing a suction catheter through the tube in association with an abrupt increase in peak cycling pressure which falls immediately after cuff deflation. A malfunctioning endotracheal tube should be changed immediately and can be done with little risk to the patient with an endotracheal tube changer. Malfunction of an endotracheal tube generally is a subtle event that does not lead to a catastrophic episode and has not, to our knowledge, been the subject of litigation.

Prolonged translaryngeal intubation creates pressure injury in the anterior and posterior larynx, where the portion of the endotracheal tube above the cuff contacts the laryngeal mucosa.[13] After 11 days of oro- or nasotracheal intubation, the incidence of endoscopically apparent laryngeal injury approaches 12%.[14] As mucosal injury progresses, the probability of postextubation cicatrization with resultant subglottic stenosis increases. Because subglottic stenosis may cause marked respiratory disability and is difficult to repair surgically, proponents of early tracheotomy argue to limit translaryngeal intubation to less than 7 to 10 days in all patients. Unfortunately, tracheotomy is not only associated with tracheal stenosis at the stoma site, but also exposes the patient to surgical complications, increased incidence of nosocomial

pneumonia, and additional life-threatening complications such as tracheoinnominate fistulae.[15] The decision to discontinue translaryngeal intubation in favor of performing a tracheotomy, therefore, is controversial, and the timing of tracheotomy is best individualized based on the patient's clinical condition and risk factors for the various airway complications. No legal definition of the duration of translaryngeal intubation exists; however, in circumstances where patients would clearly benefit from tracheotomy, such as with multiple intubations and extubations, a potential for liability exists. Physician delay in the performance of a tracheotomy has been the subject of legal proceedings.[16] In the case of *Bobrow v. Maimonides Hospital* and two physicians (1983), one physician was found negligent for failing "to perform a tracheostomy" (settlement $900,000). The patient had numerous intubations and extubations that allegedly resulted in bilateral vocal cord paralysis.

Complications of Mechanical Ventilation

Ventilator equipment failure resulting in patient injury is a relatively unusual occurrence (<2%).[11] As ventilator failure exposes patients with inadequate spontaneous ventilation to immediate clinical deterioration, respiratory therapists should check the alarm function systematically. In 1983, a Florida appellate court approved a damage award of more than 12 million dollars to a woman who suffered irreversible brain damage after "ventilator malfunction."[17] In another case, a 70-year-old woman with amyotrophic lateral sclerosis died after a respirator disconnection with an alarm left off. The jury awarded $22,000 to the plaintiff in this suit.[18]

The physician would appear to be at little risk in the situation of ventilator failure or tube disconnection. The ventilator manufacturer would be prone to litigation in the former and the nurse and respiratory therapist in the latter. All intensive care units should be equipped with backup power in the event of a hospital power failure.

Improper adjustment of ventilator settings is a source of medical complications in mechanically ventilated patients. Zwillich and colleagues[11] demonstrated that either hypoventilation or hyperventilation occurred in approximately 10% of ventilated patients and could be avoided by careful attention to arterial blood gas results. All patients undergoing mechanical ventilation should have their inspired fraction of oxygen monitored by an oxygen sensor to avoid hypoxemia or exposure to toxic concentrations of oxygen (> 0.60). Because oxygen toxicity is related to time and dose, the physician should maintain an arterial oxygen tension between 60 to 80 mm Hg depending on the clinical situation with the lowest Fio_2 possible. The United States Court of Appeal (*Owens v. Bourns, Inc*, 1985)[19] reversed a substantial jury verdict in favor of the plaintiff resulting from blindness of the plaintiff's child allegedly caused by the defective design of the defendant's infant ventilator equipment which was delivering an Fio_2 in the toxic range rather than the prescribed dosage. The court reasoned that the plaintiff's experts only established that

excessive oxygen triggers retrolental fibroplasia and did not testify "that it plays any subsequent role in exacerbating injury." The infant with respiratory distress syndrome had required high concentrations of oxygen for survival before the alleged incident. Thus, cases have been argued over the issue of oxygen toxicity, and the pulmonologist should be cognizant of the safe principles of oxygen delivery to avoid medicolegal problems. However, it would appear more difficult to implicate oxygen oxicity causing a "bad result" in adult respiratory distress syndrome (ARDS) in comparison to retrolental fibroplasia.

Barotrauma is a known complication of positive pressure ventilation (Table 24.1) and has been associated with patient mortality in one series[20] but not in another.[11] To minimize barotrauma, the lowest peak cycling pressure that will maintain adequate alveolar ventilation should be used. In *Jones v. City of New York,*[21] the court held that the jury was justified in inferring negligence from the use and operation of a respirator with defective chest tubes. In this case, a 17-year-old man died a few days after a liver transplantion when chest tubes were ineffective in managing bilateral pneumothoraces. Even though pneumothorax is a known complication of mechanical ventilation, the physician must ensure that the therapeutic modality continues to be functional until mechanical ventilation is discontinued.

Nosocomial pneumonia is a complication of prolonged endotracheal intubation (Table 24.1). Daily surveillance of the patient's clinical course and chest radiographs should allow early diagnosis and initiation of antibiotic therapy for the common pathogens involved in nosocomial pneumonia. To our knowledge, no litigation has centered on the development of nosocomial pneumonia in intubated patients.

Weaning from Mechanical Ventilation

Weaning from mechanical ventilation is part science and part clinical judgment based on a multiplicity of factors associated with the patient's overall condition. The decision to extubate a patient usually is based on the measurement of weaning (ventilatory) parameters in conjunction with arterial blood gas measurements and a trial of spontaneous ventilation. If the clinician uses the pertinent database, a correct decision on the proper timing of endotracheal extubation should be the outcome in over 90% of cases. In borderline instances, the physician should instruct the respiratory therapist or nurse in careful monitoring of the patient in the event that acute respiratory failure ensues. After these guidelines, it is unlikely that negligence would be found even with failed extubation. However, an unsuccessful extubation with a prolonged reintubation attempt puts the pulmonologist at risk for litigation. Thus, the postextubation period would appear to be a high-risk medicolegal time frame as the patient has been removed by physician orders from a life support system.

Summary

The clinician caring for the patient on a mechanical ventilator appears to be at greatest risk for litigation during endotracheal tube insertion and at the time of extubation. These are clearly identifiable events and, if a bad result ensues, the family or lawyer can easily identify a relationship between the event and the consequence. Once mechanical ventilation is initiated and the endotracheal tube is secured, tube disconnect-alarm failures represent the major medicolegal risk. Other medical complications associated with mechanical ventilation and airway management are less recognizable and usually cannot be separated from the natural history of the underlying critical illness. Acute respiratory failure requiring mechanical ventilation signifies critical illness in which poor patient outcome may be anticipated. The previously healthy postsurgical patient with a major complication from mechanical ventilation, however, presents a far greater risk for litigation.

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Pulmonary Artery Catheterization and Its Problems

Medical Aspects of Pulmonary Artery Catheterization

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During the past 20 years significant advances have been made in the care of the critically ill patient. The introduction of the flow-directed, balloon-tipped (Swan–Ganz) pulmonary artery catheter is among the notable advances in the care of such patients.[1] Although pulmonary artery catheterization has now become an integral procedure in the diagnosis and management of these patients, in recent years there has been growing concern about their overuse. In one study of 142 consecutive autopsies, 38% (55 patients) of the patients had undergone catheterization before death.[2] These data suggest an exponential increase in the use of pulmonary artery catheters. Pulmonary artery catheterization provides considerable physiologic data, which gives the treating physician a better understanding of the pathophysiology of the patient's illness and thus a more rational basis for therapy.[3] This approach, however, has not proven to result in any significant improvement in the overall outcome.[4] Moreover, the risk-benefit ratio of this catheter has not been established in the myriad of clinical situations where it has been used. However, it is important to realize that the risk of complications is substantial, and there is sufficient data to suggest a high morbidity as well as mortality associated with its use.[2,5–7] Thus, there exists a growing awareness that a careful evaluation for the risk versus benefit must be applied for each patient who receives a pulmonary artery catheter. The purpose of this review is to identify those patients who are most likely to benefit from pulmonary artery catheterization, to outline the risks associated with the procedure, and to discuss the anticipated legal problems that may arise from indiscriminate use of the catheter.

Pulmonary Artery Catheter Design

The initial pulmonary artery catheter introduced for clinical use contained two lumens.[1] A number of other features have since been added to serve special purposes. The most commonly used catheter today has four lumens and incorporates a thermistor. The four lumens permit: 1) monitoring of pulmonary artery, pulmonary artery occlusion, and right atrial pressures; 2) measurement

of cardiac output by thermodilution; 3) sampling of right atrial, mixed venous blood; and 4) infusion of fluids, anticoagulants, vasodilators, and other medications. Newer catheters (like Oximetrix P7110) have incorporated a *fifth* lumen containing fiberoptic bundles that permit transmission of light, and the return of the reflected light to the optical module for tranmission to the oximeter to monitor continuous mixed venous saturation ($S\bar{v}O_2$). Other catheter designs also incorporate electrodes allowing intracardiac rhythm monitoring and temporary pacing.[9] Heparin complex-coated catheters are also now available, which appear to minimize the thrombogenic potential of earlier catheters.[10]

Pulmonary Artery Catheter Insertion

Bedside pulmonary artery catheterization is done under electrocardiogram (ECG) and pressure monitoring. There are many access routes to the right atrium, such as the subclavian, internal jugular, femoral, and so on.[3,11] The subclavian vein approach is the fastest, but has a potential for serious complications, especially pneumothorax and subclavian artery puncture. The internal jugular vein approach, although generally considered safe, can be complicated by puncture of the carotid artery or trachea.[3,5,7,11]

Once the venous entry is achieved, the catheter is advanced until it reaches the intrathoracic veins. This is evidenced by sudden increases in fluctuations of recorded pressures. The catheter is then advanced into the right atrium. The balloon is then inflated to the recommended volume and promotes the flow-directed passage of the catheter through the right atrium, right ventricle, and into the pulmonary artery.[6,12] It is advanced until a "wedge" tracing is obtained. Migration of the catheter tip is not uncommon after initial placement. Chest roentgenograms and recommended inflation volume of the balloon provide necessary guidelines for the proper location of catheter to produce a wedge tracing. The proper proximal wedge position helps reduce complications and also ensures accuracy of various measurements and determinations.[3,11]

Indications of Pulmonary Artery Catheterization

The potential use of pulmonary artery catheterization has expanded its initial measurement capabilities.[1] Catheters are used to assess the volume status, pressures in the pulmonary vasculature, and mixed venous oxygen.[13] Cardiac output also can be measured.

Assessment of Cardiac Function

Blood pressure is a product of cardiac output and systemic vascular resistance. Hypotension may not be clinicially evident if systemic vascular resistance increases despite significant reduction in cardiac output. Similarly, significant hypotension may develop despite markedly elevated cardiac output if the systemic vascular resistance is low. Knowledge of the left ventricular filling

pressure, cardiac output, and systemic vascular resistance can help the physician to rationally develop a therapeutic program.

Mixed venous oxygen content is commonly used to follow the trends in cardiac output. With a normal oxygen consumption, an arteriovenous oxygen content difference of 4 to 5 vol% reflects adequacy of cardiac output. When this difference increases, cardiac output is frequently inadequate.[13] But, if there is a fall of arterial oxygen content, a decrease of mixed venous content will give misleading information regarding cardiac output.

It is important to remember that pulmonary capillary wedge pressure does not reflect cardiac output. In situations where fluid resuscitation is required, cardiac output must be measured because wedge pressure cannot be depended on to be a reliable guide in defining the endpoint of resuscitation. Wedge pressure will detect early onset of fluid overload or congestive cardiac failure. Simultaneous measurements of cardiac output and pulmonary wedge pressure during volume loading enables one to plot Starling's curve and thereby determine the "optimal filling pressure" in a given situation.[15] In patients with intracardiac shunt, theremodilution cardiac output is an erroneous indicator of left to right or right to left shunt.

Common Clinical Conditions for Hemodynamic Monitoring

Myocardial Infarction

Most patients with acute myocardial infarction do not require pulmonary artery catheterization. However, in patients suffering from complicated myocardial infarction with hypotension, congestive heart failure, suspected tamponade, or hemodynamic instability, data obtained by pulmonary artery catheterization may be essential for optimal management.[3,11,13] Also in such patients, the differential diagnosis of mitral regurgitation from ruptured ventricular septum can only be made by pulmonary artery catheterization.

Shock

Irrespective of the type of shock, that is, cardiogenic, extracardiac obstructive, oligemic, or distributive, pulmonary artery catheterization provides useful hemodynamic data. In fact, the original indication for pulmonary artery catheterization was for patients with cardiogenic shock. Suspected cases of extracardiac obstructive shock (pericardial tamponade, severe pulmonary hypertension whether primary or Eisenmenger) can usually be evaluated and managed without the use of invasive hemodynamic monitoring techniques. Patients with oligemic shock, however, are best managed with hemodynamic data.

Septic shock is a distributive form of shock with two distinct sites of abnormality—the central or cardiac and the peripheral.[16] The pulmonary artery catheter provides useful information regarding pulmonary vascular filling pressures, systemic and pulmonary vascular resistance, as well as cardiac output. These measurements give useful guidelines for volume resuscitation and the need for vasopressors and inotropic therapy.

Adult Respiratory Distress Syndrome

There are a number of indications for pulmonary artery catheterization in patients with adult respiratory distress syndrome (ARDS).[3,17] First, it helps in differentiation from cardiogenic pulmonary edema.[18] Second, in patients with ARDS where simultaneously elevated pulmonary microvascular pressure leads to an exponential rise in edema fluid in the lung, filling pressures should be reduced promptly while maintaining adequate cardiac output.[17] Third, patients with ARDS invariably require varying levels of positive end expiratory pressure (PEEP) in their management. Higher levels of PEEP (>10 cm H_2O) have a potential detrimental effect on cardiac output. In a hemodynamically unstable patient, it is necessary to balance the beneficial effects of PEEP on oxygenation with its detrimental effect on cardiac output. The "ideal or best" PEEP is the one that improves arterial oxygenation with lower fraction of inspired oxygen tension, where the mixed venous oxygen is highest and shunt fraction is lowest without a net reduction in oxygen delivery. Thus, pulmonary artery catheterization is crucial to the monitoring of patients with ARDS receiving therapeutic levels of PEEP. Fourth, hypotension in a patient with ARDS can occur from a variety of causes. Proper management of these patients warrants monitoring of filling pressures, vascular resistance, and oxygen transport.[3,17,18]

Acute Respiratory Failure in Chronic Obstructive Lung Disease

Most patients with acute respiratory failure and chronic obstructive lung disease respond to conventional therapy. However, on occasion, occult causes for continued respiratory decompensation may be responsible. Data from pulmonary artery catheterization will identify such occult causes by revealing wedge or pulmonary artery pressures that are disproportionately elevated for the degree of obstructive lung disease.[3]

Other Applications

Although not universally accepted, pulmonary artery catheterization has been done in certain high-risk patients with drug overdose and in patients after major cardiac or vascular surgery.[3,4] The catheter, apart from allowing blood sampling, provides a port for infusion of thrombolytic agents, vasoactive, and other drugs. Selective pulmonary angiography also can be performed via the catheter.[13]

Interpretation of Data from Pulmonary Artery Catheterization

A wide array of physiologic data, both direct and calculated, is obtained using this catheter. Interpretation of the measurement of various pressures, however, requires special attention.[13,19] In normal individuals, the pressures in the low resistance circuit are in equilibrium during diastole. However, in pulmonary vascular disease, the pulmonary artery end-diastolic pressure will not equal the wedge pressure, but remains greater than the wedge pressure. A

similar situation arises with tachycardia, where there is insufficient time for equilibrium to occur.[13,19] In patients with pulmonary hypertension, in the absence of tachycardia, the gradient between the wedge pressure and pulmonary artery diastolic pressure is an index of the increase in pulmonary vascular resistance. The wedge pressure/left atrial pressure equivalency becomes invalid if there is a mechanical obstruction to flow through the pulmonary venous system or the catheter is located in zone I or zone II in the pulmonary vascular bed.[13,20] Left atrial pressure does not equal left ventricular end-diastolic pressure when ventricular compliance is reduced or in mitral valve disease.[3,19] The left ventricular end-diastolic pressure also may exceed left atrial pressure with severe aortic regurgitation.[3] The reverse will occur, that is, the left atrial and pulmonary wedge pressure will exceed left ventricular end-diastolic pressure in mitral valve disease. In zone III position in the lung, the pulmonary artery wedge pressure approximates the pulmonary venous pressure.[13,20] An increase of alveolar pressure during PEEP or a decrease in pulmonary venous pressure (e.g., hypvolemia) reduces zone III. Under these circumstances the pulmonary wedge pressure will inaccurately reflect pulmonary venous pressure. A cross-table, lateral chest roentgenogram may help confirm the location of catheter tip relative to the left atrium.[21] If the tip is below the level of left atrium, it can be assumed to be in zone III. The loss of "a" and "v" (also may occur with overwedging) and the finding of this "wedge pressure" greater than pulmonary artery diastolic pressure may suggest non-zone III condition and warrant repositioning of the catheter.

Faced with such complexities, it is important to be aware of the situations where the wedge pressure may not accurately reflect the left ventricular end-diastolic pressure of the ventricle. This will avoid errors in decision making when the pulmonary wedge pressure is used as a monitoring tool.

Another major concern is the measurement and recording of pressures. It is important that reading of pressures be done from the screen or printout rather than directly from digital readout.[19] All values should be read at end expiration when intrathoracic pressure is lowest. Finally, it is necessary to ascertain that the catheter is in true wedge position.[3,11,19]

There are some additional problems due to positive end-expiratory pressure (PEEP), which induces changes in vascular and pleural pressures. With PEEP, pleural pressures remain positive at end expiration and can lead to artifically high intravascular pressure if transmural pressure is falling.[20] To cope with these problems, the best approach is to keep the catheter in zone III, keep PEEP less than 10 cm H_2O, take all readings from a hard copy printout, take wedge pressures at end expiration, and recognize that if the measured wedge pressure increases by more than one half of an applied increment in PEEP, one is dealing with a non-zone III condition.[19,20] Furthermore, it is helpful to follow hemodynamic and clinical changes that occur with alterations in wedge pressure, rather than attaching excessive significance to an isolated measurement of pulmonary artery wedge pressure.[3]

The thermodilution cardiac output assumes a constant blood flow during the time the indicator solution travels from right atrium to thermistor. The

accuracy of the measurements is well established and the ease of multiple repetitions is an additional safeguard against error.[22] The method is not accurate if intracardiac shunt or tricuspid regurgitation is present. Also in patients on mechanical ventilatory support, single measurements of cardiac output by thermodilution are inaccurate.[22] To overcome this invariability, it is recommended to average out three consecutive measurements performed randomly during the respiratory cycle.

Unreliable results of mixed venous samples can occur in patients with severe mitral regurgitation and with left-to-right intracardiac shunts. In patients on mechanical ventilatory support receiving a high concentration of inspired oxygen, rapid rate of blood withdrawal may lead to spuriously elevated oxygen saturation in mixed venous sample. To avoid this technical error blood should withdrawn slowly.[24]

Complications of Pulmonary Artery Catheterization

With an increase in the use of the pulmonary artery catheter, an increasing number of complications have emerged.[2–7,12,25] What were initially reported as isolated events is no longer true. The rate of complications has substantially increased with estimates of mortality ranging from 0% to 4% and morbidity ranging from 25% to 53%.[4–6]

The list of complications from the use of pulmonary artery catheter is extensive. Some of the common complications and, the necessary preventive/precautionary measures to minimize these risks, will be discussed.

Cardiac Dysrhythmias

Perhaps the most commonly reported complication of pulmonary artery catheterization is cardiac dysrhythmias. Atrial and ventricular dysrhythmias are common during insertion. In the original report by Swan et ai,[1] the incidence of premature ventricular contractions in acutely ill patients was 11%. Recently, much higher incidences of ventricular arrythmias have been reported. Elliot et al[5] observed ventricular tachycardia in 23% and ventricular ectopy in 46% of seriously ill patients. Sprung et al[6,12] encountered ventricular tachycardia in 33% to 53% of critically ill patients during insertion. Boyd et al[7] reported an 11% incidence of ventricular ectopy, of which 1.5% were potentially life threatening. Other arrythmias reported in the literature include atrial fibrillation and atrial flutter.[3] Fatal ventricular fibrillation, although rare, has also been reported.[6,12] Among these critically ill patients there are several risk factors that are responsible for the ventricular arrythmias. These include hypoxemia, acidemia, hypotension, hypokalemia, hypocalcemia, and coronary insufficiency.[12] Continuous ECG monitoring; full inflation of the balloon; avoidance of overmanipulation; correction of hypoxemia, acidemia, and electrolyte disturbances; and availability on hand of lidocaine and defibrillators are some of the important measures necessary to reduce the incidence of cardiac dysrhythmias.

Bundle Branch Block

The reported incidence of catheter-induced bundle branch block varies from 3% to 6%.[5,12] Left-sided conduction defects, right bundle branch block, and complete heart block in patients with pre-existing left branch block have been reported. Local mechanical irritation and/or trauma is believed to be responsible for the conduction disturbances. Prophylactic use of pacemakers in patients with pre-existing left bundle branch block has been recommended.

Thrombosis

Thrombosis is another commonly reported complication of pulmonary artery catheter.[1,5,10,12,25] Subclavian venous thrombosis probably occurs in 1% to 2% of subclavian placements. Deep venous thrombosis complicating internal jugular vein catheterization recently has been documented in up to 66% of patients.[25] The thrombogenic potential of the catheter or traumatic or prolonged insertion are some of the factors believed to be responsible for thrombosis. Judicious anticoagulation, continuous flush with heparin solution,[12] and use of heparin-bonded catheters[10] are some of the measures recommended to reduce the incidence of thrombosis.

Pulmonary Infarction

Pulmonary embolic complications from the use of pulmonary artery catheter are infrequent. During the past decade, the incidence of pulmonary infarction has decreased from over 7% to 1.3%.[5,7,12] This low incidence is rather surprising, when one realizes that 33% of the catheters when removed have clots on their wall, and practically all (91%) catheters were noted to have clots on their wall when the right heart was opened during open heart surgery.[7]

Peripheral migration with persistent undetected wedging of the catheter, prolonged balloon inflation in wedged position, and thrombus formation around catheter or over areas of endothelial damage are the mechanisms believed to be responsible for pulmonary infarction.[26] Most of these lesions are usually asymptomatic, often diagnosed solely on the basis of roentgenographic changes. More serious infarctions are discovered because of clinical evidence of hemoptysis. Most of the infarctions occur in the area of right lower lobe. The incidence of pulmonary infarcts can be reduced by avoidance of persistent wedging of the catheter, use of continuous heparinized flush solution through pulmonary artery, making sure the balloon is deflated after use, and roentgenographic monitoring. The new heparin-bonded catheter may further reduce the incidence of clot formation around catheters and pulmonary artery infarction.[10]

Pulmonary Artery Perforation

A very serious and potentially fatal complication of pulmonary artery catheterization is rupture of pulmonary artery.[27,28] The reported incidence is 0.2%.[7] The major risk for pulmonary artery perforation is in patients with pulmonary hypertension,[12] and those undergoing cardiopulmonary bypass.[29] Several

mechanisms have been proposed by which pulmonary artery rupture can occur,[3,12,27,28] but the most common is perforation from an overdistended balloon.

The presenting symptoms of pulmonary artery perforation are hemoptysis and pulmonary infiltrates of varying severity. Sometimes differentiation between pulmonary artery perforation and infarction may not be possible. Protection of the catheter tip by full balloon inflation before wedging thereby protecting the catheter tip, slow inflation of the balloon to wedge pressure under continuous monitoring, slight withdrawal of catheter from wedge position before flushing the catheter, and awareness of the risk factors are some preventive/precautionary measures that can be exercised to reduce this potentially fatal complication.[3,12,28] Should massive hemoptysis occur, an emergency wedge arteriogram and bronchoscopy, intubation of the unaffected lung, and emergency lobectomy or pneumonectomy may be necessary.

Balloon Rupture

Rupture of the balloon is often associated with repeated use of catheters, catheterization for prolonged periods, overinflation of balloon, and withdrawal of catheter through the introducer while the balloon is inflated.[1,5,12] Rupture should be suspected when balloon inflation is not met with the usual feeling of resistance. Aspiration of blood through the balloon lumen will also indicate that the balloon is no longer intact.[3] The main risk of balloon rupture is air embolism and embolization of distal pulmonary circulation from the fragments of the balloon.

Infections

Local and systemic infections are well-recognized complications of indwelling catheters. Apart from the risk of infection at the catheter site or from contamination of infusion solutions, pressure monitoring transducers have been identified as an occasional source of infection.[30] Contamination and colonization are more common,[5,31] but the incidence of sepsis complicating the use of pulmonary artery catheter is reported in up to 2% of insertions.[5,7,31] Catheter infections are more common if the line is left in place for more than 3 days, or if a known focus of infection existed before catheter insertion.[3,5,12]

Catheter Knotting

Knotting of the catheter is most likely to occur when loops form in the cardiac chambers and the catheter is repeatedly manipulated.[12,32] Small-bore catheters, excessive catheter length, catheter insertion without inflation of balloon are other risk factors resulting in knotting.[12] Resistance to catheter withdrawal, damped tracing, and roentgenographic evidence of loop or knot help to establish the diagnosis of catheter knotting. A knotted catheter can usually be extricated transvenously be guidewire placement. Rarely, venotomy or more extensive surgical procedures may be necessary.

Endocardial Damage

Mechanical damage to right atrial endocardium, valve cusps (tricuspid, pulmonary), chordae tendinae, papillary muscles have been associated with pulmonary artery catheterization.[2,5,7,12] At postmortem right-sided endocardial lesions have been observed in up to 50% of cases.[2] Clinical signs if present are those of valvular insufficiency or those of right-sided endocarditis.

Complications Associated with Catheter Insertion

Other than local skin infections, pneumothorax is commonly seen although usually not reported. It is most common when the subclavian vein is used as the entry site. Rarely major vascular complications may occur, and include inadvertent invasion of the carotid or subclavian artery, perforation of jugular veins, and separation of the shaft from the inducer hub with distal migration.[33] These complications to a large extent can be reduced if pulmonary artery catheter is inserted under guidance of or by experienced personnel.

Summary

Pulmonary artery catheterization has made a major impact on the management of critically ill patients. Although its use has tremendously increased in recent years, the improved outcome from the procedure is seen only in small groups of patients. In appropriately selected patients, it has helped take guesswork out of some therapeutic decisions. The use of the catheter is associated with considerable risk of morbidity and mortality. Like any invasive procedure, it is essential that the catheter be used after assessing the risk-benefit ratio in a given patient. Furthermore, pitfalls in the interpretation of data must be recognized before therapeutic decisions are made. The incidence of many complications can be minimized by scrupulous attention to detail in catheter placement and maintenance technique. Finally, it is advisable to consider noninvasive techniques as an alternate to invasive hemodynamic monitoring. Some of these techniques now being increasingly used are oximeters for transcutaneous monitoring, two-dimensional echocardiogram to estimate ventricular function, and Doppler ultrasound for measuring right ventricular and pulmonary artery systolic pressures.[34]

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Legal Aspects of the Swan–Ganz Catheter

GREGORY V. SERIO, JD

Major technologic advances in medicine have not always been a boon to practitioners. Indeed, quite to the contrary, physicians are now faced with several burdens in addition to those which routinely come with the practice of medicine. The physician must know of evolving technologies, understand the intricate aspects of new developments, and determine how they are to be applied in daily practice. This facet of medicine has not only made the practitioner more wary of new treatment modes, but it has also introduced a completely new aspect to medical malpractice litigation.

The physician who thinks that he is free of these new pressures because he does not deal with complex machines with large price tags should be warned: these evolving trends relate to and impact upon all practitioners who use any type of equipment, be it a CAT scan or even simple catheters and tubing. In fact, it is the use of devices such as catheters and not just the new methodologies that is the focus of much trouble for physicians. As simple as these instruments may be in appearance, composition, and use, physicians are accountable for injuries proximately related to the use, or misuse, of these devices unless they can illustrate a thorough knowledge of the instrument or machine, its physical makeup, its indication in a given situation, and how its use did or did not reach the standards of accepted practice.

The same principles hold true in the converse situation, that is, when a new and accepted technology or device is not used in a given situation. Again, let us

focus on catheters. In *Sochard v. St. Vincent's Medical Center* (8 Conn. App. 6, 510 A.2d 1367, 1986), the issue before the court was whether the failure to use a Swan–Ganz catheter contributed to the death of plaintiff's decedent. Whereas the plaintiff's expert, a cardiologist, testified that the failure to use the catheter made diagnosis of hypovolemia impossible, the court concluded that "there was no evidence that the patient died from a condition which would have been detected by the use of the Swan–Ganz catheter."

Catheter use has unfortunately led to adverse results. In *Taylor v. Security Industrial Insurance Co.* (454 So.2d 1260, Ct. of Appeals La., 1984), the decedent therein died as the result of a Swan–Ganz catheter, inserted in an attempt to check the decedent's lungs, which actually perforated the pulmonary artery. Also, in *Jones v. City of New York* (57 A.D. 2d 429, 1st Dept., 1977), the Appellate Division faced a case in which there was the development of a bilateral pneumothorax from the improper insertion of a chest tube and catheter that was found to be thin, soft, and inadequate. The state of the tubing and the method in which it was inserted were both found to be contributing factors in decedent's death, even though the decedent's condition, acute viral hepatitis with a hepatic coma, was found to be terminal.

Physicians, and the hospitals who most often provide physicians with catheters and other materials, as well as access to complex instruments, are faced with a significant burden, but one which can most certainly be overcome. The medical professional must have continuous instructional assistance on the tools with which they work, and frequent updates so as to keep abreast of new and evolving technologies; so too must the hospital staff earnestly inspect, test, and update these materials to assure structural integrity and reliability.

Similarly, they must be aware of *contraindications* associated with certain procedures and instruments. Indeed, the physicians and other professionals working with these tools should also allow themselves to be heard when there is evidence of faulty materials or improper use of certain items. Ongoing discussions with hospitals procedures committees and medical societies will foster greater understanding of pitfalls and could lead to certain procedures or instruments being designated as not within the standards of acceptable medical practice. This ounce of prevention can go a long way toward reducing exposure in litigation.

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Lung and Heart-Lung Transplantation

STEPHAN L. KAMHOLZ, MD AND FRANK J. VEITH, MD

Each year thousands of patients die of incurable cardiopulmonary diseases. Despite major advances in medical and surgical therapy for some of these problems, severe chronic obstructive pulmonary disease, chronic idiopathic pulmonary fibrosis, advanced diseases of the pulmonary circulation including primary pulmonary hypertension and pulmonary hypertension secondary to congenital heart disease (Eisenmenger's syndrome) still elude effective conventional therapy. These entities are progressive and often result in the death of the affected individual. Routine medical interventions are only partly effective in ameliorating some of the symptoms suffered by these patients. Since 1980 the real possibility of therapeutic lung and heart-lung transplantation has been recognized. There have been dramatic clinical successes with lung transplantation, particularly for patients with idiopathic pulmonary fibrosis,[1] and with cardiopulmonary transplantation for those individuals afflicted by end-stage pulmonary vascular disease (either due to primary pulmonary hypertension or Eisenmenger's syndrome).[2]

Historical Background

Since the first human lung transplant, performed in 1963 by Hardy,[3] numerous efforts have been made in the field of pulmonary transplantation. Between 1963 and 1980 there were 38 lung transplants performed worldwide. Thirty-four of these were single lung or lobar pulmonary transplants, 1 was a bilateral lung transplant, and 3 were cardiopulmonary transplants.[4] Numerous factors contributed to the poor outcome for most of these efforts. Only two patients receiving pulmonary transplants in this period survived more than 2 months. In these instances, (6- and 10-month survival, respectively), the transplanted lungs provided some palliation of the patients' respiratory insufficiency. However, numerous problems existed: 1) frequent episodes of lung allograft (transplanted tissue obtained from a nonrelated member of the same species) rejection due to less than optimal immunosuppressive therapy; 2) problems

related to the bronchial anastomosis (connection between the air passage of the transplanted lung and that of the recipient); 3) inadequate supply of donor lungs for seriously ill recipients awaiting transplantation (which in many instances resulted in the progressive deterioration of such individuals to a point where their general medical condition almost precluded a successful outcome of the transplant procedure); and 4) nonavailability of methods for successful preservation and transportation of donor lungs for transplantation contributed to the limitation of the number of attempts at this procedure.[5]

Since 1980, however, multiple developments have dramatically improved the feasibility and likelihood of success for both lung[6] and lung-heart transplantation. These include: 1) the development and widespread application of the immunosuppressive agent cyclosporin (Sandimmune, Sandoz) has tremendously decreased the incidence of allograft rejection in these transplant recipients and has been associated with fewer infectious complications in these patients compared with the frequency of such infections observed during treatment with previously available immunosuppressive regimens[7]; 2) substantial advances have been made in our understanding of the mechanisms of lung allograft rejection and also in our ability to detect this by a variety of methods including nuclear scanning modalities, radiographic techniques, and analysis of cells obtained from lung tissue by bronchoalveolar lavage (installation of small volumes of sterile fluid into the lung through a flexible bronchoscope which are then removed through the same instrument by gentle suction)[8]; 3) improvement in the surgical technique for lung transplantation[5,9]; 4) development and perfection of the techniques for cardiopulmonary replacement[10]; 5) new advances in short-term preservation technology for cardiopulmonary replacement have partly ameliorated the limited availability of donor heart-lung blocks for this procedure[11]; and 6) careful definition of indications for pulmonary and cardiopulmonary transplantation and development of an adherence to strict criteria for recipient selection also have materially improved the likelihood of successful outcome for such procedures.[1,12]

Current Status of Lung and Heart-Lung Transplantation

As an outgrowth of the advances described, clinically successful lung and heart-lung transplantation have emerged as therapeutic options for patients with end-stage pulmonary and cardiopulmonary disease. Since 1980 approximately 13 single lung transplants and more than 100 heart-lung transplants have been performed worldwide. The clinical successes with these procedures have helped to define and to further refine the spectrum of indications for each procedure.[13] Primary diseases of the airways and pulmonary parenchyma appear to be most amenable to unilateral lung transplantation. Protracted survival of unilateral lung transplant recipients whose underlying disease was interstitial pulmonary fibrosis has been reported by the Toronto Lung Transplant Group.[1] The use of single lung transplantation as a therapeutic interven-

tion for the almost uniformly fatal entity of paraquat poisoning has met with limited short-term success, as reported by the Montefiore Lung Transplant Group in New York[14] and by the Toronto Lung Transplant Group.[15] Both patients had significant improvement of pulmonary status as a result of the lung transplantation procedure but each ultimately succumbed to nontransplant-related complications.

Protracted survival, in excess of 3.5 years, has been achieved with single-lung transplantation in a patient with end-stage interstitial pulmonary fibrosis (IPF). This patient has enjoyed a return to a normal life-style with the capacity to perform all the activities of daily living without dependency upon oxygen therapy. He has replaced his former bed-to-chair existence with a productive return to his former employment. Similar improvements in physical status, pulmonary function, and quality of life also have been attained by subsequent IPF patients receiving therapeutic single-lung transplants.[16]

Successful cardiopulmonary transplantation (replacement of both lungs and the heart) was pioneered by the group at the Stanford University Medical Center.[2] The vast majority of patients undergoing cardiopulmonary transplantation had either primary pulmonary hypertension (a disease of unknown causation affecting the circulation of the lung) or congenital heart disease with pulmonary hypertension (Eisenmenger's syndrome). Long-term survival, in excess of 4 years, with marked improvement in clinical status has been reported for patients receiving cardiopulmonary transplants, as definitive therapeutic intervention for these diseases.[17]

Legal/Ethical Perspectives

Several major legal and ethical issues have substantial impact upon the entire field of organ transplantation.

Brain Death

Whereas selected types of transplants (e.g., kidney, bone marrow) may often be performed using organs harvested from living persons, *most* transplants, and indeed *all* lung and heart-lung transplants, are performed using brain dead heart-beating cadaver donors. Therefore, local medical practices, ethics, and legislative policies relating to the definition of brain death[18–25] materially affect this aspect of transplantation. The attendant difficulties often result in delays in brain death declaration, which adversely affect the suitability of cadaver donors, especially for lung harvest, because of the frequent development of nosocomial (hospital-acquired) pulmonary infection in these individuals.[13] (The kidneys, liver, and heart are less susceptibile to this problem because of their relative "isolation" from the external environment.) In some instances, legal constraints on the interhospital transfer of cadaver organ donors across county or state lines compounds the problem. Thus, the supply of donor organs for lung and heart-lung transplantation remains severely limited in comparison to

the number of potential transplant recipients. This actuality has fueled efforts to obtain multiple organs for transplantation from a single donor.[26–29] Recent federal legislation (P.L. 99-509) *mandates* that the family (or other next of kin) of a brain dead, potential organ donor be approached by appropriate hospital personnel for purposes of requesting organ donation.[30] This may well have a salutary effect on the limited supply of donor organs.

Potential Adverse Effects of Transplantation

Despite many advances in transplantation immunology, histocompatibility testing, surgical techniques for transplantation, and dramatic improvements in the overall success of clinical organ transplantation, significant morbidity and mortality still occur among transplant recipients.[31,32] Although this may be related to residua of the underlying disease in some instances,[14,15] allograft rejection and infectious (and neoplastic) complications remain as serious problems facing the transplant recipient. The crucial importance of pretransplant recipient education and of provision of proper *fully* informed consent for transplantation cannot be overemphasized. Although transplant surgeons have been especially attentive to such details, they are not totally insulated from malpractice litigation resulting from a patient perception of poor outcome!

An additional risk to the potential transplant recipient resides in the possibility of transmission of infectious diseases by the donor organ. Cadaveric donors are routinely screened for hepatitis B virus, syphilis, and blood-borne bacterial infection. In the face of the burgeoning AIDS epidemic, it has recently become routine to screen donors for the presence of antibody to HIV (human immunodeficiency virus).[33] Unfortunately, transplant-associated transmission of HIV infection has been documented in several instances, and reinforces the importance of testing donors for anti-HIV.

Allocation of Precious Resources

The availability of organs for all types of transplantation remains limited in relation to the number of worthy potential recipients. This has been particularly problematic for the fields of lung and heart-lung transplantation, as suggested. Which potential recipient should receive a donor organ? There is no uniform agreement, and certainly no "standard" policy applied in this decision-making process. Severity of illness, length of time awaiting a donor organ, likelihood of success related to histocompatibility match, and/or general clinical condition have all been touted as important criteria to be used in this process.[34] All too often, financial resources, access to media (appealing for donor organs via television, radio, and newspapers), or other sociopolitical factors may play an undue role in the successful quest of a particular recipient for the needed donor organ.

Who shall bear the cost of the transplant procedure, and the requisite care thereafter? Extension of current federal support for the costs of certain types of transplants has been proposed,[30] but resources are clearly not inexhaustible.[35]

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Medicolegal Issues in Pulmonary Emboli

Medical Aspects

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Significance

Pulmonary emboli (PE) are a major cause of death in hospitalized patients.[1-3] Untreated, PE has approximately a 30% mortality; the mortality is less than 10% with appropriate treatment; less than 5% die primarily because of the pulmonary embolism.[1] Pulmonary emboli originate most commonly from thrombi in the large veins of the thigh; however, calf thrombi propagate and result in PE.[4] Our ability to clinically diagnose lower extremity thrombi is extraordinarily poor. The diagnosis of PE is one of the most difficult in clinical medicine; this difficulty is compounded in the critically ill individual.[5]

Risk Factors

One or more of the following risk factors were identified in 95% of the patients with proven PE in the Urokinase-Streptokinase Pulmonary Embolism Trial (UPET): 1) age—over 40 years; 2) stasis—bedrest, the postoperative period, the ICU, long trips; 3) heart disease—congestive heart failure, atrial arrhythymias, mural thrombi, myocardial infarction; 4) thrombophlebitis; 5) trauma—especially of the knee and pelvis; acute hemiplegia; 6) surgery—risk increases over age 40 and with general anesthesia of 30 minutes or more; highest risk with pelvis and knee; 7) history of thromboembolism (especially if appropriately documented); 8) the puerperium; 9) varicose veins; 10) primary polycythemia vera; 11) widespread carcinoma—particularly adenocarcinoma of the lung, or breast; 12) birth control pills.[6,7] In addition, risk groups of hospitalized patients can be identified as follows: 1) hip fracture, total hip or knee replacement—40% to 70% incidence of venous thrombosis, 3% to 10% incidence of fatal PE; 2) general, gynecologic, neurologic, and urologic surgery— 15% to 20% incidence of venous thrombosis, 1% to 5% incidence of fatal PE; 3) intensive care unit patients—20% to 27% incidence of venous thrombosis, ? to 8% incidence of fatal PE; and 4) medical patients—< 15% incidence of venous thrombosis and < 1% incidence of fatal PE.[8]

As the diagnoses of PE is so difficult, the primary approach to PE must be prevention.

Symptoms

The most common symptoms of PE are dyspnea and chest pain (> 80%), pleuritic pain (up to 70%), apprehension (60%), and cough (50%). None of these symptoms are specific and all are very common in critically ill patients. Hemoptysis occurs in perhaps one third of patients. Uncommon presenting symptoms include syncope, seizures, and chest pain compatible with angina. A true asthmatic wheeze is extremely rare if it occurs at all.[6,7]

Physical Findings

The almost constant sign of PE is a respiratory rate of greater than 20 breaths per minute. Crackles, a pleural friction rub, and a loud or increased pulmonic second sound may be found in up to 50% of the patients. The following findings have been identified in 30% to 40% of patients: tachycardia, fever, an S3 or S4 diaphoresis, and clinical thrombophlebitis. Less common signs are hypotension, splinting of the hemithorax, clinical evidence of consolidation, cyanosis, increased venous pressure, or a prominent A wave.[6,7]

Laboratory Studies

Routine laboratory studies are of no value in diagnosing PE; however, the Creatine Phosphokinase-MB may be useful in identifying the patient with myocardial infarction.

Nonspecific electrocardiographic changes are found in almost 90% of individuals with PE.[6] Chest roentgenograms also have nonspecific abnormalities in approximately 80%.[6]

Using the information just discussed, predisposing factors, history and physical examination, chest roentgenograms, and electrocardiograms well-trained specialists in internal medicine missed the diagnosis of PE confirmed at autopsy in 67% of patients and incorrectly made the diagnosis of PE in 62% of patients.[9]

Arterial Oxygen Tension, Alveolar-Oxygen Gradient, and Arterial Carbon Dioxide Tension

A low arterial oxygen tension (Pa_{O_2}) and a widened or increased alveolar to arterial oxygen gradient ($A\text{-}aD_{O_2}$) are found in 85% to 95% of patients with PE.[10] This is due to intrapulmonary shunt and areas of low ventilation/perfusion.[11,12] This, however, is a nonspecific finding. A reduced carbon dioxide tension (PaC_{O_2}) is also an almost constant finding in the absence of pre-existing hypercarbia.

Ventilation and Perfusion Lung Scans

An abnormal lung scan can only serve as a basis for developing a probability of PE; it is never positive. A negative perfusion lung scan, however, virtually excludes PE.[13] The addition of ventilation scanning refines the prediction of

the probability of PE. A high probability ventilation/perfusion ($V/\dot{Q}$) scan is generally defined as the presence of more than one segmental or larger perfusion defect with normal ventilation in the same areas—a $V/\dot{Q}$ mismatch. False-positive high probability scans (no PE at angiogram) have been reported recently in 56%,[14] 34%,[15] and 14%[16] of patients with angiographically proven PE; false-negative low probability scans were found in 13% to 35%. The first two studies were retrospective, and in the third some 30% of individuals were excluded because of the severity of illness. Our local prospective data, however, are quite similar. In a retrospective study of 617 patients admitted to a respiratory intensive care unit, 88 consecutive lung scans were abnormal. Thus, the likelihood of obtaining a normal scan that would exclude PE is extremely small in seriously ill patients. There was no correlation between $V/\dot{Q}$ scan probability readings and the presence or absence of PE at angiography or postmortem examination in these patients.[17]

Pulmonary Angiography

This is the most reliable method, with a very low morbidity and mortality.[18] An intraluminal filling defect or an abrupt vessel cut off are considered diagnostic of PE. Partial lysis may occur over 3 to 21 days; however, clots almost never clear promptly.[19] If angiography using multiple segmental injections, oblique views, and magnification techniques is negative clinically important PE have been excluded.[20]

Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED) Study

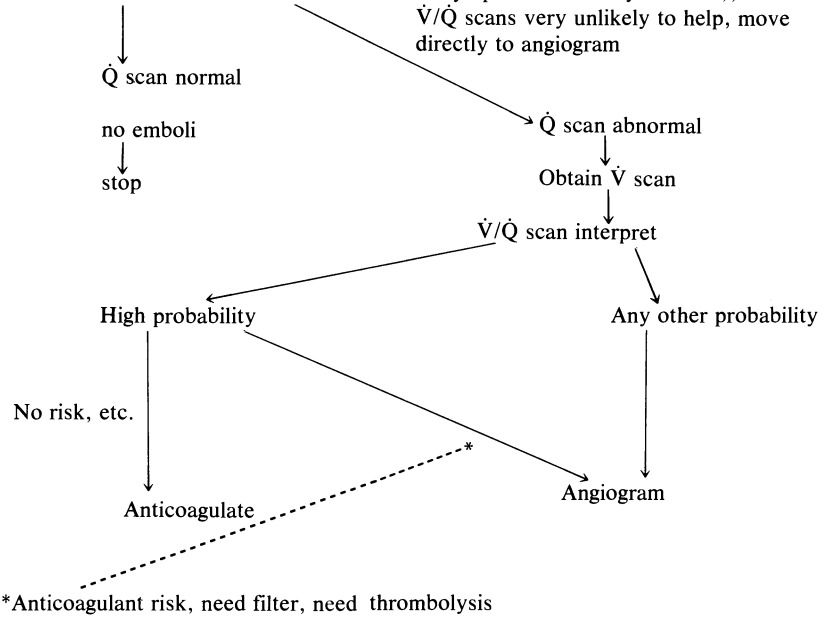
A National Heart Lung and Blood Institute multicenter study to evaluate the specificity and sensitivity of lung scans versus pulmonary angiography is in its final stages of data collection. This is the first prospective randomized trial attempting to evaluate the full spectrum of patients in whom PE are considered. In addition to the sensitivity and specificity of V/Q scanning, a more accurate incorporation of findings associated with PE may lead to a more accurate algorithm.

Diagnostic Algorithms

A prudent diagnostic approach recommended by the physician author of this chapter is outlined in Table 27.1. The identification of risk factors is a critical first step. Thereafter the findings—new signs or symptoms, a change in Pao_2, $PaCo_2$ and so on—warrant careful consideration of evaluation for PE. Once this is undertaken the clinician must integrate all the information as it becomes available in developing a probability estimate of PE. This should be used in deciding on additional studies or terminating the evaluation for PE, for example, identification of a rib fracture due to trauma as the cause of chest pain.

TABLE 27.1. A prudent diagnostic algorithm for pulmonary emboli (7/87).

1. *Risk factors and risk groups*
   Enhanced clinical suspicion of PE
2. *Signs and symptoms compatible with PE*
3. ↓ PAO_2, ↑ $A\text{-}aDO_2$, *and* ↓ $PaCO_2$
   One or more in > 85%
   Normal does not exclude, but ↓ probability of PE.
4. *Chest Roentgenograms*
   Abnormal, nonspecific > 80%.
   Normal does not exclude, but ↓ the probability of PE.
5. *Electrocardiogram*
   Abnormal, nonspecific > 80%
   Normal does not exclude, but ↓ probability of PE.
6. *Ventilation/perfusion ($\dot{V}/\dot{Q}$) scans*
   a. "Normal" lungs (no important parenchymal or airways disease)
   b. Abnormal lungs (widespread parencymal or symptomatic airways disease), since $\dot{V}/\dot{Q}$ scans very unlikely to help, move directly to angiogram



*See text for alternatives.

There are alternative diagnostic approaches in common use. Although the pulmonary angiogram performed as described is the "gold standard," there is considerable variation in the willingness of highly competent clinicians to rely on the $\dot{V}/\dot{Q}$ scan. In addition, various physicians' perception of the morbidity and mortality of angiography strongly influences its use. This issue will hopefully be resolved by analysis of the PIOPED data. In the interim many competent clinicians may choose one of the following paths: 1) a high probability $\dot{V}/\dot{Q}$ scan will be considered diagnostic under most clinical circum-

stances (the exclusions suggested in Table 27.1 are not accepted); 2) a low probability scan will be accepted as satisfactory to so lower the probability of PE that it can be excluded; and 3) a low, intermediate, or indeterminate probability scan with a) other clinical and laboratory data not compelling; and/or b) with the abnormality(s) of the $\dot{V}/\dot{Q}$ scan explained by chest roentgenographic findings attributable to another process (e.g., COPD, asthma, small postoperative pleural effusion, pneumonia, atelectasis, etc.) will be accepted as satisfactory to so lower the probability of PE that it can be excluded.

Therapy

Heparin

The treatment of acute PE is intravenous heparin. The initial intravenous dose should be given stat on the basis of a strong clinical suspicion unless there is a high risk or contraindication to using anticoagulants. A baseline activated partial thromboplastin time (APTT), or a thrombin clotting time (TCT), platelet count, and prothrombin time (PT) should be obtained. The platelet count should be repeated every 3 days to identify potential thrombocytopenia related to heparin therapy. A loading dose of 5,000 to 7,500 U of heparin is given intravenously stat; 10,000 to 15,000 U is frequently recommended if the PE is massive. This is followed by continuous intravenous heparin via an infusion pump. The dose of intravenous heparin is adjusted to achieve an APTT of 1.5 to 2 times the control or a TCT of 0.2 to 0.4 heparin units (20 to 40 seconds). Levels below 1.5× control result in increased recurrence of thromboemboli. Initial monitoring should be every 4 to 6 hours until a stable dose is achieved; then 1 or 2 times daily is sufficient. Heparin is generally given for 7 to 10 days.[8]

The most common serious complication of heparin therapy is major bleeding that occurs in about 5% to 10% in most studies (range of 0% to 50%). Gastrointestinal bleeding is most common. Risk factors include: 1) co-morbid conditions (other than that requiring anticoagulation) 1) serious heart disease, b) liver dysfunction, c) renal failure, and d) cancer or hematocrit $< 30\%$; 2) initiation of heparin at age 60 or older; 3) maximum PTT, 3× control or PR 3× control; and 4) worsening liver function. Incremental risks increase the chance of bleeding.[21] These are *not* a list of contraindications. The risk of bleeding also increases with thrombolytic therapy, aspirin, nonsteroidal anti-inflammatory agents, recent major surgery, serious trauma, uremia, alcoholism, severe hypertension, and coagulopathies. If an invasive procedure must be done, heparin should be discontinued for at least 2 to 3 hours before the procedure.

Heparin may produce mild, not immune-mediated thrombocytopenia. However, severe, IgG-mediated thrombocytopenia may be life threatening, producing thrombi in major arteries, the skin, and the pulmonary vessels. In this condition platelet aggregation occurs when heparin is added to normal platelets and the patient's serum. Heparin should be discontinued with severe thrombocytopenia.[22]

Heparin should not be used in patients with active bleeding or known

antithrombin III deficiency. We do not consider chemical identification of blood in stool as active bleeding.

Warfarin

Warfarin is given in addition to heparin for an extended period. Heparin should continue for 3 to 4 days after the prothrombin time (PT) is in the therapeutic range because the PT is prolonged before a satisfactory hypocoaguable state is achieved. Warfarin should be started on the first to third day of heparin at a dose of 4 to 10 mg per day. The dose should be adjusted to achieve 1.3 to 1.5× the control PT (using rabbit brain thromboplastin, North America) or 2 to 5× the control PT (using human brain thromboplastin, Europe). Initially, daily monitoring of the PT is necessary; it can be extended generally to 1 to 4 weeks depending on the stability of the PT on a steady dose. Warfarin is usually given for 3 months after the event. If there is a history of prior thromboembolism, warfarin is given for at least 6 months. If there is a continuing major risk factor (e.g., congestive heart failure, severe cardiomyopathy, malignancy, or multiple prior thromboemboli) many recommend indefinite warfarin therapy.[8]

Maintaining a PT in the range of 1.2 to 1.5× control can be a formidable problem because so many extraneous factors may enhance (prolong the prothrombin time) or suppress (decrease the prothrombin time) the activity of warfarin. A list or package insert given to the patient assists in maintaining stability.

Warfarin should not be given during pregnancy; it is associated with increased teratogenic and fetopathic events.

An alternative to warfarin is "adjusted dose" subcutaneous heparin. Heparin is given every 12 hours in a dose that will prolong the APTT or TCT to 1.5× control. Once this has been achieved monitoring is discontinued. "Mini" or low-dose heparin (5,000 U subcutaneously every 12 hours) is not effective. The two methods are equal in preventing recurrent thromboembolic events. The adjusted-dose heparin results in less bleeding, at a somewhat increased cost and morbidity of subcutaneous injections. Maintenance of the PT in the 1.3 to 1.5 control (North American) for warfarin or the APTT/TCT 1.5× control for heparin will result in an approximate fivefold reduction in major bleeding complications *V* a PT of 2.0 to 2.5× control.[23]

Surgery

Surgical intervention is primarily directed at venous interruption. It is generally reserved for: 1) failure of anticoagulation; 2) contraindications to anticoagulation; and 3) very large PE or a larger inferior vena cava thrombus. The most commonly used procedure in our experience is the insertion of a Greenfield filter[24]; other similar devices have their advocates. In our opinion, pulmonary embolectomy is warranted only under extraordinarily rare circumstances— a patient with a massive PE (>50% obstruction) documented angiographically, who remains hypotensive despite the use of thrombolytic therapy and pressors, and with no other serious life-threatening conditions.

Thrombolytic Therapy

We limit the use of thrombolytic therapy to patients with angiographically documented massive PE who are hypotensive; this group has a mortality in excess of 30% despite heparin.[25] This approach is consonant with that of the majority of physicians treating PE. Others advocate a more liberal approach.[26]

Patients who are to receive thrombolytic therapy should have a baseline thrombin time (TT), APTT, PT, hematocrit, and platelet count. Most individuals obtain a TT or APTT to document "activity" during therapy and a return of these values to or toward normal after therapy before giving heparin. Thrombolytic therapy is contraindicated in the presence of: 1) active internal bleeding; 2) a recent (2 months) cerebral vascular accident, or intracranial tumors; or 3) recent (less than 10 days) major surgery, child birth, internal organ biopsy, puncture of a deep vessel, gastrointestinal bleeding, serious trauma, uncontrolled hypertension (200/110 mm Hg). Thrombolytic therapy has not been shown to reduce mortality due to PE.[6] At 2 weeks, there were no differences in lung scan abnormality between the heparin and a urokinase-streptokinase group.[6] Statistically significant but clinically unimportant differences in diffusing capacity have been reported.[27] The role of tissue plasminogen activator (tPA) is being studied.

Prevention of Thromboembolism

Prophylactic therapy is highly effective. Effective prophylaxis of thromboemboli in hip and knee surgery or trauma is achieved with adjusted-dose heparin, intravenous dextran, warfarin, or pneumatic compression: minidose heparin is not effective. Dextran may lead to fluid overload or to hypersensitivity reactions. For most patients, those in intensive care units, undergoing general or gynecologic surgery, or in congenstive heart failure, so-called minidose or low-dose heparin, 5,000 U subcutaneously every 12 hours is satisfactory. Neurosurgical patients should be treated with pneumatic compression devices. Patients who undergo urologic procedures that are likely to bleed also should have pneumatic compression. If the urologic procedure is not likely to bleed, minidose heparin is acceptable.[8]

Although a combination of minidose heparin and dihydroergotamine has been shown to be more effective than heparin alone after general surgery, it is not commonly used because of the potential for ischemia.[28]

Legal Aspects

Edward B. Goldman, JD

This section outlines cases involving pulmonary emboli. It is assumed that the reader understands the basic rules of malpractice and informed consent from earlier chapters. It is also assumed that in each case there is a pre-existing

doctor-patient relationship resulting in a duty for the physician to diagnose and treat appropriately (the standard of care). Legal judgments against a physician can result from failure to follow the standard of care or failure to obtain informed consent from the patient. This section discusses cases illustrating the standard of care and discusses defenses.

It must be remembered that cases are decided based on their own individual facts. Therefore, results can vary based on the specific facts involved. Further, cases are decided several years after injury has occurred. At that time memories may not be fresh and there needs to be reliance on the medical record. If the medical record does not accurately reflect the care given, then the judge or jury may determine that care was not provided. In other words, if diagnosis or treatment was not documented, the judge or jury are free to conclude that the diagnosis was not made or treatment was not provided.

Lack of informed consent claims should be an avoidable problem in these cases. Patients must be told what diagnostic tests will be used and, if an embolus is diagnosed, what treatment is available. As pointed out in the section on warfarin, patients should be given information concerning the medication so they can be compliant. It is very important to have an informed patient so that the patient understands the actions of the medication and what things the patient should do or avoid doing. Medical sheets can be prepared indicating to the patient the drug, its uses, its indications, its contraindications, and any precautions the patient should be taking. The information is then provided to the patient with a copy placed in the medical record for documentation purposes.

To prove a malpractice case, the plaintiff must show the existence of a duty, the violation of that duty, and how the violation caused damages. Although there are some consent cases, more frequently pulmonary emboli cases focus on either failing to diagnose or failing to treat appropriately. Some case examples can illustrate these areas.

Lack of Informed Consent

In *Salis v. U.S.* (S22 F. Supp. 989, 1981), the plaintiff had known arteriosclerosis and right leg pain. A decision was made to do an angiogram to view the right leg circulation. There was no discussion of risks with the patient. The patient was not tested to see if he had any allergic reaction to the dye nor was the patient told about any potential for injury from insertion of the catheter, creation of a clot caused by breaking off plaque from the vessel walls, infection, or any other possible side effects. The angiogram was done and resulted in emboli to the lower section of the leg. Treatment to restore circulation in the leg was unsuccessful, and the leg was amputated. The plaintiff claimed that if he had been appropriately informed he would never have consented to the procedure. The court determined that there was a lack of informed consent in this case and ruled in plaintiff's favor. The decision resulted in a judgment in the amount of $169,700. This was based on $18,700 out-of-pocket expenses and $151,000 in pain and suffering. The pain and suffering was based on a 19-year

life expectancy with $25,000 for the first year and $7,000 for each subsequent year. Although this is a complication of an arterial procedure, the case emphasizes the importance of fully informing your patient of the nature of the procedure, its risks, benefits, and alternatives before proceeding. Consent documented by a written form would be very useful.

Failure to Diagnose

In *Erickson v. U.S.* (504 F. Supp. 646, 1980), a 48-year-old man was admitted to a VA Hospital to remove a cyst on the left knee. Surgery occurred July 21, 1976. Two days later on Friday, July 23rd, the patient complained that he felt bad. On Saturday, July 24th, he had a fever and some problem sleeping and was told by the nurse that "all he needed was a teddy bear." No physician saw the patient over the weekend. Monday, July 26th, the patient had a 102° F temperature and was put on intermittent positive pressure breathing (IPPB) with no tests performed. The working diagnosis was pneumonitis. The IPPB continued on Tuesday and Wednesday even though he continued to have a temperature, "felt bad," had shortness of breath, malaise, and a dusky complexion. The physicians finally ordered decongestants, arterial blood gases, chest x-rays, and a urine study but no other tests. Thursday, July 29th, the patient's blood pressure was 86/0 mm Hg and he was in respiratory distress. At this point pulmonary emboli were considered. Electrocardiogam demonstrated the patient had an acute myocardial infarction. The dopamine was given at excess doses for 80 hours resulting in irreversible ischemia in both legs and ultimately a bilateral below-knee amputation. Plaintiff's expert testified that the diagnosis of pulmonary emboli should have been made July 23rd or July 25th at the latest, that heparin should have been started, and that failure to diagnose and treat lead to the arrest. Plaintiff obtained a verdict of $500,000 which was based on $190,000 in lost future earnings, $40,000 in past lost earnings, and $270,000 for pain and suffering and disfigurement.

Failure to Treat

The case of *Brown v. Koulizakis* (331 SE 2nd 440, Virginia, 1985), illustrates both failure to diagnose and treat. The patient, age 31, had no prior circulatory or pulmonary problems. He was hospitalized for severe low back pain. Hospitalization began January 31, 1978. He was being observed by orthopedic surgery. He was told not to move around any more than he had to. February 21, 1978, he experienced "piercing discomfort" in the right upper guadrant of his abdomen, chest pain, shortness of breath, blood pressure 100/80 mm Hg, pulse 74 beats per minute, respiration 34 breaths per minute. Electrocardiogram and chest x-ray were normal, and no other tests were performed. The following day pain continued and he complained of discomfort in his lungs. Blood pressure was 100/60 mm Hg per minute, pulse 88 beats per minute, and respiration 20 breaths per minute. Diagnosis was pneumonia or "less likely a pulmonary embolus." No stat tests were requested and neither a scan nor an

angiogram were ordered. The following day the patient began coughing up blood and a lung scan was performed showing a pulmonary embolus. Before treatment could be started, plaintiff had a myocardial infarction and died. The autopsy showed a massive acute saddle-type pulmonary embolus. The court found both a delay in diagnosis and a failure to treat resulting in the patient's wrongful death.

Proximate Causation

To win a case, the plaintiff must not only prove a violation of the standard of care, but also show the violation lead to (was the proximate cause of) the injury.

In *Hersh v. Hendley* (626 S.W. 2nd 151, Texas App., 1981), the plaintiff had pre-existing circulatory problems and had had a minor stroke. He went to a podiatrist to have a foot callus surgically removed. The podiatrist performed surgery November 26, 1973, without taking a history or giving any medications to prevent formation of emboli. September 17, 1974, approximately 10 months after surgery, the plaintiff experienced chest pain and was promptly diagnosed as having pulmonary emboli. The court found a deviation from the standard of care in that a proper history should have been taken and prophylactic medications provided but found no evidence that the deviation was the cause of the emboli occurring 10 months later. The court found through expert witness testimony that the time delay was such that it was unlikely the surgery was the proximate cause of the embolus.

Requirement for Expert Witness Testimony

Generally, in medical malpractice cases, there is a need for an expert to discuss what the duty is and whether the duty was violated. It is only in cases where "the thing speaks for itself" that expert witnesses are not needed. These are cases where, for example, a hemostat is left inside someone after surgery. In pulmonary emboli cases there is invariably a need for an expert to explain the standard of care for diagnosis and treatment. In *Walton v. Jones* (286 N.W. 2nd 710, Minn, 1979), the patient had a fractured ankle. His medical history revealed asthma and prior emboli. The leg was cast and the plaintiff was discharged to return 10 days later for a cast change. The cast was changed, and the plaintiff complained of tightness around the cast, chest pain, and difficulty in breathing. Plaintiff was told by the physician not to worry. Shortly thereafter the plaintiff died of pulmonary emboli. At the trial there was no expert testimony for plaintiff. The court held in favor of the defendant because the plaintiff presented no testimony concerning standard of care and no testimony that anticoagulant treatment would have saved the plaintiff's life. The plaintiff's only medical witness was a pathologist testifying that emboli were the cause of death. The court held that plaintiff, to establish a case, would have had to present medical testimony discussing the standard of care for diagnosis and treatment.

Defenses

Defenses generally fall into the category of either factual and legal defenses. Factual defenses have to do with proving what diagnostic studies and therapy was caried out or showing that the patient was negligent because the patient failed to obey physician's orders. Legal defenses have to do with rules established by the courts and state legislatures. For example, a factual defense could be that a patient was evaluated with a scan that was negative and the patient was told to immediately return to the hospital if pain increased, the patient felt short of breath, or the patient's limb became numb or discolored. If the patient then suffers symptoms but fails to return, the patient should be found to be negligent. Legal defenses can include things like the statute of limitations having expired. Typical defenses in pulmonary emboli cases are factual in nature showing such things as no breach of the standard of care or no proximate causation between the injury and the care provided by the physician.

As always, in a medical malpractice case, the best defense is a comprehensive diagnosis and prompt appropriate treatment where both the diagnosis and the treatment are clearly and completely documented in the medical record.

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28

Legal Aspects of Human Immunodeficiency Virus (HIV) Infection: Testing and Discrimination

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Introduction

Human immunodeficiency virus (HIV), formerly known as human T-cell lymphotropic virus (HTLV-III) or lymphadenopathy associated virus (LAV), is a retrovirus that has been identified as the cause of the acquired immunodeficiency syndrome (AIDS) and AIDS-related complex (ARC).[1] HIV infection is an epidemic disease that causes profound suppression of the immune system by depletion of T-lymphocytes, especially of the helper/inducer subset bearing the CD-4 surface marker.[2] This suppression predisposes affected individuals to life-threatening opportunistic infections, Kaposi's sarcoma, and non-Hodgkin's lymphomas. HIV predominantly is transmitted through sexual contact by exposure to infected semen or cervical/vaginal secretions, or parenteral exposure to infected blood or blood components. HIV also can be passed from infected mothers to their offspring. Only a few cases have been reported involving transmission from exposure to other body fluids and body tissues.[3] Persons at increased risk of developing AIDS include homosexual and bisexual men, intravenous drug users, individuals transfused with contaminated blood or blood products (especially those with hemophilia A), heterosexual contacts of persons with HIV infection, and children born to infected mothers.

By August 1988, more than 60,000 cases of AIDS had been reported to the Centers for Disease Control, and more than half of these individuals have died.[4] It is estimated that by the year 1991, there will be about 235,000 new cases.[5] Estimates presented in the final report of the Presidential Commission on the Human Immunodeficiency Virus suggest that almost 500,000 Americans will have died or progressed to the later stages of the disease by 1992.[6] Although antiviral therapy with zidovudine (formerly called AZT) and more aggressive chemotherapies against the HIV-associated opportunistic infections, prolong the lives of patients with AIDS, it is still considered to be uniformly fatal.

Although HIV-infected individuals may not present clinically with HIV-related disease for many years, they may be subject to a number of personal, social, cultural, and legal consequences. Although the medical community primarily directs its efforts to the approximately 2% of those currently infected with HIV who are symptomatic, the general community and the media are becoming more concerned about the asymptomatic HIV-carriers. Thus, it is not surprising that HIV testing, regardless of its perceived sensitivity and specificity, has taken on a separate identity and purpose. Not for several decades has the fundamental dynamic tension between the constitutional rights of the individual and those of the community been so carefully scrutinized. This paper focuses on the legal issues surrounding HIV testing and presents several potential areas for misuse of the information with resulting discrimination.

Legal Issues Relating to HIV Infection

HIV Testing

On August 4, 1987, the Public Health Service issued guidelines for counseling and antibody testing to prevent HIV infection and AIDS.[7] These guidelines are an attempt to balance the potential personal, medical, and public health benefits of testing for HIV antibody, with the need to ensure that the use of counseling and testing facilities will not result in the unauthorized disclosure of personal information and the resultant possibility of inappropriate discrimination. Even individuals who are tested and are found to be negative for the presence of antibodies to HIV may be discriminated against on the basis that they would not have allowed themselves to be tested unless they were engaging in risk-taking behaviors.

The Utility of the HIV Test

Because HIV lies dormant in various tissues of the body, it is presumed that all exposed individuals are infected and capable of transmitting the virus for years, and possibly for life. Because a valid, reliable, and sensitive test for the detection of HIV antigen is not commercially available, serologic tests for antibodies directed against HIV have been widely used in screening for exposure to the virus. The sensitivity of the currently licensed enzyme-linked immunosorbent assay (ELISA) antibody screening test is 99% or greater. The specificity of the currently licensed tests is approximately 99% when repeatedly reactive tests are considered. Thus, when ELISA screening, in duplicate, is performed in combination with Western blot testing, the false-positive rates are estimated to be between 1 to 5 per 100,000.[8]

The presence of antibodies to HIV is not diagnostic of AIDS or any other clinical disorder. In fact, the great majority of the estimated 1.5 million seropositive individuals in the United States remain asymptomatic. However, it is also estimated that approximately 32% of these individuals will develop

AIDS within 5 years of seroconversion and an additional number of individuals will be ill with other HIV-related illnesses.[9] Lymphadenopathy is strongly correlated with disease progression; fever and weight loss, less so.[10]

A negative ELISA antibody test does not absolutely rule out exposure to HIV. It generally takes a minimum of 6 weeks from the time of exposure (infection with the virus) to develop a measurable antibody response. However, Imagawa and his colleagues raise the concern of prolonged periods of infectivity, up to 18 months, prior to seroconversion on both ELISA and Western Blot.[11] Furthermore, a few cases of antibody-negative and culture-positive individuals have been documented, as have cases of antibody-positive individuals who have later become seronegative. A significant subgroup of homosexual men develop HIV $_{p}24$ antigenemia relatively early after seroconversion. However, the majority of seroconverters do not exhibit an antigemenia (75%).[12]

Individual Rights and the Determination of HIV Infection

In an attempt to protect the individual's rights, California has enacted a confidentiality law that is sufficiently stringent so as to prohibit an obstetrician from notifying the pediatrician assisting him at a delivery that the mother has demonstrated evidence of infection with HIV. Most states have no specific laws governing the sharing of HIV-related medical information; medical personnel are bound by the established hospital policies and state laws with regard to disclosure of medical information and the sharing of the contents of medical records. The established civil laws on slander and libel are clearly applicable to circumstances where there is an inappropriate disclosure of damaging information. Health care providers face the dilemma of not knowing when or if they should notify other health care providers or even patient's spouse or sexual partner, about the serologic status of their patient. The CDC guidelines of August 14, 1987, state that persons who are HIV-antibody positive should be instructed how to notify their partners and to refer them for counseling and testing:

> If they are unwilling to notify their partners or if it cannot be assured that their partners will seek counseling, physicians or health department personnel should use confidential procedures to assure that the partners are notified.[7]

Historical legal precedent has established that a physician may be liable to possible civil action for damages if he fails to notify those potentially exposed to an infectious disease.[13] The health care provider involved with direct patient care has been determined to have an affirmative "duty to warn" other individuals known to be at risk of infectious diseases.[14] More recently, the California Supreme Court has extended the concept of the "duty to warn" to those at risk for physical harm from a patient receiving psychotherapy.[15] However, the "duty to warn" refers to specific readily-identifiable victims rather than the community at large. There is a defense available to physicians in "duty to warn cases:" liability will not attach where it can be determined that

TABLE 28.1. Factors to be considered in determining whether a clinician should warn an unsuspecting third party.

The patient's own statements to the clinician (a patient may indicate to the clinician that he or she had been tested at an anonymous test site)
The patient's credibility
The ability to identify the third party
The patient's relationship with the third party
The potential additional risk presented by a delay in notification of the third party
Whether the third party is pregnant or considering pregnancy
The likelihood that the third party believes that he/she is at risk for HIV infection
The strength of the physician–patient relationship
Other material factors

the victim has been notified of the danger from the patient.[16] Table 28.1 provides a series of factors which should be considered by the clinician in determining whether to warn an unsuspecting third party. Regardless of the final decision, the clinician must document his or her decision, and the events which follow.

An HIV-infected patient may also have a duty to warn those in danger of becoming infected. Failure to notify the sexual partner of the risk of infection, that is, from herpes, may subject that individual to liability for any resultant physical or emotional injuries.[17] In prior years, husbands have been found liable for infecting their wives with a venereal disease.[18]

Litigation focusing on defendants accused of knowingly exposing others to HIV infection has occurred. Florida and Idaho have made it a crime to willfully or knowingly expose another person to HIV.[19] Similar statutes are now being considered in other states, along with legislation allowing forcible isolation of infected people who are believed to threaten public safety. The prosecutors in these cases will be required to establish beyond a reasonable doubt that the defendant knew he or she was infected with HIV, that there was a deliberate and willful attempt to transmit HIV, and that the "victim" did not know that the defendant was infected when he or she was "exposed."

In what is believed to be the first criminal case involving exposure of a person to HIV by sexual activity, an Army private faced a court-martial and was convicted for aggravated assault charges for having had sex with three people without telling them he tested positive for HIV and for not following counseling advice to wear a condom. Under the Uniform Code of Military Justice, aggravated assault is an unauthorized act of touching that can "produce death or grievous bodily harm." The harm does not actually have to occur for such a prosecution. In this case, none of the three sex partners have been shown to be infected on subsequent HIV antibody testing. Charges were not brought for a fourth sexual partner, his fiancee. The prosecution determined that she had knowledge of his infected status and freely engaged in the high-risk behavior.

The Surgeon General of the United States Public Health Service concurs with most locally formulated policies that the testing for evidence of HIV infection should remain voluntary and confidential, that pre- and post-test

counseling must be provided, and that informed consent for testing must be obtained. In many locations, *anonymous* testing also may be obtained using identification codes or aliases. Pretest counseling should include a summary of risks and benefits of testing per se, as well as a summary of risks and benefits to the individual in the event of a negative or positive test (Table 28.1).

HIV antibody tests are routinely used to screen blood and organ donors. They are also widely used as an adjunct to counseling of individuals at risk for HIV infection. HIV antibody testing is required of all military recruits and active duty service personnel. Seropositive personnel generally are not discharged unless they are unable to perform their military duties. HIV testing is also required for Foreign Service personnel and Peace Corps Volunteers.

Other potential uses of the HIV test, such as screening job applicants, applicants for insurance policies or marriage licenses, and routine screening of hospitalized or surgical outpatients are currently the focus of an intense national debate. In June 1987, President Reagan recommended "routine" testing for such groups as federal prisoners, marriage license applicants, and patients at drug treatment programs and venereal disease clinics. It is not clear whether the word "routine" means that people who object strongly could refuse such tests. Proponents of testing claim that identifying HIV-positive individuals will help to protect those who are not infected. Objections to this proposal are that routine testing might drive those most at risk underground, and that the considerable expense of widespread testing would identify few cases while diverting monies from more productive measures, such as education and research.

The U.S. Senate has already passed a measure requiring testing for people seeking permanent immigration. Those that test positive would be denied resident status. Although not yet enacted, many bills are pending that would mandate HIV testing for various other groups. Proposals to require routine testing of hospitalized patients provoked strong objections by medical experts, who argued that such a policy would not curtail the spread of infection, but rather raise serious legal questions regarding informed consent and patients' rights. It would also represent an inefficient use of financial resources. Louisiana has recently passed legislation requiring premarital testing. However, there is no clear indication that the physician ordering the test is under any legal obligation to inform the partner (who may also be infected) of the results of the test.

HIV Testing and Confidentiality

Despite assurances of confidentiality, HIV test results must be noted in the patient's medical record, and as such, may be subpoenaed in a number of different types of legal proceedings. Furthermore, depending on local regulations, test results also may be reported to public health authorities for the purposes of surveillance and identifying case contacts. A new law in Colorado imposes a $300 fine on doctors who do not report the names of seropositive individuals to the State Department of Health, and imposes a $5,000 fine on any

state official who breaches the confidentiality of this information. These records may not be examined in any hearing, nor be released upon subpoena, discovery proceeding, or search warrant.

Discrimination

In the Workplace

The Occupational Safety and Health Administration (OSHA) has announced a plan for establishing guidelines for protecting the nation's 5 million health care workers from infectious blood-borne disease, including infectious hepatitis B and HIV. The new program does not constitute a specific, enforceable occupational health standard. Its guidelines can be enforced under the Occupational Safety and Health Act's general duty clause, which requires employers to maintain workplaces free from "recognized hazards." Reports from the CDC and the National Institutes of Health (NIH) have documented that HIV can be transmitted by accidental needle punctures as well as direct contact of infected blood with mucosal membranes.[8,20]

Hepatitis has long been identified as a known risk to health care workers. In 1982, the CDC issued voluntary guidelines for protecting health care workers from HIV.[21] These guidelines called for infectious material to be placed in an impervious bag, and gave specific cleaning instructions for equipment, linen, reusable dishes and utensils, and so on. Specific instructions were stated for cleaning "blood spills." These guidelines instruct employees in the handling and disposal of needles and other sharp items (i.e., needles should not be recapped, purposely bent, broken, removed from disposable syringes, or otherwise manipulated). Gloves, gowns, masks, and eye coverings should be used when the possibility exists that an employee may be exposed to blood or other body fluids. Hands should be washed immediately if contaminated with blood. To avoid the need for mouth-to-mouth resuscitation, employees should use mouthpieces, resuscitation bags, or other ventilation devices. Guidelines for the protection of dental-care personnel and persons performing necropsies or providing mortician's services were published by the CDC in 1983.[22]

Despite CDC guidelines and scientific data to the contrary, fears of possible transmission of AIDS by casual contact in the workplace have led to numerous dismissals of individuals with AIDS, or those belonging to a high-risk group. Indeed, in 1986, the New York City Commission on Human Rights reported 314 cases of AIDS discrimination; 63 were in the workplace. This represented a greater than threefold incidence over the previous year. Most cases of discrimination, bias, and wrongful termination fall under existing civil rights statutes. However, specific legislation forbidding discrimination due to AIDS has been adopted in several localities.

In June 1986, the Justice Department ruled that employers receiving federal funds can discriminate against people with AIDS. However, in March 1987, the U.S. Supreme Court overruled that opinion, stating that employers who

receive federal funds cannot discriminate against people who are physically or mentally impaired by contagious diseases, holding that they are handicapped within the meaning of section 504 of the 1973 Rehabilitation Act.

Controversial decisions to restrict activities of health care workers who are infected with HIV are also being considered. Recently, the County Board of Chicago limited the privileges of a physician with AIDS to technologic, teaching and supervisory functions, stating that the public's fear of contracting AIDS would deter patients from seeking medical care. The board also cited two potential legal issues. The first involves a wrongful injury (or death) suit ensuing from a health care worker transmiting AIDS to a patient. The second involves a liberal interpretation of the informed consent doctrine. A patient could claim that he or she had been the victim of the tort of battery by unknowingly receiving treatment from an HIV-infected clinician; the patient could claim that he or she would have sought treatment from a different clinician if the patient had known that the clinician was infected with HIV.

There are public health professionals who believe that a physician practicing in accordance with established guidelines does not place patients at significant risk of infection, and that whether or not a physician or other health care provider is HIV antibody positive is immaterial to the delivery of good medical care.

Availability of Medical Care

Fear of contracting AIDS has resulted in numerous instances of patients in high-risk groups being refused treatment by physicians and hospitals. Recent cases include a heart surgeon who refused to operate on carriers of HIV.[23] Although not specifically illegal, many feel that such actions are not in keeping with the physician's ethical responsibilities. Most current litigation is being argued with existing antidiscrimination and civil rights statutes.

Medical Quarantine

Thus far, only Colorado and Indiana have enacted laws permitting AIDS patients to be isolated. In a recent case in Florida, a 14-year-old boy who was seropositive for HIV was quarantined in a hospital psychiatric ward because it was believed that his continued sexual activity represented a danger to public health. In the face of growing public fear of contracting AIDS, it is likely that many local governments will adopt measures restricting the activities of patients with HIV infection who do not follow guidelines concerning prevention of the disease.

Availability of Insurance

The enormous sums projected for health care of patients with HIV-related diseases has resulted in insurance companies wanting to require HIV testing for applicants for life or health insurance, and denying policies to those who test

positive. They claim that the ability to assess risk is the basic foundation of insurance underwriting, and that denial of this ability will result in the economic ruin of the industry. Opponents of this position hold that insurance is integral to achieving quality health care, and that refusal to insure an individual on the basis of sexual preference or antibody status represents illegal discrimination. Most states have had to consider establishing laws governing the use of HIV antibody tests by insurers. California and Wisconsin have banned mandatory testing. The City Council of Washington D.C. also banned such testing in June 1986, and this action resulted in more than 90% of insurance companies refusing to continue to write individual policies within the city. Massachusetts has recently reversed an earlier ban on testing. Numerous lawsuits by homosexuals, claiming discrimination by insurance carriers, are currently in litigation.

In many states, patients with medically diagnosed and confirmed AIDS are eligible for benefits from publicly financed health and social assistance programs. However, Supplemental Social Security Insurance (SSI) will be provided only to those who have a diagnosis of AIDS (having ARC or a disabling non-AIDS HIV-related infection is not sufficient). It is estimated that the recent expansion of the CDC surveillance definition of the AIDS to include individuals with HIV-related dementia and wasting syndrome (emaciation) will increase the number of HIV-infected patients eligible for these benefits by 20%. A diagnosis of AIDS also permits preferential admission to drug abuse treatment centers and a variety of housing and social services.

Product Liability

Testing for the presence of HIV antibodies in donated blood has only been available since March 1985, when the FDA approved the ELISA screening tests for use in screening blood and blood products. Since that time, essentially all blood and blood products are routinely screened for the presence of HIV; soon blood and blood products will also be routinely screened for the presence of HTLV-I as well. The Federal government has commenced a lookback program that urges individuals who received blood or blood products before 1985 be screened for HIV infection. This program, coupled with the long latency between infection and the presentation of illness, suggests that a significant amount of additional litigation dealing with contaminated blood and blood products can be anticipated.

Attempts at recovery for alleged transmission of infections in contaminated blood or blood products has, in the past, relied on the legal theories of strict liability in tort, breach of implied warranties, and negligence. However, most jurisdictions define supply of blood and blood components as a service and not as the marketing of a product. In most instances strict liability or implied warranties are not applicable to providers of services. More recently, however, courts are beginning to alter the traditional interpretation and conclude that the provision of blood and blood products is the sale of a product. Such an interpretation would mean that the principles articulated in the Uniform

Commercial Code would apply and defendant-vendors could be held to a standard of strict liability. The issues that will present themselves in the next series of lawsuits include issues of the use of surrogate testing that may have been available before 1985, the introduction of more stringent self-deferral guidelines before 1985, and the nature of the informed consent provided to patients before the use of the blood or blood product.[24]

Summary

HIV infection is now epidemic in the United States and in many other nations. HIV testing permits infected individuals to be identified. There is strong evidence that discrimination has occurred among HIV antibody-positive individuals as well as among persons perceived as being in high-risk groups. Thus, the use of any testing program needs to be carefully considered by health departments, hospitals, and other health care providers to assure confidentiality of patient information. The public's confidence that the results of testing, coupled with an adequate counseling program, is critical if large-scale participation in a testing program is to be expected.

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Medical and Legal Aspects of Tuberculosis in Drug Addicts, Prisoners, and Patients with AIDS

Medical Aspects

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Tuberculosis

Tuberculosis is an ancient infection known to mankind in all ages and in every part of the world. The causative organism *Mycobacterium tuberculosis* is (often referred to as the tubercle bacillus) was discovered by Robert Koch more than 100 years ago. Despite easy recognition and effective therapy, tuberculosis remains a major cause of morbidity and mortality in the developing world.

Tuberculosis is caused by infection with *M. tuberculosis* or *M. bovis*. Several other mycobacterial species (e.g., *M. kansasii, M. intracellulare*) may cause similar disease, especially when the immune system of the body is deranged, but are not designated as tuberculosis, because they are not communicable.

Tuberculosis is worldwide in distribution. In the past 50 years, the infection has markedly declined in the developed countries, but it remains very high in the developing countries. It is estimated that each year about 10 million people develop tuberculosis in these countries, half being highly infectious, and at least 3 million die of the disease.

The decline in incidence in developed countries began even before the advances in diagnosis and management of the disease of the past 50 years due to improved nutrition, sanitation, and living conditions. With the introduction of chemotherapy, however, the decline in morbidity has accelerated. The decline in mortality has been greater than that of morbidity.

MORBIDITY

In the United States, the average decline in morbidity during the past 30 years averaged about 5% annually. This steady decline was interrupted between 1978 to 1981 due to the heavy influx of South East Asian refugees and averaged only 1.5%.[1] The decline resumed again between 1981 and 1984 for an average of 6.7%. However, in 1985, the observed incidence rate was 9.1/100,000 compared with 9.4/100,000 in 1984, a decline of only 3.2% from the 1984 rate. Then

in 1985 there was no decline and in 1986 a slight increase. This represents another interruption in the decline and is thought to be due to the appearance of AIDS, which impairs the body's immune response to the infection.

The situation differs in most less developed countries. There has been an overall increase in the number of tuberculosis cases during the past 3 decades, which correlates with a doubling of their population. The close relationship between the socioeconomic state of a country and the incidence of tuberculosis indicates that a decline in incidence will occur only with improvement in the standard of living.

Mortality

Mortality data from the National Center of Health Statistics show that 1,729 deaths occurred due to tuberculosis in 1984 compared with 1,779 in 1983, a decline of only 2.8%.[1] There has been no appreciable decline in mortality between 1980 and 1984. The average decline in mortality was 2.9%. In 1985, 1,276 (5.7%) of the total 22,201 cases reported to the Centers for Disease Control (CDC) were found at the time of death. Even though tuberculosis is regarded as a curable disease, 5% to 10% of patients who develop tuberculosis die of the disease. It is to be emphasized that mortality remains especially high in developing countries. Tuberculosis is still the greatest single cause of mortality in these countries.

Transmission and Pathogenesis

Infection with *M. tuberculosis* occurs by inhalation of airborne particles aerosolized by an infectious person's sneezing, singing, and speaking.[2] These airborne infectious particles are called "droplet nuclei," the dried residue of several droplets of respiratory tract secretions. Particles measuring 5 to 10 μm in size and containing a few bacilli are small enough to reach terminal bronchioles and alveoli, and in a susceptable host may establish an infection. In the nonimmune host, the bacilli may multiply freely and reach the lymphatics and the blood stream before cell-mediated immunity to tubercle bacilli has developed (6 to 8 weeks). A parenchymal infiltrate and hilar lymph node involvement constitute a "primary" (Ghon) complex. With the development of acquired immunity, the multiplication of bacilli is normally controlled in most of the infected site and the lesions heal by resolution, with fibrosis often with calcification. If the immune response is inadequate, the infection may progress to clinical tuberculosis. Even when the infection is controlled initially, organisms are disseminated to other organs of the body where they may establish foci of infection from which clinical tuberculosis may develop years or decades later.[3] The most common site for such healed lesions is the apex of the lung, where they are called Simon foci. These are the most common sites of later recurdescence of infection.[4] Similarly, sites of high oxygen tension in the growing ends of long bones and in the kidneys are more supportive of the growth of organisms than are the liver and spleen, where the oxygen tension is low.

In the developed countries, the portal of entry of the tubercle bacilli is exclusively through the lungs, as the bovine disease is practically eliminated. However, ingestion still remains a significant factor in human infection when milk from infected cows is used. Transmission from open skin lesions or fistulas is extremely rare, but occasionally may occur in workers in mycobacteriology laboratories and autopsy rooms.

Infection and Disease

Infection is not synonymous with disease. Infection is the presence of organisms within the host, whereas disease occurs from progressive pathologic changes resulting from the multiplication of bacilli and host's response to it. Tuberculous infection is more common than the disease because large numbers of infections are controlled by a natural defense mechanism.

Among persons infected with *M. tuberculosis,* the cumulative morbidity rate may be as high as 15%. The initial infection may progress to serious disease within 5 years in 5% to 10%, and a further 3% to 5% may develop late recrudescence at some time thereafter. The risk of progression to clinical tuberculosis is highest in infancy and next in adolescence. However, occurrence of primary infection and progression to disease has been reported in all age groups, even in the elderly. In a large majority of adults and elderly persons with a positive tuberculin reaction, disease is due to late recrudescence of latent or dormant lesions in the lungs. It may occur in any organ that was seeded during the bacillemic phase of primary infection, such as kidney, spine, long bones, fallopian tubes, brain, and lymph nodes. Generalized dissemination may also occur at any stage, producing almost certain death if not recognized and treated promptly.

In persons who are already infected with tubercle bacilli, considerable immunity is generally present. Later inhalation of bacilli results in rapid mobilization of defenses and elimination of the organisms before many replications and dissemination occur. However, reinfection with tuberculosis may occur when subjects are very heavily exposed or when immunity is impaired, as by AIDS.[5]

Clinical Aspects

Tuberculosis may affect any organ of the body and at any age. In developing countries, initial infection normally occurs in childhood and dissemination is common. In developed countries, the infection is more often delayed to adulthood and the infection generally directed to the lung and pleura.

Initial or primary infection is usually asymptomatic and self-limited. Occasionally, hilar or paratracheal adenopathy may be seen on the chest radiograph. In children, this may sometimes produce collapse of a segment of a lobe due to compression of bronchi. On occasion, infection progresses to disease either in the lungs as tuberculous pneumonia or by dissemination through blood stream and lymphatics to miliary tuberculosis or meningitis, especially in malnourished children in developing countries.

Adult pulmonary tuberculosis more often occurs as a result of recrudescence of dormant nodules of infection in the apices of lungs (Simon foci).[6] The characteristics of this form are chronicity, cavitation, and fibrosis. The patients may have a cough with expectoration, low-grade fever, malaise, anorexia, and loss of weight. Tuberculosis of larynx, trachea, and bronchi are generally associated with advanced cavitary pulmonary tuberculosis. If there is a subpleural focus, it may infect the pleura, producing an exudative pleural effusion.

Other organs (extrapulmonary) may become infected with tubercle bacilli during the lymphogenous and hematogenous spread of initial infection. Extrapulmonary forms of tuberculosis are more common in developing countries, due to high infection rate, poor nutrition, and involvement of younger persons.

Diagnosis

Tuberculin Skin Testing

Infection due to *M. tuberculosis* can be identified by a skin test with 5 tuberculin units (TU), which produces an area of induration measuring 10 mm or more within 24 to 72 hours. Bacille Calmette–Guérin (BCG) vaccination is also followed by a positive tuberculin reaction. In countries where BCG vaccination is used as a preventive measure, the tuberculin reaction is not helpful in identifying naturally acquired infection. In about 80% of persons with tuberculosis the test is positive, that is, the induration is $\geq$ 10 mm. This biologic test, however, depends upon the number of circulating, sensitized T-lymphocytes and may be suppressed during pleural effusion, overwhelming illness, and AIDS.

Immunity to tuberculosis is mediated by sensitized, thymus-derived lymphocytes (T-cells) that release lymphokines on stimulation by tubercle bacillary antigens. In patients with negative PPD reaction, repeat testing should be done within 2 weeks of the previous one, along with tests with other antigens, that is, mumps, trichophyton, candida. The second tuberculin test may elicit a response in persons in whom the previous response has waned with years.

Tuberculin testing is helpful in identifying infected persons on entry into nursing homes, prisons, and at the time of employment in hospitals, nursing homes, prisons, and shelters for the homeless—all places where TB exposure is common. Periodic retesting then makes it possible to detect new infections in time to prevent disease by preventive therapy with isoniazid. Such therapy has been found to be more than 95% effective.

Bacteriologic Examination

Stained specimen of sputum, tissue fluid, or tissue are used to identify mycobacteria if present in large numbers. However, a definite diagnosis of tuberculosis depends upon isolation of *M. tuberculosis* from body secretions or tissue.

As tuberculosis is most common in the lung, the most common specimen is

sputum.[7] At least three morning specimens should be collected for examination in the laboratory by both smear and culture. When spontaneously produced sputum specimen is not available, nebulized water or hypertonic saline aerosol may be inhaled to increase bronchial secretion. Pharyngeal suction may be performed in comatose persons to obtain a specimen.

In situations where sputum specimens are not available or the initial smear examinations are negative, bronchial washing, brushing, and transbronchial biopsy through fiberoptic bronchoscope or early morning gastric washing may be useful in establishing diagnosis. Occasionally, transtracheal or transthoracic needle aspiration of lung may be necessary. The materials, including tissue, are examined for smear and culture.

Other materials that may be submitted for bacteriologic examination are urine, cerebrospinal fluid, serous effusion, pus, and synovial fluid. In urogenital tuberculosis, the urine shows hematuria and pyuria without any bacterial growth in culture. Three early morning specimens should be submitted for culture. For pleurisy with effusion, thoracentesis fluid is sent for smear and culture examination. Bacilli are usually not seen in smear examination, and culture is positive in about 30%. Pleural tissue obtained from percutaneous pleural biopsy should be examined histologically and cultured for *M. tuberculosis*. Similarly, when pericardial effusion is present, a biopsy of the pericardial tissue should be cultured for tubercle bacilli. Biopsy of bone marrow, liver, and lymph node may be of great value in the diagnosis of disseminated tuberculosis.

Tuberculosis in AIDS

Recent observations suggest that human immunodeficiency virus (HIV) infection in persons infected with tuberculosis may cause recrudescence of inactive tuberculosis or dissemination of a recently acquired infection. Tuberculosis may occur in 10% to 20% of AIDS patients. Four of the five states with the largest population of AIDS cases had the largest increase in tuberculosis cases in 1986. Metropolitan areas with the largest number of AIDS cases also have reported increased numbers of tuberculosis cases. The extent of the impact of HIV infection on the morbidity and mortality of tuberculosis is still not known, but presumably it will be considerable.

Tuberculosis in Old Age and in Nursing Homes

In developed countries, tuberculosis is occurring progressively in elderly persons as the general prevalence of the disease is declining. During the past quarter century, there has been a dramatic shift of the age of the disease from childhood to very old age. Eighty percent of the cases of TB in the elderly occur in persons living privately and 20% in the 5% who live in nursing homes. The reason for this 4 : 1 disparity in the TB rate in nursing homes is largely due to transmission to nonreactors to tuberculin in nursing homes.[9] Newly infected contacts may develop disease in 7% (women) to 12% (men). Unless measures are taken to control the spread, a longstanding outbreak of tuberculosis may

develop among residents, staff, and visitors. Thus, preventive methods are necessary, consisting of identifying infected persons by tuberculin testing on entry, screening of reactors with chest radiographs, retesting of nonreactors after discovery of an infectious case, and use of preventive therapy with isoniazid according to the guidelines recommended by the Centers for Disease Control.

Tuberculosis in Prisons

In prisons, persons may have to live for long periods in close contact with many other persons in a closed environment. Some such persons are likely to harbor dormant tuberculous infection. The scene is set for an epidemic if one of the 15% to 20% reactors should develop active infectious tuberculosis. Then, the other 80% to 85% of who are tuberculin negative are susceptable to new infection. Tuberculosis may spread as a primary infection and some may develop active tuberculosis. Moreover, although employees of such institutions are at less risk, some may become infected and a few even progress to clinical tuberculosis. Thus, the problem may not remain confined to prisons but may reach the community at large.[10]

In recent years, several reports have emerged indicating a high incidence of infection and disease in the closed environment of prisons. Prevention consists of carefully identifying reactors on entry, checking reactors radiographically for active disease, periodic skin testing for detection of new infection, and following the preventive guidelines of the American Thoracic Society and Centers for Disease Control in the use of preventive chemotherapy.

Tuberculosis Among Health Care Workers

Tuberculosis has long been and remains an occupational hazard for health care workers. Although its incidence is much lower today, it is concentrated in those who are most commonly hospitalized or admitted to nursing homes. Thus, the risk of being infected by exposure to persons with unrecognized tuberculosis has increased. Several epidemiologic surveys have indicated considerable risk of disease among medical students and physicians, as well as others engaged in patient care.[11]

Procedures such as bronchoscopy, laryngoscopy, esophagoscopy, and gastroscopy upon persons with unsuspected tuberculosis can be particularly hazardous for the operator and assistants. It is advisable to use upper air sterilization with ultraviolet lights to reduce this risk. In addition, patient care personnel should be tested annually with tuberculin to detect and treat new infections before they produce disease.

Extrapulmonary Tuberculosis

For the past two or three decades, the incidence of extrapulmonary disease has remained almost constant despite a marked decline in pulmonary tuberculo-

sis.[12] In recent years, it has been observed that extrapulmonary manifestations of tuberculosis often occur more often in patients with immunosuppression.[13] Diagnosis of diseases is often delayed due to confusion with other symptomatology of the immunosuppressed patients. Acquired immunodeficiency syndrome (AIDS) may manifest extrapulmonary involvement (particularly lymphadenitis and generalized dissemination in 60% to 75% with the disease.[14,15] The incidence of tuberculosis is 10 to 15 times higher than in the general population in chronic renal failure and in patients requiring chronic renal hemodialysis. Involved sites are usually lymphatic, pleural, and skeletal. A high index of suspicion must be maintained for the diagnosis of extrapulmonary disease. Early collection of body fluid or biopsy specimen for appropriate culture and histopathologic examination facilitates the diagnosis.[16] In some suspected patients without confirming bacteriologic evidence, therapy with antituberculosis chemotherapy may be advisable because of the life-threatening nature of the situation. This should not be instituted until adequate specimens have been submitted to the laboratory to permit the diagnosis to be made eventually and susceptibility of the organisms to be determined. In 15% to 20% of tuberculin reactors who appear clinically to have tuberculosis (whether pulmonary or extrapulmonary) a positive bacteriologic diagnosis may not be forthcoming despite a careful investigation. A presumptive diagnosis is acceptable in such situations and empiric therapy instituted as a clinical trial.[16] As any approach is fraught with error, such patients must be observed carefully for clinical and radiographic response and a decision can be made in retrospect at 3 months as to the clinical diagnosis. In responsive patients, a presumptive diagnosis of tuberculosis is justified and a full course of therapy should be completed.

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Legal Aspects

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Diagnosis

In reaching a diagnosis of tuberculosis, as in any disease, a physician must conform to the accepted standard of care by applying a minimum of ordinary care as measured by the average physician in his profession.[1] This minimum includes the ordering of proper diagnostic tests. A patient may assert a claim against a physician for failing to order proper diagnostic tests if the patient shows: 1) it is a standard practice to use a certain diagnostic test under the circumstances of the case; 2) the physician failed to use the test and, therefore, failed to diagnose the patient's illness; and 3) the patient suffered injury as a result.[1]

Even if the proper test is ordered, before using such a test the patient must be informed of its possible side effects or risks and any alternative tests so that he may give an informed consent.[2,3]

One of the most common claims in malpractice suits against physicians is misdiagnosis.[1] It is important to note that although a physician does not insure correct diagnosis or treatment, he must undertake diagnosis and treatment reasonably and according to the accepted standard of medical care.[1]

Misdiagnosis or delay in diagnosis of the patient's disease due to substandard care may render the physician liable for damages if it has caused injury to the patient.[4] This duty the physician owes to the patient has been expanded in some cases to third parties. Thus, the physician may have a duty to inform third parties of the danger the patient may present to them.[4] Therefore, certain family members should be informed of necessary precautions where tuberculo-

sis is suspected. Special provisions should be made where the patient will come into close contact with many individuals, particularly in nursing homes, prisons, hospitals, and the like. The general rule is that in such cases the physician is bound to apprise one whom he should reasonably believe to be exposed to the patient and to take appropriate steps to protect that third party.[4] This may include notification of appropriate public health authorities.

Drug Treatment

The drugs used to treat tuberculosis, as with all drugs, may themselves produce complications. Therefore, not only should a patient be informed of such risk and alternatives, as mentioned, but a physician should also keep these potential complications and available alternatives in mind with regard to weighing the best treatment for the patient. This is particularly appropriate when considering chemoprophalaxis.

Once treatment is commenced, the patient should be monitored according to the acceptable standards in the profession. If the patient is not carefully monitored or if he is improperly treated, to the extent this causes harm to the patient and constitutes substandard care, the physician may be liable in damages to the patient.

Surgery

As with many diseases, there may be instances where drug therapy is the preferred treatment for tuberculosis as opposed to surgery. Particularly with regard to tuberculosis, the advent of modern medicine has enabled the physician to effectively treat the tuberculosis patient with INH, Rifampin, and similar drugs to avoid surgery. Therefore, if a physician performs surgery where drug therapy would have been the preferred treatment, he may be liable in damages to the patient.

As with diagnostic tests and drug therapy, the potential candidate for surgery should be informed of the possible risks inherent in the procedure and any alternative therapy before obtaining his consent. Once informed consent is obtained, the surgery and follow-up care will also be governed by the standard of care as measured by the average surgeon. Therefore, in those cases in which surgery is indicated, the physician must obtain informed consent, undertake surgery with ordinary skill and care, and continue to follow-up with the patient's progress accordingly.

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30

Hypersensitivity Lung Disease and Challenge Testing

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Definition

Hypersensitivity pneumonitis (HP) or extrinsic allergic alveolitis (British terminology) is defined as a pulmonary illness caused by an immunologic reaction to a variety of inhaled environmental antigens that involves the periphery of the lung.[1] The affected subject acquires an abnormal sensitivity or heightened reactivity to the inciting agent, resulting in an inflammatory host response located primarily in the alveolar-air exchange portion of the lung rather than in the conducting airways seen in asthma. The distinction is important, for certain types of asthma, notably extrinsic, IgE-mediated allergic asthma, is also a form of hypersensitivity lung disease often associated with airborne organic antigens.[2]

Historical Introduction

Ramazzini published the first description of hypersensitivity pneumonitis in 1713. He described a pneumonia-like illness in individuals working with cereal grains that were not properly dried before storage. This report was ignored until 1932, when Campbell published his classic description of farmer's lung disease. Since then, numerous papers have been published reporting similar symptoms resulting from exposure to different agents. In the late 1950s and early 1960s, reports by Dickie and Rankin[2] described the pathological findings in patients with farmer's lung disease. Literature from the late 1960s and 1970s further elucidated the radiologic, pulmonary physiologic, and immunologic[3] aspects of this disease.

A fungal and allergic etiology for bagassosis came from the work of Hearn and Holford-Stevens in Trinidad and London, who isolated thermophilic actinomycetes from bagasse dust. They demonstrated precipitins in exposed workers and positive bronchial challenge tests to extracts of the organisms.

Bagassosis is categorized as an example of hypersensitivity pneumonitis not only by its clinical and radiologic features, but also by histologic, immunologic, bronchial challenge, and animal model studies. Ten years of pertinent articles on litigation relating to hypersensitivity pneumonitis revealed only bagassosis, which was compensable in Puerto Rico.

Emanuel et al first described in 1966 an interstitial pneumonitis in paper mill workers and subsequently demonstrated that the disease was caused by sensitization to a mold *Cryptostroma corticale*. Exposure occurred when bark was stripped from moldy logs that had been stored before processing.

The incidence of hypersensitivity pneumonitis appears to be low and litigation relating to these diseases is almost negligible. However, this may be due to the lack of a precise diagnosis and the inability to identify the precipitating agent.

These diseases may be legally identified as occupational diseases because they have the following required characteristics[4]:

1. Gradual development, although possibly at a variable rate
2. Usually a continual absorption of deleterious substances
3. Continuous exposure to a particular work situation, finally causing physical impairment
4. Originated with the employment and not pre-existing
5. Natural and reasonable expected result after a considerable period at a particular occupation
6. First and early stages not always perceptible
7. Peculiarly related to a given occupation
8. Latency and progressive development

The main criteria for diagnosis of hypersensitivity pneumonitis are[1,5,6]:

1. Exposure to offending antigens revealed by history and aerobiologic or microbiologic investigations of the environment
2. Symptoms compatible with hypersensitivity pneumonitis appearing or worsening some hours after antigen exposure
3. Lung infiltrations compatible with HP visible on chest radiographs
4. Basal crepitant rales audible on auscultation of the lungs
5. Impairment of the pulmonary diffusing capacity
6. Arterial oxygen tension (or saturation) decreased at rest or during exercise
7. Restrictive ventilatory defect demonstrated by spirometry
8. Histologic changes compatible with HP in a lung biopsy specimen
9. Positive bronchial provocation test either by work exposure or by controlled inhalation challenge.

It is agreed that the diagnosis can be considered confirmed if, after adequate procedures for differential diagnosis have been applied to exclude other diseases with similar symptoms and clinical findings, the patient fulfills all of the major criteria *and* at least two of the additional criteria.

Hypersensitivity pneumonitis is due to the inhalation and subsequent sensitization to a wide variety of organic dust antigens. The offending agents may be

TABLE 30.1. Occupational hypersensitivity pneumonitides.

Disease	Exposure
Farmer's lung	Moldy hay and grain
Bagassosis	Moldy sugar cane
Mushroom worker's lung	Moldy compost
Woodpulp worker's lung	Moldy logs
Maltworker's lung	Moldy malt and barley
Humidifier/air-conditioner disease	Contaminated water, fungal spores, amoeba, endotoxin
Organic chemical HP	Isocyanates, phthalic, trimellitic, and tetrachlorophthalic anhydrides

For a more complete listing, see Schlueter[5] and Salvaggio.[6]

bacterial, fungal, serum proteins, chemical, or yet undefined agents. Table 30.1 lists some of the more common exposures that have been implicated in hypersensitivity pneumonitis.

Clinical Features of Hypersensitivity Pneumonitis

Exposure to organic dusts and chemicals frequently produces transient and reversible clinical and physiologic changes that may obscure the diagnosis. Therefore, familiarity with the various clinical presentations of hypersensitivity pneumonitis is essential to avoid a delay or failure to make the proper diagnosis. Regardless of the specific causative agent involved, the patient with HP may present with one of three different types of response.[1,5]

The classic and most common response is the acute form of the disease which resembles an acute viral or bacterial infection. It generally results from intermittent exposure to the antigenic material. Symptoms include chills, fever, sweating, chest tightness, nonproductive cough, and shortness of breath without wheezing. These symptoms develop from 4 to 8 hours after exposure and resolve spontaneously in 12 to 24 hours without treatment but tend to recur on re-exposure. This delayed response often results in failure to recognize the relationship of an environmental exposure and the occurrence of symptoms. Physical findings include rapid breathing and heart rate, cyanosis, and late bibasilar inspiratory rales. Wheezing is rarely heard. Laboratory studies reveal a leukocytosis. Immunoglobulins including IgG and IgM are usually elevated, and a positive rheumatoid factor may be present in some patients. High titers of precipitating antibody against the offending antigen can be demonstrated in the patient's serum. The chest x-ray may be negative after a brief exposure, but with more prolonged exposure, a diffuse pattern of small, somewhat discrete nodules may be seen or diffuse, soft, patchy interstitial infiltrate may be present. The typical physiologic change is restrictive in type with a decrease in vital capacity and lung volumes without airways obstruction. Hypoxia is usually present and the diffusing capacity invariably reduced. The latter

abnormality may persist for some time after other parameters have returned to normal. Long-term follow-up studies in patients who continue to have only brief and infrequent exposures to the causative agent usually do not show a significant decrement in pulmonary function.

The subacute form of HP is considerably less common and tends to develop with more chronic exposure. Symptoms develop insidiously and resemble chronic bronchitis manifested by chronic productive cough, progressive dyspnea, easy fatigue, anorexia, and weight loss. Physiologic changes may show either a restrictive or an obstructive ventilatory impairment with the former predominating. The diffusing capacity is usually low and tends to remain so for a considerable period after exposure is terminated.

The chronic form of HP occurs in individuals with prolonged low-level exposure or repeated intense exposure to antigen. Progressive dyspnea is the most common symptom and pulmonary fibrosis the predominant clinical finding. Acute attacks can be precipitated with heavy exposure to antigen. Chest x-ray shows changes consistent with pulmonary fibrosis. Pulmonary function studies show primarily a restrictive pattern with reduction in all lung volumes. Hypoxemia is frequently present at rest and almost always with exercise, and the diffusing capacity is low. Even with prolonged avoidance of exposure, the abnormalities may not resolve and, in fact, there may be continued deterioration in function.

Pathogenesis

The immunologic mechanisms involved in HP have not been clearly defined. Studies in humans with HP and animal models suggest that this disease develops as the result of a complex series of immunologically specific events involving initial sensitization, the development of granulomatous and mononuclear cell pulmonary infiltrates, and the ultimate modulation of this inflammatory response by a series of genetically determined immunoregulatory events.[6] Hypersensitivity pneumonitis exhibits features that suggest immune complex-mediated disease as well as cell-mediated hypersensitivity. The lung lesions are characterized by a predominance of T-lymphocytes and macrophages. Bronchoalveolar lavage (BAL) fluid in patients with HP has been shown to contain an increased number of lymphocytes, primarily T-lymphocytes of the suppressor type. However, elevated numbers and percentages of suppressor cells have been found in lavage fluids from asymptomatic individuals exposed to antigen as well as those with clinical disease. Some exposed individuals without symptoms of HP also have a high proportion of BAL lymphocytes, but these cells do not respond well to specific antigen stimulation as observed in HP. Considering all of this information, it has been difficult to develop an acceptable hypothesis for the immunopathogenic sequence in individuals developing HP. The earliest pathologic changes in HP are not well defined, except for those described in a patient with farmer's lung who died several days after the first attack.

Bronchiolitis obliterans was found and the alveolar capillaries demonstrated

vasculitis. The basic pathologic process in the later acute and subacute stages is an interstitial granulomatous pneumonitis.[2] There is early infiltration of the alveolar walls with predominantly lymphocytes and some plasma cells. In the chronic stage of HP the lesions become nonspecific as the granulomas disappear, and the basic change becomes one of the interstitial fibrosis resulting in destruction of the normal lung architecture.[7] In the chronic stage of HP, the overall picture is one of an interstitial pneumonitis with scarring, honeycombing, and centrilobular emphysema.

Environmental Investigation

A carefully taken history most often provides the physician with the clues that will lead to the identification of the etiologic agent. However, as exposure to organic dusts and chemicals frequently produces transient or reversible clinical and physiologic changes often occurring several hours after exposure, the patient may fail to recognize the association of a specific exposure with these symptoms.

The occupational environment has been most often implicated as the cause of HP[3,5,6,11] and therefore should take priority. Questions[8] that have proved helpful in directing attention to a potential etiologic agent include: 1) the type of industry, because certain manufacturing processes using chemicals such as phthalic anhydride, trimellitic anhydride, and isocyanates are more likely to cause respiratory problems. 2) The duration of employment, because sensitization does not usually occur immediately. It may require weeks to years of exposure and may occur after a brief heavy exposure or a background of chronic, low-level exposure. 3) The individual's work shift is important in relating the time sequence of the symptoms and functional changes with an occupational exposure as the reaction may be delayed. 4) Part-time jobs that are often not mentioned by the patient. 5) Potential hazards from areas adjacent to the worker's immediate environment. 6) The presence and effectiveness of ventilation and exhaust systems. 7) The type of personal respiratory protection that was used. 8) Is the work area air conditioned, because there have been several outbreaks of HP not only in office buildings[9] but also in factories implicating the spray-wash type air conditioning systems. If the above questions fail to yield a potential source for the problem, the worker should be requested to obtain from his employer a list of chemicals that he is exposed to in his work indicating those agents that are considered hazardous along with the appropriate Safety Data Sheets.

The Occupational Safety and Health Administration (OSHA) has promulgated the Hazard Communication Standard (HCS) commonly referred to as the Right-to-Know law.[10] This standard requires qualified employers to inform their employees of any hazardous chemicals to which they may be exposed.[10] In addition to providing Material Safety Data Sheets (MSDS), the employer must provide labels and other forms of warning and training.[11]

This standard is only binding on those employers engaged in the manufacturing industry under codes 20 through 39 of Division D in the *Standard Industrial*

Classification Manual. However, this classification encompasses employers engaged in activities that may be associated with some of the antigen sources listed in Table 30.1. A chemical is considered hazardous if it is a physical or health hazard. A health hazard is defined as "a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees."

The employer is required to make available to the employees the Material Safety Data Sheets and other information about these chemicals. However, if the specific chemical identity is a trade secret, the employee may only obtain information in the Material Safety Data Sheet concerning the properties and effects of the chemicals except in an emergency situation. In nonemergency situations, an employer must disclose the chemical identity, even if it is a trade secret, to the treating physician if: 1) the request is in writing, and 2) the request describes with reasonable detail one or more occupational health needs for the information. Additionally, the physician must explain why the specific chemical identity is essential to fulfill these needs in lieu of disclosure in the MSDS. The physician also may be required to adhere to certain confidentiality requirements set forth in the HCS. If the employer denies access to the specific chemical identity the physician may then refer his request and the employer's denial to OSHA for either enforcement of the request or affirmance of the denial. Additional sources of information include the National Institute for Occupational Safety and Health (NIOSH), which publishes criteria documents on a variety of agents and various reference books.[11,12] Once the worker files a Worker's Compensation claim, the compensation insurance company becomes involved and may be a source of information.

In some cases, it may be necessary for the physician to make a site visit to the worker's plant for a better understanding of his work environment. Where a quantitative assessment of an exposure is necessary, an industrial hygiene survey is required. On occasion, the employee will bring a number of agents that he uses in his job to the physician for evaluation and/or possible inhalation exposure studies. It should be emphasized that no materials should be removed from the plant without prior permission from management. Unless this is done, the employee could be discharged for theft.

In recent years, there have been an increasing number of reports of HP resulting from other than occupational exposures. The sources of these exposures included furnace and room humidifiers, cold water vaporizers, saunas, hot tubs, and air-conditioning systems in the home as well as in the automobile. These potential causes of HP must be excluded before the occupational environment can be implicated with certainty.

Patient Evaluation

The most important factor in the diagnosis of HP is a thorough and accurate history. Careful documentation of the time sequence and pattern of symptoms in relation to exposure at work as well as away from work is essential. A diary

kept by the patient over a period of observation can be helpful in accomplishing this objective. This is particularly true for the subacute and chronic forms of the disease where changes may be very subtle.

The physical examination is not particularly helpful because it is usually negative. The chest x-ray may show a diffuse nodular pattern or a patchy infiltrate resembling an acute pneumonia. Between the acute episodes, the chest x-ray is usually negative. With more chronic disease, the x-ray may show changes consistent with pulmonary fibrosis.

Laboratory studies are nonspecific; however, serum precipitating antibody against the offending antigen can be demonstrated in almost all cases. It must be emphasized that the presence of precipitating antibody is not adequate to make a definitive diagnosis of HP as 40% to 50% of exposed individuals may be have antibodies present in their serum without developing disease. Pulmonary function changes were described under the section, "Clinical Features."

Provocative Inhalation Challenge

At the present time, the most definitive test for the diagnosis of HP is inhalation exposure to the suspected antigenic material accompanied by monitoring of the clinical and physiologic response.[3,5,13] Although a particular agent or environment may be suspected as the cause of HP on the basis of the patient's history, provocative challenge may be necessary to clearly establish that relationship.

Choosing the type of exposure depends on the suspected source of the antigenic material. If a complex occupational exposure involves multiple chemicals or complex operations, laboratory exposure is not practical. The alternative is to have the patient return to work with pre- and postshift pulmonary function studies and a repeat at the end of the work week. A diary should be kept to record symptoms. Similar studies should be performed during a control period away from the occupational environment. Simple devices are available for measuring pulmonary function that the patient can be instructed to use and are capable of producing reliable measurements. The results of these studies, if positive, would establish a causal relationship between the work site and the disease. Ideally, if a specific antigen or suspected antigens can be identified, provocative inhalation challenge should be performed in the laboratory. Details and guidelines for inhalation challenge procedures are available.[13] In experienced hands, this procedure can be carried out safely and with minimal discomfort to the patient. However, this type of testing should not be undertaken by inexperienced personnel who may not be able to recognize when therapeutic intervention should be initiated, or in the absence of emergency facilities capable of managing a severe reaction including resuscitation and intubation. This would make the hospital laboratory the most suitable site for this procedure. Baseline pulmonary function should be at least 65% of the predicted normal. Although the immediate type reactions can be readily reversed with bronchodilator, the late reactions, peaking 6 to 8 hours postexposure, can result in significant decrements in function, requiring corticosteroids, and tend to resolve slowly even with treatment. Finally, the patient must

be off medications that may affect the response including antihistamines, theophylline, corticosteroids, beta-adrenergic agents, and sodium cromolyn.

The question of inhalation challenge resulting in sensitization to the test agent or causing aggravation of existing HP is often raised. We are unaware of any reports in the literature supporting such a response. We have performed inhalation challenge studies in more than 100 pigeon breeders and none have become symptomatic, developed HP, or shown any alteration in the course of their disease if it was already present.

Medicolegal Aspects of Inhalation Challenge

As with any diagnostic procedure or treatment, a physician should undertake the inhalation challenge cognizant of the risk that future litigation may occur in regard to the challenge itself or the symptomatology it might produce.

There are two main causes of action that may arise if the physician does not exercise reasonable care or caution before and during the inhalation challenge. One action arises when a physician fails to obtain informed consent from the patient before administering the inhalation challenge. The other action arises when a physician fails to exercise reasonable care while administering the challenge.

Except in an emergency, a physician must obtain the consent of the patient before undertaking any medical treatment. A corollary of this rule is that consent given without adequate knowledge of the risks is not an informed consent and, consequently, is ineffective.[19] Thus, a physician must first make a frank disclosure of the risks involved in the procedure he wishes to undertake. In addition to informing the patient of the risks of a particular procedure, the physician must inform him of feasible alternative methods of treatment or diagnosis. Therefore, a patient should be told of the risks inherent in the inhalation challenge, the specific symptoms that may result, and any alternate diagnostic procedure available before undertaking the challenge. The importance of informed consent cannot be stressed enough. Even when a physician is not negligent in his diagnosis or treatment of a patient, he may nevertheless be liable for malpractice if he acts before obtaining informed consent.[14]

Once informed consent has been obtained, the physician must undertake performance of the inhalation challenge with reasonable skill and care to avoid liability for malpractice. If the physician's office is not well equipped for resuscitation, the challenge should be performed in the hospital setting.

There are essentially four elements that must be present to state a claim for malpractice:

1) a physician-patient relationship;
2) the physician owed a duty to the patient;
3) the physician breached that duty; and
4) the breach of that duty was the proximate cause of the injury.

Thus, in every situation involving diagnostic tests, a physician should:

1) obtain informed consent by explaining to the patient:
   a) the risks of the particular procedure,
   b) the feasible alternative procedures, and
   c) the risk of not performing the procedure;
2) order all diagnostic tests necessary to obtain sufficient information on which to base his actions; and
3) perform those procedures with the skill and care demanded in his field.

Inhalation challenge with the causative agent in patients with HP can produce several patterns of response. The most common is a late reaction that peaks from 4 to 8 hours after exposure. It results in a restrictive impairment (decreased FVC, $FEV_{1.0}$, and lung volumes without airways obstruction, hypoxemia, and decreased diffusing capacity). The reaction usually resolves within 24 hours, but resolution can be accelerated by the administration of corticosteroids. The second pattern involves an immediate reaction usually occurring within the first 30 to 60 minutes showing airways obstruction (decreased $FEV_{1.0}$, $FEV_{1.0}/FVC$, and FEF_{25-75}). This component tends to resolve fairly rapidly without treatment only to be followed by a late reaction, as previously described. The dual reaction is more likely to occur in atopic individuals or in those who have had repeated acute attacks of HP. They also will frequently demonstrate bronchial hyper-reactivity with methacholine testing.

Thus, the environmental challenge, albeit at the work site or in the laboratory, is important in identifying a specific agent, identifying a problem area, demonstrating the clinical and physiologic response, establishing a causal relationship, and evaluating corrective measures.

Prevention and Treatment of Hypersensitivity Pneumonitis

Identification of various organic dusts and chemicals having the potential to cause HP should stimulate efforts to decrease or eliminate the exposure. Changes in work practices, for example, altering procedures for storing and handling maple logs in paper mills completely eliminated maple-bark stripper's disease. Personal protection usually is not adequate, particularly with organic chemical exposures.

Summary and Conclusions

The most effective measure in therapy, once an individual is sensitized, is complete avoidance of the offending antigen. When symptoms are present, corticosteroids are effective in accelerating the resolution of symptoms and physiologic changes. This response may be delayed or incomplete in the subacute and chronic forms of the disease.

There is insufficient data available at this time to determine with certainty

that continued exposure to antigen while controlling symptoms with medication will prevent the subsequent development of irreversible lung damage. Therefore, this approach is not recommended except under very unusual circumstances, and avoidance of exposure remains the treatment of choice.

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31

Asthma in the Emergency Room

Medical Aspects

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It is estimated that acute asthma accounts for approximately 135,000 hospital admissions annually in the United States. Physicians practicing in emergency departments have difficulty in predicting whether a patient should be admitted or whether the patient should be treated and discharged from the emergency room.

Each patient presenting to the emergency room requires a series of steps in decision making and therapy. The asthmatic condition is so variable, both between patients and within a single individual, as to preclude a stereotyped approach or rigid guidelines. There are no clear rules that can be laid down to dictate management. There is a large body of information, which makes it possible for the physician to approach the treatment of asthma in a rational and informed fashion.[1,2]

Diagnosis

The vast majority of patients enter the emergency room with a diagnosis that has been well established and well known to the patient. Generally, patients have had symptoms and received treatment for asthma before and they are often known to the emergency room they visit. The diagnosis is established by demonstration of variable airflow obstruction. This can be demonstrated by measurement of peak expiratory flow rate (PEFR).

Such a measurement is critical to the diagnosis and treatment of all patients with asthma.[7] Peak flow rate PEFR corrolates with other measures of expiratory flow, such as the 1-second forced expiratory volume. It has the advantage of not requiring the patient to perform a complete forced expiration which, in itself, can cause worsening of symptoms and bronchoconstriction. This measurement can be obtained with a small, inexpensive peak flow meter, and the measurement can be performed repeatedly during treatment. Peak flow bears the same relationship to the treatment of asthma as measurement of blood pressure does to hypertension.

History

When the patient presents with classical symptoms of asthma, treatment can be started without delay. One can then obtain historical information that will have an important bearing on subsequent management. A search for precipitating factors most commonly reveals a nonbacterial respiratory infection. Many patients develop asthma on exposure to odors. Specific information about previous intubation should be sought, because we know that patients with this history are at risk for recurrence of life-threatening asthma.

Two classes of drugs that must be inquired about are beta-blockers, and aspirin and nonsteroidal anti-inflammatory drugs. Beta-blockers deprive patients of their major adaptive defense to bronchoconstriction, through release of adrenergic beta-agonists, and are known to be extremely hazardous. Even eye drops containing beta-blockers can precipitate an attack of asthma. Aspirin and nonsteroidal anti-inflammatory drugs have an effect on the metabolism of converting arachidonic acid into mediators of asthma. These agents can induce an explosive attack, particularly in middle-aged women with sinusitis.

About 40% of women develop an excerbation of asthma at the time of menstruation. The mechanism for this is not known and there is no specific therapy. Generally, treatment is increased just before the onset of the menstrual period.

Physical Examination

Physical findings are notoriously poor guides to the severity of asthma.[4,8] Assessment of the activity of the accessory muscles is useful. Use of the inspiratory muscles is an important compensation to expiratory airflow obstruction, and failure of these muscles is the cause of respiratory failure. Inspiratory muscle activity is necessary because during expiration, forced expiratory efforts cause airway closure, and the only effective compensation to the narrowed lumen of the airway is to hyperinflate the lung. The efficient compensation for acute asthma is for the patient to breathe at high lung volumes.

Another guide to the severity of asthma is the measurement of pulsus paradoxicus, a reflection of the large negative pleural pressure swings generated during inspiration in the patient with asthma.[3] In general, the presence and severity of "paradox" correlates with severity of asthma. Absence of paradox, however, is not sufficient reassurance that asthma is mild. Further, an overanxious patient with mild asthma may be making violent inspiratory efforts so that a paradoxical pulse may be present even though asthma is mild. For these reasons, peak flow is a better measurement to assess severity of asthma.

Differential Diagnosis

In most cases the differential diagnosis is relatively clear. Although it is true that all that wheezes is not asthma, most patients who wheeze do indeed have that diagnosis. Upper airway obstruction can be associated with noisy

breathing, but stridor is usually audible over the neck. In case of doubt, a flow volume loop with measurement of inspiratory flow rates should be done. Reduction of inspiratory flow rate parallel with expiratory flow rate is consistent with upper airway obstruction. One characteristic of patients with asthma is that they cannot breath hold in contrast to patients with upper airway obstruction.

Pulmonary edema should not be confused with asthma as there will generally be a history and signs of underlying heart disease. Also the musical wheezes of asthma should not be present. Pulmonary embolism should also not be a problem in differential diagnosis, as it is not associated with wheezing. Patients with obstructive lung disease who develop pulmonary embolism may wheeze because of the increased respiratory drive. It is our experience that patients with pulmonary embolism are much more likely to be misdiagnosed as pulmonary embolism than vice versa. It is important to remember that asthma is associated with variable hyperinflation of lung units that are distal to the obstruction and is regularly associated with perfusion defects on lung scan. Thus, false-positive lung scans are common in asthma.

Anxiety attacks can present with features indistinguishable from asthma. The measurement of a normal expiratory flow rate will establish the diagnosis relatively quickly.

Evaluation of the Patient

The key to the evaluation of asthma is the measurement of PEFR. In general a value less than 100 L per minute is considered indicative of severe asthma. Most normal subjects can achieve peak flow rates of 400 to 600 L per minute depending upon age, sex, and height.

Once the diagnosis of asthma has been established and treatment instituted, there is no need for further diagnostic studies. A number of studies have established that a chest x-ray is of little value in the evaluation of patients with asthma, and in the vast majority of cases is normal. Rarely, asthma is associated with barotrauma, but this is generally of little consequence.

One point of legal significance is that mucous plugs in large airways can cause atelectasis, but it has been shown that this resolves with treatment of asthma and does not require special intervention such as bronchoscopy.

Measurement of arterial blood gases is important but is not necessary in all patients. Characteristically, patients with asthma have increased respiratory drive. Because of this respiratory drive, their alveolar ventilation is increased and the P_{CO_2} is below normal. As asthma worsens, it is impossible to sustain this alveolar ventilation with the result that alveolar ventilation falls and P_{CO_2} rises. This rise in P_{CO_2} is a clear sign of severe airflow obstruction. It indicates that treatment in an intensive care unit is necessary. If a peak flow less than 100 L per minute persists, it is appropriate to measure arterial blood gases. Most patients have some degree of hypoxemia, but P_{O_2} is rarely below 60 mm Hg, and oxygen therapy becomes important only when P_{O_2} levels drop further. We have also recently learned that respiratory acidosis in the severe asthmatic

is often preceded by metabolic acidosis, so that although the P_{CO_2} is below 40 mm Hg, the pH is not as alkaline as it should be.[9] In these patients, blood lactate is increased and it is likely that they will require intubation. In most patients, other laboratory tests are unnecessary. About 25% of patients with acute asthma show signs of right ventricular hypertrophy, including P pulmonale on the electrocardiogram. Many asthmatics also have transient hypertension which does not require any treatment.

Treatment

The most important therapy for acute asthma is the inhalation of a beta-adrenergic agonist.[10,11] It is now well documented that patients who claim to have been fruitlessly using metered-dose inhalers (MDI) often respond to the same drugs when administered by the physician in the emergency room. The sick asthmatic may have difficulty using the MDI. It is best to begin inhalation of a beta-agonist, using a jet nebulizer. A number of studies have shown that inhalation therapy is just as effective as administration of a beta-agonist by injection.

It is conventional to couple the administration of beta-agonists with intravenous aminophylline, although a number of studies have shown that theophylline adds little to the therapeutic efficacy of properly administered beta-agonists. Yet, most patients who come to the emergency room expect intravenous drug treatment. It is unwise to start theophylline therapy with a priming dose without obtaining a blood theophylline level. Most patients with asthma respond to treatment. In others, asthma persists and additional measures are required.

Corticosteroids

Steroids differ from other bronchodilators in that they act more slowly and produce bronchodilation by other mechanisms. Asthma is, in fact, a chronic inflammation of the airways that results in release of mediators of inflammation. The inflammation is probably modulated by steroids. Although a short, brief episode of bronchospasm should not be treated with steroids, asthma of longer duration may require such treatment. Often, an acute asthma attack follows the tapering of steroids. Patients with a history of life-threatening asthma or with a history of steroid use in the past should be given these drugs when they first come to the emergency room. Steroids should be rapidly tapered once asthma is under control.

Other Measures

As previously mentioned, oxygen is rarely needed. IPPB is of no proven value. Although there is interest in the use of atropine, anticholinergic drugs have proven to be of little value in acute asthma. Cromolyn has no place in the management of the acutely ill patient.

Many patients with asthma are nervous, upset, and agitated. Although these

patients would benefit from sedatives, it has been found that the administration of these drugs to hospitalized patients was associated with sudden unexpected death. What probably happened in these cases was that asthma progressed to fatal airway obstruction without warning. When these drugs were banned from the treatment of acute asthma, there was a sharp reduction in sudden deaths. Patients with acute asthma should be given sedatives or tranquilizers only after they have been intubated and placed on a ventilator.

Discharge Criteria

Patients should be discharged from the emergency room only when they are well enough to cope at home and when the physician is confident that they will not worsen. In general, one should consider discharge when the peak flow is over one-half normal. The patients who have received little therapy before entry into the emergency room generally show more dramatic improvement in flow rates than those who have been on maximal therapy. The latter are far more apt to require hospitalization. Patients with a history of life-threatening asthma must be treated with extreme caution. Only if there has been substantial improvement should they be allowed to go home.

Criteria for Hospitalization

The need for hospitalization is usually dependent on the response to therapy. A number of attempts have been made to quantify various aspects of asthma and to derive indices of severity, which are predictive of the need for hospitalization. Unfortunately, studies of this sort are flawed by the fact that the criterion for subsequent hospitalization upon which the accuracy of the index is based are largely dependent upon the amount of medication that the patient continues to take after leaving the emergency room. Even the sickest asthmatic can respond very quickly to medication.

Obviously, patients who arrive apneic in the emergency room and require intubation will have to be hospitalized. Patients with a history of life-threatening asthma who arrive on full therapy need the extra attention that could be offered in hospital.[5] Patients who remain acutely ill, despite intensive therapy, require measurements of blood gases and admission based on those criteria. The patient's own wishes and concerns play an important part in this process.

These judgments should be made with the recognition that emergency room and hospital treatment of asthma is often a matter of maintaining maximal therapy until the patient improves, coupled with continuous observation to deal with life-threatening complications. In fact, medications given in the emergency room can just as well be taken by the patient at home. Steroids can be absorbed just as rapidly by mouth as by vein. Theophylline levels are generally maintained in the ambulatory patient, and inhaled beta-agonists are just as effective as those given by other routes. Most patients can drink fluids by mouth, and a major impact of the emergency room and hospital therapy is

provision of a supportive environment in which the patient feels comfortable. The crux of the ultimate decision to admit to hospital or discharge is whether or not the patient is well enough and will stay well enough to continue to improve at home.

Indications for Intubation

A major decision that arises in the course of management of a sick patient with asthma concerns the need for tracheal intubation. Such an intervention is indicated when the patient's respiratory muscles fail to respond to the large resistive load imposed by airflow obstruction. This decision is a matter of personal judgment and cannot be dictated by a set of prescribed guidelines.

In some patients, the need for intubation is obvious because the patient arrives or becomes apneic as treatment is begun. In other patients, it is necessary to make a judgment whether or not respiratory failure is imminent. Continued breathing against a high load will lead to failure of the respiratory muscles. Patients who are apt to develop respiratory muscle failure may demonstrate progressive reduction of minute ventilation, reflected in a rising arterial P_{CO_2}, but there is no level of arterial P_{CO_2} that mandates artificial ventilation. Patients with acute hypercapnia may respond quite rapidly to therapy so that they do not require ventilatory support. In most patients, the respiratory efforts are sufficient to provide adequate alveolar ventilation. Clues to the development of respiratory muscle failure include slowing of respiratory rate and the development of intermittent paradoxical inward movement of the abdomen during inspiration, reflecting transient cessation of diaphragmatic activity.

Follow-up Therapy

Treatment of the acute episode of asthma is only the first step in management of the patient. Clearly, it is not enough to provide immediate relief of airflow obstruction, because if nothing more is done it is likely to recur. After the patient has improved and stabilized in the emergency room, an appropriate regimen must be prescribed.

Some patients who have been on little therapy and respond quickly to bronchodilators can be discharged with instructions to take a long-acting theophylline and inhaled beta-agonists. It is essential that the patient be observed in inhalation technique so that the physician knows that the medication is being inhaled into the lungs.

The bronchodilator regimen should also include a long-acting theophylline preparation designed to maintain an appropriate blood level. In many patients the dosage requirement will have been established previously. In others it may have to be calculated.

Patients who are given corticosteroids in the emergency room must be continued on maintenance therapy. Most patients can be started on 40 to 60 mg of prednisone a day, best given in divided doses. When full improvement has occurred the dose can be gradually reduced.

As part of the follow-up, it is essential that the patient be scheduled to visit a physician within a week of discharge to make certain that medication is being taken properly.[6]

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Legal Aspects

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Most discussions of medical malpractice suits center around a disputed set of facts. The ultimate determination usually turns upon the persuasiveness of the expert opinions offered on these facts.

Because the sick or asthmatic patient has something wrong at the time he enters the emergency room or consults the physician, numerous decisions involve attempts to determine if the poor result of treatment was caused by the physician's negligence or the pre-existing condition of the patient. Before any patient can recover damages, he must eliminate his condition as the competent producing cause of the failure to recuperate.

In most situations, expert medical testimony must be presented to prove that a negligent act and not the pre-existing illness was the proximate cause of the patient's condition.

As early as the year 1898, the highest court in New York established the basic definition of medical negligence in the case of *Pike v. Honsinger,* 155 N.Y. 201, 49 N.E. 760. The Court, in part, said:

. . . Upon consenting to treat a patient, it becomes his duty to use reasonable care and diligence in the exercise of his skill and the application of his learning to accomplish the purpose for which he was employed. He is under the further obligation to use his best judgment in exercising his skill and applying his knowledge. The law holds him liable for any injury to his patient resulting from want of the requisite skill and knowledge or the omission to exercise reasonable care or the failure to use his best judgment. . . .

The law is clear that a hospital is protected from liability when it follows the direct and explicit orders of the attending physician, unless its staff knows that the doctor's orders are "so clearly contraindicated by normal practice that ordinary prudence requires inquiry into [their] correctness" (*Toth v. Community Hospital at Glen Cove,* 22 NY2d 255, 265 n.3, 292 NYS2d 440, 449, n.3).

When, however, a patient comes to an emergency room of a hospital for emergency treatment and is treated by the emergency room physician, when there is no attending doctor, liability as to the hospital may ensue if the emergency room physician or staff is guilty of malpractice in the treatment of the patient (see *Mduba v. Benedictine Hospital,* 52 A.D.2d 450).

In the Mduba case, supra, page 453, the Court stated:

. . . Defendant having undertaken to treat decedent, which included both the necessary treatment and the furnishing of blood and other medicine needed in that treatment, was under a duty to do so effectively. Patients entering the hospital through the emergency room could properly assume that the treating doctors and staff of the hospital were acting on behalf of the hospital. Such patients are not bound by secret limitations as are contained in a private contract between the hospital and the doctor. Defendant held itself out to the public offering and rendering hospital services (see *Harmon v. Siegel-Cooper Co.,* 167 N.Y.244; *Santise v. Martins, Inc.,* 258 App. Div. 663, 664-665).

In treating a patient who comes to an emergency room suffering from an asthmatic attack, the emergency room physician should attempt to obtain medical and family history, particularly with regard to diseases of a known allergic nature. Patients should be questioned about their use of medications and any previous adverse reactions to the drug or drugs designated for intended use. Likewise, they must be asked if they suffered any symptoms that could be attributed to an allergic reaction, such as rashes, hives, and eczema.

All drugs should be viewed as potential allergens, capable of inducing anaphylaxis. Even with a relatively safe drug, dangers exist from adverse reactions. A small percentage of the population may be highly sensitive to these drugs, suffering from asthma attacks, pain, shock, or even death from an anaphylactic reaction. An anaphylactic reaction is a special type of adverse drug reaction in which there is hypersensitivity to the administered drug. The symptoms may vary from nausea to respiratory arrest and shock. There is no way to tell who is going to experience such an anaphylactic reaction to potential allergens, although it is known that asthmatics are far more susceptible than nonasthmatics.

If a manufacturer knows or should know that a product may cause serious injury to users, but does not warn the potentially injurious effects, either

through negligence or because of concern that sales of the product would thereby be reduced, he cannot be absolved from the imposition of strict liability in tort because an "aprpeciable number of users" would not be adversely affected. However, if there is a limited or small number of persons adversely affected by a given drug so that an adverse reaction to that drug is difficult to anticipate, that fact may well be relevant on the issue of the manufacturer's knowledge. Nonetheless, as stated in *Baskco v. Sterling Drug Inc.*, 416 F2d 417, page 430:

> The manufacturer is obliged to warn in cases where the drug may effect only a small number of idiosyncratic or hypersensitive users, and the obligation to warn attached regardless of whether the number of persons affected can fairly be said to be "appreciable."

If a patient has a pre-existing condition, but does not inform the doctor of that fact, and if the condition cannot be determined by the use of ordinary care in a physical examination and death occurs from hypersensitive or idiosyncratic reaction to the drug used, it is unlikely that any liability on the part of the physician could be established. The issue becomes whether a particular choice of treatment brings about a cure, or was in fact that "right treatment" with the benefit of hindsight. Rather, the issue is whether the treatment chosen, based on facts available to the physician at the time of the treatment, was reasonable.

It has been said that the average physician, although adept at treating pneumonia, fractures, and other common medical problems, is likely to be a novice when it comes to handling a case of chronic asthma, or in knowing how to evaluate or to consider the distinguishing facts of the differential diagnosis of pulmonary edema. That is why history and symptoms must be testified to with great accuracy, especially in a case where the malpractice involves a failure to recognize the significance of the symptoms and signs with a consequent failure to diagnose, which prevented appropriate treatment.

Generally speaking, a physician is obliged to know what the predicted or anticipated adverse effects of any drugs will be. Prescription of a drug in ignorance of its potential harm is certainly the basis for a charge of negligence against the doctor. However, if a patient's condition warrants the use of a particular drug, and if no other drug is as effective, the physician is not negligent, even if adverse effects do occur. Under these circumstances, the doctor, of course, should first inform the patient of the risks of adverse reaction of the drug, but advising him that no other drug could appropriately treat the condition. Conversely, if another drug would be as effective and less potentially hazardous, the doctor is legally obliged to prescribe it.

In this regard, it has been recently reported in a doctor's alert bulletin that recently a small number of asthmatic patients expired shortly after the administration of a beta-blocker. Nevertheless, it is well recognized that the development of beta-receptor blockers represent a major advance in pharmacology, particularly for cardiac patients. These agents apparently can aggravate bronchial spasm in asthmatics and should be used with extreme caution.

This recent news of the beta-blocker's effect on asthmatics highlights the

importance of a physician, particularly in an emergency room, taking a careful and complete history of the patient. Thereafter, if in the physician's *best judgment* a beta-blocker *must* be used for an asthmatic patient, the doctor should carefully document his or her rationale for the use of the drug (see discussion of "best judgment" in *Markey v. Eiseman,* 114 A.D.2d 887).

Moreover, the doctor should note in the record that the patient was properly and adequately informed of the risks, hazards, and benefits of the use of the beta-blocker, and he exercised a knowledgeable consent (for discussion of Informed Consent see *Suria v. Shiffman,* 107 A.D.2d 309, 486 N.Y.S.2d 724).

As Dr. Williams indicates, a major decision that can arise in the course of management of a sick patient with asthma in the emergency room concerns the need for endotracheal intubation. If a patient arrives in an apenic condition, there is a need for prompt treatment, but care must be exercised when inserting an endotracheal tube to insure that, inadvertently, the tube does not advance into a mainstem bronchus. This fact could go unrecognized until a major complication suddenly develops. It is necessary, therefore, to document in the chart that after insertion of the endotracheal tube, a chest x-ray was obtained.

A claim for medical malpractice accrues when the act complained of occurs. However, when the claim arises out of an act committed during the course of continuous treatment that is related to the original condition or complaint, the statute of limitations is tolled until the end of the course of continuous treatment of the patient by the physician or hospital (*McDermott v. Torre,* 46 N.Y.2d 399, 452 N.Y.S.2d 351).

However, the claim is one of prescribing improper medication by a specialist and the patient's general physician periodically renews the prescription without consulting the specialist, in the absence of a continued relationship between the physicians, the continued renewals are insufficient to extend the course of continuous treatment as far as the specialist is concerned (*Schwartz v. Karlan,* 107 A.D.2d 801, 484 N.Y.S.2d 635).

32

Medical and Legal Questions in Occupational Airway Disorders

Medical Questions

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Definition

Occupational airway disorders (OAD) is a condition of the airways of the lungs caused by the inhalation of a dust, vapor, or gas that originates from a substance or material that a worker manufactures or uses directly, or which is incidentally present at the worksite. There may be widespread narrowing of the airways, with slowing of forced expiration, which vary in severity and duration depending upon the intensity of the exposure and the promptness and appropriateness of therapy.[1] Depending on the pathologic and physiologic changes occurring, there may be one or more of the following symptoms present: recurrent or chronic cough with or without phlegm production; intermittent wheezing in the chest; exertional shortness of breath; and a feeling of chest tightness. Occupational airways disorder may resolve spontaneously once the exposure is terminated (or with therapy), or may progress to an irreversible chronic obstructive pulmonary disease.

As a result of the injury to the airways, there may be an associated (an presumably induced) nonspecific airways hyper-responsiveness manifested as an increase sensitivity to inhaling many different and varying nonspecific airborne stimuli, including physical agents and pharmacologic chemicals.[2] One classification of occupational airway diseases is shown in Table 32.1.

Description of Types of Occupational Airways Disorders

OCCUPATIONAL BRONCHITIS

This disorder is a nonspecific irritant response of the airways to a variety of dusts, gases, and vapors. Deposition occurs mainly in the upper and larger airways and results in no radiographic changes. The characteristic symptoms are chronic persistent cough (without localizing disease), and/or chronic or recurrent phlegm. The symptoms, to be considered significant, must be present for at least 3 months for two sequential years. Cough and/or sputum symptoms are of most diagnostic importance in nonsmokers. In smokers, the effects of

TABLE 32.1. Classification of occupational airways disorders.

Occupational bronchitis
Byssinosis
Bronchiolitis obliterans
Occupational asthma
Reactive airways dysfunction syndrome

exposure are additive, but smoking is by far the most important factor in causing symptoms.

Pathologically, there is hypertrophy and hyperplasia of bronchial mucous glands; goblet cell hyperplasia; squamous metaplasia of surfaces of large- and medium-sized bronchi; and some goblet hyperplasia of smaller airways. There is no evidence that occupational bronchitis leads to diffuse emphysema. Pulmonary function testing reveals reduced flow in the larger airways and perhaps a slight increase in the residual volume. Often there are minor changes in small airways function. While there is some correlation between the decrement in lung function measurement and the inhaled dose, there is only a fair correlation between dose and the presence of bronchitis symptoms. In some individuals, there is also airways hyper-responsiveness present, but this differs in magnitude from what is noted in asthmatic individuals. The pathogenesis of occupational bronchitis is not related to an allergic mechanism. Symptoms can be expected to improve or disappear after exposure is terminated. Some occupations and exposures reported to be associated with occupational bronchitis are listed in Table 32.2.

TABLE 32.2. Some occupations and exposures reported to be associated with occupational bronchitis.

Examples of occupations
Miners, grain handlers, wood workers, welders, fertilizer producers, firefighters, textile manufacturers, ginners, rope and twine makers, bedding and upholstery workers, coke oven workers, poison gas factory workers, agricultural workers, animal confinement workers, metal smelters
Examples of exposures
Silica dust, coal dust, cotton dust, flax dust, wood dust, grain dust, welding fumes, irritant gases (ozone, sulfur dixodie, ammonia gas, chlorine gas, nitrogen dioxide, phosgene, and other irritant gases), diesel exhaust, pottery dust, ceramic dust, vanadium dust, cement dust

Bronchiolitis Obliterans

This process affects the most distal airways and is an obstructive lung disease that follows the inhalation of toxic gases or fumes, the prototype being nitrogen dioxide.[7] Pathologically, there is peribronchial cellular infiltration, and edematous and inflamed connective tissue forming polypoid masses in terminal and respiratory bronchioles. The scientific literature suggests that a preceeding process of an organizing pneumonia is important in the pathogenesis. Bronchitis and bronchiectasis is also seen pathologically.

Clinically, there is the rapid onset of an obstructive airways disease occurring over a several month to a few years. There may be no preceding history of cigarette smoking or asthma to explain the obstructive lung disease. It is quite common for an alveolar process with pulmonary infiltrates to be noted on the initial chest radiographs. Early on, may be only bronchitis symptoms, but later the patient notes exertional shortness of breath. When pulmonary function tests are performed, there is airflow obstruction with a superimposed restrictive lung defect. Expiratory airflow resistance predominates with the maximal expiratory flow volume curve showing less severe impairment of the inspiratory flow than the expiratory flow loop. There may also be a reduced carbon monoxide diffusion measurement. It is important to recognize the disease early, since the airways obstruction may be reversible with corticosteroid treatment in some patients. However, once the disease is fully established, it is essentially irreversible.

Nonspecific airways hyper-responsiveness has not been reported to occur with this disease. The fibrosis and obliteration of the distal airways can only be documented by an open lung biopsy, and the changes observed microscopically are the result of the toxic gas exposure. Bronchiolitis obliterans differs from RADS in its location in the airways, distinct pathologic findings, and absence of airways hyper-responsiveness.

Byssinosis

Byssinosis is an acute and chronic airways disorder among those who process cotton, flax, and hemp fibers.[8] The acute airways response, characterized by chest tightness, occurs within hours upon returning to an exposure after being off work for a weekend or vacation. Besides chest tightness, there is usually an accompanying cough with or without phlegm and occasionally there is shortness of breath.

Physiologically, one notes pulmonary function changes upon return to exposure after being off work for a few days. There is an observed decrease in expiratory flows over the work shift. Usually, these changes diminish or disappear on subsequent days of work. Cigarette smoking seems to facilitate development of the disease and lung function loss seem to be additive to that caused by cigarette smoking. The contribution of acute byssinosis to the subsequent development of a chronic form of the disease has not been well documented. A current theory to explain the pathogenesis of byssinosis focuses on the pharmacologic role of bacterial endotoxins.[8]

Occupational Asthma

Occupational asthma is a condition of the lung that has as its most unique characteristic, the develpment of an increased responsiveness of the airways to a specific agent that is present in the workplace. The specific airways responsiveness develops only after there is the passage of a latent period, whereas the individual develops a unique sensitivity or allergy to the inciting material. After this induced sensitivity or allergy occurs, any further exposure to the specific agent even when very remote or in low concentrations, results in an attack of bronchospasm with reduced expiratory airflow of varying degrees, severity, and duration depending on the intensity and magnitude of the exposure. The resultant airway injury with bronchospasm has distinct biochemical, pharmacologic, and pathologic characteristics that are similar to those described for the usual nonoccupational allergic asthma.

A consequence of the airway injury from the allergy/sensitivity with the resultant asthmatic reaction and accompanying biochemical and cellular alterations, is the development of an associated and induced increased bronchospastic responsiveness of the airways to nonspecific airborne stimuli. This nonspecific airways hyper-responsiveness is to many varied and diverse stimuli, such as distilled water, inert dusts, and irritant chemicals and gases, physical agents, such as cold air, and a number of pharmacologic chemicals, drugs, and inflammatory mediators. This nonspecific airways hyper-responsiveness may persist to various degrees causing symptoms and episodic bronchospasm for months or even years, after there is no further exposure to the specific agent that caused the original lung injury.

A classification of etiologic agents can be categorized as either *large molecular weight* proteins, such as glycoproteins, vegetable gums, animal products, insect eliminations, and plant constituents, or as *small molecular weight* allergens.[3] The latter includes acid anhydrides, platinum salts, antibiotics, and diisocyanates. Table 32.3 provides a classification of some causes of occupational asthma.

In dealing with occupational asthma, one must realize that labelling a patient with a diagnosis of occupational asthma has marked legal connotations. The area of occupational asthma is rooted in medicolegal controversy over what makes asthma "occupational" versus nonoccupational. The diagnosis of occupational asthma may imply that a worker is entitled to workmen's compensation under the Workmen's Compensation Law. Occupational asthma is an occupational airway disorder caused by the inhalation of industrial dust, vapors, fumes, or gases. For a condition to qualify as a "disorder," there must be an abnormal pathologic finding, a measurable impairment of function, and/or abnormal symptomatology. In addition, certain industrial stimuli are peculiar to particular industries. Thus, for example, isocyanate might be the stimulus for a painter developing occupational asthma.

The diagnosis of occupational asthma also provokes many legal questions. Thus, for example, what would differentiate aggravation of a pre-existing asthma syndrome from the development of a new occupationally derived

TABLE 32.3. Classification of agents causing occupational asthma.

Large molecular weight	Small molecular weight
Animal proteins	Anhydrides
Laboratory animals	Phthalic
Domestic animals	Trimellitic
Birds	Hexahydrophthalic
Sea squirts	Tetrachlorophthalic
Prawns	Himic
Mites	Dyes
Animal enzymes	Azo
Subtilisin	Anthraquinones
Trypsin	Diisocyanates
Pancreatin	Toluene
Plant proteins	Diphenylmethane
Cereal grains	Hexamethylene
Coffees	Antibiotics
Soy	Metal salts
Castor bean	Platinum
Plant enzyme	Nickel
Papain	Chromium
Bromelain	Aluminum/pot room
Pectinase	Fluxes
Diastase	Colophony
Vegetable gums	Aminoethylethanolamine
Karaya	Formaldehyde
Tragacanth	Pyrethrins
Acacia (arabic)	Wood dusts
Quillaja bark	Plicatic acid/cedar
	Quillaja bark
	California redwood
	Other wood dusts

asthma? Should a patient who has preexisting asthma be subjected to the same workload as a fellow worker who does not have asthma?

REACTIVE AIRWAY DYSFUNCTION SYNDROME (RADS)

In 1985, my associates and I reported on a unique illness that was observed to occur after a single excessively high environmental or occupational exposure.[4,5] Although the illness simulated bronchial asthma, we considered it clinically different from occupational asthma because of its rapid onset; specific relationship to a single one-time, environmental exposure; no pre-existing latent period for sensitization (i.e., allergy), to occur; and the absence of an identifiable allergy/sensitivity to a specific work place exposure. The criteria for diagnosis of RADS are listed in Table 32.4.

Reactive airway dysfunction syndrome is a clinical syndrome that develops after a profound injury to the airways of the lung as a result of an excessively

TABLE 32.4. Diagnostic criteria for reactive airways dysfunction syndrome (RADS).

1. A documented absence of preceding respiratory complaints or disease
2. The onset of symptoms after as single exposure incident or accident
3. The exposure is to a gas, smoke, fume, or vapor present in high concentration and with irritant qualities to its nature
4. The onset of symptoms occurs within several hours, and often within minutes, after the exposure; RADS can last several months or years and in some cases is irreversible
5. Symptoms simulate asthma, with cough, wheezing, and dyspnea predominating
6. Pulmonary function tests show air flow limitation but may be normal at the time of the evaluation
7. Airway hyper-reactivity to many nonspecific stimuli is present in all patients; a positive methacholine challenge test can be observed even years after the exposure
8. Other types of pulmonary diseases are ruled out

high (often single) environmental or occupational exposure to an irritant gas, vapor, or fume, usually due to an accident or an uncontrolled emission.[4,5] The major pathophysiologic alteration that occurs is due to this profound airways injury which induces a state of persistent airways hyperresponsiveness to many nonspecific, varied, and different airborne stimuli, including physical, chemical, and pharmacologic agents. This alteration is characterized by recurrent episodes of bronchospasm with reversible narrowing of the airway lumina in response to the different stimuli at a level or intensity not noted in most individuals, but at the level seen in asthmatic individuals. Clinically, there is rapid onset of symptoms, usually occurring within minutes to hours after the exposure. To differentiate from occupational asthma, there is the absence of an accompanying responsiveness to a specific exposure, nor is it necessary for there to be a pre-existing latent period for sensitivity or allergy to occur to induce the disease state.

The incriminating exposures all share two characteristic features: they were irritant in nature and were present in very high concentrations, often as a result of an accident. For example, some cases were due to the inhalation of an irritating gas such as uranium hexafluoride, whereas others were to aerosols (spray paints, fumigating fog); in some cases, heating or combustion products were involved.

The mechanism to explain RADS is believed the result of induced airways inflammation from the heavy exposure. In fact, pathologic material of bronchial biopsies in two patients documented this finding.

Mechanisms Involved in Development of Chronic Occupational Airway Disease

The major allergic mechanisms to explain occupational asthma after inhalation of a foreign protein is thought to be an allergen and antibody complex reaction that activates chemotaxis and a cascade of bioactive mediators, resulting in either receptor stimulation of various cells or in direct damage to cells.[9,10] It is hypothesized that the allergen reacts with a protein in the respiratory tract to form a new antigenic determinant (NAD).[9] This hapten-cell protein NAD complex may stimulate both local pulmonary and systemic immune responses. The resulting hyersensitivity reactions in the airways may include IgE-mediated anaphylaxis, cytotoxic antigen-antibody complexes, lymphocyte-mediated reactions, or a combination of these. The complexities of chemical interactions is great because chemical hapten-protein complexes may vary markedly in their natural protein reactivity, thus adding great variety to their immunogenicity.

The respiratory bronchiole is vulnerable to acute injury from irritant gases (e.g., bronchiolitis), but the trachea and bronchi are also disproportionately injured in exposures to highly soluble agents (e.g., RADS). Alveolar edema can result from exposure to certain volatile irritants like phosgene.

Recent reports have emphasized the importance of short lived nonspecific airway responsiveness after the inhalation of relatively low levels of certain environmental pollutants, such as ozone and nitrogen dioxide, sulfuric acid aerosols, polyvinyl chloride pyrolysis products, and various respiratory infections.[11–15]

If low-level exposures can produce transient changes in airways reactivity, can high-level exposure cause more permanent airways hyper-responsiveness? Processes of importance reported for explaining the hyper-responsiveness include altered neural tone and vagal reflexes, modified beta-adrenergic sympathetic tone, and the influences of a variety of mediators including both lipoxygenase and cyclo-oxygenase products of arachidonate metabolism.[16] A common identifiable pathologic accompaniment of all the varied entities is inflammation of the airways.[17] In fact, airway inflammation has been documented in cases of RADS and asthma.[4]

There are a number of studies demonstrating the inflammatory nature of irritant exposure, that is, phosgene and chlorine, which can persist for months.[18,19] Animal investigations have shown the importance of inflammation in the pathogenesis of airways hyper-responsiveness by profound depletion of circulating granulocytes from animals and subsequent demonstration of reduction or disappearance of airways hyper-reactivity.[20] Because subepithelial irritant receptor are superficial in location, they could be affected by an extensive bronchial inflammatory response that might occur after a heavy irritant exposure. Subsequent reinervation of bronchial mucosa might drastically alter the threshold of the receptor and cause airways hyper-reactivity. Another possibility is bronchial epithelial damage leads to increased permeabil-

ity causing hyper-responsiveness on this basis. It is not known why there is such a varied response after a high-level irritant gas, fume, or aerosol exposure. Some patients respond by developing alevolar edema; others proceed to bronchiolitis obliterans and some persons develop RADS.

Diagnosis

Of all the elements used for clinical evaluation, the patient history is most important. Physical examination and chest radiographs are generally nonspecific; the latter are particularly of little value for diagnosing OAD. Pulmonary function measurements are of value in establishing the presence of airflow limitation. However, many patients with OAD have normal pulmonary function testing at the time of physician evaluation, usually weeks to months after leaving work. A variety of immunologic laboratory tests including skin tests and measurement of specific IgE and precipitins also are available for diagnosing occupational asthma. These laboratory tests are made less useful by the lack of knowledge about the antigenic nature of the reagent employed and failure to account for nonimmunologic mechanisms that may also be causing mediator release.

Many cases of occupational asthma can only be confirmed by bronchial inhalation challenge testing to the specific material/agent in question.[1] The testing to the suspected agent should be performed in a clinical laboratory under close supervision by a physician in case a severe reaction occurs. The methods of inhalation exposure differ according to the form of the agent (i.e., fume, vapor, dust) to be investigated. Specific inhalation challenge studies are most definitive when they identify a dose-response relationship to the suspected agent.

Nonspecific airways reactivity is assessed by using pharmacologic or physical stimuli. Methacholine, histamine, or carbachol are the most popularly used pharmacologic agents. Distilled water, exercise, and cold air inhalation also have been used. Guidelines for performing bronchial inhalation challenges with pharmacologic agents have been reported.[21]

Management

The major objective in managing a patient with an occupational airways disorder is prevention. For occupational asthma, the offending agent should be identified if at all possible. Until the afflicted worker can be transferred from his or her usual workplace, a properly fitting respiratory protective device can be used on a short-term basis. However, it is not a good long-term solution, partly because proper fit and function cannot be guaranteed over time. Prevention of continued exposure must be ensured as minute amounts of an agent may elicit symptoms in persons with sensitivity.

If exposure is avoided, symptoms of occupational asthma usually resolve. Several studies have documented that nonspecific bronchial hyperresponsiveness measured by histamine or methacholine challenge also can

improve after removal from the workplace. However, there are some cases that do not respond so favorably, and the reasons are not clear.[22] Clinical studies suggest that continued symptoms of occupational asthma is due to the persistence of nonspecific bronchial hyper-responsiveness. Workers with persistent occupational asthma tend to have a longer duration of exposure while symptomatic, and a higher degree of bronchial reactivity to methacholine.[23] This latter pathophysiologic process is present in RADS and accounts for the persistent symptomatology and any disability observed.

Industrial hygiene and engineering considerations are extremely important. Dust and vapor suppression may be highly effective in lowering the concentration of many inhaled irritants. The most difficult exposure to control is the short-term, intermittent high level exposure, which often occurs after some equipment or operational malfunction. This is particularly important to address because a high level accidental exposure may lead to serious consequences such as RADS. Changes instituted in the cotton industry, which included the washing and steaming of cotton before its processing, exemplify how alternations in the manufacturing process can reduce or prevent byssinosis. Changes in product formulation also can reduce exposure to inhalants. In the detergent industry, for example, the proteolytic enzyme portion of the product has been made less dusty by encapsulation procedures.

If workers are exposed to an agent known to cause an occupational airway disorder, periodic medical surveillance of the workers is recommended. Both pre-employment evaluations and regular health checkups thereafter are needed. It is valuable to have a program whereby employees are educated concerning the nature and risks of potential hazards in their workplace. The physician can assist management in identifying the risks and providing control. When specified threshold limit values are known, careful and regular monitoring must be ensured.

Allocating Causal Contributions to Workplace Exposures

There currently is no satisfactory objective method for calculating or allocating the causal contributions to disability of various workplace etiologic materials or factors. With today's state-of-art medical sciences, exact quantification of the allocation is essentially impossible. Although it is important to recognize this basic principle, one must realize that the physician making a judgment approaches this task by evaluating what information is available for making a determination. In the final analysis, it is the weighing of the significance or degree of alteration of the several different pieces of information that will best provide the basis for the physician's opinion on the matter. Thus, each "piece of the puzzle" is examined, weighed, and assessed a quantitative significance. Such information as the medical and occupational history, exposure information, severity of physiologic alterations, perhaps degree of airway methacholine/histamine hyper-responsiveness, or even documentation of immunologic hypersensitivity are the "building blocks" of quantification and create a more accurate view of the "whole picture" for determining, as best as possible,

the estimation of the proportional allocations of the various workplace exposures and other factors. Therefore, the more complete the information, the better the physician can view the "puzzle" and decipher the clinical "picture" with its various parts. In the final analysis, the estimation of the percentage contribution of various workplace factors is essentially dependent on the physician's personal experience, bias, and, ultimately, opinion based on a reasonable degree of medical certainty.

An exact and detailed occupational history is essential for examining the relationship between a worker's symptoms and workplace exposure factors. For instance, important information might include: the precise location in the work area, if known, where the symptoms develop; the exact temporal relationship between a specific exposure and the evolved symptoms; noting any improvement in symptoms after removal from the workplace. Sometimes keeping a symptom diary is helpful for better documenting such relationships and it alleviates the reliance on the worker's memory when the worker is questioned some time in the future.

The specific identification of the etiologic workplace material or factor causing symptoms in a patient with suspected occupational asthma is a necesssary prerequisite for reaching any type of decision. Without identifying the exact causative agent, a physician is hard pressed to reach any definitive decision on the matter. For example, identifying isocyanates to be present in the workplace of a worker with asthma is important. The isocyanates are a known cause of occupational asthma. On the other hand, a more casual description of a multitude of agents producing asthmatic attacks in the workplace should raise suspicions about the reliability of the complaint. The notification of a material in the workplace known to cause occupational asthma is necessary and without such specific information a diagnosis or causation cannot be accurately determined. If the material is one never previously reported to cause asthma, then it is the role of the physician to provide the "proof" of the causation, either by controlled bronchial inhalation challenge testing to the specific material in question, or less convincingly, by immunologic confirmation of hypersensitivity.

The worker with nonspecific airway hyper-responsiveness may develop reflex bronchospasm from many different workplace exposures. Generally, the exposures are irritant in nature and the bronchospastic response occurs shortly after exposure, rather than delayed for several hours. Once exposure is terminated remission of symptoms occurs promptly. Some characteristic exposures in this latter scenerio include irritant gases such as sulfur dioxide, chlorine, ammonia, ozone, or freon; metal fumes; combustion smokes or pyrolysis products; excessive dusts exposures, even nuisance dusts; especially foul odors; degreasing solvents; petroleum and aldehyde vapors; extreme temperature changes; and excessive physical exertion. Although it is true these varied stimuli cover the gamut of workplace exposures, their characteristics as a group projects a pattern consistent with the type of response expected from a worker with nonspecific airway hyper-responsiveness.

Serial pulmonary function testing is preferable to just pre- and postshift

testing and provides more objective quantitative information, especially when used in conjunction with the personal diary. Recently, portable peak flow meters have been used for documenting the temporal relationships between workplace exposures and fall in expiratory flow rates. It is necessary to take measurements several days before the exposure to document the usual daily flow rate pattern and then compare it with any subsequent workplace developing reduction in flow rate occurring with an episode of bronchospasm. One difficulty with peak flow measurements is they are very patient dependent and require optimal worker cooperation, which may not be possible in an unsupervised workplace situation.

Late-occurring asthmatic attacks are frequent in occupational asthma and have been shown to increase the degree of airway hyper-responsiveness present. This is fortuitous since serial methacholine/histamine challenge tests before and after a workplace exposure can be diagnostic of the occurrence of a true workplace-related late occurring asthmatic attack rather than reflex bronchospasm from a nonspecific irritant exposure. The quantification of the methacholine/histamine reactivity (pc20) provides an estimate of the degree of airway hyper-responsiveness. For example, a methacholine pc20 value of 8 mg/ml, and especially less than 2 mg/ml, demonstrates an extreme degree of airway hyper-responsiveness.

Actual quantification of pulmonary function test values, such as FEV-1, or pre- and postshift values are often not particularly helpful and may in fact be "normal." Often workers are evaluated weeks or months after termination of the exposure and at a time the values have returned to normal or near normal. Other types of pulmonary function testing, such as lung volumes, carbon monoxide diffusion, and arterial blood gas measurements may be helpful in differentiating other types of lung disease from asthma. Exercise testing may be useful in some cases of asthma, but generally its role in the evaluation of asthmatic patients is not well established. Controlled bronchial inhalation testing to a specific workplace agent provides important and confirmatory information as to causation.

Legal Questions

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Since 1978, every state has provided worker's compensation for disability resulting from lung disease caused by occupation.[24] The advance of knowledge within the scientific community about occupational airways disorders (with or without airway hyper-reactivity) has produced new and perplexing problems for the law of worker's compensation. Those problems have major socioeconomic implications. They question if a worker's airway disorder is *occupational* and whether he is disabled by it. The resolution of these issues is affected significantly by the following: 1) whether the etiology of the worker's airway disorder is pre-existing (i.e., non-occupational) or occupational (i.e., induced);

2) whether a sensitizing occupational allergen or stimuli causing the bronchospastic response in the worker are ubiquitous and common (to all environments) or are unique and special to the occupational environment; 3) whether the airway disorder is transitory and remissible or chronic and unremitting; 4) whether the airway disorder can be averted or effectively treated through medical management; and 5) whether the employer's liability should be limited only to that portion of a worker's disability that the occupation has causally contributed to the worker's disabling airways disorder.

When the worker's OAD results from an occupational exposure caused either by chronic workplace conditions or by an acute workplace event, the disability is compensable in most states; although some continue to require that the cause of disability be a disease that is more prevalent in the worker's occupation than generally.[25] Even if the induced OAD is on the basis of a pre-existing airway condition, the disability is still considered compensable provided that it is the result of an enhanced response by the worker with pre-existing disease to stimuli caused by an acute workplace event, akin to an industrial accident.[25,26]

The difficult case is that presented when disability is caused by the response of a worker to a material that had been chronically present in the occupational environment because of long-standing workplace conditions. A controversial Pennsylvania court decision, *Pawlosky v. W.C.A.B.*, decided the compensability of an asthmatic's disabling bronchospastic reaction to persistent chemical fumes exposure in his workplace. The case awarded compensation because the worker proved that his disabling airways disease arose out of and was related to chemicals peculiar to his employment.[27] A concurring opinion in that case would require for entitlement no more than that the disabling disease had been "caused by a condition in the employee's workplace," on the rationale that entitlement should follow if the disabling disease merely "occurred at the workplace."[27] A more cautious dissenting opinion pointed out that the worker's condition had been "subject to aggravation by many common substances, including cigarette smoke and hair spray." The dissenter warned that the majority opinion "works a major change in . . . compensation law," and he argued that entitlement should not be extended to diseases "which commonly affect the general population and are subject to aggravation by any number of substances commonly found in that part of the earth on which we live."[27] The important point to remember is that there is an accompanying nonspecific airways hyper-reactivity that is present because of the induced (occupational) asthmatic condition. It is this nonspecific airways hyper-reactivity that leads to the reactions to cigarette smoke and hair spray.

Yet to be addressed and decided is the case involving a veteran worker who develops nonoccupational (pre-existing) asthma and becomes disabled by reacting to workplace stimuli composed of ubiquitous and common matters such as contemplated by the *Pawlosky* dissenter. Consider the following hypothetical problems:

Hypo 1. The worker is a nonsmoker who works in a coal mine where dust is kept at below 1.0 mg/m^3. His work requires a 6 MET level of exertion. After 20 years in this

occupation, he develops adult-onset asthma. The first "attack" occurs while on the last day of a 3-week vacation spent at the seashore. Thereafter, all dusts (including coal mine dust) trigger attacks wherever a condition of mild dust concentrations occur. He also "hyper-reacts" to each of the following sensitizing stimuli: 1) passive cigarette smoke, 2) fumes in a vehicular tunnel or garage, 3) hair spray, 4) physical exertion, 5) cold and/or damp climate conditions, and 6) laughing and anger. To return to coal mining, with its mild dust conditions and exertional demands, would probably precipitate an "attack."

Hypo 2. The worker is a nonsmoker who works in an air-conditioned office as a clerk. Other workers are permitted to smoke cigarettes at their work stations, which are near to the claimant's desk. After 20 years in this occupation, she develops adult-onset asthma while on vacation. Hypersensitive to the same sensitizing stimuli as the worker in Hypo #1, she cannot return to her office job because of the cigarette smoke emanating from others in the office.

Should entitlement follow, as the concurring opinion of *Pawlosky* urges, merely because of this disabling nonspecific airway hyper-reactivity to ubiquitous elements or commonplace conditions present in the workplace and almost everywhere else? This has particular pertinence for RADS. Once RADS develops, the major pathophysiologic process is nonspecific airways hyper-responsiveness to many varied and different physical and chemical stimuli. Furthermore, what about the relatively mild asthmatic (nonoccupational) worker who is exposed at work to a single high-level irritant exposure and then has severe asthma (i.e., occupational aggravation of pre-existing nonspecific airways hyper-reactivity)?

Another confounding question arises when (in a case of occupational asthma) the disabling state of airways hyper-responsiveness is remissible soon after separation from the workplace and it sensitizing stimuli, but would be reactivated by returning to work. Separated from the stimuli of the workplace, the furloughed sensitive worker is asymptomatic; his occupational asthma is in remission. As he is able to function without impairment, should the worker be entitled to benefits for disability? Legal authorities would consider him qualified, notwithstanding his healthy status, provided that the underlying hypersensitivity has been caused by the worker's occupation; reasoning that it would be "unconscionable" to require further exposure to disabling sensitizing stimuli in order for him or her to qualify for disability benefits.[28] Still to be decided is the case of similar facts involving hyperreactivity to occupational stimuli by a worker with pre-existing asthma, a situation illustrated by the following hypothetical cases:

Hypo 3. The worker, an asthmatic (with associated nonspecific airway hyperreactivity), begins a new job working as an underground coal miner. Three hours after starting to work in his first day on the job, he reacts to coal mine dust. His physician tells him never to return to work at mining or any "dusty trade." The mine had always maintained air quality at or below 1.0 mg/m^3.

Hypo 4. The worker, an asthmatic with "hayfever", begins a new job operating a lawn mower at a golf course. Three hours after starting to work in his first day on the job, he

reacts to the grass cuttings (which is his preexisting allergy). His physician tells him to avoid all places where grass is being cut.

The hypothetical illustrations ask if there should be entitlement for a new employee when commonplace sensitizing stimuli (dust or cut grass) found at the workplace and elsewhere cause a clinical response even though the underlying condition of hypersensitivity (asthma) had not been occupationally caused or connected.

Another issue of importance is whether there should be a different result if the asthmatic condition can be managed by proper medical therapy that enables the worker to work in the presence of sensitizing stimuli without hyper-reacting. Anecdotes of asthmatics competing successfully in strenuous athletics are well known.[29] Refusal to submit to reasonable and standard medical management would confront the worker with the prospect of losing his disability benefits.[30]

When the underlying condition of hypersensitivity is pre-existing (i.e., not etiologically related to occupation), should the employer be 100% responsible for paying all of the disability benefit because stimuli within the workplace had merely "aggravated" the primary underlying condition? Most programs of worker's compensation declare that the employer is liable for harm that arose out of employment. The employer should therefore not be liable for harm that is unrelated to employment. Several jurisdictions have confronted the unfairness of making the employer pay for the nonwork-related portion of a worker's disability by resorting to *apportionment techniques*. In cases of the presence of nonspecific airway hyper-responsiveness, employer liability could rationally be limited to the portion of the compensation benefit that equitably reflects the portion of disability caused by employment. The approach furthers the worker's compensation social policy goal of encouraging employer accountability for workplace conditions and events by limiting employer liability to matters over which he or she can have some control.[25] Before apportionment could be applied to cases of disability due to occupational airways disorders, medical science would have to devise and provide to the law a reasonable and scientifically sound method for calculating and allocating the causal contributions to disability of the workplace and other etiologic agents.

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Legal Aspects of Respiratory Therapy

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History of Respiratory Therapy

The Greek physician Hippocrates introduced the doctrine of essential humors. He attributed all diseases to disorders within the fluids of the body. Hippocrates taught that there was an essential material derived from inspired air which entered the heart and was distributed throughout the body.

Aristotle recorded the first scientific experiment in respiratory physiology when he observed that animals kept in airtight chambers soon died. Galen envisioned a system of physiology with his own concept of a spirit, or "pneuma," penetrating all the parts. Leonardo da Vinci concentrated on the anatomical structures of the body and concluded that animals could not live in an environment that could not support flame. Vesalius was the first to observe that the lung could be made to expand by passing a reed into an animal's trachea. Finally, Servetus discovered that blood in the pulmonary circulation, after mixing with air in the lungs, returned to the heart.

Some 100 years later, in 1774, Joseph Priestly reported the discovery of oxygen by heating the red oxide of mercury. In 1880, using the knowledge gained from these earlier discoveries, Priestly, Lavoisier, and Black established a pneumatic institute in Bristol, England. Thus was born respiratory therapy.

Respiratory therapy has since developed into a major support service in hospitals throughout the world. Respiratory therapists are now involved in pulmonary function testing, cardiopulmonary resuscitation, sleep studies, and management of critically ill patients in intensive care and perinatal care.

National Standards for Licensing

Only 18 of the 50 states currently license respiratory therapists. Nationally two levels of credentialing exist: certification and registry. Certification requires

1 year of study in an approved respiratory therapy program and passing an examination. Registry requires completing 60 credits in an approved respiratory therapy program and successful completion of a written examination. A registered or certified respiratory therapist is recognized in all 50 states for practice in a hospital. This does not hold true for home care, which constitutes a major portion of respiratory care rendered to patients suffering from lung disease.

Licensing is an important issue in delivering respiratory care at home. In New York state alone, more than 1,000 respiratory therapists are practicing respiratory care without supervision. There simply are no standards regarding the practice of respiratory care in the home. With the advent of diagnostic related groups (DRGs), the number of patients whose respiratory care will be delivered at home is increasing. It is imperative that home care be provided by persons who are properly trained and licensed, thereby reducing the possibility of negligent care to the patient.

Applicable Legal Standards

A respiratory therapist is required to possess and exercise that degree of education, training, experience, skill, judgment, and due care that is possessed and exercised by a respiratory therapist reasonably skilled in the profession. As a California appellate court pointed out, "Today's nurses are held to strict professional standards of knowledge and performance, although there are still varying levels of competence relating to education and experience."[1] The same is equally true of what is required of respiratory therapists.

Some states have a single "national" standard that holds therapists everywhere to the same standards. Other states retain the old "locality rule," under which the standard of due care varies depending on whether the therapist is located. (The locality rule originated over 100 years ago in recognition of the fact that it was unfair to hold a remote country doctor to the same high standards as his or her urban colleagues who had the latest equipment, training, and breakthroughs at their disposal.)

Identifying Areas of Potential Legal Problems

There are three situations in which the respiratory therapist is most likely to encounter legal troubles. First is negligence or carelessness of the therapist in performing or administering the therapy ordered by the doctor or in failing to monitor the patient's progress or the proper working of a respirator or other machine or equipment. Second is performing the wrong therapy, one other than what the doctor prescribed. Third is correctly performing the therapy ordered by the doctor, but doing so with the knowledge that the therapy is inappropriate and potentially harmful to the patient. (A fourth category of going beyond mere therapy and practicing medicine or giving medical advice also could be added.)

In the case of *Poor Sister of St. Francis, etc. v. Catron,*[2] an Indiana appellate court ruled that while in most cases a nurse, respiratory therapist, or other hospital employee is not negligent in following the orders given by the attending physician, if the nurse or other employee knows that the doctor's orders are not in accordance with normal practice, the nurse or other employee has the obligation to inform the attending physician. If the attending physician fails to act, the nurse, therapist, or other employee must then advise the hospital authorities so that appropriate action can be taken. The court held that the nurses and inhalation therapist should have reported to their supervisor that an endoctracheal tube was being left in a patient longer than the customary 3- to 4-day period. As a result, the patient had to undergo several surgeries to repair damage caused by the tube's having been left in too long, including operations to remove scar tissue and to open her voice box. At the time of trial, the patient could not speak above a whisper and breathed partially through her nose and partially through a hole in her throat created by a tracheostomy. The court affirmed the jury's verdict against the hospital in the amount of $150,000.

Relationship Between the Respiratory Therapist and the Hospital or Doctor

Hospitals and doctors are vicariously liable under the legal doctrine of *respondeat superior* (literally, let the master, or supervisor, answer) for the negligent or otherwise wrongful acts of their employees, including respiratory therapists, while acting within the course and scope of their employment. Accordingly, hospitals and doctors in private practice should check their malpractice insurance policies to see whether they provide adequate protection for mistakes of an employee respiratory therapist.

A respiratory therapist working as an employee of a hospital or doctor generally need not carry his or her own malpractice coverage; the respiratory therapist should, however, verify that his or her employer does in fact have malpractice insurance and that the policy covers acts of the therapist. A respiratory therapist who is self-employed and works as an independent contractor should consider carrying appropriate malpractice liability coverage.

Avoid Legal Trouble

Competence and concern are the pillars of good health care and avoiding legal troubles. Nothing can replace the careful and diligent application of the skill and training received in school, at seminars, and on the job. Competence includes a commitment to continuing professional education to keep up with the advances in the field. Combine competence with a genuine concern for the patient's well-being and you have gone a long way toward a lawsuit-free career.

Another important element is establishing good communication with the doctor. The therapist who does not completely understand the doctor's

instructions should not be afraid to ask the doctor to clarify exactly what treatment is being ordered if there is any doubt in the therapist's mind.

A third factor is maintaining a good relationship with the patient. A patient will not tolerate abuse, being ignored, or being left in the dark about his or her condition. A patient whose questions are answered, whose calls are promptly returned, who receives frequent reassurances, and who otherwise believes that the therapist and staff really do care about him or her is less likely to consider suing when something goes wrong, at least if the injury is relatively minor.

Keeping adequate records is an often overlooked yet vitally important procedure every therapist should follow. Too often, doctors, nurses, therapists, and others in the health care field keep only the most cursory records, partly from being busy, partly because it is a time-consuming chore, and partly out of the fear that something they write down may come back to haunt them in a malpractice lawsuit. As to this last factor, quite the opposite is true. More suspicion arises from insufficient records than sufficient records. Thorough recordkeeping can also stop many malpractice suits dead in their tracks, when a review of the records by the patient's attorney and another doctor reveals that the patient did in fact receive proper care and the patient's injury was an untoward result.

Conclusion

Respiratory care has expanded into its own complex specialty and deserves full recognition as an independent yet integral service to the pulmonary patient. Because respiratory therapy is still a developing area, respiratory therapists are advised to exercise due care and caution when dealing with physicians, patients, and other health care workers. Respiratory therapists should not belittle the ground they have gained so far. Numerous articles in the *New England Journal of Medicine* and other professional publications demonstrate that respiratory therapy has a strong scientific basis. Indeed, in many hospitals, respiratory therapists have earned the reputation of being among the first to respond to a code or to provide services above and beyond the call of duty.

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Legal Aspects of Lasers

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This chapter discusses the legal aspects of the use of fiberoptic bronchoscopy and laser therapy. As is true with many other innovative technologies, the introduction of the laser as a component of therapeutic bronchoscopy has set the stage for a variety of medicolegal issues. The use of any technology may, on occasion, result in patient injury, and when such circumstances occur, the question of who is responsible (legally and financially) for such an injury follows close upon. In addition, the government, at the local, state, and federal level, has certain responsibilities in seeing that the public is protected from dangerous and perhaps even fraudulent devices and practitioners. As a result, a number of laws, including the Federal Food, Drug, and Cosmetic Act; portions of the Public Health Service Act; and other federal laws and corollary statutes at the state level exist to control the use of medical devices. I, therefore, discuss and analyze briefly the major medicolegal issues surrounding the use of fiberoptic bronchoscopy and lasers, including regulatory laws, product liability, and professional negligence laws. Lastly, some pertinent aspects of antitrust and other economic laws are discussed.

Governmental Regulation of Medical Devices

The primary method of governmental regulation of medical devices rests in the Federal Food, Drug, and Cosmetic (FDC) Act. It was not until the 1938 FDC Act that medical devices were subject to any type of federal regulation.[1] However, even after this law, the degree of federal regulation was perhaps cursory at best. In 1976, the sweeping and substantive Medical Device Amendments to the FDC Act were passed by Congress, which thereafter required the Food and Drug Administration (FDA) to establish a comprehensive system of reviewing and approving the marketing of medical devices in interstate commerce.[2] The 1976 amendments established a three-tiered system of medical devices, which categorized the thousands of different kinds of marketed medical devices into three groups correlated with the risk of injury

associated with the use of each device.[3] Relatively risk-free devices, such as tongue depressors, bandages, and the like, were placed in class I with concomitantly minimal government supervision and regulation over the manufacture and marketing of the device. Devices associated with the most significant risks, for example, cardiac pacemakers, prosthetic cardiac valves, and so on, were placed in class III with comprehensive and stringent regulations relating to the development, testing, manufacturing, and marketing of the devices. Class II devices were placed in a middle ground.

In very brief terms, class I medical devices are required to comply with general Good Manufacturing Practices (GMPs). Good manufacturing practices involve maintenance of certain records, quality control procedures, and general cleanliness in the manufacturing facilities.

Class II devices must meet, not only GMP requirements, but also Performance Standards. Performance Standards require that the device be shown to meet certain functional characteristics applicable to the broad category of devices.

Class III devices, in addition to meeting the foregoing requirements, also must be shown to be safe and effective before being permitted to be marketed. This class of device is therefore subject to a premarket approval by which the FDA reviews clinical evidence as to the safety and effectiveness of the device before granting approval to the manufacturer to market the item.[4] Medical lasers have been categorized either in Class II or Class III depending upon the specific application involved.[5] Manufacturers have, to a certain degree, the right to contest the classification of a device and to petition the FDA for changes relative to a device's classification.[6] As is common in all regulatory schemes, there are a multitude of procedural rights and requirements spelled out in the implementing regulations.

A fundamental understanding of this legal and regulatory scheme is necessary to practitioners who use lasers because many of the innovations in this area come from the inventive minds of the users. However, before an invention or an improvement can be put into practice or marketed, the physician must be aware of some of the prohibited acts under the Food and Drug law. The law requires, for example, that before the introduction of a new medical device into clinical practice, there must be data evidencing compliance with performance standards for a class II device and additionally data as to the safety and effectiveness of a class III device. Such data may be accumulated during the course of clinical investigations, but such investigations must be conducted in accordance with specific regulations pertaining to human experimentation.[7] These regulations require that the investigator obtain an investigational device exemption (IDE), which permits the investigator to use the device on patients to be exempted from the many requirements of the Food and Drug law applicable to approved and marketed devices. Most major medical institutions have, in accordance with the Food and Drug laws established *Institutional Review Boards,* namely, committees which serve to review and to authorize an investigator to proceed with a research project involving a new medical device. It should be noted, however, that although an IDE may exempt a device from certain FDA requirements, the device, if it emits radiation, must still comply

with other federal and state laws, including the Radiation Control for Health and Safety Act.

A physician who engages in research without appropriate approval, does so with great risks to himself. Such a physician faces not only potential civil and criminal liability, pursuant to the Food and Drug laws, but he also faces significant exposure in the event of patient injury from a malpractice suit. Evidence that the physician's research activities violated the federal law would be disastrous to the defense of what might otherwise, technically, be a defensible law suit.

In addition to the FDC Act's regulation of medical lasers, there are several other federal laws that relate to the use of medical lasers. The Radiation Control for Health and Safety Act,[8] passed in 1968, was an amendment to the Public Health Service Act designed to protect the public from dangers of electronic product radiation. This act is applicable to all products that emit electronic product radiation including ionizing or nonionizing electromagnetic or particulate radiation or any sonic, infransonic, or ultrasonic waves. The act provides for the promulgation of performance standards and general controls. The enforcement of the act falls under the purview of the FDA.

The Federal Trade Commission (FTC) and the Consumer Product Safety Commission and a variety of other federal agencies may also impinge upon the marketing and use of medical devices, including lasers. In addition, numerous states have passed laws relating to the ownership, registration, and use of lasers.[9] State law varies tremendously on this topic and the physician is urged to review the individual laws that may pertain in his or her jurisdiction.

Private, Quasi-Governmental Regulation

In the area of regulations pertaining to the use of products, the conduct of a business or profession, and a variety of other activities private entities have for many years set standards, which by custom and widespread following often attain a quasigovernmental legal status. The standards of the Joint Commission on the Accreditation of Hospitals are prime examples. With respect to medical devices, the American National Standards Institute has promulgated a variety of standards. There are currently proposed standards relating to the medical use of lasers, ANSI Z136.1, which, if and when they are ultimately adopted, will have significant weight in both product liability cases, as well as professional and hospital liability situations, as will be discussed further in a subsequent section of this chapter.[10]

Personal Injury Liability

As with any procedure, a risk of *patient* or *personnel* injury exists with medical lasers. To date the incidence of such injury appears to be extremely small; however, reports of burns, endotracheal tube ignitions, and other thermal injuries do appear in the literature.[11–13] When such injuries occur, the question

arises as to who should be held liable for such injuries and thereby be required to compensate the injured party.

Laser injuries may occur either to the patient or to the personnel involved in the procedure. Liability for such injury may fall upon not only the physician directing the procedure but also the personnel assisting the physician, the hospital, or other facility where the procedure was performed, and, lastly, the manufacturer and/or supplier of the laser. The grounds and the legal rational for the liability of each of these groups of people are somewhat different. The liability of a manufacturer or supplier is determined chiefly by what is referred to as product liability law. The liability of the physician emanates from principles of general tort law, which in the context of the practice of medicine is frequently referred to as malpractice law. The liability of the hospital or other facility also derives mainly from general tort liability with certain particular features that have evolved in recent years and relate to a hospital's vicarious or secondary liability for the actions of members of its medical staff.

Product Liability

Perhaps no area of the law has undergone as much evolution in the past 20 years as that which involves the liability of a manufacturer or supplier of a product for an injury that occurs from the use of that product. At its origin, this area of the law involves what is referred to as a tort, that is, a civil wrong between citizens. Most typically, these kinds of wrongs involve physical injuries caused by the careless or negligent conduct of a person or corporation who in the law is referred to as the tortfeasor.

A manufacturer who designs and sells a product that causes an injury may be held liable for that injury either on the legal grounds of negligence, on the theory of breach of warranty involving that product, either written, express warranty or unwritten, implied warranty or on the basis of what is referred to as "strict liability in tort." For example, the manufacturer of a medical laser, which is involved in a patient injury might be sued by the patient on the basis either of negligent design or negligent manufacture or for breach of an express or implied warranty of safety and/or the theory of strict liability in tort.

To establish a case of negligent design or manufacture, the injured patient would have to prove that the particular medical device was designed or fabricated in a careless or "substandard" fashion. In this context, substandard means that the quality, carefulness, skill, and diligence brought to bear in the design or manufacture of the device was less than that used by the average and ordinary designer or manufacturer. To prove this, the injured party normally uses expert witnesses, namely individuals who by their experience and training presumably have knowledge of what average and ordinary care would have required in the design in the manufacture of a device. In point of fact, it is often quite difficult for an injured party to prove specifically what component step or aspect of the complex designing and manufacturing process involved in an advanced technologic product might have been substandard. There are simply

too many steps, possibilities, and complexities in the design and manufacture of such a product to be able easily to identify "what went wrong."

Breach of warranty lawsuits can be based either on an express, in other words, a written guarantee or warranty, or implied or unwritten warranty. The concept of a written warranty includes any express representations made by the manufacturer concerning the product and its use. This means that promotional literature, sales brochures, the instruction manuals, as well as the actual guarantee or warranty provisions are part and parcel of an express warranty. A product that does not meet its manufacturer's written claims is in breach of warranty. Manufacturers attempt to limit their potential liability by clearly stating in their warranty provisions that they limit their liability for certain matters or they exclude any guarantees for certain conditions or circumstances. The legal prerogative of a manufacturer to limit his liability may be significantly restricted under certain federal and states laws. Again, these laws vary tremendously from one jurisdiction (i.e., state) to the next. In addition to the written components of a warranty, the law also has imposed upon products an implied warranty. This concept essentially is that a product must be reasonably designed and manufactured to perform its intended uses. The manufacturer need not state in any written materials that this is true; it is taken to be true as an implied statement. A device that does not comport with its reasonably anticipated intended uses is therefore in breach of its implied warranty.

Warranty law is an outgrowth of contract law and therefore arises in essence from an agreement between parties, normally buyer and seller. Frequently, the person who is injured from a product is not the buyer of the product, but some third party "bystander." Commonly in medical device situations, the purchaser of the device is a physician or a hospital and the injured party is a patient. Under warranty law, the patient is not part of the contract of purchase for the device and therefore is not a party to the warranty agreement. The fact that the injured party is not part of the bargain has in the past been used as a defense to a claim of breach of warranty; in other words, someone who was not part of the purchase contract cannot properly bring a suit for a breach of that contract.

In the past 25 years, the rationale of an implied warranty of safety and usefulness has transformed into the doctrine of "strict liability in tort." By this growth some of the principles of a contract lawsuit have been merged into the principles of a tort lawsuit, and in this way the law has removed any element or requirement of privity, that is, the contractual relationship between the injured party and the manufacturer, that the injured party could not meet. By transforming the legal doctrine to one of tort liability, the requirement of privity has been removed.

An injured party may therefore bring an action against a manufacturer or a supplier based upon strict liability in tort regardless of any privity or contractual relationship with the manufacturer or supplier. The injured party need not have involved in the purchase of the device, but merely must have been injured by it.

A party who brings a suit based upon the concept of strict liability in tort, must in some respects establish the same factual claims as someone who sues for breach of an implied warranty. Such would include an alleged failure to meet design or manufacturing specifications, or a failure to provide adequate instructions and warnings for use.

Over the years the law recognizing this difficulty has for a variety of jurisprudential reasons slowly shifted the burden of this proof off of the shoulders of the injured party and has placed that burden more on the shoulders of the alleged tortfeasor. In so doing, the law has developed the doctrine often times referred to as strict liability in tort. Under this theory an injured party need only prove that a product was either "defective" or "unreasonably dangerous," and that as a result an injury occurred. What is important in this doctrine is that the manufacturer or supplier of the device will be found liable for the injury caused by a defective or unreasonably dangerous product regardless of whether that manufacturer exercised average care in making the product or indeed exercised all possible human care and diligence in making the product. In other words the manufacturer may be found "guilty" or liable irrespective of whether or not that manufacturer did anything "wrong" in the sense of having been careless or negligent. In this way the law is simply recognizing that between the two parties, namely the injured individual and the corporate manufacturer, the latter is financially better able to bear the costs of an injury.

Product liability litigation is particularly interesting in medical situations because medical products, including drugs and devices, frequently are inherently and extremely dangerous and cannot, by any method or exercise of prudence, be made danger free. A manufacturer or supplier of such an inherently dangerous product is relieved of strict liability in tort to the extent that the manufacturer provides adequate warnings or instructions concerning the use of the product.[14]

Professional Liability

Obviously, a physician who performs a procedure that results in injury to a patient is the most likely target for a personal injury lawsuit brought by that injured patient. The rules of strict liability in tort, regardless of fault or carelessness, do not apply to the practice of a profession. Instead, the more fundamental rule of "simple negligence" or failure to use ordinary care and prudence is what determines liability.

There are several scenarios that illustrate the grounds for holding a physician liable for an injury a patient may suffer in conjunction with a endoscopic laser procedure. Scenario #1 involves a technical or judgmental error which gives rise to a claim of negligence or malpractice on the part of a physician. Scenario #2 involves an untoward event or a bad result, through no fault or negligence on the part of the physician, which gives rise to a claim by the patient of a lack of informed consent. Scenario #3 involves injury to another member of the

endoscopic team either as a result of the negligence of the operating physician or through no fault of that physician.

In Scenario #1, a traditional malpractice claim turns upon the definition of malpractice and in that regard what the law contemplates as the obligation of the physician in the care and treatment of a patient. The concept itself is simple, but some of the terminology used is frequently confused in the medical literature with the result that there is a significant lack of understanding as to precisely what it is that may serve properly as grounds for a malpractice case.

In almost all jurisdictions the legal obligation of a physician toward his patient is defined in essentially similar terms. The law requires that a physician bring to the care and treatment of his patient the same amount of skill, prudence, and diligence as would any other ordinary or average human being in those circumstances. Thus, the obligation is to act as would the ordinary or average person, a somewhat mythical entity. Almost universally, it is a lay jury that decides what, under any given set of particular factual circumstances, an "ordinary and average" individual would have done.

As evidence of what the ordinary or average individual would have done under any particular set of medical circumstances, the law usually draws a comparison to what the ordinary and average *physician* would have done under those circumstances. This therefore establishes professional custom and practice as the nominal gauge of the appropriateness of the actions of an individual defendant. If a defendant's conduct comported with the custom and practice of his profession, then quite arguably, he has exercised the same amount of skill, care, and diligence as would have been exercised by any average or ordinary person.

The wording used to define the obligation of a physician is different in different jurisdictions, but a reasonably illustrative definition can be found in *Bruni vs. Tatsumi,* (1976, 46 Ohio St. 2d 127). The court defined the required elements of a malpractice case as follows:

> In order to establish medical malpractice, it must be shown by a preponderance of evidence that the injury complained of was caused by the doing of some particular thing or things that a physician or surgeon of ordinary skill, care and diligence would not have done under like or similar conditions or circumstances, or by the failure or omission to do some particular thing or things that such a physician or surgeon would have done under like or similar conditions and circumstances, and that the injury complained of was the direct and proximate result of such doing or failing to do some one or more of such particular things.

It is absolutely important, however, to recognize that whereas the "standard of practice" is evidence that tends to prove that a defendant complied with the obligation to exercise ordinary and average care, such is not always dispositive. In other words, a physician can unquestioningly comply with accepted professional standards and nevertheless be found negligent. The law has always reserved unto itself the right to determine what conduct is negligent and what is not, namely what the ordinary and average person would do in a particular situation and not what a physician, an airplane pilot, an architect, or

any other specific person would do. A segment of society, indeed an entire profession, may be deemed to have established standard and practices that are in fact inadequate and therefore such standards are not a valid defense to a negligence claim. As one of the leading jurists of the 20th century, Judge Learned Hand, stated in a case involving the alleged negligence of a tugboat owner in failing to equip his vessel with the then innovative technology of a wireless transmitter and who defended himself by the contention that no other tugboat line was so equipped:

> In most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption in new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; There are precautions so imperative that even their universal disregard will not excuse their omission.[15]

Even before these words of Judge Hand, the Supreme Court of Ohio held in a medical malpractice case involving a surgical sponge left within a patient, the responsibility for which the attending surgeon attempted to avoid by establishing that surgical sponge counts were universally regarded as the responsibility of the hospital nurse:

> The overwhelming weight of authority supports the general rule that customary methods or conduct do not furnish a test which is conclusive, or fix a standard. It is obviously a dangerous practice to permit any business, trade, or profession to fix its own standards. . . . Custom will not justify a negligent act or exonerate from a charge of negligence. Long continued careless performance of a duty by any trade, business or profession will not transform negligence in to due care. Usage cannot avail to establish as safe in law that which is dangerous in fact.[16]

This principle is still viable today, much to the consternation of many physicians who are understandably surprised on those occasions in court when they discover that their compliance with all accepted and customary standards of practice and care does not exonerate them from a malpractice claim.[17]

As the foregoing citations illustrate, compliance with accepted professional custom and practice (i.e., the standard of care) may not necessarily be an absolute bulwark against a malpractice case, but it is clear that failure to comply with accepted standards and in particular to fall below those standards is fatal to the defense of a malpractice claim. Professional standards may of course emanate from a number of sources, some of which are properly entitled to more weight and credence than others. Customs and patterns of use established by the government, would seem to be entitled to considerable authority. Thus, failure to comply with FDA regulations regarding the safe use of laser equipment would seem under most circumstances to be nearly indefensible in the context of a malpractice lawsuit. Customs and standards established by national independent professional organizations or entities, such as the American National Standards Institute or professional medical societies, would also be given significant weight. Somewhat further down on the scale, but still with some probative value, would be standards, policies, or practices established at an institutional level as may be reflected in a hospital procedure

manual. Inasmuch as all of these items may go toward proving pertinent standards of practice, they may serve either as an ally or as an enemy to the defendant position.

In areas of new and evolving technology, the establishment of formal professional standards of practice is of particular concern. The law does recognize that there are frequently multiple acceptable alternative methods of patient management; witness the plethora of currently marketed cephalosporins. A physician may comply with the obligation of "ordinary and average care" by following what may be regarded as a minority position in his profession, as long as that position has at its foundation the exercise of the required degree of care. As a matter of practicality, however, needless to say it is easier to defend oneself in a majority position than in a minority position. The establishment of standards by national organizations that are either governmental or private in nature promptly creates a "majority school" with a resulting bandwagon effect. Thus, attentiveness to the emergence and evolution of such national standards is of particular importance in these areas of innovation.

A review of the current legal literature would seem to indicate that the incidence of malpractice claims arising out of the use of lasers in conjunction with bronchoscopy is relatively rare. Not unexpectedly, most of the cases have dealt either with hemorrhages after biopsy procedures[18] or with ignition injuries.[19] However, the overwhelming majority of cases litigated in this country do not result in published opinions and to ascertain the actual incidence of malpractice claims from unpublished sources is extremely difficult. Thus, significant comfort may not be drawn properly from the fact that laser-associated malpractice lawsuits rarely are reported.

Scenario #2 involves a physician against whom a claim for personal injuries is made based on a contention of lack of informed consent. In this scenario, the fundamental assumption is made that the physician did not commit any technical error or in any fashion fall below accepted standards of practice, for if he or she had done so, a straightforward malpractice claim would have been brought. Instead, recognizing that no error on the part of the physician caused the patient's injury, but that such injury was simply the result of a foreseeable risk, the patient alleges instead that had he or she known of that risk before the procedure, he or she would have declined to undergo the procedure and thus would have avoided the risk.

To establish properly a claim for lack of informed consent, the patient must prove that a known, particular risk was not disclosed, that it should have been disclosed, and that had it been disclosed, the patient properly and rationally would have declined the proposed procedure. One court has defined these elements as follows. The tort of lack of informed consent is established when:

1. The physician fails to disclose to the patient and discuss the material risks and dangers inherently and potentially involved with respect to the proposed therapy, if any.
2. The unrevealed risks and dangers that should have been disclosed by the

physician actually materialize and are the proximate cause of the injury to the patient.
3. A reasonable person in the position of the patient would have decided against the therapy had the material risks and dangers inherent and incidental to the treatment been disclosed to him or her before the therapy.[20]

The first element of this definition imposes upon the physician an obligation to disclose "the material risks and dangers." Material in this context implies something that would be significant to the average, prudent person. Material contemplates not only the frequency of a risk, but also the severity of the result. Thus, a rare, but devastating risk may be material, as might be a common, but relatively inconsequential risk. What is left between those ends of the spectrum is determined in some jurisdictions by the custom and practice of physicians and in other jurisdictions by the appropriate "expectation" of an average patient. Thus, in some states professional custom and practice is the yardstick and in others a lay person's need to know is the standard by which materiality is measured.

The second component of the definition is merely that the particular risk that was not disclosed is the one that ensues and causes injury to the patient. The tort is clearly not established if the injury results from a risk that was in fact disclosed or alternatively from a risk that was not and need not have been disclosed.

The last element of the definition is perhaps the most difficult for injured patients to establish. Generally, in an informed consent case, the patient will acknowledge that he or she was given at least some information about the risks of a procedure and most commonly the particular risks that were disclosed were those most common and most severe. The risk that allegedly was not disclosed is frequently a less common and frequently less severe risk. For example, a patient may be warned of the possibility of ignition injury or hemorrhage, which might cause death or severe injury requiring major additional treatment, including surgery. The patient may not, for example, be advised of the risk of vocal cord injury. In this type of scenario, in accordance with element #3, the patient must convince the jury that a reasonable person in that patient's condition, having accepted the risks of death or major surgery from an ignition injury or a hemorrhagic event would have declined the relatively less significant risk of vocal cord injury. It is on this type of balance that patients frequently fail in an informed consent case.

Considerable dispute exists as to the method in which best to prove that a patient's informed consent has been obtained. Some practitioners favor the use of comprehensive written informed consent forms. Other practitioners prefer merely a brief note in their records referring to the discussion they had with the patient concerning the risks and benefits of the proposed procedure. Recognizing, as previously discussed, the weight given to professional and institutional policies and practices, compliance with a hospital's particular procedures regarding informed consent and its documentation is clearly of considerable importance. The physician, especially in an innovative area, should be particu-

larly knowledgeable of his or her own institution's practices with respect to the documentation of informed consent.

The third scenario involving potential personal injury liability of the physician relates to an injury that may occur to another member of the medical team. A number of the reported injuries associated with lasers have involved nursing personnel accidently exposed to the laser.[21] Typically, as an employee of a hospital, a nurse and/or a technician is precluded by virtue of Workers' Compensation Laws from filing a lawsuit for personal injuries against his or her employer or any other fellow employee. The sole recourse for such an injured employee is through the Workers' Compensation system. However, a medical physician who is not a fellow employee of a hospital may under some circumstances not therefore be protected by the immunity of the Workers' Compensation laws. In addition, in various states injured employees, to avoid the relatively limited recovery available under the Workers' Compensation system, may attempt to go beyond that system by filing a personal injury products liability lawsuit against the manufacturer or supplier of the involved equipment. Once again, compliance with governmental and professional standards is an important element of the practitioner's defense.

Institutional Liability

The hospital or clinic which is the setting of laser treatment also faces potential liability from patient injuries. In those circumstances in which the hospital or clinic employs the physician, then such institution is automatically and vicariously liable for the negligent actions of its employees by virtue of the legal doctrine of respondeat superior, that is, "let the master respond." This does not relieve the negligent physician of his or her own personal responsibility, but merely allows the injured patient to make a claim against not only the negligent physician, but also his or her employer, most commonly, for the obvious, "deeper pockets" reason. Even in this day and age it is not infrequent for a relatively underinsured physician to become involved in a case in which his or her limits of insurance are far exceeded by actual damage suffered by the patient and the patient must therefore look to others to satisfy their claims.

To a large degree, the obligation imposed on a hospital is essentially the same as that imposed on a physician, that is, a hospital must bring to bear in its care and treatment of a patient the same amount of care, skill, and diligence as would be brought to bear by the average and ordinary hospital. Thus again, a comparison of standards of practice between hospitals is pertinent, and in this context institutional policies and procedures have gained preeminence. Hospitals have increasingly relied on published standards to evidence their compliance with this legal obligation, and the standards promulgated by the Joint Commission on the Accreditation of Hospitals are clearly foremost in this respect.

When a physician is sued, he or she must defend his or her own action. Although there may be a considerable time between an event and an ultimate

trial, the physician normally can remember at least some of the pertinent facts and conversations. On the other hand, when an institution is sued, it frequently must derive its defense from the involvement and, subsequently, the testimony of numerous individuals, some of whom may have long since left the employment of the defendant institution. Because of the obvious difficulty in proof involved with a large cast of actors, institutions typically attempt to reduce their uses and practices to writing and to use those written policies and procedures as evidence of what probably occurred in a particular case. This, of course, further augments the proliferation of hospital policies and procedures. As a result, institutions are incessantly urged to establish written policies and procedures covering all routine events.[22] Maintenance of equipment, selection and supervision of personnel, evaluation of results, and corrective actions are prominent subjects of hospital procedure manuals. Once again, the potential double edge of such written procedure manuals is apparent; compliance with the procedure manual implies at least some evidence of aprpopriate behavior, whereas failure to comply with one's own required policies is strong condemnation. In any given case it may be difficult to determine whether the benefits of a written procedure manual outweigh the detractions.

Credentialing

The discussion of the legal aspects of laser therapy would not be complete without reference to staff privileges and credentialing. A number of reported decisions involving lasers and bronchoscopy have dealt with disputes between physicians and hospitals relating to clinical privileges.[23,24] A complete discussion of the legal aspects of hospital privileges is beyond the scope of this chapter; however, whenever a new technology is introduced into medicine, there frequently arise through economic, professional, and other motivations disputes as to the proper credentialing of those practitioners who use the technology. In general, the law has deferred to physicians and hospitals and has granted them great authority in deciding who is to have access to scarce medical resources. Courts generally will not overturn a hospital's decision to deny or to revoke clinical privileges unless no rational basis for the institution's decision is apparent from a review of the record or unless the affected physician was denied an opportunity to present his or her side of the case.

Generally, the courts are loathe to interpose themselves into the particular factual disputes that arise in these areas. The courts avoid, to a large degree, second guessing the decisions of physicians and hospital committees as to what elements of skill or experience may be requisite to granting clinical privileges. If, for example, a hospital credentials committee determines that a full residency in obstetrics and gynecology is a prerequisite to performing dilatation and curettage, one court has declined to reverse that determination in favor of a board-certified family physician who contended that his training was quite adequate to perform this particular procedure.[25] The court noted that this

particular hospital had previously established a formal residency as a prerequisite for various other specific privileges, including treadmill testing and fiberoptic bronchoscopy.

Just as the courts generally refrain from interfering with a decision to deny staff privileges, similarly they defer to a hospital and a medical staff determination resulting in the revocation of staff privileges. In a recent case, a Federal Court upheld the termination of staff privileges of a pulmonologist who was found after several internal reviews and audits to have been performing an excessive number of diagnostic and therapeutic bronchoscopies.[23]

It is not only the physician who might bring suit for denial or revocation of privileges; there are also instances in which patients have sued upon such claims. In a recent New York case, a patient filed suit against a hospital that had denied his physician clinical privileges to perform transcolonscopic laser ablation of a large villous adenoma of the distal cecum.[24] The physician in this case had apparently already exhausted his own legal remedies in an attempt to obtain laser privileges, but his patient's efforts in his behalf were found to be without proper foundation, and the patient's lawsuit was dismissed. The court ruled that the patient did not have proper standing to bring this kind of lawsuit, and that the patient was in fact not an injured party by virtue of the hospital's actions in denying his physician clinical privileges.

Conclusion

The innovative use of lasers in conjunction with endoscopy raises a number of legal issues and scenarios for potential physician and institutional liability. Federal and state laws relating to the development, sale, and use of these devices impose a number of specific requirements upon physicians and hospitals that must be followed. Manufacturers and suppliers of these devices face potential product liability lawsuits and must therefore be particularly cautious and comprehensive in providing adequate instructions and warnings for the use of these devices. Physicians themselves face potential medical malpractice claims from patients who are injured in conjunction with laser treatments. Such malpractice claims may arise either from alleged technical errors and deviations from accepted standards of practice as well as alleged instances of lack of informed consent. Hospitals and clinics that provide the devices and technical personnel used in laser procedures also face potential malpractice liabilities either vicariously or as a result of the institution's own failure to comply with accepted standards. Lastly, as competitiveness and economic motivations grow in the practice of medicine, access to limited resources including hospital facilities will generate an increasing number of legal entanglements for the practicing physician. The practicing physician needs to be aware of these ramifications to minimize his or her potential legal entanglements.

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The Psychological Effects of Medical Malpractice Litigation on the Physician

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The impact of malpractice litigation on the professional practice of medicine has taken an ever-increasing share of the attention of the entire health care delivery system in the United States. In fact, a search of the literature for the medical journals listed in the Medline database from July 1, 1980 to August 1987 resulted in 2,746 articles retrieved under the descriptor of malpractice. When the search was narrowed to include only articles dealing with malpractice paired with either stress, professional impairment, professional incompetence, defensive medicine, physician impairment, or attitude of health personnel, the number is reduced but is still a considerable 179 articles. The typical focus of attention in the vast majority of the articles retrieved was 1) the financial impact on the health care provider and health care institutions, 2) the type and extent of injury to the plaintiff, and 3) useful methods to incorporate into daily practice to avoid or provide adequate defense against litigation.

What has been almost totally neglected, with the exception of a very few studies, is the effect that malpractice litigation has upon the health care provider (typically a physician) and his or her family. Clearly this issue merits investigation.

It is a fundamental principle of the study of human behavior that experience results in learning, and that learning is most often defined as a relatively permanent change in behavior. The physician's style and manner of practice may in fact change as a result of the experience of litigation.[1] He learns that what he thought was previously acceptable behavior were not sufficient to protect him. Ironically, not too long ago even the thought of "protection" was not present.

Often, when a particular phenomenon becomes quite prevalent within a group, a reflection or indicator of this is the coining of a term to describe it. Further indication of the prevalence and recognition that the phenomenon of the health care provider's reaction to the litigation climate is widespread, is the migration of such a term from the subgroup of the population in which it is used to the widespread knowledge of the term within the population at large. Such a term to describe a way (or style) of practicing medicine in reaction to the

extremely litigious climate present since about 1981[2] is called "defensive medicine," a term used both in professional and lay circles. It is clear that malpractice litigation has significant impact on the practice of medicine and the perception of medical practice by lay persons.

The number of articles in both scholarly journals and popular literature clearly attests to the prominence within which malpractice resides in the American mind. It was previously stated that there is enormous impact from involvement in a malpractice action. The reported reactions have ranged the gamut from no apparent impact to physical and psychologic symptoms to the most severe reported reaction, suicide.[3]

The vast majority of research has not investigated the physician's reaction to being accused and/or tried for malpractice. This is an important focus as the physician, in some circumstances, also may become a victim of sorts after being subjected to litigation, particularly if the action is eventually deemed to have medical merit. The potential reactions that the physician may have fall into three categories: mood or emotions, physical or physiologic symptoms, and behavioral changes.

Research directly concerned with assessing the physician's reaction has been accomplished primarily through survey methods with some follow-up individual interviews or case histories. The most extensive research has been accomplished by Charles, Wilbert, and others. Their surveys have targeted sued and nonsued physicians through surveys and follow-up interviews. Their surveys requested basic information on demographics and professional background, litigation history (number of times sued), litigation outcomes (if sued), responding to a 5-point Likert scale on a series of statements about professional reactions to the litigation and a 4-point Likert scale for 40 emotional and/or psychologic symptoms (symptoms taken from criteria lists of Diagnostic and Statistical Manual of Mental Disorders, 3rd edition [DSM-III]) that reported presence, severity, and duration. Their third article in this area reported on the general results of interviews with 80 sued and nonsued physicians from their original 1,000 (approximate) surveys.[4]

There have been some basic findings common to all of the research reported in the literature on this topic. The physician's reactions appear across two domains—behavioral (or professional conduct) and emotional (including reported physical symptoms.) The research appears representative of the few other studies accomplished in investigating this area. This research will be summarized as an example of the data collected so far.

The easier type of reaction to categorize is behavioral. Almost all physicians report that there has been a change in practicing style since the looming specter of malpractice has appeared.[5] There have been significant differences reported in the changes in behavior of sued versus nonsued physicians. In the research conducted by Charles et al,[1] sued physicians reported more frequently (t test, $P < .01$, one-tailed) that they were likely to stop seeing patients with whom the risk of litigation was perceived as being greater (48.9% v 29.5%), discourage children from pursuing medicine as a career (32% v 19%), ordered more clinical tests than their clinical judgment deemed necessary (67.6% v 59.6%), and

stopped performing certain high-risk procedures (42.8% *v* 32.6%). Both groups also reported keeping more meticulous records than before litigation or its threat (74.5% and 78.6%) and attending more continuing education courses (27.3% and 31.4%). Interestingly, both groups also reported a change in the number of working hours, the sued tended to decrease hours and the nonsued tended to increase hours.

The data reporting on the emotional component was based on responses to (as previously described) a Likert scale of emotional or physical symptoms. When they took a sum of all severity ratings as a general index of emotional distress, the sued physicians had significantly worse symptoms than nonsued physicians ($P < .01$). The sued physicians also reported significantly greater depressed mood, inner tension, anger, and frustration. When controlled for sex and age, this data remained constant. Two symptom clusters (as the authors described them) emerged from the data: a major depressive disorder (dysphoric mood with at least two additional symptoms from the DSM-III criteria list) and pervasive anger accompanied by at least four of the following eight symptoms: depressed mood, inner tension, frustration, irritability, insomnia, fatigue, gastrointestinal symptoms, or headache. A significant amount of physicians acknowledged either of these two symptom clusters, and significantly more of the sued versus nonsued physicians acknowledged the second group ($\chi^2 = 14.6$, $df = 1, P < .001$). Of the doctors who reported the onset of physical illness, half had been sued. A little more than half of the doctors reported an exacerbation of physical illness, which they related to the stress associated with the malpractice problem. Of the total sample, 17.9% ($N = 62$) reported no symptoms. Only eight of these had been sued, and 54 had not been sued. An additional area at risk is domestic stability. The family often experiences similar feelings of isolation. The marriage of the professional is affected, even without an actual lawsuit occurring. The children often demonstrate effects, possibly behavioral or emotional.[6] The injury that the suit or threat of a suit inflicts goes beyond the practitioner to the practitioner's spouse and children.

The authors, although cautioning against a carte blanche generalization to the entire physician population due the densely populated urban area from which the sample was drawn, suggested that the second cluster of symptoms described may constitute an identifiable stress syndrome with the specific psychosocial precipitator being malpractice litigation. They would place it as a subset of an adjustment disorder.

An explanation for the apparent pervasive reaction that the physician has to malpractice litigation, an intuitive look must be taken at the manner in which such litigation impacts upon him. The physician has been placed into a particularly prestigious position in society. He is considered learned and is entrusted with caring for the lives of his patients. There had been a deification by the lay public of him through their perception of his skills and practice. When one deals in the daily care of others, one is often responsible for making life and death decisions, and is looked to with admiration and trust; when one has had to surmount rigorous selection procedures to both enter medical training and then maintain one's position in medical training, and when one is

often highly compensated for one's skills (a strong measure of importance in American society), it is easy to understand that a self-perception of importance and competence develops. Now add to this formula the presentation of an official paper that seems to state categorically that one is not expert in one's skills, that a grievous, perhaps life-threatening error may have been made, that the life of a patient who entrusted his or her care to you is deeply affected in a negative way. This is a terrifying and penetrating indictment of one's personal beliefs about one's ability and competence. Added to this is the stigma that it may cause in the public perception of one's self. It is this blow that we have to study. How will this indictment of professional competence (and we often define ourselves as an extension of our profession) affect him and those around him.

The typical initial reaction reported by most physicians who have been sued is one of disbelief. How will my colleagues react; what will my family say; what will my patients say? This may lead to an effort to initially conceal the action. An attempt to conceal usually indicates feelings of shame. Shame tends to induce one to isolate others from their problem thereby resulting in isolating oneself from a potential support system.[7] Malpractice defendants report that they often feel isolated and alone. They feel this way, but very few ever attempt to seek moral support from peers. In fact, other physicians frequently avoid physicians that are being sued.[8] Isolation is a definite exacerbator to the depressive syndrome. Sued physicians have reported mood swings, shame, embarrassment, family disruption, low frustration tolerance, feeling misunderstood and defeated, decreased self-confidence, lower self-esteem, and so on.[9] They are reacting to a particularly penetrating personal attack.

All of the research reported identifiable mood disturbance in sued physicians as a reaction to this personal attack. It appears (through anecdotal study) that prelitigation adjustment and self-confidence has a strong effect on the nature of the physician's reaction. The most extreme level of disturbance reported was of deep depression and suicide.[3] The mood disturbance may not always be as severe, but it is present and can be described through the major statements that have been ascribed to by surveyed sued physicians. The following represent symptoms reported by at greater than 60% of these physicians: anger (85.6%), inner tension (83%), depressed mood (79.4%), frustration (76.8%), and irritability (64.4%). These symptoms were also at a significantly greater severity in sued than nonsued physicians ($P < .05$).[1] These represent part of the constellation that is often associated with a major depressive disorder.

The coping response may be better illustrated through some case history data. Two extremes of the cases are summarized here.[4] Dr. A reported symptoms of being somewhat depressed, anxious, and frustrated by the current malpractice climate. Although he described the suit as being annoying, humiliating, and affronting his personal competency, his symptoms were mainly anticipatory to his litigation. His ability to deal with the stresses of his suit came from some fairly good coping strategies, sharing feelings with peers and office staff, demonstrating insight into his own feelings, and a resolve to seek outside consultation if it became necessary. Another statement attributed

to this was, "I practice the best medicine I know how. If I get sued, I get sued." He had leisure activities and did not perseverate on the litigations issues. The interviewer described him as a "well-adjusted man." Despite all this, it should be noted that Dr. A was planning early retirement. Dr. B responded to a survey and he appeared to be hypervigilant, doing everything he could to protect himself from litigation. He kept careful records, ordered extra tests, and so on. He reported discouraging his children from entering medicine and was considering early retirement. Even before being sued he reported transient depression, anxiety, and frustration. When he was interviewed, he had had more than one malpractice suit. He reported that the latest suit was the most stressful period in his life. He had a helpless feeling as was indicated by the following statement, "anybody can sue anybody for anything at any time." He discontinued some high-risk procedures. He reported "looking over my shoulder" when seeing patients. He reported as a reaction to being sued depression, anxiety, anger, and insomnia continuing for more than 2 weeks. Dr. B reported that this had become a pervasive issue in his life, invading his thoughts at all times.

These two illustrative reactions suggest that although litigation, particularly medical malpractice, is always stressful, for some it is extremely debilitating. Dr A reacted with transient symptoms, but the litigation had a continuing effect on him. Dr. B developed symptoms that qualify as a major depressive episode under DSM-III criteria. He had clearly changed the style in which he practiced medicine.

The research indicates that there are easily defined psychologic and behavioral symptoms common to many physicians who experience malpractice litigation. There is a constellation that so frequently appears that the term "malpractice stress syndrome" has been coined. They are frequently severe and pervasive, affecting the physician's ability to practice unencumbered. The stress is maintained and sometimes increased by the litigation process itself, which is often long and drawn out. Another change in the behavior of nonused physicians also has emerged from the survey literature. Many have altered their style of practice to attempt to provide some protection in the event of litigation, the so-called practice of "defensive medicine." This results in undisputed increased costs, both financial and emotional.

There is a very complex picture of emotional, physical, and behavioral reactions to malpractice litigation by the physician (and often his or her family). Treatment of the problem is not defined as of yet, as physicians often find the role of patient to be difficult as well. In agreement across all of the literature specific to this area (and on depression and stress as well) is that one of the major exacerbators of symptomology is the isolation component. (Some programs have appeared to provide support for the physician and his family, thus addressing the isolation component as well.) What also must be kept in mind is that the litigation itself is quite serious and poses a serious and very real threat to the physician's professional reputation, standing in the community, and financial solvency. The results are quite clear: malpractice litigation exacts a high cost—from the patient, the physician, and society. The neglected area (perhaps only until recently) has been the cost to the physician.

Summary and Conclusion

Malpractice litigation has an adverse impact upon the physician and his or her family financially, professionally, and psychologically. Litigation, however, has become a way of life in the United States and is predicted to worsen. The physician who has been sued should be aware of the psychologic reactions he or she is likely to suffer (along with his or her family) and attempt to develop coping strategies for the same. Seeking professional help in terms of psychologic and psychiatric counseling is known to help the physician and the family cope with this difficult life event. Malpractice insurers should consider paying for these services as this is also a damage suffered from the litigation in addition to the possible financial damages, and they may find the physician a better prepared defendant in court.

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