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Ethics and the Role of Guidelines in Clinical Practice

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FROM THE EDITOR
Catching up with Evidence-Based Medicine

In academic institutions, on the wards, and in physicians' offices across the country, the daily debate about how to provide the best care for the patient continues today as it has for centuries. But these days there is one clinical challenge that subdues all but the boldest (or, perhaps brashest): "There is no evidence supporting (*insert proposed treatment here*)!" Indeed, we find ourselves now squarely in the era of evidence-based medicine (EBM), in which clinical decision making centers around "evidence" and professional societies churn out clinical practice guidelines on a regular basis to help physicians keep pace. In this month's *Virtual Mentor*, we explore the intersection of ethics and guidelines in medical practice and consider the merits of the evidence-based medicine movement that led to the prominence of such guidelines.

To those who have learned to practice medicine more recently, it's hard to imagine a clinical milieu in which supporting data were not the central justification for patient care. Somewhere along the line *evidence* stopped being just part of the rationale for clinical decision making; we capitalized the "e," and *Evidence* became nearly synonymous with rationale. In this month's history of medicine section, we hear a personal tale from David M. Eddy, MD, PhD, about the beginnings of the EBM movement.

The process of validating evidence for clinical use has become quite nuanced. Opeyemi Daramola, MD, and John S. Rhee, MD, MPH, explain in a policy forum piece how medical evidence is rated, giving valuable insight into the process by which medical research informs the development of guidelines. Indeed, this reverence for data has made it from the provider side to the bedside and all the way to the patient, as illustrated by the frequency with which patients request statistical support from physicians for their recommendations. How, then, does the physician recommend a course of action that is not yet supported by guidelines or does not yet have a wide array of clinical trial findings? Peter Angelos, MD, PhD, tackles this question in his clinical case commentary.

What remains even less well-defined is the moral authority that guidelines wield in the clinical arena. From an outcomes perspective, it is widely accepted that guidelines provide clinicians with a tool that, when adhered to, promises the physician that he or she will see a *net* benefit to his or her patient population as a *whole*. Most will maintain, however, that the classic tenets of medical ethics—patient autonomy, beneficence, and nonmaleficence—must continue to inform our clinical decision making on an individual patient-to-patient basis. Is a physician

justified in disregarding guidelines in the name of such principles? Karen E. Hoffman, MD, MHSc, MPH, and Paul L. Nguyen, MD, tackle this topic in the second clinical case commentary, along with the extent to which a physician can demand that a colleague comply with such guidelines. Indeed, most physicians will agree that a guideline may be disregarded in any individual case and that categorically following guidelines fails to consider each patient as an individual.

From this belief stems the widespread worry that legislation and reimbursement schemes will give physicians undue incentives to adhere blindly to guidelines. Jason John Luke, MD, explores the effect that the recently passed Patient Protection and Affordable Care Act will have on comparative effectiveness research and physician practices in a policy forum article.

Patients may well worry that EBM will usher in a new-age medical paternalism. Ostensibly, the progress made in the field of medical ethics in the past three decades has de-emphasized unilateral decision making by the clinician and embraced the model of shared decision making in the name of patient autonomy. In the age of guidelines, however, there is risk, if not a danger, that the physician and patient—or even the physician alone—may no longer decide what's best for each individual patient; instead, the medical system may dictate treatment through the imposition of clinical practice guidelines, reimbursement policies, or other methods of standardizing health care delivery. Could the patient's preferences simply disappear from the equation?

In their clinical case commentary, David R. Brush, MD, and John Cardasis, MD, write on the subject of handling patient requests contrary to practice recommended by clinical guidelines. This case, in which a former smoker demands a CT scan to allay her fears of lung cancer, gives rise to a clinical "pearl" that recounts the effect of smoking on the lungs and tells how many years of smoke-free living it takes to undo the damage.

Many remain concerned about the wholesale adoption of EBM. Are physicians to become mere automatons in the pursuit of numerical targets and dichotomous practices? In the journal discussion, Joshua Goldman and Tiffany L. Shih explain the epistemological limitations of EBM described in seminal journal articles. There is also reason to fear that the *art* of medicine has been lost in this era of guidelines, targets, and evidence. In our medicine and society piece, Richard Colgan, MD, shows us that both evidence-based medicine and individualized patient care have their roots in longstanding medical traditions and that art and science are indeed compatible.

It is clear that the widespread reliance upon evidence as rationale for medical decision making is unlikely to change. It is deeply entrenched in our current system, and the social benefits are great. Looking to the future, our medical education piece by Alan Schwartz, PhD, and Jordan Hupert, MD, gives insight into how these principles can be taught to future physicians. What remains to be seen is the way in

which physicians respond to the rigors of practicing evidence-based medicine, all the while keeping the patient's interest in mind.

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CLINICAL CASE
When the Evidence Isn't There—Seeking Informed Consent for New Procedures
Commentary by Peter Angelos, MD, PhD

Mr. Roberts had been having difficulty urinating and, because he was 68, figured it was just a normal part of the aging process. Eventually, however, Mr. Roberts noticed that he was starting to have pain with urination as well, and went to his physician to get checked out. A few weeks and a biopsy later, Mr. Roberts was told by his physician that he had prostate cancer. Mr. Roberts was frightened and filled with uncertainty. His physician told him not to worry and recommended an excellent surgeon with whom Mr. Roberts could discuss his treatment options.

That's how Mr. Roberts ended up at Dr. Klein's urology clinic. Dr. Klein was a renowned expert in laparoscopic prostatectomy and had built a reputation based on his unusually low rate of complications. Shortly before Mr. Roberts' visit, Dr. Klein and his colleagues had begun offering robotic-assisted laparoscopic prostatectomy to patients like Mr. Roberts. After looking carefully at Mr. Roberts' lab and biopsy reports, Dr. Klein believed that surgery was the best option for this patient.

Dr. Klein admitted that the robotic procedure was much newer to him than the laparoscopic approach he had been using with success for so many years, but he said that he believed it would soon become the standard protocol for uncomplicated prostatectomy. Nevertheless, Dr. Klein offered Mr. Roberts the choice between robot-assisted prostatectomy or the standard laparoscopic prostatectomy. The robotic surgery, for one thing, was costlier.

Mr. Roberts found himself presented with a decision he did not feel qualified to make. He asked Dr. Klein about the risks and benefits of the two techniques. Dr. Klein was able to give Mr. Roberts an accurate description of the risks of the laparoscopic procedure, both from his personal experience and from hard evidence collected by urologists over many years. When Mr. Roberts asked Dr. Klein to do the same for the robotic procedure, Dr. Klein had to rely upon his limited experience. He was able to tell Mr. Roberts that in the past few months, all of his patients had had a good experience with the robotic procedure, and he thought he was already beginning to see quicker recovery times with those patients. Dr. Klein admitted, however, that more objective data for the robotic procedure was still somewhat sparse, although rapidly accumulating.

Somewhat confused and more than a little frightened by the whole prospect, Mr. Roberts told Dr. Klein that he wanted to have the procedure that Dr. Klein thought was best for him and that he would abide by whatever decision Dr. Klein made.

Commentary

Although some might argue about the details of the case and what the data really show with respect to the benefits of robotic-assisted prostatectomy, the case raises the ethical issues that every surgeon must address when considering using a new or innovative surgical procedure on a patient. As such, it is most helpful to look beyond the differences in risks and benefits between robotic prostate surgery and laparoscopic prostatectomy and consider the more general question of how surgeons should discuss innovative surgical procedures with their patients. The ethical issues in such situations revolve around three central topics: (1) the assumption that something new must be better, (2) informed consent when risks may not be fully known, and (3) how to safely acquire new surgical skills.

To begin with, there is an overwhelming assumption by the public that whatever is new must be better. This idea is captured in the ubiquitous use in advertising of the term "new and improved." In contemporary America, where technology seems to make our computers and smartphones obsolete within years (if not months), the assumption that new must be better is deep-seated. Add to this assumption the fact that the new surgical procedure is robotic, and the public will often find its lure to be almost irresistible. This observation is not lost on marketing professionals, who have come to see that the use of a robot in surgery is taken by the public as virtual proof that the operation must be better.

Unfortunately, the allure of the new and high-tech affects not only patients but also surgeons. The desire to be doing "cutting-edge" procedures with the latest technology is very strong for many surgeons, a fact that often makes the objective assessment of the value of innovative technologies difficult for both surgeons and patients [1]. To address this issue in an ethical fashion, the surgeon must carefully separate the potential benefits to the patient from the potential benefits to the surgeon him- or herself.

Second, since a recently developed procedure has, by definition, been performed on a much smaller number of patients than the conventional method, less is known about it. This lack of information can make the informed consent process particularly difficult for surgeons and patients. In an effort to obtain full informed consent, the surgeon will undoubtedly talk about the risks and benefits of the innovative procedure, but will probably have significantly less data to share. As a result, a surgeon who is not careful might wind up conveying the assumed benefits of the new procedure without any mention of unexpected risks. A surgeon in this circumstance will often present options to the patient and allow him or her to make a decision, much as Dr. Klein has done. Although respecting the autonomous choices of patients is always a good thing, this choice can trouble a patient who has no basis for making it.

Third, the surgeon must thoughtfully consider whether he or she has taken all appropriate steps to acquire the necessary surgical skills prior to offering them to patients. Unlike new drugs, new surgical procedures do not generally require an approval process. As a result, there is no oversight about what a surgeon can offer his or her patients [2]. We must assume that in the present case scenario, Dr. Klein has gained the appropriate skills before offering the robot-assisted procedure to his patients. At the very least, Dr. Klein would be expected to have experience performing the procedure either in simulation, on a cadaver, or on an animal prior to offering it to a human.

As part of the consent process, the surgeon must fully disclose to the patient the degree of experience he or she has with the procedure they are considering together. The very fact that the technique is new and that the surgeon's experience with it is limited must be explained in the consent process.

In this case, we see that Dr. Klein has tried to be honest with Mr. Roberts about the lack of good data about the new procedure and about his lack of experience with it. As a result, Mr. Roberts is put in the position of having to make a decision with little good data upon which to base it. As so often occurs in cases like this, Mr. Roberts is "confused" and "frightened" and wants Dr. Klein to make the decision for him. Although giving patients information and options is valuable and fits into the contemporary ethos of respecting patient autonomy, patients sometimes feel that they need more than just options and choices. I might be comfortable with a waiter at a restaurant telling me what is on the menu, but I want more from my surgeon. I want an actual recommendation. How then, can Dr. Klein make a recommendation for Mr. Roberts about a procedure for which relatively little outcome data is available?

In this circumstance, Dr. Klein must objectively consider what the potential benefits of the new procedure might be and then determine what value Mr. Roberts might place on these specific benefits. For example, if the benefit is the potential for more rapid return to work, but the new procedure will be more costly, Dr. Klein must discuss these issues with Mr. Roberts, so that Mr. Roberts can weigh these particular costs and benefits. Dr. Klein is being asked, in this case, to act according to the highest levels of professionalism. He must ignore the benefits to himself of performing the new procedure and focus only on those for the patient. Although some might argue that we are asking too much of Dr. Klein, I believe that we are, in fact, asking Dr. Klein to live up to the ideals of surgery and make a decision that is in the patient's best interest.

References

1. Angelos P. The ethical challenges of surgical innovation for patient care. *Lancet*. 2010;376(9746):1046-1047.
2. Biffl WL, Spain DA, Reitsma AM, et al. Responsible development and application of surgical innovations: a position statement of the Society of University Surgeons. *J Am Coll Surg*. 2008;206(3) 1204-1209.

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CLINICAL CASE

The Debate Over Prostate Cancer Screening Guidelines

Commentary by Karen E. Hoffman, MD, MHSc, MPH, and Paul L. Nguyen, MD

Dr. Johnson had been in the private practice of primary care and internal medicine with four other internists for 15 years. Dr. Johnson and her four partners had built a flourishing practice based upon the shared ideals of evidence-based medicine, prevention, and chronic disease management. In fact, the group had monthly conferences devoted to general practice guidelines, an innovation that Dr. Johnson believed helped the group keep up to date in an ever-changing medical environment.

After 2008, though, a good deal of argument and conflict developed regarding screening for prostate cancer. In August of that year, the U.S. Preventive Services Task Force (USPSTF) issued a statement concluding that "current evidence is insufficient to assess the balance of benefits and harms of prostate cancer screening in men older than age 75 years" and "the USPSTF recommends against screening for prostate cancer in men age 75 years or older."

Dr. Johnson and three of her colleagues adhered closely to the USPSTF guidelines, but one did not. This lone physician, Dr. Smith, thought the guideline was bogus. As a result, Dr. Smith tested each of his male patients—including the elderly—annually for prostate cancer with PSA and digital rectal exam. More of his patients underwent biopsy and subsequent surgery as a result of their PSA screening, and a higher incidence of prostate cancer was diagnosed among them. Two patients had died as a result of prostate cancer in Dr. Johnson's time with the practice; one was Dr. Smith's patient and one was the patient of another partner.

Dr. Johnson was concerned because it seemed unlikely that Dr. Smith's screening had saved any lives, and a number of Dr. Smith's patients suffered from impotence or incontinence as a result of biopsy and surgery.

One morning, Dr. Johnson and her colleagues confronted Dr. Smith about his screening practice, citing the USPSTF guideline. "I don't believe in that hogwash," Dr. Smith snapped. "My patients want to know if they have cancer or not, and I'm not about to start denying them that knowledge." Deeply unsettled, Dr. Johnson and her colleagues agreed to meet in private to discuss this disagreement, and whether or not anything should be done about it.

Commentary

Opinions vary regarding the appropriate age to stop screening men for prostate cancer in the United States. Therefore it is not surprising that Drs. Johnson and Smith have different approaches for screening men age 75 and older. In our opinion, neither the policy of screening all men age 75 and older advocated by Dr. Smith nor the policy of screening no man age 75 and older advocated by Dr. Johnson is appropriate. Blanket approaches that use a strict age cutoff do not individualize cancer screening decisions and do not respect patient autonomy.

The inconsistencies among clinical practice guidelines developed by medical groups on the appropriate age to stop screening men for prostate cancer make it difficult for primary care physicians to determine when to stop. While the American Urological Association (AUA) and the American Cancer Society (ACS) guidelines recommend that screening be considered for men with an estimated life expectancy of longer than 10 years, the 2008 USPSTF guidelines recommended against screening any man 75 years old or older for prostate cancer regardless of life expectancy [1-3].

Dr. Johnson and Dr. Smith strive to practice evidence-based medicine but find limited data on screening older men for prostate cancer. Three published clinical trials have evaluated the benefits and harms of the screening. Two demonstrated that it lengthened patient survival, but none offer guidance on whether or not to screen men age 75 years or older for prostate cancer because none of the three trials enrolled men in this age group [4-6].

Proponents of halting PSA screening at age 75 rightly point out that many older men diagnosed with prostate cancer will never develop symptoms from it, since they have multiple comorbid conditions and will die from something else [7, 8]. We agree that it is important to curtail PSA screening in men with short life expectancies because these men will be exposed to the risks of the screening and treatment but will likely die before gaining any benefit from it.

Although complications are infrequent, screening can cause hematoma from the prostate-specific antigen (PSA) blood draw and infection and urinary difficulties from the diagnostic prostate biopsies. If they are diagnosed with early prostate cancer, these men may also be subjected to complications from overtreatment of indolent prostate cancer. Treatment can cause urinary incontinence, urinary retention, erectile dysfunction, and bowel dysfunction, all of which can adversely impact quality of life [9]. Men who are not treated for their early prostate cancer may experience the anxiety and uncertainty that comes with a cancer diagnosis. Efforts to curtail unnecessary PSA screening in men with short life expectancies are advocated based on the tenets of beneficence, taking action to serve the best interests of the patient, and nonmaleficence, not causing harm to the patient.

Those who disagree with the USPSTF recommendation for a strict age cutoff argue that, while many older men have multiple comorbid conditions and a relatively short life expectancy, some healthy men aged 75 years or older can be expected to live 10

or more years and may benefit from early detection of prostate cancer. The recommendations by the AUA and ACS to consider screening for men with life expectancies of at least 10 years are based in part on studies that suggest it takes 10 years to realize a survival benefit from prostate cancer treatment [10].

Older men are diagnosed with higher grade and higher stage prostate cancer than younger men [11]. These aggressive cancers can cause symptoms such as urinary retention and bone pain and can result in prostate cancer death sooner than lower grade, earlier stage cancers. Studies indicate that men older than age 75 may obtain a benefit from curative treatment of localized aggressive cancer [12-14]. If a strict age cutoff of 75 years is used, these men would not be offered PSA screening and therefore would not benefit from the early detection and treatment of aggressive prostate cancer.

While healthy older men may obtain a benefit from treatment of aggressive prostate cancer, early indolent cancers may not require treatment and instead can be monitored with serial testing, thereby avoiding the adverse effects of treatment. Proponents of using life expectancy rather than a strict age cutoff of 75 years stress the importance of considering the clinical situation of individual patients and advocate their stance based on the principle of beneficence, taking actions that serve the best interests of the patient.

The Institute of Medicine (IOM) defined clinical practice guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [15]. They can serve as a guide for busy general practitioners who do not have the time to review all of the primary information that form the basis of the guidelines. However, the key word of the IOM definition is that the guidelines should *assist* practitioners in their decision making. Guidelines require interpretation and should not be mindlessly applied as a template of care for all patients, particularly when there are inconsistencies between clinical practice guidelines developed by medical groups. As Battista et al. have written, "Guidelines should enhance clinical judgment, not replace or stifle it" [16]. When employing guideline recommendations, physicians must remember their responsibility to individual patients and be mindful of their values and unique clinical situations. In the case at hand, while Dr. Smith can be faulted for completely disregarding guidelines to the potential detriment of his own patients, Dr. Johnson can also be faulted for adhering to guidelines without considering their applicability to the individual patient before her.

When a man aged 75 years or older presents to the clinic, should Drs. Johnson and Smith screen him for prostate cancer? In our opinion, a strict age cutoff should not be used to make that clinical judgment. Instead, physicians should consider the patient's life expectancy, values and unique clinical situation to arrive at individualized screening decisions. For men with a short life expectancy who are more likely to be harmed than to benefit from prostate cancer screening and subsequent treatment, prostate cancer screening should not be recommended. For

men with a life expectancy of more than 10 years, prostate cancer screening should be considered. This does not imply all men aged 75 and older with at least 10 years of life expectancy should have a PSA test. Given the uncertainty of the benefit of prostate cancer screening for healthy older men, physicians should discuss the potential beneficial and adverse effects of prostate cancer screening. This information together with personal preferences should be used to arrive at a shared decision with the patient regarding screening. We acknowledge that having a conversation about whether or not to pursue prostate cancer screening requires additional clinical time; however, it is essential for individualized cancer screening decisions that respect patient autonomy.

Another dilemma faced by Dr. Johnson and colleagues is whether or not to confront Dr. Smith with their concerns about his practice. They may hesitate because they are uncomfortable about challenging his perceived authority with his own patients. However, if a physician believes that patients are being harmed by the practices of another physician, then he or she cannot be a passive bystander; there is a duty to intervene. Therefore, we hope Dr. Johnson and colleagues will discuss their concerns with Dr. Smith. The process of peer review and peer feedback that commonly takes place in large practices and medical centers is a safety net that helps ensure that physicians provide high-quality care that is within acceptable standards of practice. Ideally, the discussion between Drs. Johnson and Smith will lead to a review of the primary literature and improvement in patient care for both of them.

References

1. American Cancer Society. Guidelines for the early detection of cancer. http://www.cancer.org/Healthy/FindCancerEarly/CancerScreeningGuidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer. Accessed December 9, 2010.
2. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2008;149(3):185-191.
3. Carroll P, Albertsen PC, Greene K, et al. Prostate-specific antigen best practice statement: 2009 update. http://www.auanet.org/content/media/psa09.pdf. American Urological Association. Accessed December 9, 2010.
4. Andriole GL, Crawford ED, Grubb RL 3rd, et al. Mortality results from a randomized prostate-cancer screening trial. *N Engl J Med*. 2009;360(13):1310-1319.
5. Hugosson J, Carlsson S, Aus G, et al. Mortality results from the Goteborg randomised population-based prostate-cancer screening trial. *Lancet Oncol*. 2010;11(8):725-732.
6. Schroder FH, Hugosson J, Roobol MJ, et al. Screening and prostate-cancer mortality in a randomized European study. *N Engl J Med*. 2009;360(13):1320-1328.
7. Sung JC, Kabalin JN, Terris MK. Prostate cancer detection, characterization, and clinical outcomes in men aged 70 years and older referred for transrectal ultrasound and prostate biopsies. *Urology*. 2000;56(2):295-301.

8. Newschaffer CJ, Otani K, McDonald MK, Penberthy LT. Causes of death in elderly prostate cancer patients and in a comparison nonprostate cancer cohort. *J Natl Cancer Inst*. 2000;92(8):613-621.
9. Sanda MG, Dunn RL, Michalski J, et al. Quality of life and satisfaction with outcome among prostate-cancer survivors. *N Engl J Med*. 2008;358(120)1250-1261.
10. Bill-Axelson A, Holmberg L, Filen F, et al. Radical prostatectomy versus watchful waiting in localized prostate cancer: the Scandinavian prostate cancer group-4 randomized trial. *J Natl Cancer Inst*. 2008;100(16):1144-1154.
11. Cooperberg MR, Cowan J, Broering JM. Carroll PR. High-risk prostate cancer in the United States, 1990-2007. *World J Urol*. 2008;26(3):211-218.
12. Alibhai SM, Naglie G, Nam R, Trachtenberg J, Krahn MD. Do older men benefit from curative therapy of localized prostate cancer? *J Clin Oncol*. 2003;21(17):3318-3327.
13. Nguyen PL, Chen MH, Renshaw AA, et al. Survival following radiation and androgen suppression therapy for prostate cancer in healthy older men: implications for screening recommendations. *Int J Radiat Oncol Biol Phys*. 2009;76(2):337-341.
14. Hoffman KE, Chen MH, Moran BJ, et al. Prostate cancer-specific mortality and the extent of therapy in healthy elderly men with high-risk prostate cancer. *Cancer*. 2010;116(11):2590-2595.
15. Field MJ, Lohr KN, eds; Institute of Medicine. *Clinical Practice Guidelines: Directions for a New Program*. Washington, DC: National Academies Press, 1990.
16. Battista RN, Hodge MJ, Vineis P. Medicine, practice and guidelines: the uneasy juncture of science and art. *J Clin Epidemiol*. 1995;48(7):875-880.

Further Reading

Hoffman KE, Nguyen PL, Ng AK, D'Amico AV. Prostate cancer screening in men 75 years old or older: an assessment of self-reported health status and life expectancy. *J Urol*. 2010;183(5):1798-1802.

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CLINICAL CASE
Responding to Patient Requests for Nonindicated Care
Commentary by John Cardasis, MD, and David R. Brush, MD

When Dr. Wainwright entered the room late on a Friday afternoon, the last new patient of his weekly thoracic surgery clinic awaited him anxiously. Mrs. Kitson sat rigidly upright on the edge of the exam table, wringing her hands, as he pulled up the stool.

"Hello, Doctor. We've never met before, but I just wanted you to know that I've heard wonderful things about you. You performed surgery on my best friend just a few months ago as a matter of fact," Mrs. Kitson blurted out, giving her friend's full name.

"Pleasure to meet you, Mrs. Kitson. I remember Mrs. Martin well," Dr. Wainwright replied. And he did remember Mrs. Martin. She was one of the most difficult lung cancer resections he had done in a long time. An unfortunate story, Mrs. Martin had been diagnosed 4 months before with locally advanced lung cancer, and removing all the cancer proved impossible for Dr. Wainwright and his colleagues." I haven't seen her for a couple of months," he said. "I hope she's doing well."

"Very well," Mrs. Kitson said, rubbing her palms against her thighs.

"Well, what brings you in today?"

Without hesitation, Mrs. Kitson said: "I'd like a CAT scan. As soon as possible. I know my situation isn't exactly the same as my friend's, but I just have to know if I have lung cancer. I can't go through what she went through."

Over the next few minutes, Dr. Wainwright attempted to understand the reason for Mrs. Kitson's anxiety. It turned out that she had smoked a pack of cigarettes a day for 5 years a couple of decades earlier. However, she did not have any of the symptoms Dr. Wainwright asked about, such as cough, hemoptysis, or weight loss, and knew of nobody in her family who had had lung cancer. Dr. Wainwright explained to Mrs. Kitson that since she was asymptomatic, there was no evidence that screening for lung cancer would do her any good. In fact, the current position of the U.S. Preventive Services Task Force was: "the evidence is insufficient to recommend for or against screening asymptomatic persons for lung cancer with either low-dose computerized tomography, chest x-ray, sputum cytology, or a combination of these tests." Furthermore, there was the cost to consider, as well as

the risks of high-dose radiation exposure and the possibility of invasive work-ups of otherwise benign lesions.

"I know it probably sounds silly to you," Mrs. Kitson said, "but I have to be sure."

Although she clearly had no clinical indication for a CT scan, Dr. Wainwright wondered to what extent Mrs. Kitson's "whole" health, her well-being, might depend on getting the scan. But, then, couldn't that same reasoning be used for everyone who wanted an unnecessary scan?

Commentary

Patients request testing or treatments that are not supported by guidelines, are not medically indicated, and may even be potentially harmful. Such requests may be based on misinformation, misunderstanding, anxiety, or even hypochondriasis. As access to medical information continues to increase, patients will approach physicians with a greater, though often incomplete, knowledge of potential diagnoses and treatments and will make more specific requests. How should physicians approach these requests in a manner that provides good care for patients, avoids nonindicated care that could be harmful, and maintains a good working relationship with the patient?

Mrs. Kitson is worried that she has lung cancer and believes a CT scan will reassure her. She is focused on the potential benefit of her request, but may not be aware of the potential risks. There is currently no evidence that performing a screening chest CT in an asymptomatic patient with a 5-year, pack-a-day smoking history would be of significant benefit. Given the low lung cancer incidence in patients like Mrs. Kitson [1], the small chance of discovering a lung cancer with CT screening is offset by the greater likelihood that the scan would either be normal or reveal an abnormality that would require further evaluation.

Pulmonary nodules are one of the most common abnormalities discovered with CT scanning. The majority of these nodules are small and benign, but confirming that often requires additional CT scans at intervals for a period sometimes stretching up to 2 years. So, while a CT scan could be normal and reassuring for Mrs. Kitson, there is a substantial risk that she could have to spend as long as 2 years fearing that the nodule found on scan was cancerous, probably undergoing an invasive biopsy in the meantime to ensure the abnormality was benign. Such false positive screening CTs cause great psychological distress and lead to invasive procedures that would not otherwise have been performed.

Even if Mrs. Kitson undergoes the screening CT, and the result is normal, she may still have been harmed. A typical chest CT exposes a patient to 8 millisieverts (mSv) of radiation. These doses can quickly add up as patients are repeatedly exposed to CT scanning, whether for follow-up of a diagnosis, redundancy with visits to different hospitals, or, as with this patient, as a salve for anxiety.

As medical imaging becomes more ubiquitous and more powerful, the long-term consequences of medical ionizing radiation exposure is being examined more closely. While there have been no prospective studies on the cancer risks of CT scans, there have been studies of individuals exposed to equivalent amounts of radiation and their incidence of malignancy. Studies of nuclear power plant workers, individuals exposed to residual radiation from nuclear fallout, and radiologists before protective equipment was used [2-5] have shown an increasing incidence of cancer in individuals who had radiation exposure from 10 to 100 mSv, with some linking a increased cancer risk to doses as low as 5 mSv.

Two recent studies in the *Archives of Internal Medicine* [6, 7] estimated the risk of cancer in a patient population exposed to varying levels of radiation from CT imaging. Extrapolating cancer data from the aforementioned population studies, the first study estimated that the risk for a 40-year-old woman undergoing a chest CT for developing a radiation-related malignancy was 1 in 720. If she were 20 years old, the risk increased to 1 in 390. The second study estimated that approximately 30,000 future cancers would be caused by the diagnostic radiation exposure in the year 2007, comprising 1.5 to 2 percent of cancer incidence. So even a "normal" reassuring CT scan is not without inherent, albeit delayed, risk.

The job of a physician is not only to diagnose illness and perform procedures but to also determine whether the diagnostic test or treatment is warranted in the first place. Physicians are not obligated to offer testing or treatments that are not medically indicated—even if patients demand them [8]. Often physicians must determine what is medically indicated by weighing the risks and benefits associated with fulfilling the patient's request. In the case of Mrs. Kitson's request, a CT scan to screen for lung cancer is not medically indicated. No studies of patients like her have shown a benefit [9], and there are both the considerable false-positive risk and the risk associated with ionizing radiation to consider. While Mrs. Kitson might benefit psychologically from a normal test, she could suffer greater distress from a false-positive result. Without a substantial medical benefit and with numerous potential risks, we would not proceed with CT scanning.

How should the physician proceed if, after a discussion of the risks and benefits, Mrs. Kitson still pleads to be tested? Is a physician who refuses to comply with her request restricting her autonomy? Respect for autonomy is usually referenced when patients exercise their negative rights, such as the right to refuse a test or intervention. Positive rights—the rights to demand something be done—are more circumscribed in medicine [10]. Medicine is rife with examples in which a patient's ability to obtain specific testing or treatments is limited. Many medications and services cannot be obtained by patients without a physician's approval, not to mention insurance coverage. If patients' autonomy were absolute, then a competent patient's demands for testing or treatment would always have to be honored. Such a system would contradict the physician's obligation to protect the patient from unacceptable harm and unnecessary risk. Doing harm to a patient in the service of his

or her autonomy fails to fulfill the physician's professional duty and compromises the principles of sound medical care.

This does not mean, however, that a physician should be dismissive of the patient's concerns. As advocates for the patient, physicians need to discern why requests are being made. What initially may seem to be an idiosyncratic idea, such as an elderly patient's request for syphilis testing because it was a recent diagnosis on *House*, may turn out to stem from a real risk—for example, the patient has been sexually active with a new partner, but did not wish to disclose her new status to her physician.

Even if requests are investigated and no medical indication is discovered, understanding why the patient is making the request will help the physician care for the patient. Topic-specific education that clarifies misunderstandings and incorrect information may resolve the conflict. The physician who intends to decline the patient's request should take care to explain the reasoning behind the decision. Otherwise, the patient may well suspect that the doctor is merely ignoring his or her concerns or acting in the interest of cost containment, rather than his or her best interest.

In this case, Mrs. Kitson's fear that she may suffer the same fate as her friend may be the driving force behind her request. A careful discussion of her goals and education about the risks and benefits associated with her requests are essential. Dr. Wainwright should decline to proceed with CT scanning, but should be sure to explain why.

Mrs. Kitson may be satisfied and reassured by the encounter and may continue the patient-physician relationship, or, her concerns unallayed, she may seek another physician's opinion. Alternatively, she may pursue the scan through a commercial vendor, which is within her rights. But as long as patients make requests of the physician within the parameters of the patient-physician relationship, physicians should evaluate those requests and apply their knowledge and expertise to give only those services that are medically indicated.

References

1. Peto R, Darby S, Deo H, et al. Smoking, smoking cessation and lung cancer in the UK since 1950: combination of national statistics with two case-control studies. *BMJ*. 2000;321(7257):323-329.
2. Brenner DJ, Doll R, Goodhead DT, et al. Cancer risks attributable to low doses of ionizing radiation: assessing what we really know. *Proc Natl Acad Sci USA*. 2003;100(24):13761-13766.
3. Richardson D, Sugiyama H, Nishi N, et al. Ionizing radiation and leukemia mortality among Japanese atomic bomb survivors, 1950-2000. *Radiat Res*. 2009;172(3):368-382.
4. Cardis E, Vrijheid M, Blettner M, et al. Risk of cancer after low doses of ionising radiation: retrospective cohort study in 15 countries. *BMJ*. 2005;331(7508):77.

5. Yoshinaga S, Mabuchi K, Sigurdson AJ, Doody MM, Ron E. Cancer risks among radiologists and radiologic technologists: review of epidemiologic studies. *Radiology*. 2004;233(2):313-321.
6. Smith-Bindman R, Lipson J, Marcus R, et al. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. *Arch Intern Med*. 2009;169(22):2078-2086.
7. Berrington de Gonzalez A, Mahesh M, Kim P, et al. Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Arch Intern Med*. 2009;169(22):2071-2077.
8. Jonsen AR, Siegler M, Winslade WJ. *Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine*. 5th ed. New York: McGraw-Hill Professional; 2002.
9. US Preventive Services Task Force. Lung cancer screening: recommendation statement. *Ann Intern Med*. 2004;140(9):738-739.
10. Brett AS, McCullough LB. When patients request specific interventions: defining the limits of the physician's obligation. *N Engl J Med*. 1986; 315(21):1347-1351.

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MEDICAL EDUCATION

Insights from Teaching Evidence-Based Medicine

Alan Schwartz, PhD, and Jordan Hupert, MD

As members of the Departments of Pediatrics and Medical Education at the University of Illinois at Chicago, we have taught evidence-based medicine to medical students and pediatrics residents together for over a dozen years. In that time, we have experimented with many models of teaching and learning, conducted research into the impact of EBM education on physicians' use of evidence [1, 2], and developed online tools and systems to support both students and practicing clinicians [3, 4].

Our earliest curricula focused on introducing concepts and skills of EBM into inpatient pediatrics morning reports through a set of weekly sessions repeated in each 4-week rotation [5]. These later evolved into a cumulative curriculum for ambulatory pediatrics and national workshops for faculty teaching EBM held at UIC, other sites in the U.S., and at the Pediatrics Academic Society meetings. In recent years, we have taught EBM in the context of a mandatory, semiweekly morning conference for residents and clerks on pediatric rotations.

In this commentary, we outline what we consider to be key insights in the teaching and practice of evidence-based medicine.

Emphasis on Medicine

Evidence-based medicine is, first and foremost, medicine. As a facet of medical practice, EBM should be consistent with the professional ethics and responsibilities of the physician, including the primacy of the patient [6]. Early in our development of EBM activities, we discarded the traditional "journal club" format, in which articles are reviewed on the basis of their recent publication, in favor of asking students to identify patients in their care about whom they had unresolved questions. The patient's care and context drives the development of a question, and the skills of evidence-based medicine—literature search, critical appraisal of methods, and interpretation of results—are all employed to benefit the current patient or similar future patients.

Not All Evidence is Created Equal

Early opponents of evidence-based medicine as an organizing principle in medical education often criticized a straw man position in which only randomized controlled trials (RCT) were accorded the status of valid evidence (and some early and zealous proponents of EBM took positions that made this criticism seem apposite). Of course, RCTs are neither the sole source of evidence nor even always an appropriate

source of evidence, given the question to be answered [7]. EBM is about using the best available evidence [8].

It is important, however, for students to know that sources of evidence differ in the strength of the conclusions that can be drawn from them, and to understand why. Critical appraisal checklists provide rough rubrics for this assessment, but cannot substitute for teaching students the ways in which choices made in study design entail trade-offs.

Evidence is not limited to the clinical research literature. Critiques of EBM have rightly noted the essential role of experienced clinical judgment, preferences of patients, and knowledge of physiological processes. Teaching EBM is not the same as teaching medicine. Nevertheless, an understanding of clinical research and the ability to reason statistically are requisites for the practice of medicine.

Needs of Learners and Practitioners Differ

In some ways, teaching EBM is like teaching microscopy. We teach microscopy to medical students because we expect physicians to be able to understand reports of lab findings, knowing that, in practice, time is limited and a physician's attention is better directed to the patient than to statistical calculations. Similarly, we believe that medical students and residents should master the fundamentals of searching the primary literature and become acquainted with secondary sources, even though we expect physicians in practice to use guidelines, systematic reviews, expert synopses, and decision support tools far more often than they conduct critical appraisals of the primary research literature. Mastery of EBM fundamentals facilitates effective use of the secondary literature, critical appraisal of the primary literature when new studies have emerged that have not yet been synthesized, and thoughtful guidance when a patient presents with an article in hand.

The development of online tools to enhance EBM practice and learning has also been a focus of our efforts. Computing risk reductions and likelihood ratios is not the most salient aspect of interpreting medical statistics. Rather, it is the ability to understand the relationships between interventions and outcomes, or test results and disease probabilities. Online calculators allow students and residents to manipulate the features of statistical scenarios to achieve this deeper understanding.

Learners also have opportunities that are not always afforded to physicians in practice. Our trainees are assigned to identify patients, formulate questions, and review evidence individually throughout the year, but they also present their cases and conclusions to small groups consisting of other trainees and faculty. These group discussions encourage deeper consideration of the evidence and reflection on its implications for patient care, and more than once have resulted in faculty and trainees publishing research letters in response to articles discussed.

Nonphysicians May Be Evidence Experts

One of us is a physician; the other, a social scientist. That we are both capable of effectively understanding the design and results of clinical studies reminds us that expertise with evidence is not equivalent to expertise as a physician. Indeed, our research has demonstrated that medical librarians can be trained to outperform physicians in evidence appraisal and interpretation. Physicians can rely on these "clinical informationists" [9] to serve as consultants much as they rely on experts in laboratory medicine to perform and report diagnostic tests. In the time-sensitive milieu of medical practice, we and others have found that physician-librarian teams can be efficient and effective by allowing librarians to engage their deep knowledge and skills in accessing clinical literature (together with their training in statistical analysis and interpretation) and freeing physicians to formulate questions about their patients and bring the results back to the bedside to enhance clinical care.

EBM Is Necessary, but not Sufficient, for Medical Decision Making

We frame EBM as a step in the process of making good medical decisions, rather than as an academic exercise to satisfy the physician's curiosity. Decision making is a much broader activity and requires inputs that are not usually the focus of EBM teaching: patient preferences, costs, ethical considerations, and other features of the health care delivery system [10]. Because it provides a framework for understanding the essentially uncertain nature of medical diagnosis and treatment, EBM is an early and essential step in the development of a medical decision maker. In our recent year-long EBM curricula, we have often introduced more advanced decision-making concepts, including decision thresholds and cost-effectiveness analysis.

Conclusion

Critics characterize evidence-based medicine as a constraining influence, directing students and practitioners to subjugate their clinical judgments to guidelines that address average patients rather than specific patients. But proponents of including EBM in medical education believe that uncritical and habitual clinical decision making can lead to substantial and unwarranted variation in care. We at UIC, like educators at many medical schools, think it is ethically imperative that our graduates consistently challenge their understanding and practice medicine in accord with the field's best knowledge of effective care. Patient-focused EBM education is a critical step in this process.

References

1. Schwartz A, Hupert J. A decision making approach to assessing critical appraisal skills. *Med Teach*. 2005;27(1):76-80.
2. Schwartz A, Hupert J. Medical students' application of published evidence: randomised trial. *BMJ*. 2003;326(7388):536-538.
3. Schwartz A. Evidence Based Medicine (EBM) and Decision Tools. MedEdPORTAL. http://services.aamc.org/jsp/mededportal/retrieveSubmissionDetailById.do?subId=209. Accessed December 15, 2010.

4. Schwartz A, Millam G. A web-based library consult service for evidence-based medicine: technical development. *BMC Med Inform Decis Mak*. 2006;6:16.
5. Schwartz A, Hupert J, Elstein AS, Noronha P. Evidence-based morning report for inpatient pediatric rotations. *Acad Med*. 2000;75:1229.
6. Straus SE, Richardson SR, Glasziou P, Haynes RB. *Evidence-Based Medicine: How to Practice and Teach EBM*. 3rd ed. Edinburgh: Churchill Livingstone; 2005.
7. Norman GR. Examining the assumptions of evidence-based medicine. *J Eval Clin Pract*. 1999;5(2):139-147.
8. Straus S, Haynes B, Glasziou P, Dickersin K, Guyatt G. Misunderstandings, misperceptions, and mistakes. *Evid Based Med*. 2007;12(1):2-a-3.
9. Davidoff F, Florance V. The informationist: a new health profession? *Ann Intern Med*. Jun 20 2000;132(12):996-998.
10. Schwartz A, Bergus GR. *Medical Decision Making: A Physician's Guide*. Cambridge, UK: Cambridge University Press; 2008.

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THE CODE SAYS
The AMA *Code of Medical Ethics*' Opinion on Physician Pay-for-Performance Programs

Opinion 8.056 - Physician Pay-for-Performance Programs
Physician pay-for-performance (PFP) compensation arrangements should be designed to improve health care quality and patient safety by linking remuneration to measures of individual, group, or organizational performance. To uphold their ethical obligations, physicians who are involved with PFP programs must take appropriate measures to promote patients' well-being.

(1) Physicians who are involved in the design or implementation of PFP programs should advocate for:
(a) incentives that are intended to promote health care quality and patient safety, and are not primarily intended to contain costs;
(b) program flexibility that allows physicians to accommodate the varying needs of individual patients;
(c) adjustment of performance measures by risk and case-mix in order to avoid discouraging the treatment of high-risk individuals and populations;
(d) processes to make practice guidelines and explanations of their intended purposes and the clinical findings upon which they are based available to participating physicians.

(2) Practicing physicians who participate in PFP programs while providing medical services to patients should:
(a) maintain primary responsibility to their patients and provide competent medical care, regardless of financial incentives;
(b) support access to care for all people and avoid selectively treating healthier patients for the purpose of bolstering their individual or group performance outcomes;
(c) be aware of evidence-based practice guidelines and the findings upon which they are based;
(d) always provide care that considers patients' individual needs and preferences, even if that care conflicts with applicable practice guidelines;
(e) not participate in PFP programs that incorporate incentives that conflict with physicians' professional values or otherwise compromise physicians' abilities to advocate for the interests of individual patients.

Based on the report "Physician Pay-for-Performance Programs," adopted November 2005.

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JOURNAL DISCUSSION
The Limitations of Evidence-Based Medicine—Applying Population-Based Recommendations to Individual Patients
Joshua J. Goldman and Tiffany L. Shih

Tonelli MR. The philosophical limits of evidence-based medicine. Acad Med. 1998;73(12):1234-1240.

In the last three decades, evidence-based medicine (EBM) has become the gold standard for clinical practice. In fact, physicians who forgo evidence-based recommendations in favor of treatments supported by personal experience or undocumented recommendations make themselves more vulnerable to liability and subsequent indictment and may even appear arbitrary or unscientific.

Nevertheless, EBM's rise to prominence in clinical practice has stirred up some physician opposition, particularly from older health care professionals, who perhaps better recognize the growing divide in perceived value between the art of medicine and the science (a subtlety younger generations of physicians born into a system focused on EBM may not be able to appreciate as acutely). Some physicians view EBM measures as a form of "cookbook medicine" that discounts and interferes with individual physicians' medical judgment [1, 2]. Physician resistance also stems from the concern that some EBM measures rely on inadequate and occasionally contradictory information [3]. In "The Philosophical Limits of Evidence-Based Medicine," published in *Academic Medicine* in 1998, Mark R. Tonelli, MD, MA, argues that EBM fails to account for intangible factors in the individual case, in addition to being innately limited in philosophical scope. In other words, EBM cannot replace clinical judgment or account sufficiently for the complexity of individual cases. The limitations of EBM must be acknowledged and addressed so that it can be used effectively and without compromising patient care.

Defining EBM
Tonelli defines evidence-based medicine as a twofold concept. First, EBM is an optimal method for developing and describing population-based medical evidence—what he calls "a school of medical epistemology" [4]. Secondly, EBM "attempts to describe a clinical practice centered on evidence derived from clinical studies" [4]. Tonelli argues that the shortcomings of EBM arise from presupposing the validity of the epistemological framework. As he sees it, EBM does not satisfactorily integrate clinical experience, patient and professional values, pathophysiologic rationale, and expert opinion into treatment; the solution is a shift from minimizing "nonevidentiary knowledge" (individual clinical experience, physiologic principles, expert opinion, understanding of professional and patient values—that is, what is

often referred to as the art of medicine) to a system that integrates nonevidentiary knowledge into clinical decision making.

Two years after the publication of Tonelli's paper, Buetow et al. [5] expanded this argument, agreeing that strictly equating EBM's "evidence" with "scientific evidence" and sidelining such factors as clinical expertise denigrated an important aspect of the practice of medicine. They suggest that EBM should recognize multiple dimensions and modalities of knowledge, including basic science, physiological theory, practical expertise, and ethical standards. This multidimensional definition of evidence better characterizes the contemporary view of EBM and may be a first step toward rectifying the devaluation of these factors. That said, simply acknowledging the validity of these dimensions of clinical judgment may ameliorate the semantic problem of what constitutes "evidence" or appease those who oppose devaluing the art of medical practice, but it does not resolve the limitations of EBM (both practical and philosophical).

Practical Limitations

To expand the definition of EBM too broadly, Tonelli explains, would erode the meaning of the term "evidence-based"—which is to say, it would just be a new label for the mix of strategies and judgment calls known as clinical medicine. Tonelli points out that the concept of "evidence-based" (as opposed to, for example, experience-based or physiology-based medicine) is predicated on giving "general priority" to "knowledge derived from clinical research" [4]. A host of questions remain about how other types of knowledge might be usefully, rather than haphazardly, integrated into EBM. How would one go about standardizing nonevidentiary knowledge so that its incorporation into clinical practice was not wildly variable or arbitrary? How would one decide in what situations value-based or opinion-based alternatives would better serve the individual case than the evidence-based recommendation? Does *standardization* of care—assuring a high quality of care for all patients—inherently entail a shift away from *individualization*, or can we achieve both?

Despite increasing access to well-designed clinical trials and systematic reviews, Tonelli argues, EBM cannot overcome the gap between clinical research and practice. The practical limitations of EBM include "obstacles to the development, dissemination, and incorporation of medical evidence" [4]. For one thing, data sources are often called into question because the companies that stand to gain the most from an intervention's success fund the studies that investigate them. For another, rare diseases that affect small patient populations have little clinical data to rely upon. And no matter how many studies are done or how strong the evidence is, every variable in the circumstances of each patient cannot be accounted for. What is a physician to do when the validity of evidence is called into question, clinical trials on a particular subject simply do not exist, or there are nonempirical matters to be considered?

Philosophical Limitations

Tonelli asserts that "to the extent that [there are] *relevant differences* between individuals [that] cannot be made explicit and quantified, an epistemologic gap between research and practice must remain" [6]. He offers the example of two patients experiencing abdominal pain who have identical history, examination, and laboratory data. Patient A proves to have appendicitis and Patient B does not. Tonelli claims that "there may be non-quantifiable differences between patients, perhaps detectable by an experienced surgeon, that provide additional clues to the diagnosis" before surgery [6].

If we think that improvements in imaging technology in the last 12 years can substitute for the experienced surgeon's judgment, consider this example. Again, imagine two patients with identical histories of present illness, examination, and laboratory data. The only difference between the two patients is that Patient A has a loving wife who drives him to and from his appointments, while Patient B lives alone and takes the bus to his appointments. Patients A and B have identical tumors treatable with radiation applied daily for 4-6 weeks or chemotherapy taken by mouth at home. Let's suppose that the radiation treatment has a higher 5-year survival rate than the at-home treatment.

Though clinical trials cannot quantifiably assess the effect on outcome of either a patient's attitude and motivation in obtaining treatments or assistance and support from family, it is easy to see that these variables may affect the patient. A strictly evidence-based recommendation would be that both patients undergo radiotherapy, because it provides the best outcome by survival rate. Experience and logic-based knowledge might suggest that Patient B would be better served, given his transport situation, with the less inconvenient chemotherapy. After all, if the patient misses radiotherapy sessions because he misses the bus, the trial data no longer applies, and who knows what the survival rate would be.

Furthermore, not all nonquantifiable variables are as clear-cut as those in this example. Happiness and other emotional attributes have been scientifically linked to hormonal changes that affect the immune system [7]. If the only difference between patients A and B were outlook on life, reasons to live, pain, or happiness, how would their treatment options be affected? How should the patient be individually assessed to account for these differences if they are not addressed by the original prospective clinical trials? If, in a physician's experience, these aspects have an effect on the success of a particular treatment or the prognosis of a particular disease, then are these cases in which experience-based judgment should take precedence over empirical data? As Tonelli puts it, "a good clinician cannot ignore these individual differences, at least if clinical medicine is to remain a discipline aimed at the treatment of individuals" [8].

Tonelli argues that EBM has greatly changed the way clinical judgment in medicine is understood. Deviating from EBM guidelines is immediately considered suspect until proper justification is provided. With this in mind, physicians often act to avoid liability (a practice known as "defensive medicine"), recognizing that citing their

personal experience with similar patients, however expansive, will not be nearly as helpful in court as citing a study from a reputable journal, whether the data supports the best decision for this individual patient or not.

Tonelli warns against misunderstanding the nature of EBM and its limitations, which can result in the undesirable consequence of "devaluation of the individual, a shift in the focus of medical practice from the individual to society at large, and the failure to appreciate and cultivate the complex nature of sound clinical judgment" [8]. In an attempt to form a universally relied-upon bank of clinical knowledge, the EBM movement has encouraged more "objective" decisions that neglect nonquantifiable individual variations. While practicing EBM may maximize the likelihood of positive outcomes over a large population, it does not promise "the best decision in a particular situation" [8].

Ethical Limitations

Another pertinent aspect of the gap between research and practice is that "no amount of empiric data can ever tell us what we ought to do in any particular situation, as conclusions regarding what ought to be done are value-based" [8]. If you look again at our prior example, the data clearly shows that the *survival* of Patient A will be maximized by radiotherapy. The data, however, cannot tell us whether that is the outcome that is most important to the patient, most in line with his values. Parsing possible interventions to offer the patient requires some understanding of these values. Patient values are again nonquantifiable variables best uncovered by simply discussing them with the patient and offering options that best comply with the answers given. If patients value quality over quantity of life, if they wish to be able to be home for the remainder of their treatments, if they prefer not to have surgery, if their religion or values dictate any of these decisions, the physician will need to adapt, engage in joint decision making, and offer options that suit patient needs.

Conclusion

As EBM evolves, it is easy to imagine a world where population statistics dictate medical decision making. Further *integrating* knowledge modalities into or with EBM (as opposed to replacing either one) and continuing to incorporate joint decision making into clinical practice (to safeguard the importance of individual patient values) may lessen the dangers of that paradigm.

Adding other bases of knowledge into the category of clinically relevant evidence may alleviate the burden of practical limitations in EBM, but EBM must grant priority to research-derived recommendations in order to retain its meaning as a label. Furthermore, the standardization of use of other knowledge modalities presents its own difficulties, and the proper situations in which these modalities should take precedence over EBM or be used at all remains nebulous at best. As Tonelli says, "evidence can never directly dictate care; the evidence cannot tell us when it is best to ignore the evidence" [9]. As long as these questions remain unanswered, keeping the focus of clinical practice on the individual will remain the duty of the physician.

References

1. Hasnain-Wynia R. Is evidence-based medicine patient-centered and is patient-centered care evidence-based? *Health Serv Res*. 2006;41(1):1-8.
2. Scalise D. Evidence-based medicine: pressured by payers and regulators, hospitals and physicians must transform yesterday's abstract concept into a nuts-and-bolts blueprint from how they deliver care. *Hospitalconnect.com*. Dec. 15, 2004. http://www.hhnmag.com/hhnmag_app/hospitalconnect/search/article.jsp?dcrpath=HHNMAG/PubsNewsArticle/data/0412HHN_FEA_Cover_Story&domain=HHNMAG. Accessed December 17, 2010.
3. Wyer PC, Silver SA. Where is the wisdom? I—a conceptual history of evidence-based medicine. *J Eval Clin Pract*. 2009;15(6);891-898.
4. Tonelli MR. The philosophical limits of evidence-based medicine. *Acad Med*. 1998;73(12):1235.
5. Buetow S, Kenealy T. Evidence-based medicine: the need for a new definition. *J Eval Clin Pract*. 2000;6(2):85-92.
6. Tonelli, 1236.
7. Barak Y. The immune system and happiness. *Autoimmun Rev*. 2006;5(8):523-527.
8. Tonelli, 1237.
9. Tonelli, 1239.

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CLINICAL PEARL
Health Effects of Smoking and the Benefits of Quitting
Edward D. Gometz, MD, MS, MIA

Smoking is the most important and preventable cause of morbidity and premature mortality in the developed and developing world. The overall smoking rate in the United States has slowly diminished over the past four decades, transforming the habit from a cultural centerpiece to a target of social exclusion. Several states have taken bold action to protect residents from the well-known and extensively documented adverse effects of using tobacco products. Since smoking regulations are a local affair, significant variability exists from state to state, with smoking prevalence rates ranging from a high of nearly 30 percent in Kentucky and West Virginia to lows of below 13 percent in California and 10 percent in Utah [1]. Despite these public health victories, the downward trajectory of smoking rates has leveled off in the past 5 years. In fact, according to the Centers for Disease Control and Prevention (CDC), one in five Americans still lights up regularly. If all states had prevention programs like those in California and Utah, 5 million fewer people would be smoking [1, 2].

However, despite extensive efforts to curb smoking in the United States and parts of the European Union, the cigarette industry is still flourishing in other regions of the globe. Worldwide, between 80,000 and 100,000 kids start smoking *every day.* Approximately one quarter of children alive in the Asian Pacific Region will die from smoking [3]. These sobering numbers are not just the problem of our international neighbors; rather, they directly impact the U.S. health care system, given the rising numbers of immigrants entering the United States each year. The trends in mortality for the six leading causes of death in the United States have been stable or decreasing, save one: chronic obstructive pulmonary disease (COPD).

In data from the years 1970 and 2002, the percentages of death rates for heart disease, stroke, and accidents decreased the most, ranging from 40 to 60 percent reductions. In contrast, death rates for COPD doubled during those years [4]. The legacy of our romanticization of cigarettes throughout most of the twentieth century is catching up to smokers and ex-smokers as they age and manifest more health complications. The skyrocketing COPD rates seen today represent those who picked up the habit decades ago, when cigarette smoking was less regulated. An impact on the rate of COPD is not expected to reflect recent antismoking legislation victories for some time to come.

Consequences of Tobacco Use

Fifty percent of smokers die of a smoking-related disease, and the life expectancy of one in four smokers is reduced by as much as 15-20 years [5]. Before the advent of widespread tobacco use in World War II, lung cancer was rare [6]. So rare, in fact, that doctors were required to report cases of lung cancer to the federal government to help identify the local environmental cause of the condition among an affected population, much like reporting cases of mesothelioma today. Now, it is estimated that over 85 percent of all lung cancer is tobacco-related [5]. While most people recognize that smoking is highly destructive for their lungs, many have yet to come to terms with how smoking affects the rest of the body. Damage to one's skin, mouth, hands, feet, respiratory system, heart, bones, and reproductive system becomes readily evident in long-time smokers [7-9]. Areas of the body damaged by smoking include:

- Skin: Poor blood circulation due to chronic vascular insults leads to impaired oxygen delivery to the skin, causing lasting damage to collagen and epithelial tissue. This phenomenon also contributes to poor wound healing, making elective surgeries risky and emergency surgeries dangerous [7].
- Mouth: Smoking can contribute to bad breath, mouth and jaw cancer, recurrent pharyngitis, and a reduced sense of taste and smell, as well as stained, yellowed teeth and plaque. Smoking reduces the flow of saliva, which, because saliva cleanses the lining of the mouth and teeth and protects the teeth from decay, promotes infection [7].
- Hands and feet: Poor circulation leaves hands and feet chronically poorly perfused and cold. Walking can become painful due to peripheral vascular disease induced by smoking, which can even lead to eventual amputation. The blood vessels in the fingers that hold cigarettes can also become so severely impaired that gangrene can set in and lead to amputation, forcing stubborn smokers to switch to the other hand [7].
- Respiratory system: Smoking can lead to lung cancer, chronic bronchitis, continuous shortness of breath due to emphysematous injury in COPD, and persistent cough often with pneumonia [8].
- Heart: No organ except for the lungs is more affected by smoking than the heart and its circulation. Cigarette smoking by itself increases the risk of coronary heart disease; a smoker's heart is 2 to 4 times more likely to have coronary artery disease than that of a nonsmoker [5]. When smoking acts with other factors such as diabetes, it greatly increases this risk. Smoking increases blood pressure, decreases exercise tolerance, and increases the blood's tendency to clot [7]. Smoking also increases the risk of recurrent coronary heart disease after bypass surgery and raises the rate of abdominal aortic aneurysms fivefold [8, 9].
- Bones: Osteoporosis, spine and hip fractures, and degenerative disc disease can all be directly linked to smoking [7].
- Reproductive System: Infertility is often a complication with chronic smokers, both male and female. While smoking lowers the sperm counts and decreases sperm motility in men, women have impaired ovulation and egg function [7]. Maternal smoking is associated with several complications of

pregnancy including abruption placentae, placenta previa, bleeding during pregnancy, premature and prolonged rupture of the membranes, and preterm delivery. Smoking during pregnancy also retards fetal growth and causes an average reduction in birth weight [10]. High levels of nicotine have even been found in cervical mucus contributing to cervical cancer [11].

- Malignancy: In addition to the malignancies mentioned above, smoking also increases the risk of cancers of the throat, esophagus, stomach, pancreas, kidneys, bladder, and colon and acute myeloid leukemia [9, 12-14].

Health Benefits of Smoking Cessation

The potential health benefits of smoking cessation are substantial. Stopping smoking reduces the future risk of tobacco-related diseases, slows the progression of existing tobacco-related disease, and improves life expectancy by an average of 10 years [5]. Quitting can bring immediate health benefits at any age, regardless of how long one has smoked. It is never too late to quit. Within the first 24 hours of quitting, a person's blood pressure, heart rate, and peripheral circulation begin to improve. The carbon monoxide content of the airways within the lung can decrease to normal levels by the end of the first day.

By 48 hours, all nicotine has left the body, and the former smoker's taste and smell are on their way to recovering. After 1 to 3 months, an ex-smoker's lung function may have already improved by as much as 30 percent [7], and, about 6 months later, shortness of breath has significantly improved, and that chronic "smoker's cough" is becoming less of a daily occurrence [15].

One year after cessation, the risk of a heart attack drops to *half that of the risk of smokers*. All else being equal, no other single intervention or modern "miracle drug" can make this claim. The risk of lung cancer falls by 50-60 percent after a decade of abstinence. After 15 years of abstinence, the risk of heart attack and stroke falls to that of people who never smoked [7].

Promoting Smoking Cessation

The medical community has refined hospital discharge protocols for patients who suffered heart attacks by making sure, in general, that they are taking an ACE inhibitor, beta-blocker, aspirin, and statin. However, none of these important inventions come close to the impact that a patient can make on his or her health through smoking cessation. Physicians play an essential role in promoting this point as vigorously as they promote compliance to medical therapy. Tobacco use should be added to a patient's problem list along with hypertension, diabetes, and heart disease. In many clinics, smoking status is just another vital sign that intake nurses record along with temperature, blood pressure, and pulse. Although medical schools traditionally teach medical students to put tobacco use in the "social history" section of a history and physical, it is much more apropos in the "past medical history" section.

The attempt to apply the "3 Ts" (tension, trigger, treatment) model of behavior change proposes that, at a given time, a smoker experiences some degree of motivational tension, which in the presence of a trigger may initiate or enhance quitting [5]. Seventy percent of smokers want to quit, but only 3-7 percent will be successful on their own [16]. Long-term tobacco abstinence is extremely difficult and may require several attempts using multiple cessation strategies before a smoker achieves his or her ultimate goal. The average smoker has tried to quit six to nine times, and the quit rate only reaches 15-30 percent with more effective interventions such as behavioral and pharmacological therapies [16].

It is imperative that physicians continue to work with patients on an ongoing basis to find cessation modalities that work for them. Nicotine replacement therapies (such as the gum, patch or inhaler) and Bupropion increase quit rates 1.5- to 2-fold [17]. Early results with Varenicline are also promising, with quit rates increased 2- to 3-fold over placebo. Bringing in social support systems such as friends and family may be effective as well. It is becoming ever more likely that a combination of factors from the physician's office, social pressures from loved ones, cultural repudiation of public smoking, and growing statewide restrictions and taxes will ultimately be effective in turning the tide of tobacco smoking.

References

1. US Centers for Disease Control and Prevention. VitalSigns web site. http://www.cdc.gov/vitalsigns/TobaccoUse/Smoking/index.html. Accessed December 3, 2010.
2. Maugh TH. U.S. smoking rate hasn't changed, CDC says. *Los Angeles Times*. September 08, 2010. http://articles.latimes.com/2010/sep/08/science/la-sci-smoking-20100908. Accessed December 3, 2010.
3. World Health Organization. The Tobacco Atlas. http://www.who.int/tobacco/statistics/tobacco_atlas/en/. Accessed December 3, 2010.
4. Jemal A, Ward E, Hao Y, Thun M. Trends in the leading causes of death in the United States, 1970-2002. *JAMA*. 2005;294(10):1255-1259.
5. Young RP, Hopkins RJ, Smith M, Hograth DK. Smoking cessation: the potential role of risk assessment tools as motivational triggers. *Postgrad Med J*. 2010;86(1011):26-33.
6. Yesner R. Small cell lung cancer: sex and survival. *Arch Pathol Lab Med*. 2007;131(11):1631-1633.
7. Office of the Surgeon General of the United States. The health consequences of smoking–nicotine addiction; 1988. http://profiles.nlm.nih.gov/NN/B/B/Z/D/_/nnbbzd.pdf. Accessed December 3, 2010.
8. Peto R. Smoking and death: the past 40 years and the next 40. *BMJ*. 1994;309(6959):937-939.
9. Jemel A, Thun MJ, Ries LA, et al. Annual report to the nation on the status of cancer, 1975-2005, featuring trends in lung cancer, tobacco use, and tobacco control. *J Natl Cancer Inst*. 2008;100(23):1672-1694.

10. Shiverick KT, Salafia C. Cigarette smoking and pregnancy I: ovarian, uterine, and placental effects. *Placenta*. 1999;20(4):265-272.
11. McCann MF, Irwin DE, Walton LA, Hulka BS, Morton JL, Axelrad CM. Nicotine and cotinine in the cervical mucus of smokers, passive smokers, and nonsmokers. *Cancer Epidemiol Biomarkers Prev*. 1992;1(2):125-129.
12. Office of the Surgeon General of the United States. The health consequences of smoking: a report of the surgeon general. http://www.surgeongeneral.gov/library/smokingconsequences. Accessed December 3, 2010.
13. Cigarette smoking increases colorectal cancer risk. *ScienceDaily*. December 3, 2009. http://www.sciencedaily.com/releases/2009/12/091203090103.htm. Accessed December 3, 2010.
14. Office of Surgeon General of the United States. The Health Benefits of Smoking Cessation: A Report of the Surgeon General. http://profiles.nlm.nih.gov/NN/B/B/C/T/. Accessed December 3, 2010.
15. Anthonisen NR, Skeans MA, Wise RA, Manfreda J, Kanner RE, Connett JE; Lung Health Study Research Group. The effects of a smoking cessation intervention on 14.5-year mortality: a randomized clinical trial. *Ann Intern Med*. 2005;142(4):233-239.
16. Cigarette smoking among adults—United States, 2000. *MMWR*. 2002:51(29);642-645. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5129a3.htm. Accessed December 15, 2010.
17. Fiore MC. US public health service clinical practice guideline: treating tobacco use and dependence. *Respir Care*. 2000;45(10):1200-1262.

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HEALTH LAW

The Role of Practice Guidelines in Medical Malpractice Litigation

Timothy K. Mackey, MAS, and Bryan A. Liang, MD, JD, PhD

Clinical Practice Guidelines (CPGs) play a dual role in medical malpractice claims. They can be used in litigation by an accused physician as a defense (exculpatory evidence) and by patients alleging a breach of the standard of care (inculpatory evidence). Establishing a breach in the standard of care is key in litigating medical malpractice claims under the negligence standard, in which a defendant physician attempts to assert that he or she has complied with the standard of care and a plaintiff conversely contends the acceptable standard was not met [1]. Studies have shown that CPGs have an impact on the outcomes of these cases [2].

Though CPGs may provide physicians with needed guidelines and consensus on care based on clinical evidence, the use of such guidelines in medical malpractice litigation is largely dependent upon state evidentiary practices and rulings [3]. Further, although CPGs may promote and standardize use of efficient and evidence-based clinical treatment, they may also limit physician autonomy and impose inflexible or unrealistic standards on clinical practice [4]. A brief examination of the juridical and legislative history of CPGs will show that these considerations need to be taken into account in medical tort reform efforts.

Learned Treatises Doctrine

The legal employment of CPGs is rooted in the early use of medical treatises in U.S. jurisprudence. In the 1923 case *Frye v. United States* [5], the court established that the admissibility of scientific evidence required "general acceptance" in the scientific community, leading to the possible use of medical treatises under this condition of admissibility.

As medical treatises became more accepted as evidence, much ambiguity arose regarding both what would qualify as admissible "scientific" evidence and, perhaps more importantly, how such treatises could be specifically used [1]. In 1949, the U.S. Supreme Court provided some guidance, holding in *Reilly v. Pinkus* that the applicability of medical treatises specifically extended to cross-examination or the impeachment of expert witnesses [1]. In 1975, the Federal Rules of Evidence were instituted and then adopted by many state courts, further expanding the scope of treatise use and allowing expert witnesses to employ them as direct substantive evidence supporting their testimony [1].

Finally, in 2000, the Federal Rules of Evidence, specifically Rule 702, were further revised. This revision set forth requirements that expert testimony be based upon

"reliable principles and methods" related to the clinical intervention at issue, in order to be construed as scientific knowledge and thus admissible [1]. This progression of the learned treatise doctrine opened the door for the use of CPGs as admissible evidence as a "learned treatise," which allows consideration and admission of CPGs as a "reliable authority" for use in expert testimony [6].

The Evolution of Clinical Practice Guidelines

CPGs originated as a means of improving the quality of care by attempting to bridge wide regional variation in clinical practice, balancing overuse and underuse of medical services, and providing a medium for communicating outcomes-based and cost-effective clinical practices to physicians [6].

CPGs have proliferated rapidly; they are used by many organizations involved in health care, including the federal and state government, professional medical societies, managed care groups, the insurance industry, other health care payors, and peer-review organizations [2]. They are also key to the U.S. government's efforts to enhance the quality of clinical care, judging by the Agency for Healthcare Research and Quality (AHRQ) investment in the development and dissemination of CPGs [7].

What we are learning, however, is that, in addition to varying in scope and quality, many CPGs (such as those created for utilization review by payors or those promulgated by specialty societies, which may conflict with other specialty societies' standards) are designed to meet the needs of the drafting organization, rather than defining a specific, applicable standard of care for every case. This has complicated the adoption of CPGs in establishing the standard of care in particular cases [6].

The Growing Costs of Medical Malpractice

Medical malpractice adds both directly and indirectly to the cost of health care [6]. Direct costs include insurance premiums, expenses for damages, litigation fees, and indirect costs including the practice of "defensive medicine," i.e., when physicians provide unnecessary tests and procedures in an effort to limit their liability [6].

It has been estimated, for example, that 10 percent of medical services cost is linked to medical malpractice litigation and defensive medicine practices; a study conducted by the Department of Human and Health Services estimated the direct cost of medical malpractice at 2 percent of health care spending [8]. A more recent study estimates the annual cost of medical liability and defensive medicine was $55.6 billion in 2008 [9]. To alleviate concerns about the cost of malpractice cases and payments, some medical malpractice tort reform efforts have led to pilot projects in which CPGs are used as standardized tools in assessing liability [1].

Trends and Variations

The scope and admissibility of testimony that relies on CPGs to define the standard of care or establish expert witnesses' credibility varies state to state. Increasingly, when considering testimony supported by CPGs, courts look to such factors as the type of case, the source of the guideline, the forum, the expert's own

acknowledgment of its relevance and reliability, and whether the expert's testimony is itself reliable [1]. Courts have also exercised their own discretion concerning the quality, relevance, and reliability of CPGs, rejecting guidelines that they consider prejudicial or that failed tests of impartiality [1]. This includes materials that may represent individual financial conflict of interests or ghostwriting, which can invalidate the integrity of scientific materials [10].

Importantly, there is a growing trend of CPG admissibility as an affirmative defense in malpractice suits, reversing earlier challenges in many states. For example, a cardiologist examined a patient complaining of chest pain and ordered a chest x-ray, resting EKG, and an exercise treadmill EKG. The physician then concluded that the patient did not require hospital admission. The patient died at home 3 hours later from cardiopulmonary arrest. His widow filed suit for medical malpractice, claiming the cardiologist breached the standard of care [11].

The trial court held for the physician based largely on guidelines created by the American College of Cardiology and American Heart Association that were introduced by the physician. The patient appealed; the appellate court affirmed the trial court. The appellate court found that the guidelines were recognized by a majority of experts as the standard of care for the profession. The court therefore concluded that CPGs were relevant and had authoritative power as substantive evidence in malpractice litigation [11].

Similarly, a plaintiff who was suffering from a partial blockage of her left common carotid artery underwent carotid endarterectomy and later suffered a stroke, resulting in permanent brain damage and disability. The plaintiff filed a malpractice suit, alleging that the physician had violated state informed consent law by not informing her of the availability of chelation therapy as an alternative treatment [12].

This case did not even go to trial. The lower court ruled in favor of the defendant's motion for summary judgment—a process in which the judge reviews materials and arguments for both sides and concludes there is no triable issue. The judge based the decision in part upon numerous guidelines introduced by the physician, including those issued by the American Medical Association, American Heart Association, American Academy of Family Physicians, American College of Cardiology, and American College of Physicians, all of which concluded that chelation therapy was not recognized as an acceptable treatment for coronary or other arterial atherosclerosis [12].

The patient appealed. In its ruling, the appellate court affirmed the lower court decision, permitting use of CPGs as a defense against plaintiff claims that physicians should use therapies not widely recognized by the medical community.

Malpractice Tort Reform

As the use of CPGs grows, tort reform incorporating them has been proposed in many forms. These include (1) the use of contracts by insurers to bind physicians and

patients to guidelines as a way of establishing the standard of care in the case of a future malpractice claim or a requirement for malpractice insurance or physician participation in managed care programs, (2) judicial notice, in which the court provides an impartial and court-appointed medical expert to establish the appropriate set of guidelines to be used as the standard of care in a case, and (3) using compliance with CPGs as an affirmative defense or safe harbor that can be used by physicians as exculpatory evidence [6].

The use of CPGs as exculpatory evidence has been given special scrutiny due to its use in the state of Maine as a statutory demonstration project in the 1990s [6]. Maine's Medical Liability Demonstration Project, undertaken to improve quality of care and reduce defensive medicine practices by encouraging compliance with CPGs, adopted 20 practice guidelines in four specialties (anesthesiology, emergency medicine, obstetrics and gynecology, and radiology) with the goal of reducing health care costs in areas burdened by costly malpractice claims [13]. Under the reform, physicians who adhere to these state adopted CPGs were provided an affirmative defense against medical malpractice claims, and the guidelines could not be introduced as inculpatory evidence [6].

Results, however, have not been encouraging. Studies that examined the impact of the project did not show significant reductions in defensive medicine practices or in malpractice claims, and the law's provisions had low utilization in court [6].

Furthermore, broader tort reform that provides such safe harbors may also cut the other way by interfering with clinical judgment. Mandated CPGs may unduly compel physicians to comply with such guidelines due to liability considerations even if they conflict with clinical judgment, potentially leading to adverse outcomes for patients [6].

Hence, the role of CPGs in malpractice tort reform may be limited. It has been argued that adherence to CPGs should not be the basis upon which liability is established, but instead should continue to be used only to support expert testimony [6].

Future Trends

The Patient Protection and Affordable Care Act passed by Congress in 2010 did not specifically address medical liability reform or the role of CPGs, but did authorize $50 million for demonstration projects to test alternative medical liability systems [14]. However, limitations of the legislation and the proposed demonstration projects have been the subject of criticism [15]. Recently, Peter Orszag, the former director of the Office for Management and Budget, advocated for the adoption of safe harbors for physicians who follow evidence-based guidelines, particularly in the context of comparative effectiveness research [16]. Blue Cross and Blue Shield Association, one of the nation's largest insurers, has also called for the creation of safe harbors from medical malpractice claims for physicians who follow guidelines established

through comparative effectiveness research [17]. How such proposals will use CPGs in legal review of patient injury claims will be an important concern.

Conclusion

The use of CPGs in medical malpractice has evolved over several decades of case law, legal precedence, and rules and regulations and is the source of continued debate. Key in this discussion is the appropriate use of CPGs to establish impartial and scientifically sound support for expert testimony. Future reform will need to address the challenges of balancing the advantages and disadvantages of CPGs as authoritative sources in establishing the standard of care both by the clinician and in the courtroom.

References

1. Recupero PR. Clinical practice guidelines as learned treatises: understanding their use as evidence in the courtroom. *J Am Acad Psychiatry Law*. 2008;36(3):290-301.
2. Hyams AL, Brandenburg JA, Lipsitz SR, Shapiro DW, Brennan TA. Practice guidelines and malpractice litigation: a two-way street. *Ann Intern Med*. 1995;122(6):450-455.
3. LeCraw LL. Use of clinical practice guidelines in medical malpractice litigation. *J Oncol Pract*. 2007;3(5):254.
4. Samanta A, Mello MM, Foster C, Tingle J, Samanta J. The role of clinical guidelines in medical negligence litigation: a shift from the Bolam standard. *Med Law Rev*. 2006;14(3):321-366.
5. *Frye v United States*, 293 F1013 (DC Cir 1923).
6. Mello MM. Of swords and shields: the role of clinical practice guidelines in medical malpractice litigation. *Univ of Penn Law Review*. 2001;149(3):645-710.
7. Agency for Healthcare Research and Quality. National guideline clearinghouse. http://www.guideline.gov. Accessed November 7, 2010.
8. Nussbaum A. Malpractice lawsuits are “red herring” in Obama plan. *Bloomberg Online*. June 16, 2009. http://www.bloomberg.com/apps/news?pid=newsarchive&sid=az9qxQZNmf0o. Accessed November 7, 2010.
9. Mello MM, Chandra A, Gawande AA, Studdert DM. National costs of the medical liability system. *Health Aff (Millwood)*. 2010;29(9):1569-1577.
10. Liang BA, Mackey T. Confronting conflict: addressing institutional conflicts of interest in academic medical centers. *Am J Law and Med*. 2010;36(1):136-187.
11. *Frakes v Cardiology Consultants, PC*, 1997 Tenn App 597 (Tenn Ct App 1997).
12. *Moore v Baker*, 989 F2d 1129 (11th Cir 1993).
13. US General Accounting Office. Medical malpractice: Maine’s use of practice guidelines to reduce costs. 1993. http://archive.gao.gov/t2pbat5/150172.pdf. Accessed November 7, 2010.

14. Patient Protection and Affordable Care Act, 42 USC 18001 (2010). http://frwebgate2.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=SiXmZL/1/1/0&WAISaction=retrieve. Accessed December 10, 2010.
15. Arvantes J. Health care reform law fails to provide remedies for medical malpractice. *American Academy of Family Physicians News Now*. October 20, 2010. http://www.aafp.org/online/en/home/publications/news/news-now/government-medicine/20101020tortreform.html. Accessed November 7, 2010.
16. Orszag P. Malpractice methodology. *New York Times*. October 20, 2010. http://www.nytimes.com/2010/10/21/opinion/21orszag.html. Accessed November 7, 2010.
17. Blue Cross health plans recommend institute to study treatments' effectiveness. *BNA Health Care Daily Report*. 2007;12(88).

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POLICY FORUM

The Role of Comparative Effectiveness Research in Developing Clinical Guidelines and Reimbursement Policies

Jason John Luke, MD

Since the passage of the American Recovery and Reinvestment Act in 2009 and, subsequently, the Patient Protection and Affordable Care Act in early 2010, there has been national attention on comparative effectiveness research (CER). Popular-media exposes have described the variability of medical care and costs throughout the United States. In the medical literature, CER has been put forth as part of the long-term solution for controlling health care costs. The Patient Protection and Affordable Care Act (Affordable Care Act) [1] established an independent, trust-endowed, not-for-profit corporation named the Patient-Centered Outcomes Research Institute (PCORI) to lead the U.S. government's CER efforts. The PCORI will conduct primary research and systemic reviews in coordination with federal agencies and will focus specifically on subpopulations of patients, such as minority groups, the elderly, and those with chronic diseases. This information will then be available for Medicare's use, as well as the public's. It is clear that CER will be influential in health care in the United States going forward, and understanding the role of this research in the development of guidelines, reimbursements, and day-to-day patient care will be important to both physicians and patients.

Broadly understood, comparative effectiveness research is a comparison of some form of health-related intervention with another, based on a predefined parameter such as survival, side-effect profile, quality of life, or other outcome. The Federal Coordinating Council for Comparative Effectiveness Research defines it as "the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in 'real world' settings" [2]. The interventions and strategies studied range from medicine and device comparisons to diagnostic testing, behavioral change and delivery system strategy analyses.

Not all efficacy research is CER. For example, comparing a new anti-cancer drug to a placebo in a large phase-III clinical trial may give a sense of whether the drug acts upon that disease. This would not be considered CER, however, given that the patient groups are highly selected, the treatment environment is controlled, and the comparison is to a treatment that is unlikely to be administered to a patient outside of the trial. Rather, one could employ the term "CER" if the effects of two different anti-cancer drugs were compared in a subpopulation of patients to assess whether one extended life or had fewer side effects. CER emphasizes intervention comparisons that are based in everyday practice and have particular relevance to

certain populations of patients. The Institute of Medicine has said that the purpose of comparative effectiveness research is "to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels" [3]. Even given these definitions however, CER has different significance to different groups.

No Direct Cost-Effectiveness Comparisons

The debate surrounding the inclusion of CER in the Affordable Care Act was well documented (e.g., in the furor over so-called death panels); eventually, a compromise limited the role of CER in the development of Medicare's reimbursement policies and regulatory decisions. In understanding the role of CER in Medicare and U.S. health care more generally, it is important to clearly separate CER from *cost*-effectiveness research like that undertaken by regulatory bodies in such countries as the United Kingdom. Cost-effectiveness research takes a comprehensive, lifelong approach to understanding the impact of an intervention, considering multiple factors such as length of survival and quality of life, and comparing the total cost of different interventions. CER also employs a comprehensive approach, but the quality of the intervention is judged solely on the basis of outcome parameters such as survival, quality of life, and so on. Cost can be considered as an outcome parameter but is not necessarily a component for comparison [4].

Several sections of the Affordable Care Act impose restrictions on the use of comparative effectiveness research by Medicare. For example, section 1182(e) states that the PCORI

> shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs [5].

Even further, the Act significantly limits the impact of CER, specifying that the PCORI "shall ensure that the research findings not be construed as practice guidelines, coverage recommendations, payment, or policy recommendations" [6].

What role is there, then, for cost measurement going forward and how will CER impact the individual physician's practice?

Though analysis of efficacy by cost is specifically disallowed by the legislation, generation of cost data is not. Thus, it is reasonable for this information to be available to the public. The cost analysis could then be undertaken by nongovernmental bodies such as professional societies, insurance companies, and patient advocacy groups. If the analysis influenced the development of professional guidelines, compendia listings, or routine patient care, it would eventually be reflected in Medicare reimbursement as standard-of-care treatment. Paradigms have been offered for incorporating both the quality of an intervention and its cost. Pearson and Bach, for example, suggest that, upon development of a new health care

intervention, Medicare could stratify the evidence supporting the intervention and reimburse based on whether there was an improvement, the outcome was comparable, or there was insufficient evidence to support the intervention. If evidence was insufficient, a fixed time period could be given to gather evidence that the intervention was either comparable to or an improvement upon the former treatment [7].

CER and Individual Physicians

CER's effects on individual physicians will become clearer over time. Already, guideline statements from respected sources—such as the American College of Chest Physicians and American College of Cardiology, to name two—are gaining prominence. Physicians rely on these guidelines in making daily treatment decisions, and the lay population uses them in understanding treatment and in malpractice litigation [8]. As an example of this, a recent survey of community oncologists and nurses noted that approximately 91 percent refer to medical guidelines when treating patients, though barriers to their use continue [9]. Furthermore, as the quality metrics become more entwined with insurer reimbursement criteria, payment to practitioners will probably be more closely tied to documentation of quality care, as demonstrated by adherence to guidelines influenced by CER. Understanding up-to-date CER will become even more necessary if the current reimbursement system eventually moves away from the fee-for-service model to any sort of bundled reimbursement, in which payment is tied to overall management of given conditions rather than to each procedure or intervention.

Conclusion

The issues of waste and variability of care throughout the U.S. medical system are well documented, and comparative effectiveness research has been proposed as a potential method to improve these problems. The Patient Protection and Affordable Care Act introduced a governmental approach to formalizing CER in the United States, which should soon begin generating patient-care-related information. While Medicare will not consider cost when analyzing these results, outcome data will be available to help individual physicians improve the quality of care for the population at large and for subpopulations.

References

1. Patient Protection and Affordable Care Act, 42 USC 18001 (2010). http://frwebgate2.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=SiXmZL/1/1/0&WAISaction=retrieve. Accessed December 10, 2010.
2. Federal Coordinating Council for Comparative Effectiveness Research. *Report to the President and Congress; June 30, 2009*. US Department of Health and Human Services. http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf. Accessed December 10, 2010.
3. Institute of Medicine. *Initial National Priorities for Comparative Effectiveness Research*. Washington, DC: National Academies Press; 2009.

4. Garber AM, Sox HC. The role of costs in comparative effectiveness research. *Health Aff (Millwood)*. 2010;29(10):1805-1811.
5. Affordable Care Act, 42 USC 18001, sec 1182(e) (2010).
6. Affordable Care Act, 42 USC 18001, sec 6301(d)(8)(A)(iv) (2010).
7. Pearson SD, Bach PB. How Medicare could use comparative effectiveness research in deciding on new coverage and reimbursement. *Health Aff (Millwood)*. 2010;29(10):1796-1804.
8. Samanta A, Mello MM, Foster C, Tingle J, Samanta J. The role of clinical guidelines in medical negligence litigation: a shift from the Bolam standard? *Med Law Rev*. 2006;14(3):321-366.
9. Association of Community Cancer Centers. Use of clinical practice guidelines in community cancer centers; 2010. http://www.accc-cancer.org/education/education-guidelines.asp. Accessed December 10, 2010.

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Rating Evidence in Medical Literature

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A 24-year-old medical student comes to your clinic having had purulent rhinorrhea for 14 days, preceded by symptoms of upper respiratory infection. She reports having facial pain, frontal headache, nasal congestion, fever, and overall malaise. Nasal endoscopy reveals inflamed nasal mucosa with significant edema bilaterally. There is purulent rhinorrhea in the left middle meatus. Both cheeks are tender to the touch. You prescribe a 10-day course of amoxicillin and daily use of an intranasal steroid spray. She agrees with the use of amoxicillin but questions your nasal steroid recommendation. She proceeds to ask you about the effectiveness of intranasal steroids as adjunctive therapy and the strength of reported evidence supporting this recommendation.

An eager learner observing a seasoned physician will often probe the origin of the physician's recommendation. Today's patients are encouraged to seek more education about their health. Thus, they are not shy about questioning their physician's recommendations. If the efficacy of an intervention has been established, how does it compare to available alternatives? How does one reach conclusions about the strength of relevant comparisons?

Evidence-Based Medicine

A concise and widely cited definition of evidence-based medicine (EBM) was formulated by David Sackett, one of its pioneers [1]. Sackett and colleagues define EBM as the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" [1]. In practice, the provision of compassionate EBM reflects the integration of evidence from research, wisdom from clinical experience, and respect for the patient's values and preferences, while recognizing existing circumstances [2, 3]. Most journals and specialty academies are dedicated to the continuous pursuit of high-quality studies and explicit grading recommendations in order to provide effective guidelines to physicians [4].

To understand the strength of guidelines and management strategies, one must be familiar with the different levels of evidence. The Oxford Centre for Evidence-Based Medicine (OCEBM) provides a popular scale for stratifying evidence from strongest to weakest on the basis of susceptibility to bias and the quality of the study design [5]. A modified and condensed version of the OCEBM scale is presented in table 1. A similar hierarchy is used by the U. S. Preventive Services Task Force in grading evidence [6, 7].

Table 1. Modified presentation of the Oxford Centre for Evidence-Based Medicine levels of evidence [5].

Grade of Recommendation	Level of Evidence	Type of Study
A	1a	SR (with homogeneity) of RCTs and of prospective cohort studies
	1b	Individual RCT with narrow confidence interval, prospective cohort study with good followup
	1c	All or none studies, all or none case series
B	2a	SR (with homogeneity) of cohort studies
	2b	Individual cohort study
	2c	Outcomes research, ecological studies
	3a	SR of case control studies, SR of 3b and better studies
	3b	Individual case control study, nonconsecutive cohort study
C	4	Case series/case report, poor quality cohort studies
D	5	Expert opinion, bench research

SR: systematic review; RCT: randomized controlled trial.

Randomized controlled trials (RCTs) are considered the gold standard in modern medicine for determining the efficacy of a treatment. Individual RCTs are level 1b evidence. Systematic reviews of homogenous RCTs are regarded as the highest level of evidence—level 1a. These systematic reviews consist of information synthesized from individual, well-designed RCTs where participants are similar and have equal chances of being assigned to an intervention group, a control group, or a placebo group. Systematic reviews of trials with blinded investigators and subjects (i.e., double-blinded RCTs) are even more desirable than reviews of non-double-blinded trials. These studies go through rigorous measures to eliminate bias, but they tend to be expensive and time-consuming.

In the case of our medical student, a literature search would reveal a published Cochrane Database systematic review of double-blinded RCTs. This review reported that intranasal corticosteroids (INCS) had been found to be effective as monotherapy or as adjunctive treatment when compared to placebo treatment for acute rhinosinusitis [8]. This review examined 475 studies but excluded 471. In the selected four studies, which had a robust total of 1,943 participants, those treated with INCS had earlier resolution or improvement of symptoms than those receiving a placebo. This systematic review selected high-quality, double-blinded placebo-controlled RCTs with homogenous design, clear reporting of outcomes, and an adequate number of subjects to establish clinical significance.

Cohort studies are considered level 2b evidence. In this design, a population (cohort) is defined according to the presence or absence of a variable that may potentially influence the occurrence of a specific disease. Cohort studies can be prospective or retrospective. In prospective cohort studies, people at risk for certain diseases are followed over time to investigate trends or risk factors in those who get the disease. Predictor variables are measured before outcomes occur. In retrospective cohort studies, the sample is defined and predictor variables are reported after the outcomes have occurred. Epidemiology studies that compare outcomes of people who had a certain exposure to unexposed subjects are examples of cohort studies.

Suppose you are counseling a 35-year-old woman whose husband is addicted to smoking tobacco about the risk of environmental tobacco smoke (ETS) on cardiovascular health. Because the deleterious effects of smoking tobacco are well-established, it would be unethical to perform a RCT to answer this question. An appropriate cohort study, such as one performed by Iribarren et al., would be the highest level of study that can be performed ethically and pragmatically to address the question in this scenario [9]. Iribarren et al. investigated the independent effect of exposure to environmental tobacco smoke (ETS) on the risk of stroke among 27,698 lifelong nonsmokers. They found that 20 hours or more a week of ETS exposure at home (compared to less than 1 hour a week) was associated with a 1.29-fold and a 1.50-fold increased risk of first ischemic stroke among men and women, respectively.

In matched-case control studies (level 3b evidence) investigators retrospectively evaluate two groups—one group with disease and the other without disease—with the intent of finding risk factors or trends. Subjects are matched for age, sex, and other demographics. For example, in a Swedish nationwide study, Lagergren et al. convincingly demonstrated that people who have weekly symptoms of esophageal reflux disease were eight times more likely to have adenocarcinoma of the esophagus than matched subjects without these symptoms [10]. In other words, these investigators looked for the prevalence of reflux (predictor variable) among subjects with confirmed esophageal adenocarcinoma (cases) and compared it to the prevalence of reflux symptoms in a sample of those who did not have adenocarcinoma of the esophagus (control).

A case report that provides information on the diagnosis, intervention, and outcome for a single individual is level 4 evidence. Case series—articles written about a series of patients with a specific diagnosis—are also regarded as level 4 evidence. Both case reports and case series describe characteristics of patients with certain diseases and may help identify questions for future research. These studies are ranked lower than other designs because of associated bias, lack of random sampling, the absence of controls or a comparison group, and heterogeneity of subjects. While these studies do not meet criteria necessary for achieving higher evidence level status, they are quite common in reporting outcomes in surgical specialties. Some diseases treated by surgical intervention (or nonintervention) do not lend themselves well to the higher level study designs previously mentioned. For example, performing sham surgeries for the sake of a controlled trial is ethically unacceptable. Systematic review of case series and case reports are helpful in identifying trends that lead to positive outcomes in diseases with high morbidity or that are treated surgically.

Grading Evidence in Medical Literature

Different specialty academies and journals have historically adopted unique systems to grade medical evidence and indicate the strength of disease-specific treatment guidelines [4, 6]. Grading systems arm physicians with information to help them make consistent, well-informed decisions and limit disparities in health care. Each system has its own shortcomings. A detailed explanation of the disadvantages of each system is beyond the scope of this article. (The reader is referred to a review

paper by David Atkins et al., which appraised six prominent systems for grading levels of evidence [6]).

In 2002, the Agency for Healthcare Research and Quality (AHRQ) conducted a review of available methodologies for grading the strength of a body of scientific evidence [11]. This review identified three important characteristics to consider in assigning a grade to studies: quality, quantity, and consistency. Quality, as discussed above, refers to the methodologic rigor or extent to which bias was minimized in a study. Consistency refers to the similarities in design, population, outcome, and data analysis in studies attempting to answer the same question. Quantity refers to the number of subjects in individual studies and number of studies included in reviews. Seven systems fully addressed these key elements [11].

Grading of recommendations is useful when there is a need for a consensus guideline regarding the approach to a particular disease. Systematic reviews report the levels of evidence present in given studies and then assign grades to recommendations from these studies that reflect the strength of the intervention and likelihood of a successful outcome. The OCEBM system has grades of recommendations. Under this scheme, a grade A is a strong recommendation for or against an intervention. After critical appraisal, well-designed level 1a to 1c studies tend to result in grade A recommendations, level 2a to 3b studies result in grade B recommendations, and recommendations derived from level 4 studies are typically labelled grade C. Level 5 studies or "troubling," "imprecise" studies at any level above 5 generate grade D recommendations (table 2). For example, recommendations from expert opinion without objective critical appraisal tend to be regarded as inconclusive and cannot be given a grade stronger than D.

Another popular grading system is the Strength of Recommendation Taxonomy (SORT) used by the journal of the American Academy of Family Physicians [4]. While the algorithms behind these systems are not identical, the outcomes are fundamentally similar. The simplified version in table 2 underrepresents the complexity of the system, and the reader is encouraged to peruse the algorithm behind these grading systems [4-6, 11].

Table 2. Similarities between the SORT and OCEBM grading systems.

	Grading System	
	SORT*	**OCEBM****
A	Recommendation based on consistent and good quality patient-oriented evidence	Consistent level 1 studies
B	Recommendation based on inconsistent or limited-quality patient oriented evidence	Consistent level 2 or 3 studies or extrapolations from level 1 studies
C	Recommendation based on consensus, usual practice, disease-oriented evidence, case series for studies of treatment or screening, and/or opinion	Level 4 studies or extrapolations from level 2 or 3 studies
D		Level 5 evidence or troublingly inconsistent or inconclusive studies of any level

*SORT: Strength of Recommendation Taxonomy
**OCEBM: Oxford Centre for Evidence Based Medicine

Final Comment

One must be careful not to adopt an inflexible approach of only applying recommendations of greater strength. The practice of evidence-based medicine is not "cookbook" medicine, and therefore the basis for patient care decisions should not be restricted to randomized trials or meta-analyses [1, 12]. There are uncommon diseases and complex pathologies that cannot be investigated with study designs that achieve levels of evidence higher than 3 or 4.

In returning to our case illustration, let us assume that our medical student actually has chronic rhinosinusitis with nasal polyposis. She was counseled by a previous otolaryngologist that a surgical polypectomy may be performed to achieve better control of her disease. You perform a literature search and find level 3 and 4 evidence that supports polypectomy as an option. Although the level of evidence is not any higher than 3 or 4, surgery is not necessarily an inappropriate recommendation for the patient. As discussed earlier, study design limitations are inherent to some situations and therefore the physician must make a "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" [1].

References

1. Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence-based medicine: what it is and what it isn't. *BMJ*. 1996;312(7023):71-72.
2. Dickersin K, Straus SE, Bero LA. Evidence based medicine: increasing, not dictating, choice. *BMJ*. 2007;334(Suppl 1):s10.
3. Burton MJ. Evidence-based medicine and otolaryngology-HNS: passing fashion or permanent solution. *Otolaryngol Head Neck Surg*. 2007;137(4 Suppl):S47-51.
4. Ebell MH, Siwek J, Weiss BD et al. Strength of recommendation taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. *Am Fam Physician*. 2004;69(3):548-556.
5. Oxford Centre for Evidence-Based Medicine. Levels of evidence. http://www.cebm.net/index.aspx?o=1025. Accessed December 15, 2010.
6. Atkins D, Eccles M, Flottorp S, et. al. Systems for grading the quality of evidence and the strength of recommendations I: critical appraisal of existing approaches; The GRADE Working Group. *BMC Health Serv Res*. 2004;4(1):38.
7. Hadorn DC, Baker D, Hodges JS, Hicks N. Rating the quality of evidence for clinical practice guidelines. *J Clin Epidemiol*. 1996;49(7):749-754.
8. Zalmanovici A, Yaphe J. Steroids for acute sinusitis. *Cochrane Database Syst Rev*. 2007;2:CD005149.
9. Iribarren C, Darbinian J, Klatsky AL, Friedman GD. Cohort study of exposure to environmental tobacco smoke and risk of first ischemic stroke and transient ischemic attack. *Neuroepidemiology*. 2004;23(1-2):38-44.
10. Lagergren J, Bergstrom R, Lindgren A, Nyren O. Symptomatic gastroesophageal reflux as a risk factor for esophageal adenocarcinoma. *N Engl J Med*. 1999;340(11):825-831.
11. West S, King V, Carey TS, et al. *Systems to Rate the Strength of Scientific Evidence*. Rockville, MD: Agency for Healthcare Research and Quality; 2002. Evidence Report/Technology Assessment series; no. 47.

12. Smith GC, Pell JP. Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomized controlled trials. *BMJ*. 2003;327(7429):1459-1461.

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MEDICINE AND SOCIETY
Is There Room for Art in Evidence-Based Medicine?
Richard Colgan, MD

John Arbuthnot served as physician to Queen Anne of England at the turn of the eighteenth century. He was careless about his business affairs and often let others take credit for his work. In doing so, he suffered financially. Upon the death of the queen, Arbuthnot lost his job, causing his friend, the writer Jonathan Swift, to lament, "he knew the art but not the trade." Two hundred years ago, as well as today, there is no higher praise for a physician than being said to know the art of medicine.

In this era of evidence-based medicine, clinical guidelines and outcome measures, one may wonder what has become of the patient-physician relationship? Whom do we serve: a review board, the insurance company, the public, or the patient? Whatever happened to the "art" of medicine? Is it lost? No, it is still here, being practiced every day by great healers, and by great I mean the nonfamous, Clydesdale-workhorse physicians. They are part of a long tradition of doctors who have understood that rigorous medical science and humane patient care share a common core: observation.

Evidence-based medicine is not, in fact, new. The "father of medicine," Hippocrates of Cos, advocated for the scientific investigation of patients' ailments, breaking away from the previously held belief that a person who was sick had displeased the gods. Although Hippocrates probably cannot take sole credit for the ideas in the *Corpus Hippocraticum*, from this compilation of his works we learn that he had more to say than "primum non nocere."

Hippocrates believed that good observation made physicians better prognosticators. His own observations were apt; some of his aphorisms have been borne out by modern medicine: "Pneumonia coming on pleurisy is bad" [1] and "Patients who are naturally fat are apt to die earlier than those who are slender" [1]. Hippocrates also advocated that physicians practice ethical behavior when caring for patients. Just as many physicians do today upon graduating from medical school, physicians of his day willingly took an oath committing to these practices.

Rhazes, one of the greatest physicians of the Middle Ages, was recognized for both his contributions to medical science and his dedication to the art of medicine. Rhazes strongly encouraged scientific inquiry, particularly the observation of patients. He challenged Galen's theory of the four humors and was later vindicated.

Rhazes not only promoted the practice of evidence-based medicine in the Middle Ages, but was known as much for his kindness and compassion to others as for his intelligence. He famously treated the impoverished sick free of charge, and was so troubled by poverty and suffering that he gave away his fortune and died in destitution.

Avicenna, another healer from the Middle Ages, was known for advocating the practice of observation and experimentation—to ethical ends. He wrote of the necessity of studying drugs before exposing the public to them. Furthermore, recognizing that many could not afford to see a doctor, he wrote self-help manuals so that the poor could have a practical resource for coping with health problems and cared for those who needed help at no cost.

The twentieth century also saw its share of great healers who knew both the art and the science, such as Canadian medical educator Sir William Osler and American educator Francis Weld Peabody. Peabody was director of the Thorndike Memorial Laboratory at Boston City Hospital during a time marked by astounding progress and discovery in the science and technology of medicine. Though an active researcher, Peabody exhorted physicians not to neglect the human elements of medicine; he felt that the "art of medicine and the science of medicine [were] not antagonistic but supplementary to each other" [2]. He wrote that "one of the essential qualities of the clinician is interest in humanity, for the secret in the care of the patient is in caring for the patient" [3].

History confirms that evidence-based medicine has been with us for a long time, and that evidence is never enough. From the time of Hippocrates forward, observation of the patient, the search for an imbalance of humors or other signs and symptoms, uncovered evidence of what the cause of the illness might be. Today, we have what might seem like a strange situation, in that the evidence that some physicians value most highly comes not from the patient but from lots of other people, e.g., participants in randomized controlled trials (RCTs), the so-called gold standard for evidence.

But in fact, this is in many ways traditional: the practice of evidence-based medicine is rooted in the observation of human beings both sick and well. The art lies in using those skills to assess whether the RCT evidence fits or does not fit the person sitting across from you in the exam room, taking into account the patient's biopsychosocial and spiritual makeup and the previous experiences of both the patient and the physician.

The question of whether or not the art of medicine has been lost is best answered not by looking outward to tally what percentage of today's physicians are scientists or artists of medicine, but by looking inward and constantly taking an inventory: "How am I doing? Could I do better? Did I do what was truly needed for this patient?"

I would like to think that I have learned the art of medicine, but I know that being a healer is not a destination but a journey. In the words of Robert Browning, I confess to you that "that which I strive to be and am not comforts me" [4]. As long as we continue to work towards being whole doctors, the art of medicine will remain very much alive.

References

1. Adam F, trans. *The Genuine Works of Hippocrates*. Vol 2. New York: W. Wood and Company; 1886: 283.
2. Peabody FW. *Doctor and Patient*. New York: The Macmillan Company; 1930: 29.
3. Peabody FW. The care of the patient. *JAMA*. 1927;88(12):877-888.
4. Browning R. Rabbi Ben Ezra. *The Oxford Book of English Mystical Verse*. Oxford: The Clarendon Press; 1924: 194.

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The Origins of Evidence-Based Medicine: A Personal Perspective, January 2011

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HISTORY OF MEDICINE

The Origins of Evidence-Based Medicine—A Personal Perspective

David M. Eddy, MD, PhD

Medical decision making has gone through a fundamental change in the last 40 years. Simply put, the foundation for decision making has shifted away from subjective judgments and reliance on authorities toward a formal analysis of evidence. In the past, treatments were recommended if physicians believed patients would benefit. Now, before recommending a treatment, physicians ask: what's the evidence?

What caused this change? Evidence-based medicine (EBM) as we know it today is the confluence of several related but initially separate lines of research, and everyone who participated in the movement has his or her own story. Mine began when I decided to drop out of residency in cardiovascular surgery to get a doctorate in engineering mathematics. One day in the fall of 1974, I was asked to give a talk on how physicians make decisions. I chose diagnostic mammography as the example, because Betty Ford and Happy Rockefeller had just been diagnosed with breast cancer. I planned to write out the decision tree I presumed their physicians had used, fully expecting to find strong evidence, good numbers, and sound reasoning that I could describe to my audience. But to my amazement I found very few numbers, no formal rationale, and blatant errors in reasoning. How could that be?

Perhaps it was because mammography was relatively new. I decided to look at a treatment that had been in use for more than 75 years—that for ocular hypertension. Tens of millions of people were receiving it; surely there would be solid trials to support those decisions. But there weren't. There were only eight controlled trials, all very small and poorly designed. But perhaps most startling, six of the eight trials showed that patients got worse with treatment, not better. I then tried to conduct a formal decision analysis of another treatment. Experts I consulted quickly pushed me away, saying that there wasn't sufficient evidence or data to do such an analysis. That clinched it. If there wasn't sufficient information to develop a decision tree, what in the world were physicians basing their decisions on? I then realized that medical decision making was not built on a bedrock of evidence or formal analysis, but was standing on Jell-O.

I wrote up the work on mammography as an informal report and sent it to some colleagues in 1975. I also submitted a paper to *JAMA* arguing that many widely used treatments and tests were in fact not backed by good evidence or reasoning, using ocular hypertension as the example. I received several letters and calls from ophthalmologists expressing their fury. The editors of *JAMA* said they would publish

the expose of ocular hypertension treatment, but recommended over the telephone that I not include the more general points about poor evidence. Because my main purpose was to call attention to the need for better evidence, not to embarrass ophthalmologists, I pulled the paper. It was widely circulated and debated in the underground, but never published. Indeed, few editors were willing to publish exposes of poor evidence and physician uncertainty in the early years, although some did [1-4]. The evidence about treatment of ocular hypertension was eventually published, but in the less-threatening context of screening [5].

Influencing National Guidelines

From that starting point, I worked to introduce formal analyses of evidence on several fronts. The unpublished paper on mammography somehow worked its way to the National Cancer Institute (NCI), which was working with the Blue Cross Blue Shield Association (BCBSA) to develop coverage policies for cancer screening. I was asked by the NCI and BCBSA to apply the methods I had described in the mammography report to analyze other screening tests. For that I built a mathematical model to analyze the appropriate use and frequencies of various tests (1976-1978). I know of no earlier documented use of formal evidence and analytical methods to design coverage policies.

The American Cancer Society learned of that work and asked me to help them rewrite its guidelines for cancer screening. It took 2 years to do the work and get it approved by the society's board. Again, I believe this is the first application of formal methods, evidence, mathematical modeling, and cost-effectiveness analysis in designing a national guideline. As the primary author of the report, I inserted a preamble:

> In making these recommendations, the Society has four main concerns: First, there must be good evidence that each test or procedure recommended is medically effective in reducing morbidity or mortality; second, the medical benefits must outweigh the risks; third, the cost of each test or procedure must be reasonable compared to its expected benefits; and finally, the recommended actions must be practical and feasible [6].

For me, these are the seeds of evidence-based medicine, although I didn't use those words in the report. The conclusions—such as 3-year Pap smears, no mammography screening for women under 50, no screening of smokers with chest x-rays—were very controversial, with wide coverage in the national media [7]. Because of the controversy, the society and I went on the road to defend the guidelines; over the next few years I gave well over 100 speeches promoting and defending the use of evidence and formal methods in medical decision making.

Rethinking Guidelines Altogether

The second arena in which I worked was formalization of the concept of guidelines. The discovery that decisions were not based on formal thinking about evidence and numbers raised the obvious question: What were they based on? Reading medical

textbooks and journals with that question in mind quickly led to the answer. Medicine was riddled with thousands of very simple "if-then" rules that are still used today. For example, "Treat to BP less than 140/90 mmHg or BP less than 130/80 mmHg in patients with diabetes or chronic kidney disease" [8]. The value of this type of simplification is clear: a physician doesn't have to think through evidence and numbers and make difficult tradeoffs; all he or she has to do is learn the rules of thumb. The difference between today and 1980 is that today's rules of thumb tend to be backed up by formal analyses [9] whereas three decades ago they simply appeared, with the unstated justification that they were "standard and accepted practice."

I wrote an article for the *New England Journal of Medicine* to draw attention to what I then called "clinical policies" (guidelines, maxims, dicta, indications and contraindications, recommendations) and their implications for the quality of care [10]. That paper was picked up by the Council on Medical Specialty Societies (CMSS), which held a national conference to push the idea of improving methods for clinical policies and guidelines. The CMSS asked me to conduct workshops to train specialty societies in the methods, which began in the late 1980s and resulted in a manual of methods [11].

The ideas and methods spread, receiving a big boost in 1993 when the Agency for Healthcare Research and Quality (then called the Agency for Health Care Policy and Research [AHCPR]) began its guideline program, which was later converted to evidence-based practice centers (1997). The ideas were publicized in the U.K. in 1991, when Richard Smith, then editor of BMJ, invited me to give a speech in Manchester and wrote a controversial editorial about it [12]. They became firmly planted with the founding of the Cochrane Collaboration in 1993.

Guidelines for Insurance Coverage

The third approach to promoting evidence-based medicine was reworking coverage policies. In 1984, BCBSA asked my help in creating a formal evidence-based process for determining whether new technologies should be covered. I worked with them to develop five criteria that every new technology must meet. The second and third criteria were that "scientific evidence must permit conclusions concerning the effect of the technology on health outcomes" and "the technology must improve the net health outcome." In addition to requiring evidence, these criteria introduced a crucial distinction between evidence for health outcomes (e.g., heart attacks) as opposed to physiological variables (e.g., blood pressure, cholesterol). These criteria are still in place and became the starting points for criteria developed subsequently by other organizations such as Medicare.

In the 20 years I served as the chief scientist of the Medical Coverage Advisory Committee to BCBSA(1984-2005), the most serious test of the criteria was use of high-dose chemotherapy and bone marrow transplant for breast cancer. Because of lack of evidence about health outcomes [13], insurance companies held the line against coverage for several years until many buckled under intense legal, political,

and media pressure. But the holdout enabled initiation of controlled trials that eventually showed the treatment to be ineffective.

Performance Measurement

The fourth domain was performance measurement, which was introduced by the National Committee for Quality Assurance in 1993. I was appointed to their Committee on Performance Measurement, and chaired the subcommittee on methods where we introduced criteria that performance measures must meet. The cornerstone was good evidence that improving performance on some care process or treatment target would actually improve health outcomes.

While all this was occurring, others were working on related ideas. Some of the most prominent endeavors were Archie Cochrane's book on the importance of controlled trials [14], Jack Wennberg's work on wide variations in practice patterns [15], Weinstein and Stason's paper on cost effectiveness [16], the founding of the Society for Medical Decision Making (1979), and studies from RAND showing high rates of inappropriate care [17]. The realization that fundamental changes were needed in medical decision making was occurring on many fronts.

"Evidence-Based" Enters the Lexicon

Although I had been using the term "evidence-based" in speeches and workshops at least since 1985, I first published it in a 1990 article about evidence-based guidelines [18]. This was part of a series of 28 articles I was writing for *JAMA* about guidelines, evidence, and costs [19]. The term then got a big push when David Sackett and his colleagues used it in the title of a paper they published in *JAMA* 2 years later [20]. As the subtitle of their paper implies ("A New Approach to Teaching the Practice of Medicine"), their focus was on medical education and individual physician decision making, not the design of guidelines, coverage policies, or performance measures. Furthermore, their definition of evidence-based medicine ("The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research" [21]) gave considerably more power to subjective judgment ("clinical expertise") than I was willing to accept in the criteria I had been developing for guidelines and other types of policies.

I felt it was important to make a distinction between the evidence-based policies I had been promoting and evidence-based individual decision making being developed by Sackett and his colleagues, and offered a unified definition [22]. Today, the great majority of the time, the term "evidence-based medicine" is used in the context of guidelines and other policies, not medical education or individual physician decision making. But despite these differences, there is no doubt that the paper by Sackett and colleagues helped propel the term into common usage.

Evidence-based medicine now has a life of its own, with scores of books, courses, programs, and even departments in medical schools dedicated to it. Current students and younger physicians now take for granted the requirement for evidence and

explicit formal analysis, barely knowing that this was not the case just a few decades ago.

References

1. Eddy DM. Probabilistic reasoning in clinical medicine: problems and opportunities. In: Kahneman D, Slovic P, Tversky A, eds. *Judgment under Uncertainty: Heuristics and Biases*. New York: Cambridge University Press; 1982: 249-267.
2. Eddy DM. Flying without instruments: analyzing medical policies by consensus and expert opinion. *John A. Hartford Foundation Bulletin*. Winter 1983.
3. Eddy DM. Variations in physician practice. the role of uncertainty. *Health Aff*. 1984;3(2):74-89.
4. Eddy DM. The quality of medical evidence: implications for quality of care. *Health Aff (Millwood)*. 1988;7(1):19-32.
5. Eddy DM, Sanders L, Eddy JF. The value of screening for glaucoma with tonometry. *Surv Ophthalmol*. 1983;28(3):194-205.
6. Eddy DM. ACS report on the cancer-related health checkup. *CA Cancer J Clin*. 1980;30(4):193-240.
7. Brody JE. Cancer society reports it finds some detection tests unneeded. *New York Times*. March 21, 1980:1.
8. Reference card from the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7). http://www.nhlbi.nih.gov/guidelines/hypertension/phycard.pdf. Accessed November 20, 2010.
9. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7). http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.htm. Accessed on November 20, 2010.
10. Eddy DM. Clinical policies and the quality of clinical practice. *N Engl J Med*. 1982;307(6):343-347.
11. Eddy DM. *A Manual for Assessing Health Practices and Designing Practice Policies*. Philadelphia, PA: American College of Physicians; 1992.
12. Smith R. Where is the wisdom? The quality of medical evidence. *BMJ*. 1991;303(6806):798-799.
13. Eddy DM. High-dose chemotherapy with autologous bone marrow transplantation for the treatment of metastatic breast cancer. *J Clin Oncol*. 1992;10(4):657-670.
14. Cochrane AL. *Effectiveness and Efficiency: Random Reflections on Health Services*. London: Nuffield Provincial Hospitals Trust; 1972.
15. Wennberg JE, Gittelsohn A. Small area variations in health care delivery. *Science*. 1973;182(4117);1102-1108.
16. Weinstein MC, Stason WB. Foundations of cost-effectiveness analysis for health and medical practices. *N Engl J Med*. 1977;296(13):716-721.

17. Chassin MR, Kosecoff J, Solomon DH, Brook RH. How coronary angiography is used: clinical determinants of appropriateness. *JAMA*. 1987;258(18):2543-2547.
18. Eddy DM. Practice policies: where do they come from? *JAMA*. 1990;263(9):1265, 1269, 1272, 1275.
19. Eddy DM. *Clinical Decision Making. From Theory to Practice*. Sudbury, MA: Jones and Bartlett Publishers; 1996.
20. Evidence-Based Medicine Working Group. Evidence-based medicine: a new approach to teaching the practice of medicine. *JAMA*. 1992;268(17):2420-2425.
21. Sackett DL, Rosenberg VM, Gray JA, Haynes RB, Richardson WS. Evidence-based medicine: what it is and what it isn't. *BMJ*. 1996;312(7023):71.
22. Eddy DM. Evidence-based medicine: a unified approach. *Health Aff (Millwood)*. 2005;24(1):9-17.

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Suggested Reading and Resources

Adam F, trans. *The Genuine Works of Hippocrates*. Vol 2. New York: W. Wood and Company; 1886: 283.

Agency for Healthcare Research and Quality. National guideline clearinghouse. http://www.guideline.gov. Accessed November 7, 2010.

Alibhai SM, Naglie G, Nam R, Trachtenberg J, Krahn MD. Do older men benefit from curative therapy of localized prostate cancer? *J Clin Oncol*. 2003;21(17):3318-3327.

American Cancer Society. Guidelines for the early detection of cancer. http://www.cancer.org/Healthy/FindCancerEarly/CancerScreeningGuidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer. Accessed December 9, 2010.

Andriole GL, Crawford ED, Grubb RL 3rd, et al. Mortality results from a randomized prostate-cancer screening trial. *N Engl J Med*. 2009;360(13):1310-1319.

Angelos P. The ethical challenges of surgical innovation for patient care. *Lancet.* 2010;376(9746):1046-1047.

Anthonisen NR, Skeans MA, Wise RA, Manfreda J, Kanner RE, Connett JE; Lung Health Study Research Group. The effects of a smoking cessation intervention on 14.5-year mortality: a randomized clinical trial. *Ann Intern Med*. 2005;142(4):233-239.

Arvantes J. Health care reform law fails to provide remedies for medical malpractice. *American Academy of Family Physicians News Now*. October 20, 2010. http://www.aafp.org/online/en/home/publications/news/news-now/government-medicine/20101020tortreform.html. Accessed November 7, 2010.

Association of Community Cancer Centers. Use of clinical practice guidelines in community cancer centers; 2010. http://www.accc-cancer.org/education/education-guidelines.asp. Accessed December 10, 2010.

Atkins D, Eccles M, Flottorp S, et. al. Systems for grading the quality of evidence and the strength of recommendations I: critical appraisal of existing approaches; The GRADE Working Group. *BMC Health Serv Res*. 2004;4(1):38.

Barak Y. The immune system and happiness. *Autoimmun Rev*. 2006;5(8):523-527.

Battista RN, Hodge MJ, Vineis P. Medicine, practice and guidelines: the uneasy juncture of science and art. *J Clin Epidemiol*. 1995;48(7):875-880.

Berrington de Gonzalez A, Mahesh M, Kim P, et al. Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Arch Intern Med*. 2009;169(22):2071-2077.

Biffl WL, Spain DA, Reitsma AM, et al. Responsible development and application of surgical innovations: a position statement of the Society of University Surgeons. *J Am Coll Surg*. 2008;206(3) 1204-1209.

Bill-Axelson A, Holmberg L, Filen F, et al. Radical prostatectomy versus watchful waiting in localized prostate cancer: the Scandinavian prostate cancer group-4 randomized trial. *J Natl Cancer Inst*. 2008;100(16):1144-1154.

Blue Cross health plans recommend institute to study treatments' effectiveness. *BNA Health Care Daily Report*. 2007;12(88).

Brenner DJ, Doll R, Goodhead DT, et al. Cancer risks attributable to low doses of ionizing radiation: assessing what we really know. *Proc Natl Acad Sci USA*. 2003;100(24):13761-13766.

Brett AS, McCullough LB. When patients request specific interventions: defining the limits of the physician's obligation. *N Engl J Med*. 1986; 315(21):1347-1351.

Brody JE. Cancer society reports it finds some detection tests unneeded. *New York Times*. March 21, 1980:1.

Browning R. Rabbi Ben Ezra. *The Oxford Book of English Mystical Verse*. Oxford: The Clarendon Press; 1924: 194.

Buetow S, Kenealy T. Evidence-based medicine: the need for a new definition. J Eval Clin Pract. 2000;6(2):85-92.

Burton MJ. Evidence-based medicine and otolaryngology-HNS: passing fashion or permanent solution. *Otolaryngol Head Neck Surg*. 2007;137(4 Suppl):S47-S51.

Cardis E, Vrijheid M, Blettner M, et al. Risk of cancer after low doses of ionising radiation: retrospective cohort study in 15 countries. *BMJ*. 2005;331(7508):77.

Carroll P, Albertsen PC, Greene K, et al. Prostate-specific antigen best practice statement: 2009 update. http://www.auanet.org/content/media/psa09.pdf. American Urological Association. Accessed December 9, 2010.

Chassin MR, Kosecoff J, Solomon DH, Brook RH. How coronary angiography is used: clinical determinants of appropriateness. *JAMA*. 1987;258(18):2543-2547.

Cigarette smoking among adults—United States, 2000. *MMWR*. 2002:51(29);642-645. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5129a3.htm. Accessed December 15, 2010.

Cigarette smoking increases colorectal cancer risk. *ScienceDaily*. December 3, 2009. http://www.sciencedaily.com/releases/2009/12/091203090103.htm. Accessed December 3, 2010.

Cochrane AL. *Effectiveness and Efficiency: Random Reflections on Health Services*. London: Nuffield Provincial Hospitals Trust; 1972.

Cooperberg MR, Cowan J, Broering JM. Carroll PR. High-risk prostate cancer in the United States, 1990-2007. *World J Urol*. 2008;26(3):211-218.

Davidoff F, Florance V. The informationist: a new health profession? *Ann Intern Med*. Jun 20 2000;132(12):996-998.

Dickersin K, Straus SE, Bero LA. Evidence based medicine: increasing, not dictating, choice. *BMJ*. 2007;334(Suppl 1):s10.

Ebell MH, Siwek J, Weiss BD et al. Strength of recommendation taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. *Am Fam Physician*. 2004;69(3):548-556.

Eddy DM. *A Manual for Assessing Health Practices and Designing Practice Policies*. Philadelphia, PA: American College of Physicians; 1992.

Eddy DM. ACS report on the cancer-related health checkup. *CA Cancer J Clin*. 1980;30(4):193-240.

Eddy DM. *Clinical Decision Making. From Theory to Practice*. Sudbury, MA: Jones and Bartlett Publishers; 1996.

Eddy DM. Clinical policies and the quality of clinical practice. *N Engl J Med*. 1982;307(6):343-347.

Eddy DM. Evidence-based medicine: a unified approach. *Health Aff (Millwood)*. 2005;24(1):9-17.

Eddy DM. Flying without instruments: analyzing medical policies by consensus and expert opinion. *John A. Hartford Foundation Bulletin*. Winter 1983.

Eddy DM. High-dose chemotherapy with autologous bone marrow transplantation for the treatment of metastatic breast cancer. *J Clin Oncol*. 1992;10(4):657-670.

Eddy DM. Practice policies: where do they come from? *JAMA*. 1990;263(9):1265, 1269, 1272, 1275.

Eddy DM. Probabilistic reasoning in clinical medicine: problems and opportunities. In: Kahneman D, Slovic P, Tversky A, eds. *Judgment under Uncertainty: Heuristics and Biases*. New York: Cambridge University Press; 1982: 249-267.

Eddy DM. The quality of medical evidence: implications for quality of care. *Health Aff (Millwood)*. 1988;7(1):19-32.

Eddy DM. Variations in physician practice. the role of uncertainty. *Health Aff*. 1984;3(2):74-89.

Eddy DM, Sanders L, Eddy JF. The value of screening for glaucoma with tonometry. *Surv Ophthalmol*. 1983;28(3):194-205.

Evidence-Based Medicine Working Group. Evidence-based medicine: a new approach to teaching the practice of medicine. *JAMA*. 1992;268(17):2420-2425.

Federal Coordinating Council for Comparative Effectiveness Research. *Report to the President and Congress; June 30, 2009*. US Department of Health and Human Services. http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf. Accessed December 10, 2010.

Field MJ, Lohr KN, eds; Institute of Medicine. *Clinical Practice Guidelines: Directions for a New Program*. Washington DC: National Academies Press, 1990.

Fiore MC. US public health service clinical practice guideline: treating tobacco use and dependence. *Respir Care*. 2000;45(10):1200-1262.

Frakes v Cardiology Consultants, PC, 1997 Tenn App 597 (Tenn Ct App 1997).

Frye v United States, 293 F1013 (DC Cir 1923).

Garber AM, Sox HC. The role of costs in comparative effectiveness research. *Health Aff (Millwood)*. 2010;29(10):1805-1811.

Hadorn DC, Baker D, Hodges JS, Hicks N. Rating the quality of evidence for clinical practice guidelines. *J Clin Epidemiol*. 1996;49(7):749-754.

Hasnain-Wynia R. Is evidence-based medicine patient-centered and is patient-centered care evidence-based? *Health Serv Res.* 2006;41(1):1-8.

Hoffman KE, Chen MH, Moran BJ, et al. Prostate cancer-specific mortality and the extent of therapy in healthy elderly men with high-risk prostate cancer. *Cancer*. 2010;116(11):2590-2595.

Hugosson J, Carlsson S, Aus G, et al. Mortality results from the Goteborg randomised population-based prostate-cancer screening trial. *Lancet Oncol*. 2010;11(8):725-732.

Hyams AL, Brandenburg JA, Lipsitz SR, Shapiro DW, Brennan TA. Practice guidelines and malpractice litigation: a two-way street. *Ann Intern Med*. 1995;122(6):450-455.

Institute of Medicine. *Initial National Priorities for Comparative Effectiveness Research*. Washington, DC: National Academies Press; 2009.

Iribarren C, Darbinian J, Klatsky AL, Friedman GD. Cohort study of exposure to environmental tobacco smoke and risk of first ischemic stroke and transient ischemic attack. *Neuroepidemiology*. 2004;23(1-2):38-44.

Jemal A, Ward E, Hao Y, Thun M. Trends in the leading causes of death in the United States, 1970-2002. *JAMA*. 2005;294(10):1255-1259.

Jemel A, Thun MJ, Ries LA, et al. Annual report to the nation on the status of cancer, 1975-2005, featuring trends in lung cancer, tobacco use, and tobacco control. *J Natl Cancer Inst*. 2008;100(23):1672-1694.

Jonsen AR, Siegler M, Winslade WJ. *Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine*. 5th ed. New York: McGraw-Hill Professional; 2002.

Lagergren J, Bergstrom R, Lindgren A, Nyren O. Symptomatic gastroesophageal reflux as a risk factor for esophageal adenocarcinoma. *N Engl J Med*. 1999;340(11):825-831.

LeCraw LL. Use of clinical practice guidelines in medical malpractice litigation. *J Oncol Pract*. 2007;3(5):254.

Liang BA, Mackey T. Confronting conflict: addressing institutional conflicts of interest in academic medical centers. *Am J Law and Med*. 2010;36(1):136-187.

Maugh TH. U.S. smoking rate hasn't changed, CDC says. *Los Angeles Times*. September 08, 2010. http://articles.latimes.com/2010/sep/08/science/la-sci-smoking-20100908. Accessed December 3, 2010.

McCann MF, Irwin DE, Walton LA, Hulka BS, Morton JL, Axelrad CM. Nicotine and cotinine in the cervical mucus of smokers, passive smokers, and nonsmokers. *Cancer Epidemiol Biomarkers Prev*. 1992;1(2):125-129.

Mello MM, Chandra A, Gawande AA, Studdert DM. National costs of the medical liability system. *Health Aff (Millwood)*. 2010;29(9):1569-1577.

Mello MM. Of swords and shields: the role of clinical practice guidelines in medical malpractice litigation. *Univ of Penn Law Review*. 2001;149(3):645-710.

Moore v Baker, 989 F2d 1129 (11th Cir 1993).

Newschaffer CJ, Otani K, McDonald MK, Penberthy LT. Causes of death in elderly prostate cancer patients and in a comparison nonprostate cancer cohort. *J Natl Cancer Inst*. 2000;92(8):613-621.

Nguyen PL, Chen MH, Renshaw AA, et al. Survival following radiation and androgen suppression therapy for prostate cancer in healthy older men: implications for screening recommendations. *Int J Radiat Oncol Biol Phys*. 2009;76(2):337-341.

Norman GR. Examining the assumptions of evidence-based medicine. *J Eval Clin Pract*. 1999;5(2):139-147.

Nussbaum A. Malpractice lawsuits are "red herring" in Obama plan. *Bloomberg Online*. June 16, 2009. http://www.bloomberg.com/apps/news?pid=newsarchive&sid=az9qxQZNmf0o. Accessed November 7, 2010.

Office of Surgeon General of the United States. The health benefits of smoking cessation: a report of the surgeon general. http://profiles.nlm.nih.gov/NN/B/B/C/T/. Accessed December 3, 2010.

Office of the Surgeon General of the United States. The health consequences of smoking–nicotine addiction; 1988. http://profiles.nlm.nih.gov/NN/B/B/Z/D/_/nnbbzd.pdf. Accessed December 3, 2010.

Office of the Surgeon General of the United States. The health consequences of smoking: a report of the surgeon general; 2004. http://www.surgeongeneral.gov/library/smokingconsequences. Accessed December 3, 2010.

Orszag P. Malpractice methodology. *New York Times*. October 20, 2010. http://www.nytimes.com/2010/10/21/opinion/21orszag.html. Accessed November 7, 2010.

Oxford Centre for Evidence-Based Medicine. Levels of evidence. http://www.cebm.net/index.aspx?o=1025. Accessed December 15, 2010.

Patient Protection and Affordable Care Act, 42 USC 18001 (2010). http://frwebgate2.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=SiXmZL/1/1/0&WAISaction=retrieve. Accessed December 10, 2010.

Peabody FW. *Doctor and Patient*. New York: The Macmillan Company; 1930: 29.

Peabody FW. The care of the patient. *JAMA*. 1927;88(12):877-888.

Pearson SD, Bach PB. How Medicare could use comparative effectiveness research in deciding on new coverage and reimbursement. *Health Aff (Millwood)*. 2010;29(10):1796-1804.

Peto R. Smoking and death: the past 40 years and the next 40. *BMJ*. 1994;309(6959):937-939.

Peto R, Darby S, Deo H, et al. Smoking, smoking cessation and lung cancer in the UK since 1950: combination of national statistics with two case-control studies. *BMJ*. 2000;321(7257):323-329.

Recupero PR. Clinical practice guidelines as learned treatises: understanding their use as evidence in the courtroom. *J Am Acad Psychiatry Law*. 2008;36(3):290-301.

Reference card from the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7). http://www.nhlbi.nih.gov/guidelines/hypertension/phycard.pdf. Accessed November 20, 2010.

Richardson D, Sugiyama H, Nishi N, et al. Ionizing radiation and leukemia mortality among Japanese atomic bomb survivors, 1950-2000. *Radiat Res*. 2009;172(3):368-382.

Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence-based medicine: what it is and what it isn't. *BMJ*. 1996;312(7023):71-72.

Samanta A, Mello MM, Foster C, Tingle J, Samanta J. The role of clinical guidelines in medical negligence litigation: a shift from the Bolam standard? *Med Law Rev*. 2006;14(3):321-366.

Sanda MG, Dunn RL, Michalski J, et al. Quality of life and satisfaction with outcome among prostate-cancer survivors. *N Engl J Med*. 2008;358(120:1250-1261.

Scalise D. Evidence-based medicine: pressured by payers and regulators, hospitals and physicians must transform yesterday's abstract concept into a nuts-and-bolts blueprint from how they deliver care. Hospitalconnect.com. Dec. 15, 2004. http://www.hhnmag.com/hhnmag_app/hospitalconnect/search/article.jsp?dcrpath=HHNMAG/PubsNewsArticle/data/0412HHN_FEA_Cover_Story&domain=HHNMAG. Accessed December 17, 2010.

Schroder FH, Hugosson J, Roobol MJ, et al. Screening and prostate-cancer mortality in a randomized European study. *N Engl J Med*. 2009;360(13):1320-1328.

Schwartz A. Evidence Based Medicine (EBM) and Decision Tools. MedEdPORTAL. http://services.aamc.org/jsp/mededportal/retrieveSubmissionDetailById.do?subId=209. Accessed December 15, 2010.

Schwartz A, Bergus GR. *Medical Decision Making: A Physician's Guide*. Cambridge, UK: Cambridge University Press; 2008.

Schwartz A, Hupert J. A decision making approach to assessing critical appraisal skills. *Med Teach*. 2005;27(1):76-80.

Schwartz A, Hupert J. Medical students' application of published evidence: randomised trial. *BMJ*. 2003;326(7388):536-538.

Schwartz A, Hupert J, Elstein AS, Noronha P. Evidence-based morning report for inpatient pediatric rotations. *Acad Med*. 2000;75:1229.

Schwartz A, Millam G. A web-based library consult service for evidence-based medicine: technical development. *BMC Med Inform Decis Mak*. 2006;6:16.

Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2008;149(3):185-191.

The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7). http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.htm. Accessed on November 20, 2010.

Shiverick KT, Salafia C. Cigarette smoking and pregnancy I: ovarian, uterine, and placental effects. *Placenta*. 1999;20(4):265-272.

Smith GC, Pell JP. Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomized controlled trials. *BMJ*. 2003;327(7429):1459-1461.

Smith R. Where is the wisdom? The quality of medical evidence. *BMJ*. 1991;303(6806):798-799.

Smith-Bindman R, Lipson J, Marcus R, et al. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. *Arch Intern Med*. 2009;169(22):2078-2086.

Straus S, Haynes B, Glasziou P, Dickersin K, Guyatt G. Misunderstandings, misperceptions, and mistakes. *Evid Based Med*. 2007;12(1):2-a-3.

Straus SE, Richardson SR, Glasziou P, Haynes RB. *Evidence-Based Medicine: How to Practice and Teach EBM*. 3rd ed. Edinburgh: Churchill Livingstone; 2005.

Sung JC, Kabalin JN, Terris MK. Prostate cancer detection, characterization, and clinical outcomes in men aged 70 years and older referred for transrectal ultrasound and prostate biopsies. *Urology*. 2000;56(2):295-301.

Tonelli MR. The philosophical limits of evidence-based medicine. Acad Med. 1998;73(12):1234-1240.

US Centers for Disease Control and Prevention. VitalSigns web site. http://www.cdc.gov/vitalsigns/TobaccoUse/Smoking/index.html. Accessed December 3, 2010.

US General Accounting Office. Medical malpractice: Maine's use of practice guidelines to reduce costs. 1993. http://archive.gao.gov/t2pbat5/150172.pdf. Accessed November 7, 2010.

US Preventive Services Task Force. Lung cancer screening: recommendation statement. *Ann Intern Med*. 2004;140(9):738-739.

Weinstein MC, Stason WB. Foundations of cost-effectiveness analysis for health and medical practices. *N Engl J Med*. 1977;296(13):716-721.

Wennberg JE, Gittelsohn A. Small area variations in health care delivery. *Science*. 1973;182(4117);1102-1108.

West S, King V, Carey TS, et al. *Systems to Rate the Strength of Scientific Evidence*. Evidence Report/Technology Assessment series; no. 47.
Rockville, MD: Agency for Healthcare Research and Quality; 2002.

World Health Organization. The Tobacco Atlas. http://www.who.int/tobacco/statistics/tobacco_atlas/en/. Accessed December 3, 2010.

Wyer PC, Silver SA. Where is the wisdom? I—a conceptual history of evidence-based medicine. J Eval Clin Pract. 2009;15(6);891-898.

Yesner R. Small cell lung cancer: sex and survival. *Arch Pathol Lab Med*. 2007;131(11):1631-1633.

Yoshinaga S, Mabuchi K, Sigurdson AJ, Doody MM, Ron E. Cancer risks among radiologists and radiologic technologists: review of epidemiologic studies. *Radiology*. 2004;233(2):313-321.

Young RP, Hopkins RJ, Smith M, Hograth DK. Smoking cessation: the potential role of risk assessment tools as motivational triggers. *Postgrad Med J*. 2010;86(1011):26-33.

Zalmanovici A, Yaphe J. Steroids for acute sinusitis. *Cochrane Database Syst Rev*. 2007;2:CD005149.

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