5

Beyond MQSA

Although much of this report has focused on improving the quality of breast cancer detection as implemented through the Mammography Quality Standards Act (MQSA), this goal can be further advanced through additional measures that extend be- yond the current purview of MQSA. Mammography is only one component of a multistep process in breast health care—quality care is thus dependent on performance standards across the cancer care continuum (IOM, 1999). As noted in Chapter 2, the best possible care will result from effective communication and coordination among breast imagers, surgeons, pathologists, and primary and other care providers.

This chapter examines broader approaches to optimizing breast cancer detection through an exploration of the context in which mammography is performed, including challenges associated with broad implementation of reminder systems, the complex issue of medicolegal liability, and the growth of breast imaging technologies that complement mammography, but for which there are no equivalent mandated quality assurance standards.

REMINDER SYSTEMS

Considerable research indicates that adherence to recommended screening intervals is important to maximizing the life-saving potential of screening mammography (Hunt et al., 1999; Tabar et al., 1999; Michaelson et al., 2000; Blanchard et al., 2004). Several studies, including meta-analyses of randomized controlled trials, have demon- strated that the use of patient reminders is associated with an increase in screening mam- mography and other preventive health measures, although the reported magnitude of this effect is variable (Balas et al., 1996; Shea et al., 1996; Mandelblatt and Yabroff, 1999; Stone et al., 2002; Gimotty et al., 2002; Blanchard et al., 2004; Quinley et al., 2004). However, the Task Force on Community Preventative Services recently conducted a sys- tematic review of studies on reminder systems and concluded that there is strong evi- dence for the effectiveness of patient reminders to increase breast cancer screening (Task Force on Community Preventative Services, 2005). Thus there is ongoing interest in de- termining which types of reminders are most effective and cost-effective in increasing mammography use and frequency in different practice settings, particularly among eligi- ble women who have never had a screening mammogram and those who are overdue for a repeat mammogram.

Mammography in the United States has been described as opportunistic, meaning that a woman generally requests a mammogram on her own initiative and/or as a result of a recommendation by her physician. Perhaps not surprisingly, many American women do not receive mammograms at recommended intervals, as illustrated by a multiyear study of mammography utilization in a large screening center at Massachusetts General Hospital (Blanchard et al., 2004). It showed that more than half of women who received a mammogram in 1992 had fewer than five mammograms during the subsequent 10 years (the expected number if following a 2-year screening interval), and that only 6 percent

received annual mammograms during the entire 10 years. Similarly, data from the New Mexico Mammography Project revealed that between 1994 and 1997, 30 percent or fewer women had adhered to the Project's established annual screening recommendations (Gilliland et al., 2000). On the other hand, researchers who examined one of the few examples of organized breast cancer screening in the United States—a not-for-profit managed health care plan serving more than 350,000 people in the state of Washington— found that women who were enrolled in the plan's screening program had a 61 percent lower risk of late-stage breast cancer, compared with women who were not enrolled inthe program, using primarily a 2-year interval of screening (Taplin et al., 2004).

Unlike organized breast cancer screening programs in European countries, the United States has not established centralized registers or reminder systems to alert women when they are due for a mammogram. While there are many obstacles to the de- velopment of European-style systematized screening in the United States, a variety of reminder systems (see Box 5-1) that have been implemented in both opportunistic and organized screening programs could be further expanded. However, as the findings inBox 5-1 indicate, no single type of mammography reminder system has been found to be superior to others in all populations and situations.

It would also seem that a reminder system that monitors multiple diseases and health risks would be better—from the point of view of both patient and health care provider—than the sort of single-disease intervention typified by mammogram reminders. Related needs such as screening for breast and cervical cancers may be more effectively addressed in combination than through approaches that target single interventions (Valanis et al., 2003). Because many health organizations are committed to increasing rates of preventive care, there is significant potential for developing reminder systems to coordinate multiple prevention activities. For example, an evolving collaboration among the American Cancer Society, the American Heart Association, and the American Diabe- tes Association could lead to the development of systems that integrate preventive care and testing for each of these diseases (Eyre et al., 2004).

The Committee concluded that patient reminder systems are an important and effective tool to encourage women to undergo breast cancer screening at recommended intervals, and that broader use should be encouraged. However, the variability of practice settings in the United States makes it difficult to recommend any one particular type of reminder system, or to mandate their use under MQSA.

MEDICOLEGAL LIABILITY AND THE QUALITY OF CARE

As noted in Chapter 4, concerns about the likelihood and consequences of malpractice liability may discourage radiologists from interpreting mammograms. Malpractice lawsuits (described in Box 5-2) have become increasingly common, costly, and time-consuming. Malpractice liability insurance rates have also risen. Physicians interpreting mammograms are particularly concerned about the high frequency of malpractice lawsuits involving delayed diagnosis of breast cancer and the expense of paid claims for such suits.

The escalation of medicolegal costs could perhaps be contained through medical liability reform. However, this is a complex topic of considerable controversy. Many approaches to reform have been proposed, but there is widespread disagreement in the

BOX 5-1 Reminder System Models and Comparisons

Some women use electronic or paper-based calendar tools to alert them when it is time to schedule their mammogram. Certain primary care practices and mammography programs notify women that they are due for screening by letter (an “outreach” reminder system); others insert a notice into a woman's medical chart instructing her primary care physician to advise her to schedule a mammogram at her next visit (a “provider-based” reminder system). Either type of reminder system can be readily automated for use, particularly if electronic medical records are used.

However, simply constructing such a reminder system does not guarantee its effective use. Several studies have attempted to determine and compare the effectiveness of various reminder systems for a variety of preventive health measures, and to assess the reasons why such systems often fail. Reminders that depend on regular encounters between patient and health care provider are inherently limited. Even women with consistent access to medical care switch health plans and, as they age, tend to see their physicians more for chronic health problems than for preventive care. Moreover, research indicates that physicians frequently ignore or neglect to mention chart reminders, often due to lack of time.

Evidence indicates that outreach reminders to patients are more effective than provider-based reminders in increasing rates for preventive care procedures, including mammography. A 1998 meta-analysis of 16 U.S. studies in which controls did not re- ceive any type of reminder found that women who received a mailed reminder were approximately 50 percent more likely to get a mammogram, and that letters tailored to the health risks faced by individual women were even more effective; more recent studies add to the support for such outreach reminders. The combined weight of this research suggests that mammography rates could be increased if mammography facilities, as well as primary care providers, implemented a routine outreach reminder system for eligible women.

Comparisons of the cost-effectiveness of various mammogram reminder systems have favored postcards and telephone-plus-letter interventions. However, Vogt and colleagues argue that “to be maximally effective, reminder systems need to concentrate on the rarely screened.” These researchers examined the cost-effectiveness of letter and phone outreach interventions to deliver breast and cervical cancer screening to approximately 41,000 women who had been unscreened for at least 3 years. A combination of letter plus follow-up phone call, the most cost-effective option, led to mammography screening in about half of women who received the intervention; this was more than twice the rate of compliance among women who received the letter alone, and five times the rate of compliance among women who were reminded only by routine system and environmental prompts. “An initial letter gets the motivated people in cheaply . . . [while] a personal phone call in which the appointment can be scheduled motivates those who are more reluctant,” the researchers conclude. Unscreened and underscreened women tend to be older. Lower mammography rates have also been found for women living in rural areas, those with low incomes and/or socioeconomic status, and minority women.

Reminder letters were found to increase mammography among long-term noncompliant older women, and were associated with a higher rate of repeat mammography among women Medicare members (predominantly age 65 and older), particularly those aged 75 and older. A comparative study of reminder systems used by primary care pra-

Continued

BOX 5-1 *Continued*

ctices in Kansas found that significantly fewer rural practices employed such systems, a difference that apparently contributed to (but did not entirely explain) disparities in rural–urban mammography rates.

By contrast, letter reminders were found to be ineffective in prompting predominantly low-income, black members of a Detroit health maintenance organization to schedule mammograms. Although a study of low-income women in Colorado found that phone outreach intervention involving multiple reminder calls significantly increased mammography among previously nonadherent women, it is important to note that the subjects in this study were chosen based on their ability to receive phone calls. Researchers in the Detroit study found that nearly half of its potential participants had either unlisted or absent telephone numbers; under such circumstances, provider-based reminder systems may have the best chance of improving mammography rates. Taken as a whole, these findings indicate that a "one size fits all" approach to mammography reminders is unlikely to be effective. In much the same way that tailoring reminders to individual women improves their impact, so may reminder systems need to be designed to reach specific populations.

SOURCES: Yarnall et al. (1998); Schellhase et al. (2003); Bankhead et al. (2001); Somkin et al. (1997); Wagner (1998); Mayer et al. (2000); Rakowski et al. (2003); Fishman et al. (2000); Valanis et al. (2003); Saywell et al. (1999); Vogt et al. (2003); Simon et al. (1998); Engleman et al. (2004); Harrison et al. (2003); Quinley et al. (2004); Crane et al. (2000).

United States on what reforms, if any, would be beneficial for improving the delivery of quality health care, in part because the full effects of reforms are difficult to predict. In order to explore the potential of one approach—a no-fault liability system linked with high performance requirements—to simultaneously improve the quality of breast imag- ing, reduce the burden of lawsuits, and ensure fair and timely compensation in the event of a misdiagnosis, the Committee recommends that the feasibility of such a system be tested within breast imaging Centers of Excellence, as described in Chapter 2. The fol- lowing section provides the context and justification for rewarding and promoting high- quality care with protection from claims of negligence.

The Costs and Consequences of Malpractice Litigation

Although malpractice liability may make a modest positive contribution to patient safety in some areas of medicine (Hyman and Silver, 2004), there is a lack of consistency underlying which cases of medical negligence are argued in court, and the amount of damages awarded in these cases. The degree of negligence does not appear to be rationally linked to either of these outcomes (Studdert et al., 2004). A research team at Harvard University reviewed the medical records from more than 30,000 hospital discharges and 3,500 malpractice claims in the state of New York. The authors reported that only 2 percent of negligent injuries resulted in claims, and only 17 percent of claims seemed to involve a negligent injury (Localio et al., 1991). A follow-up study found that the severity of the patient's injury, not the doctor's negligence, was predictive of the amount of dam-

BOX 5-2 The Malpractice Claims Process

The majority of medical malpractice claims are taken to civil courts, where the plaintiff's attorney (for the patient) argues that the defendant (physician) has harmed a patient through professional negligence (tort). To prove the claim of negligence, the attorney must show that the physician failed to fulfill his or her duty to the patient and that this failure resulted in injury and damage to the patient. The duty a doctor has to a patient is generally defined as adhering to a "standard of care," which, in turn, is vaguely defined by the courts as being "reasonable" or "ordinary" medical treatment. Often a physician with the same expertise as the defendant serves as a witness for the prosecution toclaim that the standard of care was not followed by the defendant. Increasingly, pub- lished medical standards or guidelines written by medical professional societies or hospi- tals, or discussed in medical textbooks and monographs, are used to establish the stan- dard of care.

Once a physician has been found negligent, the jury then decides how much monetary compensation the doctor should provide the patient. Such "damages" usually in- clude "general or noneconomic damages" for the pain and suffering that resulted fromthe injury in question, and "special or economic damages" that are designed to cover the medical expenses, lost income, funeral expenses, or other miscellaneous costs associated with the injury incurred. If an attorney is able to show that a physician's negligence was reckless or willful, then an additional amount of "punitive damages" are awarded to the patient or the patient's family, although this rarely occurs. Attorneys usually charge their clients a percentage of the damages awarded as their fee for arguing the case. These fees can be as much as 40 percent of the total damages awarded. In addition, it can take years to resolve a claim through the court system.

SOURCES: Congressional Research Service (2004); Posner et al. (1996).

ages paid to the patient (Brennan et al., 1996). Similar results were found in another study conducted in Utah and Colorado in the late 1990s (Thomas et al., 2000).

An increasing number of medical malpractice cases and rising amounts of damages awarded by juries or through negotiated settlements may have helped fuel a dra- matic increase in medical malpractice insurance rates (Studdert et al., 2004; Vidmar etal., 2005). The current high cost of such insurance is also likely due, in part, to other fac- tors such as insurance market dynamics, a downturn in the economy that lowered the in- terest rates paid in bonds invested by insurance companies, and the rising cost of medical care (Public Citizen, 2004; Thorpe, 2004; Black et al., 2005). But a U.S. Government Accountability Office (GAO) report concludes that these are lesser factors than rising claim costs (U.S. Government Accountability Office, 2003). Between 1994 and 2001, theaverage medical liability award increased 176 percent. In 2002, medical malpractice in- surers paid more in claims, with a median of $30,000,[1] than they received in premiums (Jury Verdict Research, 2002). A Medical Group Management Association (MGMA)

[1] The average was $3.9 million due to a small number of very high claims.

survey[2] found physician groups faced an average rate hike of 53 percent in malpractice premiums between 2002 and 2003 (MGMA Center for Research, 2003).

Comprehensive data to establish direct links among malpractice costs, provider actions, and access to health care is lacking (U.S. Government Accountability Office, 2003; Public Citizen, 2004). Nonetheless, concerns about malpractice liability could po- tentially lead some physicians to limit services, retire early, move to other states where liability premiums are stable, or choose less litigious specialties. The American Medical Association (AMA) asserts that such choices have resulted in serious patient access problems in 20 states (AMA, 2004). A recent Harris poll[3] suggests that the growing threat of medical liability might influence a doctor's choice of specialty. Nearly a third of doctors surveyed indicated that they chose a specialty they thought was less likely to be affected by legal claims. Another 43 percent of respondents said they have considered leaving medicine because of concerns about medical malpractice. Three-quarters of those surveyed said the threat of litigation affects their ability to provide quality medical care (Harris Interactive Inc., 2002). Ninety-four percent of respondents claimed unnecessary or excessive care is often given to avoid medical malpractice lawsuits, even though GAO and the Congressional Budget Office (CBO) have reported that there is no empirical evi- dence to document the practice of defensive medicine (U.S. Government Accountability Office, 2003; CBO, 2004). An AMA survey[4] of medical students found that about half said that medical liability was a factor in their choice of specialty (AMA, 2003).

Medical Liability and Mammography

The delay in diagnosing breast cancer in women leads to more malpractice claims than any other medical condition and is second only to the neurological impairment of newborns in the expense of paid claims, according to a 2002 Physician Insurers Association of America (PIAA) report. The settlements and judgments in mammography cases nearly doubled from 1992 to 2002 (PIAA, 2002).

The large number of malpractice suits stemming from mammography is partly due to the high volume of screening mammograms conducted each year in this country (Brenner, 2000). But many of these malpractice cases may be rooted in the misguided public perception that mammograms are infallible and provide clear-cut evidence of any cancer that might be present in the breast (Lerner, 2001; Kopans, 2004; IOM, 2005). Fifteen to 20 percent of breast cancers are not visualized on mammograms, and approximately 30 percent of breast cancers can, only in retrospect, be seen on previous mammo-

[2] MGMA's questionnaire was made available to a convenience sample of members on the association's website. Thus, the results may not be scientifically valid or representative of all medical groups. MGMA collected responses from 700 group practices that employ more than 16,000 physicians (mean group size was 9 physicians). MGMA has 19,000 members who manage more than 11,000 organizations, which employ nearly 240,000 physicians.

[3] Three hundred physicians were interviewed online using Harris Interactive's Physician Panel. One hundred hospital-based nurses and 100 hospital administrators were interviewed by telephone. The three sample groups were selected because they were thought to make up the key constituents in the delivery of medical care, and also were thought to potentially have different views on the subject matter and perhaps even different abilities or incentives to be either forthcoming or reserved on the subject matter.

[4] In August 2003, an e-mail with a hyperlink to the online survey was sent to 20,976 medical students for whom the AMA had e-mail addresses. A total of 3,952 surveys were completed and returned, for a response rate of 19 percent. The stated purpose of the survey was to examine medical students' awareness of the medical liability situation, concerns related to the current medical liability environment, and the impact of those concerns on choice of specialty and state of practice.

grams interpreted as normal (Martin et al., 1979; Bird et al., 1992; van Dijck et al., 1993; Reintgen et al., 1993; Harvey et al., 1993; Burhenne et al., 1994; Duncan and Wallis, 1995; Ganott et al., 1999; Warren-Burhenne et al., 2000; Saarenmaa et al., 2001). Even experienced radiologists specializing in breast imaging will prospectively miss cancers that are evident in retrospect.

In mammograms, cancers are often obscured by normal glandular and connective tissue in the breast, are located in areas difficult to visualize, or mimic benign structures (Brenner, 2000; IOM, 2001, 2005). The dense, obscuring breast tissue common in younger women makes mammograms particularly difficult to interpret. This is, in part, reflected in the fact that more than one-third of paid claims for delayed diagnosis ofbreast cancer involved women under the age of 40, who comprise less than 5 percent of invasive breast cancer cases (PIAA, 2002).

A 2002 PIAA study found that in nearly 80 percent of the lawsuits for failure to diagnose breast cancer, the results of the first mammogram were reported as negative or equivocal (PIAA, 2002). Testimony by an expert radiologist that conflicts with that of the defendant is often used to support a medical malpractice claim related to a missed breast cancer diagnosis after interpreting a mammogram. But expert witnesses often misstate to juries what the standard of care is (Homer, 2004; Berlin, 2004), and radiologists often vary in their interpretation of subtle findings in a mammogram. One study of the "nor- mal" mammograms of women who were diagnosed with breast cancer shortly after the mammograms were taken found 80 percent of them had subtle, nonspecific findings in the area of the breast where the cancer was found. When two expert radiologists reviewed these negative mammograms, they concurred that most of the subtle findings were below the threshold for intervention (Ikeda et al., 2003a). The author of this study concluded, in a response to a letter to the editor, that "just because 'something' is visible where cancer develops subsequently does not mean that a defendant radiologist was negligent in choosing not to recommend recall for additional imaging. Our results show that failure to act on every subtle mammographic finding at a site where cancer develops later does not necessarily imply failure to conform to the standard of care" (Ikeda et al., 2003b). Nonetheless, unrealistic public expectations for mammography may deter radiologists from contesting even seemingly frivolous cases (Berlin, 2003).

There also is debate in the medical literature over whether delays of less than a year in the diagnosis of breast cancer significantly alter prognosis (Berlin, 2001). Most breast cancers are slow-growing tumors whose spread would not be affected significantlyby such delays. Others have such aggressive tendencies that an earlier diagnosis would not necessarily improve outcome. Despite this debate, the average amount paid for breast cancer diagnosis delays of less than 6 months was $227,000 in 2002 (PIAA, 2002).

As noted in Chapter 2, fear of litigation could potentially affect the way radiologists interpret mammograms, with "defensive medicine"[5] becoming more common. Mammography screening programs in North America have a higher percentage of false-positive readings than similar programs in other countries (Smith-Bindman et al., 2003; Yankaskas et al., 2004). Although this difference could be due to differences in the population of women screened, in how they are screened, or in how abnormal mammograms are defined, it could also be due to the risk of being sued for malpractice being of higher

[5] Defensive medicine is defined as medical actions undertaken to avoid liability rather than to benefit the patient.

concern to American doctors (Elmore et al., 2003). No causal relationship can be definitively shown, but the near doubling of the false-positive rate in the United States from 1985 to 1993 closely paralleled the increasing rates of mammography-related malpracticesuits (Elmore et al., 2002). In addition, one survey of U.S. radiologists found nearly three-quarters of them believed concerns about malpractice moderately or greatly in- creased their recommendations for diagnostic mammography and ultrasounds, and more than half (59 percent) believed this concern moderately or greatly increased their recom- mendations for breast biopsies (Elmore et al., in press).

Reforming the Medical Liability System

In response to the recent medical malpractice trends, many states, as well as the U.S. Congress, have introduced tort reform bills (see Box 5-3). Recently proposed legislation in Florida targeted medical malpractice suits directed at radiologists who perform mammograms (H.B. 1087, S.B. 2306).[6] The original Radiologists Performing Mammograms bill would have provided Florida-licensed radiologists performing mammography with immunity from tort liability unless they were found to be grossly negligent or failed to adhere to practice criteria the bill establishes. These criteria included adhering to MQSA standards and American College of Radiology (ACR) guidelines for mammogra- phy procedures, participating in a facility's quality improvement program, and communi- cating any unexpected findings on a mammogram to the referring physician or other ap- propriate individuals, even if the findings do not warrant immediate treatment.

The bill underwent extensive revision in committee. The final version, signed into law, omitted the malpractice immunity clause and created in its place a Workgroup on Mammography Accessibility to study the availability, quality of care, and accessibility of mammography in Florida (Florida House of Representatives Staff, 2004). However, the state could not conclusively determine whether malpractice claims were having a detrimental effect on access to mammography services due to a lack of comprehensive and accurate medical liability insurance and claims data specific to Florida (The Workgroup on Mammography Accessibility, 2004; The Florida Legislature: Office of Program Pol- icy Analysis & Government Accountability, 2004). Nonetheless, based on the available national data and recognition that mammography is not a perfect test, the Workgroup recommended medical malpractice reform measures, including a limit on noneconomic damage awards, establishment of an expert panel to review presuit images for “probable cause” before advancing the case for further legal action, and a change in the burden of proof for alleged medical liability cases involving breast cancer, from the greater weight or preponderance-of-the-evidence standard to the clear-and-convincing standard (The Workgroup on Mammography Accessibility, 2004).

In recent years, the U.S. House of Representatives has passed several national tort reform bills, but none have been passed by the Senate. In 2004, the Senate debated S. 11, Patients First Act of 2003. This bill would have imposed caps on noneconomic damages and punitive damages, permitted defendants to be held liable for no more than their share of responsibility for a plaintiff's injuries, and required that damage awards be reduced by the amounts plaintiffs receive from collateral sources. The bill also would have limited

[6] Radiologists Performing Mammograms Act. H.B. 1087/S.B. 2306, Florida State Legislature, Regular Sess. (2004).

BOX 5-3 Tort Reform Legislation

Most tort reform focuses on limiting access to court, modifying liability, and/or capping the size of awards granted. Limiting access to court is accomplished by requiring screening panels to determine whether the merits of claims are worthy enough to go to court, or by creating a statute of limitations—a specified period within which a plaintiff is permitted to sue after experiencing or discovering the injury. Liability is modified by passing laws that set standards for expert witnesses and/or medical practices, or by making each defendant in multidefendant cases liable only for his or her share of responsibility for the plaintiff's injury. This elimination of the standard “joint and several liability” com- mon law rule may only apply to noneconomic damages or to defendants responsible for less than a specified percentage of the plaintiff's harm.

The size of awards granted can be limited by specifying a cap on the amount of damages allowed. Usually this cap only applies to noneconomic (pain and suffering) damages, but it can also be applied to economic or punitive damages. Alternatively, the size of awards granted can be indirectly lowered by other rulings that regulate attorneys' fees, often reducing the maximum percentage of attorneys' contingency fees. Another tactic is to have rules mandating “collateral source offsets” and “periodic payments.” Collateral source rules deter plaintiffs from double dipping—receiving monetary compensation for losses that can be recouped from other sources, such as an insurance company, an employer, or the government. Periodic payments enable defendants to pay plaintiffs in installments, usually done annually, rather than paying a lump-sum award. The costs of periodic payments tend to be less than conventional lump-sum settlements.

California was one of the first states to enact tort reform measures. Its Medical Injury Compensation Reform Act (MICRA), which was enacted in 1975, has served as a model for many state and federal efforts at tort reform. This Act puts a $250,000 limit on noneconomic damages, limits attorneys' contingency fees, creates a statute of limitations, provides for periodic payments of future damages, and limits double dipping by enabling a defendant to introduce evidence of collateral source payments as they relate to damages sought by the plaintiff. More than half of the states similarly cap noneconomic damages in medical malpractice suits, with ceilings ranging from $250,000 to $700,000, and about one-third of the states regulate attorneys' fees.

Studies are beginning to reveal the effects of state tort reform measures. Most studies show that caps on damages significantly reduce payouts in medical malpractice cases, but their effect on medical malpractice insurance premiums is less clear. Since MICRA was enacted, the increase in medical liability premiums in California is one-third of what it has been for the rest of the nation, although additional state legislation to re- form the insurance industry also likely had an impact on premium increases. Collateral source offsets appear to reduce payouts and the frequency of claims, but not the cost of malpractice insurance premiums. Other studies show inconsistent results or a lack of effects from creating a statute of limitations, regulating attorneys' fees, or establishing pretrial screening panels. One study linked state legislation capping damages to higher growth over time in the supply of physicians in the state.

SOURCES: Congressional Research Service (2004); Public Citizen (2004); Studdert et al. (2004); Thorpe (2004); California Physician (2003); CBO (2003); U.S. Government Accountability Office (2003); Hellinger and Encinosa (2003); Kessler and McClellan (2000).

attorneys' contingent fees, created a statute of limitations, and enabled periodic payment of future damages. In addition, S. 11 would have required expert witnesses in health care lawsuits to meet specific qualifications (Congressional Research Service, 2004).

When the Senate failed to pass S. 11, a similar bill was introduced in March 2004. This bill, S. 2207, the Pregnancy and Traumatic Care Access Protection Act of 2004, had the same stipulations as S. 11, except it limited their application only to cases involving obstetric, gynecological, emergency, or trauma care. This bill targeted medical specialties most affected by rising malpractice insurance premiums, but also failed passage in the Senate, as did a similar bill, S. 2061, Healthy Mothers and Healthy Babies Access to Care Act (Congressional Research Service, 2004; Heil et al., 2004a, 2004b). More recently, Centers for Medicare and Medicaid Services (CMS) Administrator Mark McClellan indicated that the Bush Administration would consider a range of options to reform the medical liability system, including requirements to report medical errors, to set up expert review panels, and to establish early offer programs. He noted that there is growingevidence that a set of changes is needed to ensure justice for all parties in the medical malpractice system. Senate Majority Leader Bill Frist also has indicated that he favors more comprehensive changes (Health Care Information Center, 2005).

No-Fault Systems for Medical Liability

Although state and national efforts at tort reform might eventually succeed in stemming the number of malpractice cases and in lowering malpractice insurance premiums, critics point out that these efforts are not likely to improve the quality of patient care or make compensation for injuries more accurate or fair (Thorpe, 2004; Studdert et al., 2004; Hyman and Silver, 2004). These critics call for more sweeping malpractice re- forms, including those that offer mechanisms other than civil tort suits to resolve dis- putes. Options include private settlements, structured mediation, or the hearing of casesin front of a medical court. Responsibility for malpractice situations could also be placed at the institutional level (enterprise liability), such that hospitals or other medical facili- ties would assume primary responsibility for any claim brought against an affiliated clini-cian and would cover their physicians' liability costs at rates that vary according to the institution's overall injury experience (Studdert et al., 2004). Both an Institute of Medicine report and the Florida Governor's Select Task Force on Healthcare Professional Liability Insurance have endorsed pilot projects that explore such institutional liability as well as administrative compensation schemes akin to workers compensation (IOM, 2003; Studdert et al., 2004).

In the latter case, “no-fault” standards would replace negligence as the basis for compensation and give an administrative body the power to determine compensation for medical injury claims without the need to prove negligence, as is done for workers compensation for injuries sustained at the workplace. No-fault systems already exist in other countries such as Sweden and New Zealand (Studdert and Brennan, 2001). Sweden's system has been in place for 30 years, and physicians are actively involved in filing claims in the majority of cases (Espersson, 1992). When a claim is made, the physician files a report and an adjuster makes an initial determination of eligibility before forwarding the case for final determination to one or more specialists retained to help judge compensability. About 40 percent of claims receive compensation that addresses both economic and noneconomic losses within 6 months of initiation, on average. Patients who are dis-

satisfied with the outcome may pursue a two-step appeals process that consists of review by a panel followed by an arbitration procedure (Espersson, 1992). The concept of avoidability is central to the compensation criteria. In short, the reviewers must determine whether an injury resulted from treatment, whether the treatment was medically justified, and whether the outcome was unavoidable (Studdert and Brennan, 2001).

In the United States, the no-fault approach is rarely used. Florida and Virginia have each used a small-scale, no-fault system since the late 1980s for newborns with se- vere, birth-related neurological impairment. Studies indicate that these programs have been effective in providing consistent and timely compensation, and have also reduced administrative costs (Horwitz and Brennan, 1995; Sloan et al., 1997; Studdert et al., 2000). Doctors are charged varying annual fees to pay for these two programs, but other entities, including hospitals, health plans, and taxpayers, could also theoretically bear some of the cost. It is difficult to estimate the cost of a large-scale program in other areas of medicine, but one study suggests that the cost of a no-fault system in Utah and Colo- rado would be nearly equivalent to malpractice premiums paid in those states eventhough four times as many people would receive compensation (Studdert et al., 1997; Thomas et al., 1999).

Critics have noted that no-fault systems may not provide feedback to educate physicians about errors, and lack incentives to improve the quality of care. These factors would be addressed in the design of breast imaging Centers of Excellence by incorporat- ing high performance standards, advanced medical audits with feedback, and the finan- cial incentives for quality improvement, such as scaling of insurance premiums based on performance measures (as well as participation in the no-fault system itself). Indeed, by removing the fear of litigation, such systems would create a safe harbor in which physicians could more easily reveal mistakes and learn from them.

Adopting a no-fault system in exchange for this highest level of quality assurance could also benefit patients. The goal of a no-fault system would be to provide access to higher quality mammography services, while also consistently and fairly compensating women in the event of a misdiagnosis without having to endure a long, difficult lawsuit with uncertain outcome. As a result, women would be empowered to make informed choices about where to seek breast imaging services, and would benefit from more open and honest dialogue with physicians. Furthermore, patients who are dissatisfied with the outcome of a case review could appeal the decision and seek arbitration. Even under the ideal conditions within Centers of Excellence, some cancers will be missed because of the inherent limitations of mammography. However, women who experience a misdiagnosis would be more likely to be compensated, and in a shorter period of time, than with the current medical liability system. Under the current system, many women with a misdiagnosis are not compensated at all, and for those who are, compensation varies enormously. In addition, lawsuits often take many years to resolve, and can be difficult, stressful, and costly for the patient.

OVERSIGHT OF OTHER BREAST IMAGING MODALITIES

Mammography currently is the principal screening modality for breast cancer. But other imaging techniques are routinely used for diagnosing breast cancer, and researchers continue to explore new and existing imaging technologies for breast cancer screening and diagnosis, as noted in Chapter 4 (IOM, 2001, 2005). For example, studies suggest

ultrasound or magnetic resonance imaging (MRI) may be useful for screening select populations, such as women at high risk for breast cancer and women with breast implants. In addition, physicians are increasingly using image-guided biopsy procedures to aid in the localization and excision of breast lesions.

Thus, the Committee considered whether there is a need for national standards and quality assurance programs for other breast imaging modalities and for image-guided biopsy techniques, which are not now governed by any national mandates. Currently there is no standardization of quality assurance for other breast imaging procedures, although accreditation programs do exist for breast ultrasound, stereotactic breast biopsy, and general MRI, as described below. These programs are offered by the American College of Radiology and the American Institute of Ultrasound in Medicine (Dershaw, 2000; ACR, 2004a).

Ultrasound Accreditation

Several studies have demonstrated that the effectiveness of ultrasound at detecting abnormalities depends on the expertise of the operator (Abuhamad et al., 2004). Diagnostic errors made by radiologists are the main cause of obstetric ultrasound malpractice cases, according to one study (PIAA and ACR, 1997). The Routine Antenatal Diagnostic Imaging with Ultrasound (RADIUS) trial found the detection of fetal abnormalities was nearly three-fold higher when the sonographer was highly trained in ultrasonography (Ewigman et al., 1993).

Prompted by these findings, the American Institute of Ultrasound in Medicine (AIUM) established a program for voluntary accreditation of ultrasound practices in the United States and Canada in 1996. This accreditation is provided for practices that show evidence of physicians' training in ultrasonography, credentialing of sonographers, Continuing Medical Education (CME) for both physicians and sonographers, and protocols and quality assurance procedures that ensure proper and safe practice of ultrasonography. In addition, practices applying for AIUM accreditation must submit four case studies for each specified area of accreditation—obstetrics, gynecology, breast, and/or abdo- men/general ultrasound. These case studies are scored by independent reviewers accord- ing to minimum criteria for ultrasound practices set by AIUM (Abuhamad et al., 2004).

AIUM's accreditation program was followed in 1998 by one for breast ultrasound by the ACR (ACR, 2004c). A facility may apply for breast ultrasound accreditation, or for breast ultrasound plus biopsy accreditation. The facility must submit sets of clinical ultrasound images that demonstrate breast lesions and/or breast lesions with accurate needle placement. The images are scored by a review panel of qualified radiologists. Physicians must have sufficient training in ultrasound, meet the ACR qualifications for screening and diagnostic mammography, conduct a recommended minimum number of ultrasound-guided breast biopsies and/or ultrasound exams per year, and have sufficient CME in breast ultrasound or ultrasound-guided breast biopsies. Sonographers must be certified by the American Registry of Diagnostic Medical Sonographers, or have post-primary certification (“advanced registry”) in breast sonography by the American Registry of Radiologic Technologists. Sonographers also must attend a minimum number of CME programs and regularly perform breast ultrasound exams. In addition, each facility must submit outcomes data on the number of procedures done, cancers found, benign lesions identified, and ultrasound-guided biopsies needing repeat biopsy or causing com-

plications. Facilities also must meet equipment specifications and provide documentation of a quality control program (ACR, 2004c). As of January 2005, 435 facilities had obtained accreditation in breast ultrasound, up from 337 in March 2002.

Although obtaining accreditation in ultrasound is voluntary, some state Medicare programs and private insurers are starting to require facility accreditation and/or sonographer certification for reimbursement for ultrasound exams (Krotz, 1998). Some experts estimate that about half of sonographers in the United States lack certification (Krotz, 1998). It is not documented what proportion of facilities performing breast ultrasound exams or guided biopsies are accredited, nor is there firm evidence that voluntary accreditation programs in ultrasound have improved the quality of ultrasound exams and interpretations. One study found that facilities applying for reaccreditation by AIUM had significantly improved scores for their obstetric and gynecologic case studies compared to their scores when they first applied for accreditation (Abuhamad et al., 2004). This improvement could be due to more experience, however, and not due to the accreditation process itself.

Stereotactic Breast Biopsy Accreditation

Stereotactic breast biopsy, which entails removal of breast tissue with a needle under mammographic guidance for proper placement, is currently exempt from MQSA regulations. However, since 1996, the ACR has offered an accreditation program in the procedure, with quality standards that are consistent with those of MQSA. By January 2005, this voluntary program had accredited 430 units at 423 facilities. An accreditation program offered by the American College of Surgeons with the assistance of the ACR also accredits stereotactic breast biopsy, but only seven surgical facilities currently par- ticipate. Among those facilities seeking ACR accreditation for stereotactic biopsy, the initial pass rate is 68 percent, roughly equivalent to the 70 percent pass rate for mammog-raphy when MQSA was first enacted (the mammography accreditation initial pass rate is now 88.3 percent) (Destouet et al., in press). Although exact numbers are not available, the ACR estimates that several thousand facilities perform this procedure without ac- creditation. In such facilities, mammography units that have not been accredited under MQSA can be used for stereotactic biopsies.

In order to become accredited, facilities must submit clinical images that demonstrate accurate needle placement for a suspicious lesion, as well as phantom images, to the ACR for expert review. Physicians must have adequate training and CME attendance, as well as initial and continuing experience conducting stereotactic breast biopsies and managing patients recovering from biopsies. Radiologic technologists must be certified; receive training in breast radiology, radiation safety and protection, and quality control; and perform mammography on a regular basis. Radiologic technologists also must have initial and continuing experience in stereotactic biopsies and mammography, and must attend a minimum number of relevant CME programs (ACR, 2004e).

The ACR accreditation program for stereotactic breast biopsy also specifies requirements for the medical physicist and the equipment at a facility, and requires documentation of quality control, including conducting specific annual tests. Facilities must also conduct ongoing medical audits of their stereotactic breast biopsy procedures to evaluate and improve performance, including noting the numbers of procedures done, cancers diagnosed, benign lesions identified, lesions needing repeat biopsy, and biopsy

complications requiring treatment (ACR, 2004e). But the use of these results to improve performance is not overseen by the ACR and ultimately is the responsibility of the physician in charge of the facility. Appropriate benchmarks for each of these outcomes measures have not yet been established in peer-reviewed literature (Dershaw, 2000).

Most states do not require accreditation to perform stereotactic breast biopsies. But the Food and Drug Administration has stated in the past that unless nearly all facilities performing stereotactic breast biopsies become voluntarily accredited, a mandatory program would be instituted under MQSA (Dershaw, 2000). As noted in Chapter 3, the Committee recommends that these interventional mammographic procedures, as well as standard presurgery wire localization procedures, be included now under MQSA regulations.

MRI Accreditation

There are no breast-specific MRI accreditation programs, although the ACR has begun a dialogue to examine the possibility of establishing such a program.[7] Since 1996, the ACR has offered a whole-body MRI accreditation program. This program specifies a minimum amount of training, experience, and CME attendance for physicians, technologists, and medical physicists or MRI scientists at facilities conducting MRI. It also requires MRI equipment to meet all state and federal specifications and performance requirements, as well as to perform adequately in quality control tests conducted regularly at the facility. MRI safe practice guidelines must also be written, enforced, reviewed, and documented at least annually by the MRI supervising physician. Facilities must submit clinical images of specific sites in the body to the ACR for evaluation by MRI experts, but the breast is not one of the body sites specified (ACR, 2004d). Although some gen- eral MRI machines are being used for breast imaging, use of a dedicated breast coil is imperative for obtaining high-quality images (Schnall, 2003; Lee, 2004).

Time to Mandate Accreditation of Breast Ultrasound and MRI

As noted in Chapter 4, several recent reports have suggested that ultrasound and MRI may be useful for breast cancer screening among high-risk women. These data are not yet definitive, but the publicity accorded these studies is leading to increased use of the technologies, whether warranted or not. These two imaging technologies are also commonly used for the diagnosis of breast cancer. However, concerns have been raised regarding variability in breast MRI image quality because imaging methods have not been standardized for this procedure, but different approaches can affect the quality of the image produced (Bosmans et al., 2000; Orel and Schnall, 2001; Schnall, 2003; ACR, 2003). In addition, although the ACR has developed assessment categories for breast ul- trasound and MRI similar to those for mammography, interpretation of images generated by these methods is quite variable (Goscin et al., 2001; Baker and Soo, 2002; Flobbe et al., 2002; ACR, 2003).

In the past voluntary accreditation programs have not been widely adopted, including voluntary programs for mammography accreditation prior to MQSA. Given the small proportion of facilities undergoing voluntary accreditation, it may now be advisable to mandate accreditation of some other commonly used breast imaging methods like MRI

[7] Personal communication, P. Butler, Senior Director, Breast Imaging Accreditation Programs, American College of Radiology, January 2005.

and ultrasound. Among those facilities currently choosing to undergo voluntary accreditation for breast ultrasound, the initial pass rate is now 80 percent, compared to 66 per- cent in 1998 when the program began. The average proficiency of facilities that currently choose not to undergo voluntary breast ultrasound accreditation is likely to be lower, similar to the mammography experience prior to MQSA. Expansion of accreditation re- quirements to these breast imaging methods is likely to result in significant improvement in quality of practice, similar to what has been observed for mammography.

Some large health care insurers are encouraging providers to participate in voluntary accreditation programs. For example, United Healthcare, the nation's largest health insurer, plans to label ACR-accredited radiology facilities with an "Excellence in Radiology" moniker in their provider directories with the intent of compelling patients to seek accredited facilities (Thompson, 2004). United Healthcare will also disseminate the ACR Appropriateness Criteria (ACR, 2004b), which provide consensus guidelines on imaging utilization in various clinical scenarios, with the goal of curbing improper use of imaging procedures.

Such tactics are commendable, but making accreditation mandatory would likely have a broader impact. As long as the number of facilities participating in voluntary programs is small, a large number of women will undergo imaging procedures that may be of questionable quality and utility. By making accreditation mandatory for commonly used breast imaging procedures, all patients would be assured that providers meet mini- mum standards for competence and quality. Although such a move may reduce the num- ber of facilities or physicians offering the procedures, presumably those that were com- mitted to quality and accuracy would seek accreditation and continue to provide services. The burden on facilities could be minimized initially by forgoing onsite inspections as is currently required for mammography under MQSA. Ideally, a panel of experts and pa- tient advocates would routinely review the status and use of various breast imaging pro- cedures to update the requirements for accreditation or inspections as needed.

Proposals for mandatory accreditation of other medical imaging procedures have been raised recently as well. The Medicare Payment Advisory Commission has proposed setting national standards of expertise for providers who bill Medicare for performing and interpreting diagnostic imaging, due to evidence of varying quality and because diagnostic imaging is the fastest growing category of physician services covered by Medicare (Miller, 2005). Concerned about potential cuts to Medicare reimbursement rates, theACR is also lobbying Congress to support legislation that would limit Medicare reim- bursement for MRI, computed tomography (CT), and positron emission tomography(PET) procedures to facilities and physicians with defined qualifications (Brice, 2005). Such legislation would likely include mandatory federal accreditation for MRI, CT and PET, and would set minimum standards for training, CME, and interpretive volume.

Medical technology is constantly evolving, and much has changed since MQSA was originally enacted. The intent of MQSA to ensure quality breast cancer screening and diagnosis could be undermined if it continues to focus solely on mammography without recognizing that high-quality screening mammography cannot reduce breast cancer morbidity and mortality in the absence of accurate pathologic interpretation and appropriate treatment. Although the latter was beyond the scope of the study charge, the Committee stresses that ensuring high-quality treatment is equally as important to reducing the bur-

den of breast cancer as ensuring high-quality screening and diagnosis (IOM, 1999; Zapka et al., 2003), as discussed in Chapter 2.

Breast Biopsy Options

Women who are referred for breast biopsy have a number of options available to them, in addition to the traditional open surgical biopsy. Several forms of minimally invasive needle biopsies, which are performed under image guidance (either mammogra- phy or ultrasound), can provide accurate diagnosis (Verkooijen and Core Biopsy After Radiological Localisation [COBRA] Study Group, 2002; Collins et al., 2004). Such procedures are generally better tolerated and are less costly than surgery (Rubin et al., 2001; Verkooijen et al., 2002). This has led to a shift of biopsy procedures from surgery to radiology, as well as an increase in the number of surgeons performing interventional imaging procedures.

However, not all women may be aware of these alternatives, and the choice of procedure may depend on what is offered to them by a particular health care provider. Although variability in the quality of biopsy services among providers or facilities has not been studied, the lack of standards and oversight could potentially result in significant differences.

Although stereotactic breast biopsies should be regulated under MQSA as noted above and in Chapter 3, ultrasound-guided biopsies do not fall under the purview of MQSA. Furthermore, health care providers may be more inclined to perform ultrasound-guided biopsies if stereotactic methods were to be regulated. Mandatory accreditation for other breast imaging techniques such as ultrasound could remove the incentive to provide one procedure over another, and the variability in physician recommendations and performance of these procedures might be reduced. However, another useful approach might be to include a requirement that women be given patient education materials prior to undergoing a breast biopsy. These materials would delineate the limitations, advantages, and disadvantages of different breast biopsy procedures and systems, and could prompt women to ask providers and facilities questions, such as whether they are accredited or certified for particular procedures. California has established a precedent for this with their state law, which requires that any woman about to have a breast biopsy be given a pamphlet on breast cancer diagnosis and treatment (California Department of Health Ser- vices, 2004). Michigan law also requires that all women diagnosed with breast cancer receive a copy of a similar booklet prior to choosing a treatment plan (Michigan Depart- ment of Community Health, 2003). The National Cancer Institute (NCI) might be the ap- propriate institution to develop such a product because it has recently developed an in- formational brochure for women who are trying to decide whether to undergo lumpectomy or mastectomy (National Cancer Institute, 2004). This sort of patient educa- tion has been shown in a randomized trial to significantly affect women's choices (Whe- lan et al., 2004), and the NCI brochure has been well received by some patient advocates (Ready, 2004).

SUMMARY AND CONCLUSIONS

In considering the broader context and intent of MQSA, the Committee studied a variety of measures that could extend and reinforce the Act's success to date in improv-

ing access to quality services for the early detection of breast cancer. The breast imaging Centers of Excellence described in Chapter 2 could test the feasibility of replacing a complex, costly, and punitive medicolegal system with one that rewards and encourages quality care and continuous improvement. In recognition of the importance of a multidisciplinary approach to breast cancer detection, the Committee stresses the need to extend quality assurance, as embodied by MQSA, to stereotactic breast biopsy and standard presurgery wire localization procedures, breast ultrasound and ultrasound-guided biopsy, and breast MRI under the next MQSA reauthorization. This will entail a name change to the Breast Imaging Quality Standards Act (BIQSA). Although quality assurance standards are not currently mandated for these technologies, current accreditation programs could provide the basis for national standards and could greatly improve the overall quality of breast cancer detection, diagnosis, and treatment. However, in the case of MRI, accreditation programs specific for breast imaging will need to be developed and established before accreditation can be mandated. Finally, in order to continue to build on the success of MQSA, a panel of experts and patient advocates should be established to review the need for accreditation or certification of future breast imaging technologies. Achieving the overarching goal of reducing the burden of breast cancer depends on the performance of multiple steps that include screening, diagnosis, and treatment—delivering high-quality care at each of those steps is essential to reduce breast cancer morbidity and mortality.