

Patient Safety in Obstetrics and Gynecology

An Agenda for the Future

Mark D. Pearlman, MD

The effect of medical errors and unsafe systems of care has had a profound effect on the practice of obstetrics and gynecology. From 1975 to 2000, medical malpractice costs for obstetrician-gynecologists have risen nearly four-fold higher than that of other medical costs. In addition, it has been estimated that defensive medicine may cost society \$80 billion per year. Most importantly, many obstetrician-gynecologists are frustrated and seem to be abandoning the parts of their practice they perceive to put them at higher liability risk. This article discusses other medical specialty society efforts that have been successful in addressing the area of patient safety. Efforts to better track quality outcomes has been initiated by the American College of Surgeons through the National Surgical Quality Improvement Project, and the American Society of Anesthesiologists has demonstrated both dramatically improved outcomes and reduced liability costs through a concerted patient safety effort. The author proposes

See related article on page 1058.

From the Department of Obstetrics and Gynecology, the University of Michigan Medical School, Ann Arbor, Michigan.

An earlier version of this essay was presented as the John Figgis Jewett Lecture of the Massachusetts Medical Society on July 20, 2005.

Corresponding author: Dr. Mark D. Pearlman, 1500 E Medical Center Drive, L4000 Women's Hospital, Ann Arbor, MI 48109-0276; e-mail: Pearlman@med.umich.edu.

© 2006 by The American College of Obstetricians and Gynecologists. Published by Lippincott Williams & Wilkins.

ISSN: 0029-7844/06

changes in four areas to specifically address patient safety in obstetrics and gynecology, including: the development of reliable and reproducible quality control measures (and a system to track them); national closed claim reviews to better understand and address the most important safety and liability areas for obstetrician-gynecologists; work prospectively with pharmaceutical and surgical device manufacturers to develop innovative new products that would increase the likelihood of safe outcomes; and create a culture of safety in obstetrics and gynecology by incorporating safety education into all levels of training.

(*Obstet Gynecol* 2006;108:1266-71)

There is a great deal of angst about the future of obstetrics and gynecology. At or near the top of the list of major concerns are medical-legal issues and liability reform. At the intersection of medical malpractice and liability reform lies the topic of patient safety.¹ Although caps on liability often dominate the discussion of tort reform, I believe there is a more fundamental issue—we have a moral obligation, irrespective of liability concerns, to improve systems of health care for women and to reduce unnecessary morbidity.

On the one hand, there exist regular multimillion dollar judgments against obstetric-gynecology physicians and hospitals, seemingly capricious jury decisions, a decreased interest in obstetrics and

gynecology by senior medical students, early retirement among obstetric-gynecology physicians, and a strong sense of injustice in our tort system. On the other hand, although one can debate the exact numbers, there is an extraordinarily high frequency of patient injuries due to errors. The annual incidence of deaths related to medical errors in our hospitals may be the eighth leading cause of death in the United States.²

Since the Institute of Medicine report, *To Err Is Human*, was published in 1999,² much discussion has been generated about fixing the problem of error-related injuries in health care. A variety of approaches have been suggested, and some have already been partially implemented: developing systematic methods for addressing error reduction rather than blaming individuals, improving communication among members of health care teams, providing team training, improving medical education about error theory and prevention, and instituting the 80-hour work week for residents. Although many believe these efforts have merit, they are relatively new initiatives and have not yet demonstrated evidence of any substantial reduction in the frequency of injuries resulting from medical errors since 1999.³ More recently, the Institute of Medicine released a report suggesting that 1.5 million preventable adverse drug events occur each



year in the United States, many resulting in permanent injury or death (Aspden P, Wolcott J, Bootman L, Cronenwett LR, editors. Preventing medication errors. Committee on Identifying and Preventing Medication Errors Board on Health Care Services. Institute of Medicine of the National Academies, 2006. Available at: http://newton.nap.edu/pdf/0309101476/pdf_image/R1.pdf. Retrieved August 1, 2006.). Recommendations included improved communication between patients and their physicians regarding medication use (eg, more thorough discussion of adverse effects, contraindications, drug–drug interaction as well as patients keeping better records of their own medications). In addition, increased use of technology such as electronic access to drug information using personal digital assistants, use of electronic prescriptions to reduce legibility errors, checking for allergies and drug–drug interactions.

THE EFFECT OF DEFENSIVE MEDICINE PRACTICES IN OBSTETRICS AND GYNECOLOGY

The sobering realities of liability issues in our specialty are well documented. The average obstetrician–gynecologist will be sued 2.64 times during his or her career. Over the period 1975–2000, medical costs rose a remarkable 449%, whereas during the same period tort costs rose an astounding 1,642%.⁴ Many obstetricians have chosen to take an aggressive approach in their own practices to manage this problem. Defensive medicine is an interesting side effect of the medical tort system. Some might even call it a growth industry. Phillip Howard, a Washington attorney, one of the founders of the advocacy group “Common Good,” speaking at the

Annual Clinical Meeting of the American College of Obstetricians and Gynecologists (ACOG) in 2004, suggested that approximately \$80 billion are spent each year in the United States on defensive medical practices.⁵ He argued that this amount of money would be more than enough to provide medical care to the estimated 40–50 million uninsured people each year in the United States.

To reduce errors and improve outcomes in the overall health of the population, meaningful quality outcome measures must be used.

How prevalent is defensive medicine in obstetrics and gynecology? In 2003, Studdert, Brennan, and Sage⁶ conducted a large survey of defensive medicine practices of over 200 Pennsylvania obstetricians and gynecologists, along with 600 physicians in other high-risk specialties such as neurosurgery, orthopedic surgery, radiology, emergency medicine, and general surgery. This study assessed the behavior of high liability risk physicians in a high liability setting state with somewhat disturbing results. This was a very seasoned group of physicians: 96% of those who responded had at least 10 years in practice. Using the definition of defensive medicine described earlier, the authors found that a remarkable 93% of these physicians reported practicing defensive medicine. Among obstetricians and gynecologists, 54% stated that they often ordered more tests than medically necessary. Nearly

one third admitted to prescribing more medication than was medically indicated. Two thirds stated that they often referred patients to other specialists in unnecessary circumstances to avoid the risk of being sued. Obstetricians and gynecologists were also statistically more likely to avoid certain high-risk procedures or interventions that their patients needed, and nearly one half avoided caring altogether for high-risk patients.

Equally worrisome was the finding that 46% of survey respondents had already stopped or were going to stop all obstetrics in the next 2 years, and another third will stop or soon stop complex obstetric care. Nearly 40% of this group stated that they will stop certain high-risk gynecologic procedures they now perform. Significantly, having been previously sued did **not** affect the likelihood of whether the respondents practiced defensive medicine. Rather, two factors were the strongest predictors of practicing defensively: 1) whether the doctor felt he or she had adequate insurance coverage; and 2) doctors who described their insurance premiums as being severely burdensome to their finances. Thus, economic concerns seem to be more likely to cause physicians to practice defensively than simply the risk of being sued.

Perhaps even more disturbing is the avoidance of certain types of high-risk patients. In the Pennsylvania study, this practice was reported more commonly by obstetric–gynecologic physicians than by those in other specialties. Avoiding high-risk patients also has the greatest potential for harm, particularly in rural areas where alternative sources of care may not be available. It can have a profoundly deleterious effect on essential health services for women.

Irrespective of the positive or negative effects on health care, the



economic effects of defensive medicine practices are staggering—particularly with health care costs approaching more than 16% of the gross domestic product.⁷ It is also a sign of an unhealthy system when physicians are knowingly ordering tests that they readily admit are not likely to benefit their patients.

THE NEED FOR QUALITY CONTROL MEASURES

Although many doctors are practicing defensively and shunning high liability areas of practice, what is happening overall to the quality of care in obstetrics and gynecology? To reduce errors and improve outcomes in the overall health of the population, meaningful quality outcome measures must be used. Many outcome measures have been developed for obstetrics and gynecology. However, too often, adopted measures are influenced unduly by the variety of stakeholders who participate in measures development. Having sat on the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Committee for the development of quality measures in obstetrics and gynecology for several years, I have observed the process and work product of this influential group. At that time, the Committee consisted of about 20 individuals, including representatives of health maintenance organizations, the medical insurance industry, nursing, the American Medical Association, JCAHO, and three obstetrician–gynecologists. When candidate measures were introduced, discussion centered on the effect of the proposed measures on outcomes, the positive and negative effect of various stakeholders, economic considerations, ease of data collections, and so on. Not surprisingly, the selected outcome measures were not always evidence-based measures intended to drive im-

proved patient care, or the measure of quality of one institution compared with another, or trends of one institution over time. Rather, the outcome measures were frequently a consensus choice ultimately selected by JCAHO to address the concerns of its various constituencies. One could strongly argue that certain selected measures, such as cesarean delivery rates or vaginal birth after cesarean rates, fail to have any meaningful effect on the health of pregnant women and their infants.

As a specialty, obstetrics and gynecology has a way to go to effectively and systematically track outcomes of our procedures, either short or long term. As a result, opportunities to identify best practices or, alternatively, identify and correct substandard care are not done consistently. Another specialty society, the American College of Surgeons (ACS), adopted a program initiated in the Department of Veterans Affairs system to collect and report risk-adjusted event data for a variety of surgical procedures. This methodology was expanded 8 years ago to private sector hospitals to determine whether the methodology is appropriate in general surgical practice in these hospitals. Over the past several years, this tool has moved from research to practice.⁸

The ACS program is based on data collected by a dedicated surgical nurse who assembles data on 133 variables, including preoperative risk factors, intraoperative variables, and 30-day postoperative mortality and morbidity outcomes for patients undergoing major surgical procedures in both inpatient and outpatient settings. These data are then analyzed centrally to ensure accuracy and consistency with a random sampling methodology. The data can then be reviewed in semiannual reports, on-line re-

ports, and through ad hoc reports. Finally, and most importantly, the data are acted upon by comparison of individual hospitals to national benchmarks and best practices. Best practices can then be adopted with on-going data collection to assure that outcomes have improved. The ACS National Surgical Quality Improvement Project is available to all private sector hospitals that meet the minimum participation requirements, complete a hospital agreement, and pay an annual fee of \$35,000. Hospitals can benefit from participating in the ACS National Surgical Quality Improvement Project for many reasons; most importantly the program can contribute to the reduction of surgical mortality and morbidity. In October, 2002, the Institute of Medicine named the project the “best in the nation” for measuring and reporting surgical quality and outcomes.⁹

HOW ONE MEDICAL SPECIALTY OVERCAME ITS MEDICAL LIABILITY PROBLEMS

Much has been made of the effect of the liability environment on the increased cost of medicine and escalating malpractice insurance premiums. Tort reform has been touted by many as the cornerstone of a solution for our current liability crisis.

In the early 1980s one specialty chose to address the liability crisis with a different approach. In 1985, the American Society of Anesthesiologists (ASA) founded the Anesthesia Patient Safety Foundation. Notably, this was 15 years before the Institute of Medicine report was published. The Foundation included anesthesiologists, nurses, insurance companies representing the malpractice industry, and even some medical device companies that made anesthesia equipment.



The Anesthesia Patient Safety Foundation started the process by systematically reviewing closed claims, not a routine method in the 1980s; and through this procedure, it was able to identify the major causes of deaths in the operating room. Most were related to failed intubations, inadvertently disconnected ventilator tubing, and carbon monoxide poisoning.⁹ Through the work of this Foundation and with the support of the ASA, sweeping changes were put in place. Pulse oximetry, which had been used only sporadically in the operating room before, became part of the ASA standard of care. Shortly thereafter, capnography was also added as standard. These changes were no small matter when they were first introduced, because pulse oximetry and capnography equipment together cost nearly \$10,000. But hospitals quickly purchased this equipment because they recognized the increased potential liability of not doing so. Not surprisingly, with widespread adoption, the cost of these devices came down. Another interesting finding in the closed claims data were that many deaths secondary to carbon monoxide poisoning occurred on Mondays in the operating room. Cases of CO poisoning were very unusual in any single hospital's experience; and only the large-scale, systematic review identified this trend. Through careful analysis, it was discovered that carbon monoxide filters were drying out over the weekend when they were not used, rendering them ineffective in extracting CO. A simple but broad-based policy of changing filters on Monday morning virtually eliminated this problem.

The Anesthesia Patient Safety Foundation was also among the first patient safety organizations to develop simulation mannequins to

train all anesthesia residents in difficult intubation, emergency tracheotomy, and the management of many high-risk situations, all of which problems had been identified through closed claims data.

The results of the combined efforts of the Anesthesia Patient Safety Foundation and the ASA were dramatic. Anesthesia-related intraoperative deaths plummeted to 1 in every 200,000–300,000 procedures, compared with about 1 in 5,000 operations in the early 1980s—more than a 98% reduction in deaths. No one change created this safer environment. The real difference was an across-the-board belief that the best approach to the safety and liability problem was to address the part of the problem they could address—to understand the cause of the deaths and to identify solutions to prevent them. And most importantly, to implement those solutions broadly.

The effect on malpractice premiums and lawsuits against anesthesiologists has been quite revealing as well. In 2001, anesthesiology lawsuits accounted for 3.8% of all medical malpractice compared with more than twice that in 1972. Adjusted to 2005 dollars, payments on awards have dropped from approximately \$300,000 in the 1970s to \$180,000 in the 1990s. Most interestingly, inflation-adjusted malpractice premiums for anesthesiologists have declined from approximately \$32,600 in the early 1980s to \$20,572 in 2002.⁹

OBSTACLES TO PATIENT SAFETY REFORM

In the June 2005 issue of *Journal of the American Medical Association*, two influential individuals in the patient safety field, Lucian Leape and Donald Berwick, outlined the (too) slow progress in patient safety efforts since the Institute of Medicine report was released in 1999.³ They

blamed in large part the so-called culture of medicine—a culture that is deeply rooted, both by custom and training, in autonomous individual performance and a commitment to progress through research. These traits have resulted in profound advances in biomedical science and delivered unprecedented cures to millions of people. But the tenacious commitment to individual, professional autonomy creates a barrier to progress in the patient safety arena. Creating cultures of safety requires major changes in behavior, changes that we as professionals often perceive as threats to our authority and autonomy. Given this challenge to fundamental change, combined with the introduction of a nonblaming, systems approach to errors, which is quite foreign to the training of most practitioners, it is not surprising that progress has been slow. Other problems that create huge disincentives to move forward include the lack of robust and accurate measures of quality in obstetrics and gynecology and a reimbursement system that does not recognize safe practices. Despite these barriers, most physicians, nurses, pharmacists, and other health care providers are actively engaged in the effort to improve our patient care and provide safer environments in our delivery suites, our operating rooms, and our offices.

There are tools available to provide safer care. Computerized physician order entry programs are eliminating many, but not all, medication errors. Electronic medical records are increasingly being used throughout the United States to assure access to critical medical information. Meaningful quality measures and safe practices, such as reducing ventilator-related pneumonias, catheter-related sepsis, and medication errors, are gradually being implemented. Perhaps most



important, a change in the culture of shared effort and responsibility between physicians, nurses, pharmacists, and other health professionals is slowly taking place. At my institution (University of Michigan), clinical pharmacists regularly participate in rounds on a wide variety of clinical services with physicians, assisting with medication selection, educating students, house officers, and faculty, but most importantly, catching potential medication errors before they reach the patient. The experience has been uniformly positive, and expansion throughout the inpatient arena is moving forward.

Also, experimental and pilot programs are being investigated with Centers for Medicare and Medicaid Services and other payers to evaluate the effectiveness of incentive pay for outstanding safe performance, and the whole “pay for performance” idea is gaining momentum and currently being implemented in parts of the United States. The Accreditation Council for Graduate Medical Education has introduced practice-based learning and systems-based practices into the evaluation process of all approved training programs, as well as implementing the 80-hour work week. And the unethical practice of not disclosing injuries to patients is rapidly disappearing from our landscape.

CHANGES IN OBSTETRICS–GYNECOLOGY THAT CAN IMPROVE PATIENT SAFETY: A CALL TO ACTION

We cannot reasonably expect others to determine the best and safest practices in obstetrics–gynecology. We have a moral imperative as a specialty to fully engage in the identification of our own best practices, to advance safety research in obstetrics and gynecology, and to implement broadly those practices

which are best. This is no simple task. It will require time, commitment, resources, and a radical restructuring of our view of physician autonomy. Working in teams and sharing responsibility for patient well-being are not traditional behaviors of physicians, and we must learn from our mistakes. These behavior changes, however difficult, will benefit our patients and us.

We are at a crossroads in obstetrics and gynecology. Some have invested in tort reform as the strategy to solve our problems, but I do not believe that tort reform alone will change outcomes. It will not change or improve the care we provide to our patients. However, we can control our own destiny by actively pursuing aggressive changes in how we approach safe care.

To initiate these changes, I propose the following steps:

1. Develop reliable and reproducible quality control measures for obstetrics and gynecology that go beyond measures such as cesarean delivery or vaginal birth after cesarean rates. As an example, the Weighted Adverse Outcome Index described by Mann et al (Mann S, Pratt S, Gluck P, et al. Assessing quality in obstetrical care: development of standardized measures. *Jt Comm J Qual Patient Saf* 2006;32 [in press]) offers a useful model for how to establish such valid measures, although further testing and validation needs to be done on a more comprehensive basis before it can be accepted as a standard. Encouraging increased funding for continued research and testing in this important area should be a high priority for ACOG and other stakeholders.
2. Support the establishment of

closed claim reviews on a nationwide basis and incorporate the results into practice bulletins. Although closed claims reviews have been performed in obstetric and gynecologic settings, they most often have been undertaken regionally. As a result, the lessons learned may reflect local practice patterns, but more likely, they are lost due to a perceived lack of applicability beyond those provincial borders. To truly transform the quality of care in obstetrics and gynecology and improve patient safety in a meaningful way, the College should engage fully in this effort, not only by simply evaluating and analyzing closed cases but also by incorporating the important lessons learned into practice bulletins. This step would not only provide a safer harbor for good practice, but it could potentially transform practice to make it safer.

3. Create partnerships with the pharmaceutical and medical devices industries to develop safer drugs and equipment and to provide training for health care professionals in the safe use of complex new equipment (eg, robotics). Our national societies should partner with companies to produce simulation training modules and credentialing procedures that would require physicians to be tested in the safe use of sophisticated devices before being granted privileges to use such technologies in the operating room on patients.
4. Incorporate patient safety education into all levels of training as a requirement for initial and continued board certification—from undergraduate medical education, through residency



and other postgraduate training programs, and continuing with a demonstration of both the understanding and practice of safest medical practice systems. As one important element of this proposal, the College should focus on training department chairpersons (academic and nonacademic) to support and disseminate accepted methods in patient safety, such as team training, appropriate antibiotic and deep vein thrombosis prophylaxis before surgery, and root cause analysis methodology, among others. The American Board of Obstetrics and Gynecology can also assist in assuring that patient safety principles are integrated into practices by emphasizing these in board certification examinations and by selecting relevant patient safety-related articles in the ABC program

Changes such as I am proposing will help shape our efforts in patient safety over the next 3 to 5 years and beyond. We must work

together to provide a mechanism for research into safer methods of practice and to engage industry with a mission of improved safety for the procedures we perform. The ACS is participating in the National Surgical Quality Improvement Project, which carefully tracks important outcomes from common operations. Our College should join this effort as well, so that we can learn from best practices and employ them in our own patient care. The American College of Obstetricians and Gynecologists can assist us by providing the foundation upon which we can implement changes in practice. These changes will require work and money and time—and the combined efforts of all of us.

REFERENCES

1. Clinton HR, Obama B. Making patient safety the centerpiece of medical liability reform. *N Engl J Med* 2006;354:2205–8.
2. Kohn LT, Corrigan JM, Donaldson MS, editors. *To err is human: building a safer health system*. Committee on Quality of Health Care in America. Institute of Medicine. Washington (DC): National Academy Press; 1999.
3. Leape LL, Berwick DM. Five years after To Err Is Human: what have we learned? *JAMA* 2005;293:2384–90.
4. Black BS, Silver CM, Hyman DA, Sage WM. Stability, not crisis: medical malpractice claim outcomes in Texas, 1988–2002. University of Texas Law & Economics Research Paper No. 30; Columbia Law & Economics Research Paper No. 270; University of Illinois Law & Economics Research Paper No. LE05-002. Social Science Research Network 2005. Available at: <http://ssrn.com/abstract=678601>. Retrieved August 10, 2000.
5. Howard PK. Is the medical justice system broken? *Obstet Gynecol* 2003;102:446–9.
6. Studdert DM, Mello MM, Sage WM, DesRoches CM, Peugh J, Zapert K, et al. Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. *JAMA* 2005;293:2609–17.
7. Health insurance cost: facts on the cost of health care. National Coalition on Health Care. Washington (DC), 2004. Available at: <http://www.nchc.org/facts/cost.shtml>. Retrieved May 29, 2006.
8. About ACS NSQIP: History of the ACS NSQIP. American College of Surgeons, National Surgical Quality Improvement Program, 2005. Available at: http://acsnsqip.org/main/about_history.asp. Retrieved May 17, 2006.
9. Anesthesiologists and patient safety. *Wall Street Journal* (Eastern edition). July 19, 2005. p A15.

