

# the Reporter

## A TMB complaint: one physician's perspective part 2

*Editor's note: Victoria Soto, JD is an Austin-based attorney who represents physicians before the Texas Medical Board (formerly the Texas State Board of Medical Examiners). Ms. Soto also advises health care professionals and medical groups in administrative, transactional, policy, and protocol matters related to their practices. In her article, readers will follow a fictitious physician, Dr. Goodnews, through the TMB complaint, investigation, and litigation process. Part one of this article is available in the November-December 2005 issue of the Reporter.*

When we left Dr. Goodnews, he was at the beginning of the complaint process with the Medical Board. Early in the process, he had hired an attorney who had experience with the Medical Board.\* His attorney guided him in his initial response to the Board, answering the allegations against him. To Dr. Goodnews, having an experienced attorney on his side was a profound relief. "Not having the right attorney during this process is like a surgeon trying to operate blindfolded," he told his colleagues.

Dr. Goodnews was having trouble maintaining a positive outlook. As he told a colleague, "I won't have any peace until this thing is behind me. It's all I can do to keep this from my children. I even contemplated keeping it from my wife, but that is nearly impossible considering that she is my unofficial office manager." Though he was sympathetic, Dr. Goodnews' colleague, Dr. Strongfellow, had initially believed that Dr. Goodnews must have done something wrong to find himself the subject of a Board investigation. Now Dr. Strongfellow felt that he owed his friend an apology because he himself had received a letter from the Board. (Dr. Strongfellow's complaint was of a different type altogether. Dr. Strongfellow

suspected that the complaint against him originated with his former wife following a nasty divorce. Of course, because the identity of the complainant is anonymous, he would never be able to prove this. Now, like his friend Dr. Goodnews, all he can do is face the music and comply with the system.)

During the complaint/disciplinary process, it is very important for Dr. Goodnews to comply with the requests of the Board investigator. The investigator's job is to gather information that will be sent to the Board expert. In turn, the Board expert will determine whether or not the physician violated the standard of care.

Board experts are chosen from among the Board Expert Panel. This panel is composed of physicians of all specialties whom the Board has deemed qualified to review standard of care cases. The full list of the Board Expert Panel is public information, but the identity of the expert reviewing a particular case is confidential. Therefore, Dr. Goodnews has no way of knowing the individual Board expert reviewing his case. However, the Board expert will know the identity of the physician under investigation. To Dr. Goodnews and other physicians facing a Board investigation, this does not seem fair. In their attempts to make the process fair, the Medical Board chooses an expert from a different jurisdiction (zip code) than that of the physician under investigation. Dr. Goodnews believes it would be a fairer process if his identity were unknown to the expert, just as the panel expert's identity is unknown to him. This would eliminate the human factor of bias due to competition or prejudice. Dr.

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Goodnews' attorney assumes the Board may say that the reason for this is that redacting both identities is both cost and time prohibitive. However, the need to assure fairness for the physicians should be just as important as the need to protect the expert.

If the Board expert has decided that there is enough evidence to suggest that a physician has violated Board rules, the case is scheduled for an Informal Settlement Conference (ISC). The disciplinary action that can result from an ISC can range from a dismissal to a license revocation. What comes out of the ISC is a recommendation to the full Board. This recommendation goes to the Board for ratification in the form of an agreed order that has been signed by the physician. This means that the physician has accepted the disciplinary action offered by the Board in lieu of challenging the ISC recommendations. The physician may come to this decision if the Board has proven at the ISC that Board rules were violated and the physician agrees with the Board's findings. The full Board will review the agreed order and decide whether to ratify it, send the agreed order back for revision, or send the case directly to the State Office of Administrative Hearings (SOAH) asking for revocation, among other things.

Dr. Goodnews received notice of his ISC, and his attorney begins to prepare him for the conference. (Actually, his attorney has been preparing for a probable ISC from the very beginning. This is another reason why it is so important to hire an experienced attorney early.) The defense of the case is designed to reveal the truth of the facts, as told by the physician and his attorney, along with all of the evidence that they have compiled. Dr. Goodnews' attorney advises him on what must occur to show the ISC panel that he is, in fact, innocent of the allegations. If the situation were one in which the allegations were clearly true, then he would have to show the panel how that error or action would not occur again.

The ISC panel is made up of two individuals, including one member of the Medical Board. The other may be a member of the District Review Committee (DRC). The DRC is a local committee made up of physicians and public members who live in the district. DRC members assist the Board during the investigative/disciplinary process. The physician member of the ISC panel could come from either the Board or the DRC. This panel is given the Board's evidence, called the ISC packet, which has been compiled by the Board's litigation attorney. The physician receives this packet along with the notice of an ISC. It is imperative that the physician and his attorney respond to this notice. They should acknowledge that they received the notice, will attend the ISC, and will respond with a defense presentation packet of their own. This presentation packet should be delivered to the Board who will give the packet to the ISC panel members at least 10 days before the ISC hearing. The contents of the packet depend on the preparation of the attorney and the physician.

The ISC is informal in that the rules of evidence do not apply. The ISC involves two ISC panel members and the Board's hearings coordinator, an attorney advising the panel on the rules and regulations they are to follow. The hearings coordinator also advises the panel on the rules and regulations that the physician has allegedly violated. The other parties in attendance are the Board litigation/prosecutor attorney, the physician (Dr. Goodnews), and his attorney. The Board investigator may also be in attendance. The ISC process could last anywhere from 30 minutes to a couple of hours, depending on the complexity of the case. The Board prosecuting attorney makes an opening statement and the physician or his attorney may have the opportunity to make an opening statement. This depends on who is on the ISC panel and their style of conducting the ISC. Once the ISC panel has heard enough evidence to make a determination, the ISC recesses for a period of deliberation.

During the ISC for Dr. Goodnews, the Board presented its case in the form of an opening statement. Dr. Goodnews was fortunate to have an ISC panel very familiar with the process and the panel

allowed Dr. Goodnews' attorney to give an opening statement. The panel then began questioning Dr. Goodnews about the specifics of each case. Though nervous, Dr. Goodnews had been prepared very extensively by his attorney. He quickly realized that an informal settlement conference hearing was anything but "informal." It was also unlike anything he had experienced before, including testifying in court. He answered the questions in a very precise and effective way, but by the time his questioning was over, his back was tense and in pain. Following this question-and-answer session, the ISC panel recessed for deliberation.

During the break, Dr. Goodnews sat silently in the lobby with his attorney. He noticed the Board's newsletter sitting on a table next to him. "Is there any way you can keep me out of that newsletter, if the Board decides that I am guilty of the allegations?" he asked his attorney. She replied that the Texas legislature mandates that the Board publicly report all disciplinary actions. The newsletter is one way the Board carries out this mandate. If found guilty of the allegations, Dr. Goodnews' name will appear in the newsletter. However, his attorney tells him that she hears that the Board is planning to restructure how disciplinary actions are reported in the newsletter. The minor administrative penalties will be separated from the more egregious disciplinary actions. So, although all disciplinary actions will be reported, the serious offenses may eventually be separated from the minor offenses.

When the Board attorney came to tell Dr. Goodnews that the panel had reached a decision, the ride up one floor to the hearing room in the elevator seemed to be a long one. What was more disturbing to him was that the Board attorney failed to make eye contact with either him or his attorney. Never in his 20 years of practicing medicine did he think that his career would come to this. He went over and over in his mind all the patients he had treated, all of the familiar faces of families from one generation to the next coming to him for help in healing and support. He loved being a doctor for the state of Texas. Heck, he loved being a Texan. This was his state and his Board, but the feeling he had at this moment was still foreboding. His attorney turned to him in the elevator and said, "Leopold, we prepared well for this and you did an amazing job in that ISC room. I am proud of you. No matter what happens, know that you are an amazing doctor and an asset to this state and that you will survive this."

Upon entering the ISC room, Dr. Goodnews noticed that the Board had provided water and facial tissue on the prosecuting and defense tables. He had not seen them before. As he sat down, he noticed that the tissue was only on the defense tables. He quickly realized what the tissue was there for and he imagined that tears flowed often in that room out of grief and sadness. But that day, they flowed for relief when the panel came back with a recommendation of dismissal to the full Board. With the allegations dismissed, Dr. Goodnews could begin to put his experience with the Texas Medical Board behind him and go back to the profession and patients he loved.

*\* Many medical liability insurance policies will provide coverage for legal expenses that occur if the policyholder faces a disciplinary proceeding. TMLT policies include a special endorsement called Meddefense which provides legal expense reimbursement for disciplinary proceedings, including actions by the TMB. For more information or to find out if you qualify for reimbursement under Meddefense, please call TMLT at 800-580-8658.*

*Additional information on the TMB and its investigation process, is available in TMLT's online CME course "TSBME Investigations" found at [www.tmlt.org](http://www.tmlt.org).*

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# Preventive care and health maintenance

## Course author

Tanya Babitch is a risk management representative at TMLT.

## Disclosure

Tanya Babitch has no commercial affiliations/interests to disclose related to this activity.

## Target audience

This one-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for malpractice liability.

## CME credit statement

TMLT is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

TMLT designates this educational activity for a maximum of 1 category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

## Ethics statement

This course has been designated by TMLT for 1 hour of education in medical ethics and/or professional responsibility.

## Directions

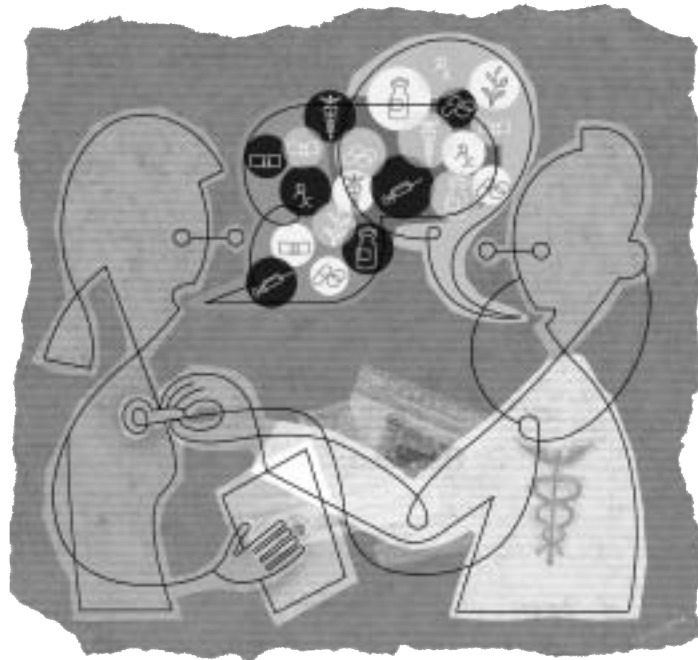
Please read the entire article and answer the CME test questions. In order to receive credit, submit the completed test and evaluation form to TMLT. All test questions must be completed. Please print your name and address clearly. Allow four to six weeks from receipt of test and evaluation form for delivery of certificate.

## Estimated time to complete activity

It should take approximately one hour to read this article and complete the questions.

## Release/review date

This activity is released on January 27, 2006, and expires on February 1, 2008. Please note this CME activity does not meet TMLT's discount criteria. Physicians completing this CME activity will not receive a premium discount.



## Who to trust?

Choosing appropriate preventive health services and screening programs for your patients can be a remarkably challenging task. The Internet and increased media coverage have produced patients with advanced knowledge of health care topics and increased expectations of their physicians. The current media climate has effectively “upped the ante” for physicians trying to decide which guidelines to follow to ensure their patients are well cared for. With higher patient expectations comes the potential for a rise in malpractice claims. There is an increased focus upon the physician's duty to make sure that patients receive adequate preventive care. Conflicting guidelines from different sources have only added to both physician and patient confusion. Who can you trust?

In the U.S., the leader of preventive services research is the U.S. Preventive Services Task Force. “The U.S. Preventive Services Task Force (USPSTF), first convened by the U.S. Public Health Service in 1984, and since 1998 sponsored by the Agency for Healthcare Research and Quality (AHRQ), is the leading independent panel of private-sector experts

in prevention and primary care.

The USPSTF conducts rigorous, impartial assessments of the scientific evidence for the effectiveness of a broad range of clinical preventive services, including screening, counseling, and preventive medications. Its

## Objectives

At the conclusion of this educational activity, the reader will be able to:

1. Identify reliable sources for preventive health services guidelines.
2. Describe four “controversial” issues in preventive health services.
3. Identify malpractice risks of failing to recommend appropriate preventive services.
4. Implement strategies to improve patient compliance with preventive services recommendations.

recommendations are considered the ‘gold standard’ for clinical preventive services. The mission of the USPSTF is to evaluate the benefits of individual services based on age, gender, and risk factors for disease; make recommendations about which preventive services should be incorporated routinely into primary medical care and for which populations; and identify a research agenda for clinical preventive care.”<sup>1</sup>

The USPSTF uses only evidence-based research to determine their recommendations, and willingly acknowledges that there are many services whose benefits and harms have not been well measured. In many areas, research is simply not yet adequate to make a strong judgement for or against a treatment.

Another government source of recommendations is the National Women’s Health Information Center, a division of the HHS, which offers guidelines for women’s preventive health screening.<sup>2</sup> The American Cancer Society has also developed detection and screening guidelines for the public. The CDC web site includes “a searchable storehouse of documents containing CDC recommendations on a variety of health, prevention, and public health practice issues.”<sup>3</sup>

Specialty societies are a reliable source for preventive care guidelines, and the American Academy of Family Physicians (AAFP), American College of Obstetrics and Gynecology (ACOG), and American Academy of Pediatrics (AAP) have all developed clinical guidelines for their members. Many of these guidelines are adopted from the USPSTF recommendations. The American Medical Association has published guidelines for adolescent preventive health services.

### Preventive service guidelines

The USPSTF uses grades to indicate the strength of evidence for net benefit of interventions. Using grades A, B, C, D, and I, the USPSTF rates each screening test or service. An “A” rating indicates that the USPSTF strongly recommends that clinicians provide the service to eligible patients, and that they “found good evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.” A “B” rating indicates that the USPSTF recommends that clinicians provide the service to eligible patients, and that they “found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.” Ratings C, D, and I range from “no recommendation” to “recommends against.”<sup>4</sup> Patients with increased risk factors, however, may benefit from interventions rated C, D, and I. Each patient’s history and risk factors must be considered by the health care

provider and benefits versus harms of each service weighed. For higher risk patients, guidelines from other specialty societies can be considered and an individualized plan developed.

The table on page 5 outlines the USPSTF “A” and “B” Guidelines. Details on the USPSTF guidelines are available at [www.ahrq.gov/clinic/pocketgd.pdf](http://www.ahrq.gov/clinic/pocketgd.pdf). This 172-page document covers a wide range of screening guidelines. An interactive preventive services selector is also available at <http://198.76.191.14/ipss/asp/search.asp>. The services selector reflects current USPSTF recommendations, and can be used to identify appropriate services based on patients’ age, sex, and pregnancy status.

Screening and immunization guidelines for adults and children have been developed by the AAFP, and are available at [www.aafp.org/x7661.xml](http://www.aafp.org/x7661.xml). These guidelines include comprehensive age charts indicating appropriate screening and immunization schedules. The AAFP cites the USPSTF as their main source of information and recommendations. Newborn and children’s preventive services guidelines are well outlined on the AAP website, which posts a document that includes a “Compendium of Resources on Newborn Screening Policy and System Development” and guidelines on pediatric developmental stages.”<sup>5</sup>

The AMA has developed its’ monograph, “Guidelines for Adolescent Preventive Services (GAPS),” which is available on the AMA website.<sup>6</sup> An age-specific table of guidelines from the National Women’s Health Information Center can be accessed at their website.<sup>2</sup> All these resources can be printed and used for patient education as well as reminders for physicians. Many of these sites also include recommendations for health education and counseling on lifestyle choices.

### Controversial decisions

Some of the most challenging decisions for physicians and patients to make are prompted by newly available technology or new research on established screening methods. For example, recent research on prostate specific antigen (PSA) testing has muddied the waters for physicians trying to determine the best screening procedures for their male patients. One study cited in a recent *New York Times* article revealed that researchers found prostate cancer in as many as 15% of men with PSA levels below 4. One study found that in most men, PSA levels below 10 may be caused by age-related increase in prostate size — not by cancer. A third study found that a majority of men who have cancers detected by PSA tests

may do well for 20 years with no treatment other than physician monitoring for rising levels. A Swedish study published in the *New England Journal of Medicine*, however, found that when all cancers (more and less aggressive) were evaluated together, men “who had their prostates removed had a lower risk of death and of metastatic cancers than those who did nothing.”<sup>7</sup>

Unfortunately, there are no black-or-white answers for physicians and patients. Risk factors such as family history, weight, race, and rising PSA levels must all be evaluated individually for each patient. An increasing number of physicians are adopting a “watch and wait” attitude.<sup>7</sup> Recommendations from the American Cancer Society and the American Urological Association are for men 50 years and older to have yearly PSA testing, which differs from the USPSTF guidelines.

Many physicians are frustrated by the controversy over “evidence-based” guidelines, such as those from the USPSTF. A case published in *Family Practice Management* indicates that evidence-based guidelines can still be a point of contention:

“You might be able to take it to the bank, but apparently taking the evidence to court can be dangerous. A recent issue of the *Journal of the American Medical Association* published the chilling story of Daniel Merenstein, a family physician who ended up facing a malpractice suit because he did just what he was supposed to do. As a third-year resident, he saw a 53-year-old, educated patient to whom he carefully explained the pros and cons of PSA testing. He documented the shared decision not to order the test. He never saw the patient again. The patient’s next physician, however, ordered the PSA test without discussion; the level was very high, and he was later determined to have incurable, advanced prostate cancer. Merenstein and his residency program were subsequently sued.” “In the course of the trial, the plaintiff’s attorney successfully made evidence-based medicine (EBM) into ‘a dirty word,’ according to Merenstein. He defined EBM as a cost-saving method and stated his belief that the few lives saved were not worth the money. He urged the jury to return a verdict to teach residencies not to send any more residents on the street believing in EBM. While Merenstein himself was acquitted, the residency [program] was found liable for \$1 million. That’s a lesson, all right.”<sup>8</sup>

Physicians must balance evidence-based guidelines with their patients’ individual histories and their own clinical experience. All of these factors must be weighed for each patient. Doctors, specialty societies,

## USPSTF table of recommended preventive services

Recommendation	Adults		Special populations	
	Men	Women	Pregnant women	Children
Alcohol misuse screening and behavioral counseling interventions	✓	✓	✓	
Aspirin for the primary prevention of cardiovascular events <sup>1</sup>	✓	✓		
Bacteriuria, screening for asymptomatic			✓	
Breast cancer, chemoprevention <sup>2</sup>		✓		
Breast cancer, screening <sup>3</sup>		✓		
Breastfeeding, behavioral interventions to promote <sup>4</sup>		✓	✓	
Cervical cancer, screening <sup>5</sup>		✓		
Chlamydial infection, screening <sup>6,7</sup>		✓	✓	
Colorectal cancer, screening <sup>8</sup>	✓	✓		
Dental caries in preschool children, prevention <sup>9</sup>				✓
Depression, screening <sup>10</sup>	✓	✓		
Diabetes mellitus in adults, screening for type 2 <sup>11</sup>	✓	✓		
Diet, behavioral counseling in primary care to promote a healthy <sup>12</sup>	✓	✓		
Hepatitis B virus infection, screening <sup>13</sup>			✓	
High blood pressure, screening	✓	✓		
Lipid disorders, screening <sup>14,15</sup>	✓	✓		
Obesity in adults, screening <sup>16</sup>	✓	✓		
Osteoporosis in postmenopausal women, screening <sup>17</sup>		✓		
Rh (D) incompatibility screening <sup>18, 19</sup>			✓	
Syphilis infection, screening <sup>20</sup>	✓	✓	✓	
Tobacco use and tobacco-caused disease, counseling to prevent <sup>21, 22</sup>	✓	✓	✓	
Visual impairment in children younger than age 5 years, screening <sup>23</sup>				✓

1. Adults at increased risk for coronary heart disease.

2. Discuss with women at high risk for breast cancer and at low risk for adverse effects of chemoprevention.

3. Mammography every 1-2 years for women 40 and older.

4. Structured education and behavioral counseling programs.

5. Women who have been sexually active and have a cervix.

6. Sexually active women 25 and younger and other asymptomatic women at increased risk for infection.

7. Asymptomatic pregnant women 25 and younger and others at increased risk.

8. Men and women 50 and older.

9. Prescribe oral fluoride supplementation at currently recommended doses to preschool children older than 6 months whose primary water source is deficient in fluoride.

10. In clinical practices with systems to assure accurate diagnoses, effective treatment, and follow-up.

11. Adults with hypertension or hyperlipidemia.

12. Adults with hyperlipidemia and other known risk factors for cardiovascular

and diet-related chronic disease.

13. Pregnant women at first prenatal visit.

14. Men 35 and older and women 45 and older.

15. Younger adults with other risk factors for coronary disease. Screening for lipid disorders to include measurement of total cholesterol and high-density lipoprotein cholesterol.

16. Intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.

17. Women 65 and older and women 60 and older at increased risk for osteoporotic fractures.

18. Blood typing and antibody testing at first pregnancy-related visit.

19. Repeated antibody testing for unsensitized Rh (D)-negative women at 24-28 weeks gestation unless biological father is known to be Rh (D) negative.

20. Persons at increased risk and all pregnant women.

21. Tobacco cessation interventions for those who use tobacco.

22. Augmented pregnancy-tailored counseling to pregnant women who smoke.

23. To detect amblyopia, strabismus, and defects in visual acuity.

and associations such as the American Cancer Society frequently vary slightly in their recommendations. According to an article in the *New York Times*, federal guidelines now advise a woman's first Pap test to be done three years after first sexual intercourse (or by age 21), once per year until age 30, and every two to three years after age 30 if they have had three negative screenings in a row. However, of ob-gyns surveyed in 2003, 75% said they recommend that women have yearly Pap tests, even after past negative screenings.<sup>9</sup>

Mammogram recommendations also vary. Both ACOG and the federal guidelines recommend that "women 40 to 49 be screened every one or two years, and every year after 50,"<sup>9</sup> but the American Cancer Society recommends yearly mammograms starting at age 40. Once again, patient history must be closely considered when developing a screening plan for patients.

Physician-taught self-examination is another area where questions arise. Although the USPSTF concludes that evidence is insufficient to recommend for or against teaching or performing breast self-examination, it is the individual physician's decision whether to do so. By rating the screening with an "I," the USPSTF indicates that the evidence "is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined,"<sup>4</sup> not that there is evidence against performing a screening or test. Per the USPSTF, little evidence is available to assess the benefits of screening for testicular cancer,<sup>4</sup> but one may question how it could be harmful to the patient. One concern may be false-positives in healthy patients, which can lead to further unwarranted testing. Although there may not be hard evidence of benefit, many physicians feel more comfortable teaching patients to perform these self-examinations. Physicians may wish to review the USPSTF's 2005 guidelines and rationale for each recommendation in detail.

Full body CT scanning has been touted as a potential lifesaver and has been embraced by some patients as a way to take control of their own health. However, the FDA states, "At this time the FDA knows of no data demonstrating that whole-body CT screening is effective in detecting any particular disease early enough for the disease to be managed, treated, or cured and advantageously spare a person at least some of the detriment associated with serious illness or premature death. Any such presumed benefit of whole-body CT screening is currently uncertain, and such benefit may not be great enough to offset the potential harms such screening could cause."<sup>10</sup>

Also weighing in with opinions are the American College of Radiology, USPSTF, and the AMA, all of whom do not recommend full body CT screening. Although patients may believe that full body scans can help "catch anything brewing," per the FDA and these specialty societies, the risks of radiation exposure outweigh the potential benefits.

New consideration is being given to the benefit versus harm of testing older patients for various cancers. *The New York Times* reports, "In a recent issue of *The American Journal of Medicine*, evidence for the pros and cons of screening older people for cancers of the colon and rectum, breast and cervix was reviewed by Dr. Louise C. Walter of the University of California, San Francisco, and her co-authors. These experts considered only medical issues, not the costs of tests and treatment. They emphasized 'decisions about screening for cancer in older persons require weighing potential benefits and harms for each person rather than relying on arbitrary age cutoffs.' They also said 'older patients who would decline follow-up or treatment should not be screened.' And, for those bothered by the discomfort and risks of screening, 'the decrease in the quality of life in the present may outweigh the small chance of future benefit.'"<sup>11</sup>

Genetic testing has become increasingly commonplace in the past 10 years. Testing for hundreds of conditions has become available for patients of all ages, but the value of testing for some of these conditions is unknown. The increased availability of genetic "home-testing" kits has opened up new areas of concern. Is the general public truly able to understand the nuances of "genetic predisposition" for disease? The possible misuse of genetic information has also given rise to increased ethical concerns. Although the federal government has enacted laws to prevent discrimination due to genetic predisposition, the possibility of discrimination from insurance companies and the workplace cannot be discounted.

Screening for cancer susceptibility genes has also become more common. The USPSTF does not recommend routine referral for genetic counseling for women with breast cancer susceptibility genes (BRCA) who have a negative family history of breast cancer. The task force does recommend that women whose family history is associated with increased risk for mutations be referred for genetic counseling. The USPSTF does acknowledge that they found "insufficient evidence regarding important adverse ethical, legal, and social conse-

quences that could result from referral and testing of high-risk women."<sup>4</sup>

While genetic testing for prenatal conditions is not considered controversial, primary care providers may find it difficult to determine which tests are necessary. While obstetricians are familiar with prenatal genetic testing, researchers at the Université de Montreal warn, "Primary care physicians are unprepared for the increase in demands for prenatal genetic testing. Often, they do not possess the necessary knowledge, skills or attitudes to provide genetic counseling. Yet, since the demand for prenatal genetic services is growing faster than the number of genetic professionals, the responsibility of genetic counseling will fall to these physicians. Physicians who lack genetic literacy may find themselves the targets of lawsuits for wrongful birth and wrongful life. Wrongful birth and wrongful life claims (in the context of genetics) both assert that but for the physician's negligence, the handicapped child would not have been born. Such medical malpractice suits against physicians exist in the United States, the United Kingdom, Canada and Australia."<sup>12</sup>

Primary care physicians who perform obstetrics may be held to the standards of obstetricians. Newly available medical screening options increase the challenge of choosing appropriate testing.

### Malpractice risks

Physicians are expected to keep abreast of all the newest recommendations for their patients. The failure to keep up with the most current national guidelines and recommendations of their specialty societies could be considered below the standard of care. According to data from the Physician Insurers Association of America (PIAA), the most common cause of malpractice claims against primary care physicians is "diagnosis error." If a physician has failed to perform or at least recommend standard screening tests, they are in a weakened position when trying to defend their care.

Recent guidelines from the American Gastroenterological Association have stressed the importance of screening patients who have a family history of colon cancer as early as age 20 to 25.<sup>13</sup> A case in the PIAA's *Spring 2003 Research Notes* outlines the need for primary care physicians to order and encourage appropriate screening tests. "A 54-year-old female, who had been treated by the same primary care physician, an internist, for years, was diagnosed with end stage colon cancer. It was found that the physician had not ordered any screenings, either fecal occult blood test, or a colon-

oscopy during the patient's annual exams. The claim settled for \$650,000."<sup>13</sup>

Failure to order recommended screening tests for patients may be considered below the standard of care by consultants who review the case, and by a jury who may eventually hear the case.

### Encourage patient compliance

Once physicians have determined the screening guidelines they will use for their patients, they need systems to remind the practice and patients about which tests should be done when. Several office systems can help with these tasks. In *Family Practice Management* Dr. Steven Elgert suggests, "Build decision aids and reminders into your systems. Checklists, flow sheets and other tools can help prompt physicians and staff to follow the standardized processes that have been developed. These tools are particularly effective if they are built into a practice's systems and become automatic. For example, imagine seeing a patient with diabetes in your office, and as you open his or her chart on the computer it automatically reminds you to order certain overdue laboratory tests. Such technology is available. Simpler reminder systems may involve measures such as posting a sign in your exam room that prompts all patients with diabetes to remove their shoes as a reminder to you to conduct needed foot exams."<sup>14</sup>

Similar reminders can be used for preventive screening. Using flow sheets and problem lists can be helpful. Paper charts may have a problem list or flow chart that includes screening reminders that can be completed by the physician or staff when done. The physician is encouraged to note the date that each test was completed. To make referencing the information quick and easy, this list could be the first thing seen when the chart is opened.

Electronic records often have a summary screen that includes information about preventive health screenings. Encourage staff to keep these areas updated. Electronic or paper reminder systems can also be useful. Electronic records may have reminders built in that can be used for general preventive screening or for disease-specific testing.

If the practice does not have electronic records, scheduling software may be used for a reminder system. Reminders for screening mammograms, Pap smears, or colonoscopies can be typed in to a day's schedule years in advance. Diagnostic mammograms, repeat Paps, and any other non-routine testing should be included in a "tickler" system that reminds the practice that a patient needs more testing. It may also be

helpful to schedule preventive screening or diagnostic testing for the patients. It can then be noted in a calendar. Keep a record of what is ordered in a "pending" log or file. This allows the practice to discover test results that have not been received.

Whenever possible, preventive visits should be planned and scheduled for patients. Patients should be encouraged to schedule their next visit as they check out with the desk, even if they prefer to "wait and see." Yearly reminders can be mailed to patients to let them know they need to schedule an appointment. If the system allows, generate reminder letters to patients who have not been to the practice for more than a year.

### The noncompliant patient

What is a physician to do when their patient refuses preventive care or screening? Many physicians face this issue on a daily basis. Patients may have a myriad of reasons for not complying with their physician's recommendations. Financial issues frequently play a part in patient unwillingness to be tested. It is not surprising that uninsured patients may be hesitant to pay for tests when they feel well, but recent studies are showing that even patients with some coverage may be influenced by the costs of screening.

A recent *American Medical News* article reports, "High-deductible health plans combined with health savings accounts are an increasingly popular choice for employers and patients but could hurt long-term outcomes by discouraging necessary care, according to new poll data from market-research firm Harris Interactive. An online Harris survey including 900 patients enrolled in high-deductible health plans found they were less likely than those with traditional plans to get preventive care such as Pap tests and prostate-specific antigen tests."<sup>15</sup> If a patient has not had any symptoms and they have no family history of health problems, they may be unwilling to pay for recommended screening tests.

Few patients look forward to a colonoscopy, a Pap smear, or a mammogram. Preventive health procedures can be uncomfortable or painful. If a patient does not fully understand the procedure, they may be afraid to have it done. Cultural or religious issues may also be a factor in a patient's noncompliance. Some unwilling patients may be in denial, and do not want to believe that they could ever get cancer or any other serious disease. Many physicians have dealt with patients who seem to believe that if they get tested, they will have

cancer, but if they avoid testing they can remain blissfully ignorant and cancer-free. Fear can cause patients to act irrationally, but by listening carefully, physicians may be able to identify the source of the fear and discuss it.

Physicians are encouraged to be patient and aware of these issues when addressing health screening. Use plain language, and be sure patients understand the risks of not complying with recommendations. Many patients will answer the question, "Do you understand?" with a "yes," even if they do not. It may be helpful to ask the patient to describe the screening test and risks of not having it in their own words.<sup>16</sup> You may also wish to distribute written materials about screening tests.

If a patient persists in not complying with your advice, it is important to document these discussions. Noncompliant patients may have bad outcomes, and the patient or their family members may later say that the advice was either not given or not clear. The only proof that these recommendations were made will be your detailed medical record. When recommending preventive health screening, document your discussions as carefully as any treatment recommendation, especially if the patient is expressing reservations about complying. If the medical record clearly reflects the detailed discussion with the patient and their refusal to comply with the recommendations, the physician is in a better position to defend a malpractice claim.

One useful tool for this type of documentation can be an "Informed Refusal," form\* which is signed by the patient. The informed refusal form outlines the risks of not complying with a recommended test or treatment. Informed refusal allows you to document the discussion with the patient and their acknowledgement. Some physicians who use this form believe that it may increase patient compliance. By using the informed refusal form and requiring that the patient sign it, the physician demonstrates the seriousness of the recommendation. Good documentation is the key for physicians who want to demonstrate their appropriate recommendations and defend themselves from malpractice claims.

Unfortunately, some patients can never be convinced to follow their physician's advice. While many physicians feel that it is not necessary to "fire" a patient for non-compliance, there are some who choose to terminate the physician-patient relationship.

The relationship should only be terminated after careful consideration of what is best for the patient. The patient's health

should never be compromised by termination. The patient should be medically stable, and adequate notice must be given. A termination letter should be sent by both U.S. postal service and certified mail, return receipt requested. The letter should outline how long the physician will continue to see the patient and encourage the patient to find another physician. Include an authorization to release records for the patient to send back with their new physician's information. The letter may also recommend resources for the patient to locate a new physician, such as the phone number for the county medical society or, if applicable, the provider directory of their health insurance plan. Termination of the physician-patient relationship should be used only as a last resort, when the physician feels that the relationship is no longer therapeutic.

### Conclusion

As evidence-based guidelines gain acceptance in both the medical community and the general public, physicians will be held to new standards. Preventive services guidelines are becoming more widely known by patients. While guidelines vary from source to source, physicians may wish to review both the USPSTF guidelines and their specialty society's recommendations. Patients are best served by an individual evaluation of their medical history. Published guidelines are a useful tool to determine minimum screening guidelines, but if the patient's history indicates that more testing is warranted, the physician's recommendations should not be limited.

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### Additional resources

**American Cancer Society's Cancer Detection Guidelines (for people at average risk)**  
Available at [www.cancer.org/docroot/PED/content/PED\\_2\\_3X\\_ACS\\_Cancer\\_Detection\\_Guidelines\\_36.asp?sitearea=PED](http://www.cancer.org/docroot/PED/content/PED_2_3X_ACS_Cancer_Detection_Guidelines_36.asp?sitearea=PED)

**American College of Preventive Medicine's Clinical Preventive Services recommendations**  
Available at [www.acpm.org/clinical2.htm](http://www.acpm.org/clinical2.htm)

\* For a sample "Informed Refusal" form, please contact the TMLT Risk Management Department at 800-580-8658.

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# closed claim studies

## Failure to examine and diagnose *C. difficile* infection

by Barbara Rose and Laura Brockway

*The following closed claim studies are based on actual malpractice claims from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physicians' defensibility. The ultimate goal in presenting these cases is to help physicians practice safe medicine. An attempt has been made to make the material less easy to identify. If you recognize your own claim, please be assured it is presented solely to emphasize the issues of the case.*

### Presentation and physician action

A 69-year-old woman had been treated by her family physician for hypertension, asthma, osteoporosis, COPD, urinary tract infections, and allergic rhinitis over a period of four years. The physician last saw the patient on May 5 for a sprained ankle.

On June 23, the patient called the physician's office complaining of back pain in her left side radiating to her leg. Lumbar x-rays were ordered, but were never completed. Pharmacy records indicate that a prescription for hydrocodone was filled on June 28. The physician authorized hydrocodone refills on July 4, July 11, and July 18. The physician testified at her deposition that it was her "guess" that the hydrocodone was given for persistent back pain.

On July 7, the patient called the office with complaints consistent with a urinary tract infection. The physician prescribed a seven-day course of Cipro, and the prescription was filled that day. On July 22, the patient called complaining of a persistent, productive cough. The physician prescribed a 10-day course of Ceftin and Tussionex. On July 28, the patient again called the office reporting that she was not feeling better and had a slight fever. The physician prescribed Tessalon Perles and recommended that she continue the antibiotics. The patient called again on July 29 to report gas pain and loose bowel movements. The physician told the patient to discontinue the Ceftin and

she called in a five-day course of Cipro. The patient was also advised to take Immodium. During these telephone calls, the physician never spoke directly to the patient. All the telephone contacts and documentation of the telephone contacts were completed by the receptionist, an employee with no formal medical training.

On July 31, the patient came to the emergency department (ED) of a local hospital with symptoms of diarrhea and a low-grade fever. The ED physician found the patient to be hypotensive and dehydrated. Lab studies indicated an elevated white count and hyponatremia. Intravenous fluids were started and the patient was admitted under the care of an internal medicine physician to rule out sepsis, colitis, or diverticulitis. A KUB film showed layered and dilated loops of small bowel, believed to be an ileus. Stool cultures revealed antibiotic-induced *Clostridium difficile* bacteria. The internist requested a surgical consult. The surgeon believed that the patient had pseudomembranous colitis secondary to *C. difficile* infection. He recommended naso-gastric suction and fluid resuscitation, and noted that if the patient's condition worsened she would require a subtotal colectomy.

Over the next two days, the patient's condition deteriorated. She remained hypotensive and oliguric despite IV fluids, Dopamine, and Vancomycin. A nephrologist was consulted and he recommended continued conservative treatment.

On August 3, the patient's urine output decreased to zero and she became severely acidotic. The surgeon took the patient to the OR for exploratory surgery. He resected a large segment of ischemic distal ileum. The colon was described as normal in appearance. The patient's condition deteriorated after surgery and life support measures were discontinued.

### Allegations

A lawsuit was filed against the family physician, alleging that she negligently

failed to see the patient on July 28 and July 29 and failed to diagnose *C. difficile* colitis that led to the patient's death.

### Legal implications

Family physician defense consultants who reviewed this case could not support the defendant's actions. Both consultants stated that the physician should have seen the patient on either July 28 or July 29 when she called and reported no improvement in her symptoms and new-onset diarrhea. Failure to see the patient in the office at this point was below the standard of care. In her deposition, the family physician testified that antibiotic-induced *C. Difficile* infection "was not on her radar screen" with respect to the patient's telephone complaints.

While the defense consultants were critical on standard of care issues, they were both supportive in their causation opinions. Both family physicians and an infectious disease expert claimed that the cause of death was due to ischemic and infarcted small bowel. "Her acute onset of GI symptoms and progression of illness that was fatal within 5 days is more likely due to ischemic infarcted bowel than complication of *C. difficile* colitis. *C. difficile* in the stool was a bystander. The *C. difficile* colitis affects the colon and very rarely the disease is seen above the distal end of the ileum. Her colon is reported as completely normal."

Conversely, the plaintiffs were able to locate expert testimony that linked the patient's death to the *C. difficile* infection. This family physician expert stated that the *C. difficile* infection caused the patient to become dehydrated and hypotensive. This led to a decrease in blood perfusion to the small intestine that caused its infarction and the patient's death. Under cross examination, this expert conceded that there was no good scientific basis for his causation opinions.

The defense disputed this causation argument based on the general surgeon's

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# Failure to intubate and prevent aspiration

by Barbara Rose and Laura Brockway

## Presentation

A 52-year-old man fell from a tree and fractured his ankle. His family brought him to the emergency department of a local hospital at 8:30 p.m. The on-call orthopaedic surgeon evaluated the patient and diagnosed a distal comminuted fracture of the left lateral tibia. The patient was scheduled for surgery the next morning. The records indicate that he had a history of coronary artery disease, prior MI, hypothyroidism, and depression.

## Physician action

An anesthesiologist performed a preoperative assessment on the patient the next morning. The patient's son, who was a paramedic, was present. During this interview, the anesthesiologist recommended a spinal anesthetic with endotracheal intubation. The patient's son wanted a general anesthetic in conjunction with a laryngeal mask airway (LMA). The anesthesiologist — who was told that the patient had not eaten since before midnight — agreed to this form of anesthesia. The patient had eaten a large meal at 11 p.m. and was taking narcotics for pain.

The surgery was performed without complication until the anesthesiologist removed the LMA and noted that the patient had vomited. The anesthesiologist estimated that less than 1 cc had been aspirated and called for a pulmonology consult and pulmonary treatments.

At 2:14 p.m., eight minutes after arriving in the PACU, the patient vomited coffee ground emesis. A short time later, his oxygen saturations fell from the 70s into the 40s. The respiratory therapist arrived with equipment to intubate and ventilate the patient. The anesthesiologist told her that it was his decision to make and he did not want to intubate the patient. The respiratory therapist later testified that the anesthesiologist "blew her off." At 3:15 p.m., the pulmonologist arrived and recommended that the anesthesiologist intubate the patient immediately. The patient was intubated at 3:17 p.m. and put on a ventilator.

The anesthesiologist recorded that the patient had suffered postoperative hypoxemia secondary to aspiration. The patient's family became very angry with the anesthesiologist and had him removed from the case. The pulmonologist took over the care of the patient, who remained in ICU for 32 days with severe ARDS. The patient was also treated with medication for GERD while in the ICU. He was discharged to a rehabilitation facility. He progressed slowly during rehabilitation because of atrophy of his legs and foot drop.

A neurologist examined the patient and found that he had deficits in short-term memory and impaired speech. The patient was also depressed. An EEG revealed cerebral dysfunction in the left and right frontal temporal areas.

## Allegations

A lawsuit was filed against the anesthesiologist and allegations included:

- failure to properly intubate the patient;
- failure to provide a safe anesthetic technique;
- failure to institute appropriate measures to prevent aspiration pneumonitis;
- failure to prevent and treat hypoxemia;
- failure to timely perform intubation;
- failure to correctly assess the severity of the patient's acute respiratory failure; and
- failure to properly document care of the patient and the risks associated with the anesthesia technique.

The patient claimed total disability due to the foot drop and is unable to work.

## Legal implications

The defense was unable to locate an expert supportive of the defendant's actions. Overall, the anesthesiologists reviewing this case were critical of the delay in recognizing a significant aspiration event when the patient was in the PACU. When the patient vomited in the PACU, his oxygen saturations decreased for an extended period indicating possible ARDS. The reviewers felt that the anesthesiologist should have immediately intubated the patient and called for a pulmonology consult with bronchoscopy. The respiratory therapist was also very critical of the delay in intubation.

Reviewers were also critical of the decision to use LMA in a patient with a history of GERD and MI. The patient had a "history that dictated protection of the airway." However, it is unclear whether or not the family told the anesthesiologist that the patient had been treated for gastric reflux disease and UGI obstruction. Additionally, the anesthesiologist was not informed that the patient consumed a large meal at 11 p.m. while taking narcotics, which can delay gastric emptying.

The defense was able to develop significant arguments concerning causation and damages. During his deposition, the patient did not present himself as someone who has suffered a significant hypoxic injury. He answered all the questions but was very slow to speak and think. His primary complaints were associated with a foot drop of an undetermined cause. While the plain-

tiff's neurology and neuropsychological experts believed the patient sustained anoxic brain damage, a neurologist who treated the patient following the incident had a different opinion. He agreed that the patient has cognitive impairments and memory deficits, but does not think the patient has neurological deficits. It is his opinion that the patient is depressed and is unable to deal with his life-changing injury. (The patient was treated for depression prior to this incident).

Complicating the clinical issues in this case were the actions of the anesthesiologist in altering the medical records. There are comments on the hospital copy of the anesthesia record that do not appear on the anesthesiologist's copy. The significant change to the record is the indication that the patient's head was elevated during surgery to prevent aspiration. Additionally, two sets of postoperative orders were found.

## Disposition

This case was settled with the consent of the anesthesiologist. The inability of the defense to find supportive expert testimony and the records alterations led to the decision to settle this case.

## Risk management considerations

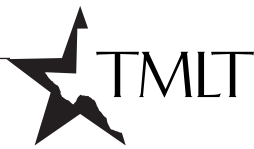
Three issues in this closed claim are relevant for comment. One of the physician reviewers commented regarding the defendant's change of anesthesia preference based on the wishes of the son. It is risky for a physician to alter medical decisions at the request of family members without compelling evidence to do so. Would endotracheal intubation have changed the outcome?

Records are to be completed contemporaneously and thoroughly to reflect accuracy in the care given. Late entries in a record can be identified, and if not labeled as a late entry with the current date and reason for the addition, will reflect negatively on the physician.

Conflict among members of the health care team becomes an avenue for a plaintiff to search for evidence of negligence and malpractice. Open communication, a willingness to listen, humility, and shared respect among the professionals involved in one patient's care may enhance patient safety and reduce medical errors. These goals are shared by all who participate in the delivery of health care.

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description of the patient's colon during surgery. The colon appeared normal and *C. difficile* pseudomembranous colitis so severe as to kill a person should cause the colon to appear abnormal even by external examination. However, the subsequent physicians (the general surgeon and the internal medicine physician) did not support the defense causation argument. Both stated that the infection contributed to the patient's death.

### Disposition

This case was taken to trial. During jury deliberations, a settlement was negotiated and payment was made on behalf of the family physician with her consent. The jury returned a defense verdict based on the causation arguments.

### Risk management considerations

When physicians hire and train their staffs, the assignment of duties is expected to reflect the background and skills of the employee. Physicians may delegate many tasks to staff, but maintain the responsibility to verify each staff member's competency

to perform as trained. Allowing a receptionist to gather information from a patient with physician decision-making based on the content of the message may be acceptable with established, well-known and reliable patients. However, treating a patient based on phone messages needs to be done judiciously. It reflects more prudent practice for the physician who does not have medically trained or licensed staff for phone triage to speak directly with the sick patient. This defendant physician would likely have elicited more information and scheduled the patient for an office visit. Diagnosing and treating by phone can become a "slippery slope" as in this case.

Although not a focus of the allegations in this claim, the treatment of the patient's complaint of back pain with radiation to the left side was also treated via phone with pain medication prescribed and lumbar x-rays ordered. The x-rays were never done and this was not discovered or followed in the defendant's practice. All practices need to implement a system to verify receipt of reports for outside tests (e.g. lab, imaging studies), and response from consultants. Such a system will allow discovery of the

patient who did not comply or the absence of a report. Such delays in continuity of care may lay the foundation for failure to diagnose and treat in a timely manner.

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**Editor's note:** Special thanks to Jerry Frankel, MD, FACS, who wrote in response to last issue's closed claim study involving a retained surgical retractor. Dr. Frankel wrote about a study published in the *New England Journal of Medicine* which found that in most cases of retained instruments there was a count, but it was incorrect. According to the article, the factors contributing to incorrect instrument counts were: obese patient, emergency surgery, or change in OR crew during procedure. The authors suggest that radiographic screening of high-risk patients at the end of the procedure could prove useful in detecting foreign bodies inadvertently left behind. (Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *N Engl J Med*. 2003 Jan 16;348(3):229-35.)