

Clinical Standards in Medicine

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Medical negligence litigators seek to establish which clinical standards are pertinent to their case, define what these clinical standards are, and then set out to demonstrate how the clinical standards were not followed.

Historically, from the physicians' point of view, the issue of "clinical standards" has evoked much apprehension and concern. Physicians claim, and with some fervor, that creating specific standards of care can not be done because each patient is unique, the variables are often myriad and complex, and the deductive reasoning and creative process which leads to a successful diagnosis and treatment would be hindered. They further argue that clinical standards will ultimately increase physicians' liability exposure and thus will do more harm than good.

In spite of this, during the past four to five years the interest level has continually increased throughout the health care system in pursuing the development of standards of care and several dozen specialty boards are now actively involved in standards development. In the final analysis, carefully written standards may actually help physicians control and limit their liability risks. The current lack of formal standards introduces into malpractice actions a definite unpredictability. Formal standards, by contrast, define a set of expectations that are known in advance of a patient's evaluation. Compare this with the present situation in which each side supports or condemns the level of patient care in a retrospective manner.

Forces both inside and outside of medicine are responsible for the trend towards the development of clinical standards. Physicians have been motivated by their desire to establish acceptable levels of care within the various specialties. This ultimately homogenizes and standardizes the basic approach to patient's problems, is patient-centered, allows for the development of quality assurance and improvement programs, and demonstrates to the public that physicians as a group are concerned about the quality of care they provide to their patients.

Forces outside of medicine, however, are probably more potent than these internal forces at bringing increasing pressure to the issue of standards development. Malpractice carriers see the creation of widely-accepted clinical standards as one route towards reduced malpractice losses. Ditto for several states, including Maine and New Jersey, which have mandated the development of clinical standards because of their involvement in underwriting malpractice insurance plans.

The high cost of medical care has been a major motivating factor for third-

party payors to support the development of clinical standards. Likewise, the federal government is taking an increasingly active role in the genesis of clinical guidelines. Several agencies, including the Department of Health and Human Services, are being charged with the task of establishing many of these standards of care for specific medical problems, including, for example, back pain and depression.

The existence of clinical standards would enable malpractice litigators to be more selective in their choice of cases. In situations where a clinical standard was followed but where there was an adverse patient outcome, litigators would be less inclined to pursue the matter. In situations where deviation from clinical standards, the litigation process would still allow physicians to explain their reasoning and, in and of itself, is not de facto proof of negligence.

The actual development of clinical standards is complex, time consuming and expensive. In general, these standards should be developed by physician organizations, particularly the specialty societies utilizing appropriate ancillary input from administrators, economists, etc. They should be based on current information and clinical experience and be as comprehensive and specific as possible. They should be periodically reviewed and revised and widely disseminated.

The "standard" should be thought of as a guideline or parameter rather than something that should be adhered to at all times without exception. This more accurately reflects the reality of medicine where nothing is absolute. The "standard", therefore, is equivalent to a recommendation about the management of a particular problem. This definition is broad enough to provide a framework for the development of applicable, non-rigid approaches to clinical problems in medicine.

Potential limitations should be recognized and dealt with such as the possibility that a particular standard becomes obsolete because of new discoveries or advances; or situations where environmental factors such as disaster, overcrowding, or multiple high acuity emergencies negate the applicability of standard clinical policies. Likewise, policy standards can never supersede the physician's clinical judgement which must be taken as the final word in making patient care decisions. This is because of the immense number of clinical variables and continually changing circumstances in both stable and unstable patients with complex multifactorial systemic medical problems.

For maximum effectiveness and utility, it is clear that standards should be developed in the areas that place the patient at highest risk for death or debility. For the physician, these are often the areas of greatest liability. Also, it is important that standards are developed for common presenting complaints rather than for obscure uncommon entities. Finally, because cost-containment has become a central issue, clinical standards should also target

those conditions or situations that may result in high charges.

One of the first clinical problems targeted for standards development was Chest Pain. As a prototypic example of clinical policy development, the Specialty Board responsible for the development and implementation of this standard created three conceptual entities which can be applied to all clinical problems. They are "actions", "variables", and "findings".

Actions are defined as either "rules" (principles of good practice in most situations) such as ordering an electrocardiogram on an elderly patient with shortness of breath and severe chest pain, or "guidelines" (actions that should be considered but may or may not be performed depending on the patient, the circumstances, and a multitude of other factors) such as ordering imaging studies on any patient with chest pain. In those situations where a rule isn't followed, the physician would be required to document in writing his justification for its avoidance.

Understanding the difference between rules and guidelines made it possible to create a rational categorization of the patient's history and physical examination. Any patient presenting with chest pain, as a rule, should have a history taken which determines the character of the pain, any associated symptoms, and the patient's past medical history. As a rule, the physician must also perform a physical examination that includes vital signs, and both a cardiovascular and pulmonary examination.

For each of these rules, there are corresponding guidelines which may or may not be appropriate to act on. For example, under character of pain, it may or may not be useful to ask about the onset of the pain, the severity, the location, whether radiation occurs, its frequency, duration, similar previous episodes, precipitating or mitigating factors, its relationship to exertion, rest, movement or deep breathing and so on. It is clear to physicians that although this information is relevant for many patients presenting with chest pain, there are times when this information does not apply and has no real utility, such as the young otherwise healthy patient with fever who complains of chest pain only when coughing.

Similarly, there are no absolutes about what constitutes appropriate adherence to the guidelines for physical examination. A physician may decide, based on the overall clinical picture of the patient, to listen to the lungs, percuss the lungs, X-ray the lungs, assess the oxygenation of the lungs by doing pulse oximetry or arterial blood gases and so on. It would be left up to the physician to decide whether these things were or were not appropriate to do.

The decision to do or not to do is based on the "findings" for any given "variable". The variable is defined as a component of any aspect of the history, physical examination, lab analysis, differential diagnosis, or disposition. Examples would be the patient sex or age, the chest X-ray, or

the vital signs.

The finding is defined as the value of the variable, such as male, 64 years old, enlarged heart, and a rapid irregular heart rate.

Although this clinical policy standardizes the approach to evaluating chest pain, the researchers responsible for its development emphasized its limitations stating that the reality of medical practice is that the physician is often gathering data, performing interventions and making decisions simultaneously, sometimes within a short period of time. Once again, the clinical policy is a reasonable standardized approach to the evaluation of chest pain but can never supersede the physician's clinical judgement which, because of the immense number of clinical variables and continually changing circumstances, must be taken as the final word in making patient care decisions.

Clinical standard development is here to stay. Although they are a cause of consternation among many physicians because of their potential for use against physicians in medical malpractice lawsuits, they will, in the long run, help physicians continue to practice higher quality medicine, avoid malpractice, and more easily defend against frivolous or spurious lawsuits.

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