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ADVANCING EMERGENCY CARE

Clinical Policies and Their Role in Risk Management and Liability

An Information Paper

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The U.S. system of medical liability attempts to achieve several goals. First it compensates patients who suffer the results of medical negligence (or simply adverse medical outcomes) and eventually acts to 'weed' out incompetent physicians and compensate victims. On a broader scale it attempts to improve patient care, though its ability to accomplish this goal is unlikely.[1] Physicians are frequent targets of malpractice claims, with an estimated 20% of physicians named in a suit each year. However, only a small percent of negligent injuries actually end up as claims; and only 17% of claims result from negligent injuries.[2] In spite of the low ratio of claims actually due to negligence, more than $28 billion is spent on litigation and defensive medicine. The current system does not work for either the plaintiff (who often must wait years for compensation where there was injury due to medical malpractice) or for the defense (for whom the stress of litigation is significant and at times career ending).

Standard of care and the use of expert witnesses is a relatively new concept in law. English law primarily allowed the witnesses to testify to the facts of a case, and any opinion introduced was that of the judge. Early experts were appointed by the court and were presumed to be unbiased. However in England and the U.S., the complexity of medicine and industry required experts outside the court. Frye v. U.S. introduced the concept of 'general acceptance' as a standard for admissible evidence.[3] This was actually a murder case in which an early version of a lie detector was used. The court would not admit the evidence as it was not generally accepted and ruled that such acceptance required its use/acceptance by some minimum number of 'experts.'

1975 Federal Rules of Evidence 702-5 provided guidance for expert witnesses.[4] Though these rules applied only to federal cases, they quickly were adopted in other venues. These rules allowed expert witnesses to express opinions gained from authoritative sources, personal beliefs and interpretations of data, unpublished data, etc. This has led to today's malpractice environment where we have the battle of the experts, with the expert who convinces the jury either with evidence or with argument often winning the case. Medical liability is about identification of incompetence and error, and about compensation to the victim. While juries are often swayed by the scientific evidence or by a cogent argument, they are also swayed by the human tragedy and desire to compensate a patient even when little or even no guilt is present.

Clinical guidelines have the potential for providing an unbiased 'expert witness.' Guidelines can provide a potential protection for both the patient and the physician. Guidelines that are produced by true experts, without bias, may provide improved patient safety and at the same time produce cost savings. In 1990 the IOM (in *Clinical Practice Guidelines: Directions for a New Program*) defined practice guidelines as: "… systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[5] In 2011, the IOM in *Clinical Practice Guidelines We Can*

Trust, updated the definition to: "Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."[6]

Within a few short years guidelines were created for a myriad of conditions by small groups of physicians, large specialty societies, industry and others. As described below there were several problems with early guidelines, some of which linger to today.

Guidelines are at times contradictory. Data is subject to bias in its collection and its interpretation within a guideline. Applying findings from a specific population or setting are not always applicable to another. Therefore, disagreement between experts is common. Some physicians argued their circumstances and experience so differed from particular guidelines that local modifications or exceptions of guidelines should be permitted, a position supported by the AMA.[7] It may not be possible to develop evidence based guidelines applicable to every clinical situation. The development of evidence based guidelines takes a considerable amount of time and effort.

Industry sponsored guidelines were common. Not surprisingly these often promoted specific treatments. But even early guidelines from professional societies were (and to some extent remain) biased. For example, a guideline from a surgical specialty produced by those who perform procedures, using surgical literature may support an operative approach, while a guideline from a medically based specialty would support a non-operative approach. In more recent years, more stringent rules for the creation of guidelines have removed some of the complaints about earlier versions. Professional societies create guidelines using professional methodologists who evaluate and weigh the evidence, and librarians who perform professional literature searches. Yet guidelines may still have some inherent problems. There may be conflicting guidelines between national organizations. Disagreement may exist within a committee evaluating the evidence. In the absence of high level evidence, lower grades of evidence may be used and recommendations must be made, with the lowest level of evidence being expert opinion or consensus of the group writing the recommendation. The leading experts in a field often are tapped to serve on these committees, but in today's world, these individuals often have some ties to industry and other conflicts.[8] In addition guidelines may become outdated as evidence accumulates, frequently prior to the next guideline revision.

Guidelines are negatively viewed by some as examples of 'cookbook' medicine without flexibility, despite evidence that checklists and other standardized aids have improved the safety of anesthesia. Physicians may still need to use clinical judgement to decide if the guideline is applicable to the clinical situation. The public is suspicious that guidelines are primarily driven by cost savings. And while individuals feel strongly that money is wasted by unnecessary testing, they may not view it as unnecessary when it is used by them or their family.

Nonetheless, guidelines play an important role in improving care to patients as well as potentially reducing costs by decreasing practice variation and preventing unnecessary tests. As the voice of 'experts' they could, and some would argue should, play a role in protecting physicians who follow the guidelines from malpractice suits. The argument could be made that appropriately vetted guidelines are a national standard of care, and that if followed should provide legal protection. Herein there lies a potential to decrease defensive medicine and possibly decrease the number of claims filed. The guidelines would provide a way to rapidly evaluate potential claims for their merit. They could also be used in claim defense.

However there has not been consistent acceptance of guidelines as expert opinion. In a JAMA article, a resident describes a case where the United States Preventative Services Task Force (USPSTF) guidelines

for PSA testing were followed and the discussion of shared decision making between the patient and physician was documented.[9] The PSA was not drawn, consistent with the guideline and the discussion, and the 53 year old patient was later discovered to have advanced and lethal prostatic cancer. The jury accepted that the physician followed the guideline and stated that instead of discussion the physician should have 'just done the test.'

Wickline v. State (California)[10] involved a physician who followed Medicare guidelines for length of stay. In that case, the physician followed the guidelines but stated he disagreed with them. While the court found that the physician did act within guidelines established by Medicare, they stated 'the physician who complies without protest when his medical judgement dictates otherwise cannot avoid his ultimate responsibility for patient care'.

Federal law creating Medicare Peer Review Organizations included a provision for immunity from civil liability for physicians 'in compliance with or reliance upon professionally developed norms of care and treatment.'[11] However that statute has never been invoked so it remains untested.

Several states have experimented with using guidelines to provide some degree of safe harbor for physicians who follow them. The state of Maine attempted to decrease the cost of defensive medicine by providing legal protection to physicians if they complied with guidelines created by their peers. Four specialties participated including emergency medicine, which included the NEXUS rule as one of the guidelines.[12] The demonstration project included a provision that guidelines could only be entered into evidence by the defense (though if entered, they could be challenged by the plaintiff). Failure to follow a guideline could not be initiated by the plaintiff. However after several years, this project was ended, as only 1 case used the guidelines as part of their defense. This may have been due in part to a reluctance of the defense to use a 'novel' argument, concerns that it raised the argument of 'cookbook' medicine, or perhaps cases with bad outcomes where guidelines were followed never were tried.

Other states including Florida, Vermont, Kentucky and Minnesota have all attempted similar rules, again without significant impact- no decrease in malpractice premiums, no decrease in healthcare costs. While many within the AMA have been supportive of guideline generation and reducing costs, it has not officially endorsed the use of guidelines as a defense.[11] There is concern among both legal and medical professionals of the 'snowflake theory', that no two patients are alike.

Physicians likely benefit from following guidelines. In addition to better patient outcomes, healthcare costs may be less and there may be some legal protection. There is also potential increased risk from not following a guideline. In a study of OB/Gyn cases, there was a six-fold increase in the risk of litigation among physicians who did not follow a guideline.[13] In a specialty such as emergency medicine, with a considerable heterogeneity in patient population and disease presentation, this risk of litigation is not a small concern.

The adoption of guidelines may also create a new breed of expert witness, one whose role is to claim or refute that a patient did or did not meet criteria to have their care dictated by a clinical guideline. While the creation of decision rules and the legal safe harbor would, in theory, be beneficial, it could create a new avenue for plaintiff attorneys to prove a guideline was not followed.

Cases that relate to guidelines may be resolved much faster since there is a way to rapidly evaluate a potential claim for their merit. It is likely that cases which fall under a guideline, and the guideline is followed, are screened out prior to filing or trial thereby decreasing the number of claims filed. In a study of closed cases in Oregon, use of guidelines as a defense would have changed a decision in favor of the plaintiff in just 1% of the 266 cases reviewed.[14]

Patients, in aggregate, benefit from care which follows guidelines. Also, the guideline could facilitate shared decision making between the physician and patient. However, guidelines may not provide for the best care for a given individual. Guidelines which cover the use of imaging provide an example where the good of the many may not be the good of the few. Patients with low pretest probability and negative d-dimers have a very low (but not zero) probability of pulmonary emboli. It is in society's best interest to limit the ionizing radiation and cost associated with CT scanning large number of patients in search of that final 1-2% of patients. Yet the patient who is in that small percentage, and the jury sympathetic to an injured party, may find the concept difficult to grasp. They may not see the exorbitant cost, the theoretical increase in future cancers, and the unnecessary testing/treatment for false positive scans as appropriate when faced with the injured party.

There may also be some risk for the individuals and the organizations who create guidelines. This is particularly true when there are conflicts of interest, and especially if those conflicts are not declared. Guidelines that conflict with those of another group, or that become outdated, are problematic. Wickline v. State (California) also found that third parties such as those who develop guidelines can be held liable.

ACEP currently produces several clinical guidelines each year, utilizing external librarians to perform literature searches and methodologists to rank the evidence. While experts in specific areas may have conflicts of interest, especially in the area of research funding, every attempt is made to declare and make public those conflicts. As of 2012, all clinical policies are open for public comment before they are finalized for Board presentation. Evidence presented in the comments is carefully reviewed and used to modify or sustain the proposed policy.

ACEP and other societies continue to explore the legality of safe harbors for physicians who follow rigorously developed, evidence based guidelines. But is it truly a safe harbor? Are they actually safe without legislation to back them up? The Saving Lives, Saving Cost Act introduced by Representatives Andy Barr (R-Ky) and Ami Bera (D-Ca) would provide for safe harbor at the federal level for physicians who adhere to guidelines.[15] Professional medical organizations that have published clinical practice guidelines could submit them to the Secretary of Health and Human Services who would then approve and publish the guidelines. Physicians could move state-level malpractice cases to the federal level. Evidence of adherence to the guideline would be established by an independent medical panel composed of three members who are experts in the relevant field of clinical practice.

The creation of safe harbors with evidence-based non-biased clinical guidelines may improve patient safety and our medical legal environment. It has the potential to improve doctor/patient communication with informed shared decision making. Defensive practices and provider practice variation may be reduced. But keeping the guidelines up to date may be a challenge. Development and implementation of guidelines involves time and cost but may be worth the effort in the long run.

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