

Clinical Cases

## **Preoperative Screening: Medical or Legal Guidelines?**

### **Clinical judgment and experience often trump evidence-based practice guidelines in physicians' medical decision-making process.**

Commentary by Mark Tonelli, MD, and Erin Egan, MD, JD

Ms Wannamaker is tired of visiting the emergency department at her community hospital, but on this occasion, her abdominal pain is simply too excruciating to let it go. A working mother of 2, Ms Wannamaker is not apt to let a little stomach pain keep her down. With a sharp wit, she would be quick to tell you about her struggles and accomplishments over her 49 years of life. As Dr. James enters the room, she is happy at the sight of a familiar face and manages to let out a partial smile.

"Hello, Ms Wannamaker. I'm sorry we see each other again under these circumstances. How is your stomach today?"

"It's the same old thing, only worse this time. Still hurts on the right side, right about here," she says, pointing to the right upper quadrant. "And it happened again after I cheated on my diet the other day, you know, at the fast food place."

"How long has the pain been going on?" Dr. James asks.

"About a full day and then some. Plus I feel like I might throw up. Do you think it's related to those gallstones or that colic you talked about last time?"

"It just might be, but let's talk a bit more and then have a look..."

The only abnormal findings in Dr. James's physical examination include a slightly elevated temperature (37.9° C) and pain in the right upper quadrant upon palpation. The relevant blood test results are within normal limits. Dr. James, already aware that Ms Wannamaker's biliary colic might now be acute cholecystitis, orders an ultrasound examination that confirms the diagnosis.

"Ms Wannamaker, I'm sorry to tell you that we'll need to get surgery involved. As I mentioned last time, that gallbladder of yours needs to come out..."

To help his surgery colleagues, Dr. James begins the indicated treatment for acute cholecystitis and preoperative screening, as he often does. He adds an ECG and further blood work (eg, coagulation studies).

Later in the day, Dr. Thorp, the general surgeon, comes to discuss the case with Dr. James and concurs with the diagnosis. Somewhat glibly, Dr. Thorp mentions, "I see you're still ordering those coagulation studies for preoperative screening across the board. You know, we stopped doing that for patients without a suggestive medical history a while ago. For low-risk procedures, it's not worth it. Costs too much and is probably unnecessary."

"I know, I know. But like I said, it would only take 1 adverse event and 1 lawsuit to ruin a career. Someday you'll thank me."

**Commentary**

by Mark R. Tonelli, MD, MA

In this era of evidence-based medicine (EBM), Dr. James seems either very brave or very foolish to recommend a course of action that appears contrary to the best available evidence produced from clinical outcomes research. Certainly, if his decision to order coagulation studies for Ms Wannamaker stems only from force of habit, a decades-old pattern of practice that sends his unthinking hand over the lab order form producing an invariable pattern of checked boxes, his ordering would be indefensible. But Dr. James does have a reason for ordering the test, not one based on clinical research but on a concern regarding legal liability, should a bleeding complication occur with Ms Wannamaker's diathesis having been undetected prior to surgery. His reason is not a scientific one, certainly not evidence-based, but it cannot simply be dismissed out of hand. Rather, one must consider whether his reason for ordering the test is sufficient to outweigh, or "trump," the clinical evidence that suggests a contrary course of action.

Clinical judgment in medicine has traditionally been understood to involve different kinds of reasons and reasoning. The EBM movement has sought to make reasoning from empirical evidence, derived from well-designed clinical research, the preeminent and preferred form of clinical reasoning, initially de-emphasizing all others. But other kinds of medical knowledge exist and remain valuable [1]. Experiential knowledge, gained directly from the practice of clinical medicine, provides a direct and personal foundation for clinical practice. Similarly, the understanding of physiologic principles and adherence to a theory of disease and healing form another knowledge base that may influence clinical decisions. Each of these kinds of medical knowledge has strengths and weaknesses when invoked as a warrant for medical decision making. They differ in kind, not in degree, and none, including empirical evidence, necessarily takes precedence over the others. That is, empirical evidence is not necessarily more prescriptive or compelling than clinical experience or pathophysiologic rationale in any particular case. The importance of one over another varies depending on the specifics of the case at hand [2]. For instance, low tidal volume ventilation improves outcome in populations of patients with respiratory failure due to acute respiratory distress syndrome (ARDS). But if a particular patient with ARDS develops malignant ventricular arrhythmias each time the tidal volume is reduced and a respiratory acidosis develops, the clinician faces a compelling pathophysiologic reason not to reduce the tidal volumes in that patient despite the imperative of the empirical evidence.

Two other topics, in addition to these 3 different forms of medical knowledge, are important in considering any clinical decision. First, the preferences of the individual patient may be paramount. Even the best empirical evidence can only tell us what treatments are most likely to produce a specific outcome; whether that outcome is relevant to an individual patient—and worth the associated costs or burdens—requires an understanding of that person's goals and values. Second, one must always consider system features: the economic, logistic, legal, and cultural barriers or facilitators of care. The cost, availability, or legality of specific interventions may preclude use even in the setting of strong empirical and experiential evidence in support. For instance, studies that demonstrate that early revascularization with balloon angioplasty improves outcomes in myocardial infarction will be neither helpful nor prescriptive in a community that does not have the resources or personnel to operate a cardiac catheterization lab 24 hours a day. More subtly, the very system of health care delivery, as well as professional and societal values, may appropriately influence decisions regarding the care of individuals.

## **Expert Judgments**

Dr. James, presumably with full knowledge of the relevant research, has decided to act in apparent disregard of that empirical evidence in ordering coagulation studies on Ms Wannamaker. He does so invoking an argument based on the health care delivery system in which he operates. This system feature cannot simply be dismissed because it is not based on empirical evidence; rather it must be examined more carefully to see if it merits relegating that kind of evidence to secondary importance. Certainly Dr. James could support his decision by noting that the US legal system relies on the testimony of experts rather than empirical evidence, that the legal notion of standard of care bears no relationship to evidence-based guidelines, and that juries may award for the plaintiff in spite of evidence-based practice decisions [3]. And certainly the cost of a malpractice suit, in personal and financial terms, can be huge. Dr. James, given the system in which he practices medicine, can defend his choice as the most prudent. We might disagree with the relative weighting he assigned to the avoidance of liability, but no appeal to clinical outcomes research will likely be persuasive in changing his mind.

In the current era of evidence-based medicine, knowledge and understanding of the empirical evidence is absolutely necessary for the delivery of quality medical care. But such knowledge is not sufficient for optimal clinical practice. Rather, clinicians must continue to utilize all the forms of knowledge available to them, to solicit patient goals and values, to understand the relevant features of the system in which they practice. They must be able to negotiate these topics in a way that results in the best advice or treatment for an individual patient. Clinical judgment still demands complex reasoning skills. In the absence of sound clinical judgment, thoughtless adherence to the evidence or any other single source of medical knowledge will result in the practice of "cookbook" medicine.

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Mark Tonelli, MD, MA, is an associate professor of medicine in the Division of Pulmonary and Critical Care Medicine and an adjunct associate professor in the Department of Medical History and Ethics at the University of Washington, Seattle.

## Commentary 2

by Erin A. Egan, MD, JD

The exchange between Dr. James and Dr. Thorp highlights a common tension in medicine: how should clinical decisions be made? Dr. James is advocating a defensive strategy, while Dr. Thorp apparently favors adherence to clinical guidelines. Answers to several questions are essential for resolution of this tension. First, what is the basis for the development of the guidelines in question? Second, does adherence to guidelines have any legal effect? Third, does defensive medicine actually protect physicians from liability? Finally, what is the right thing to do?

Clinical guidelines are standardized protocols for evaluation or treatment. They may be very broad or specific to a particular manifestation of an illness, a particular clinical context, or a particular patient population. Ideally, guidelines are based on the best clinical evidence available. There are even guidelines for developing effective and reliable guidelines, emphasizing the importance of evidence in guideline development [1]. Both the Institute of Medicine and the American Medical Association have addressed the issue of quality guidelines as a policy matter [2,3]. Well-developed guidelines reflect the best evidence on the issue and base management or decision recommendations on the probability of generating the best outcome.

As Dr. James notes, some guidelines are developed for cost containment reasons, and other guidelines reflect more of a group consensus on an issue without a formal evidentiary basis. Because guidelines are developed for these disparate purposes, it is important for any clinician to be aware of the purpose and foundation of the guidelines in question. High quality, evidence-based guidelines attempt to distill out those clinical practices that generate the best outcomes; the guidelines attempt to formalize the results of an evidence-based medicine approach which is defined as the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" [4]. Therefore, the crucial initial step in the application of guidelines in clinical practice is to evaluate the guidelines themselves and determine what they will contribute to a particular clinical situation.

## Medical Guidelines and the Law

Guidelines do have legal relevance, although this is an area that is still poorly defined and evolving. Few legal cases

have actually involved use of guidelines. One search of all published cases in US courts between January 1980 and May 1994 found only 37 cases [5]. While this seems to indicate that guidelines are not a major influence in legal decisions, evidence indicates that attorneys rely heavily on guidelines in determining whether or not to file suit and whether or not to settle a suit before trial [6]. In addition, there is some evidence that lawsuits occur more frequently when physicians deviate from clinical protocols or guidelines, and in 79 percent of lawsuits where there was deviation from an existing guideline, that deviation was the main allegation in the lawsuit [7].

To establish how Dr. James and Dr. Thorp should be using guidelines to direct any aspect of Ms Wannamaker's care, the first issue is the source of the guidelines. There are several sources of guidelines for preoperative evaluation, some based on particular clinical scenarios like cardiac risk, some emphasizing cost control, and others emphasizing the evidence base for deciding which tests improve outcomes. If the guidelines Dr. Thorp is referring to are evidence-based guidelines created to facilitate high quality care, then Dr. James is less likely to be correct in thinking that deviating from them will protect the patient or himself.

After determining whether the guidelines apply to Ms Wannamaker and purport to further goals that Dr. James and Dr. Thorp value, Dr. James should be aware that most of the evidence regarding guidelines indicates that it is legally beneficial to follow guidelines, not deviate from them. Legal literature contains more extensive analysis of how to use guidelines to prove care was poor than how to use them to prove care was competent, but generally it is to the physician's advantage to show compliance with existing guidelines [6]. This does not mean that guidelines *must* be followed, and it does not mean that the law expects physicians to use guidelines in the place of clinical judgment. On the rare occasions that guidelines are used in legal situations, however, they are either used to allege negligence because a physician deviated from them, or offered as a defense to suggest that proper care was rendered by a physician because the care was in accordance with guidelines.

Dr. James is practicing defensive medicine by ordering tests that are not clinically indicated and offer no clear benefit to the patient but do offer a potential benefit to the physician if a problem occurs later. Another perspective on defensive medicine is that it does benefit the patient in the rare instance that an unexpected abnormality is detected in time to prevent an injury. Good evidence-based guidelines, however, assess outcomes; therefore, the guidelines should have an inherent determination of the safety or risk of the recommendations. Defensive medicine, practiced solely in the nebulous hope that someday it will save the provider from being sued, costs an estimated \$5 billion to \$15 billion annually [8]. When issues of justice in health care are as tangible and serious as they are in the United States today, increasing costs for purely hypothetical benefit is difficult to justify.

Guidelines are useful tools for synthesizing a large amount of information and evidence to solve a clinical problem. They promote the laudable goal of incorporating the best possible evidence into patient care decisions. Ultimately, however, patient care decisions should be based on the best interest of the patient, consistent with ethical standards. Evidence is one aspect of determining what is in the patient's best interest. Clinical judgment, technical factors, and the patient's wishes are additional and indispensable considerations. Making medical decisions to further the physician's own interest (protecting him- or herself from future liability) is not appropriate in light of the ethical considerations of beneficence and justice. Making poorly informed decisions in an effort to protect a patient from a rare complication is ethically appropriate but scientifically inadequate. Guidelines, when used properly by clinicians in their proper context and for their proper indications, resolve some of this scientific inadequacy and assist the physician in working with the patient to make the best treatment decisions.

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Erin Egan, MD, JD, is a clinical instructor in general medicine at Loyola University Medical Center and in the Neiswanger Institute for Bioethics and Health Policy at Loyola University Stritch School of Medicine.

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