GUIDELINES FROM THE INFECTIOUS DISEASES SOCIETY OF AMERICA

Practice Guidelines for Infectious Diseases: Rationale for a Work in Progress

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The Origin of Guidelines

The originator of guidelines is difficult to determine. I used to believe that it was Moses and his Ten Commandments, a set of rules that have not achieved full implementation. Instead, I believe it all began with Hammurabi, the Mesopotamian King of Babylon [1]. A statesman and codifier of traditions, he wrote a code of 282 laws and guidelines and posted them throughout his kingdom. He ruled during the Middle Bronze Age, between 1728 and 1686 B.C., or ~500 years before the Mosaic Code was promulgated. Examples of the medical guidelines in the Code of Hammurabi are as follows:

Code 215: If a physician makes a large incision with an operating knife and cures it, or, if he opens a tumor (over the eye) with an operating knife and saves the eye, he shall receive 10 shekels in money.

Code 216: If the patient be a freed man, the physician receives five shekels.

Code 217: If the patient is the slave of someone, his owner shall give the physician two shekels.

Incidentally, Hammurabi's Code was probably the inspiration for Medicare's Physician Payment Review Commission as well as the pattern setter for managed care, namely, fee-for-service (code 215), health maintenance organizations (code 216), and Medicaid (code 217).

The Problem for Physicians

What is now happening to physicians has its precedents, but it is still a shock to the physician body politic. As managed care organizations assume a larger role in the control of medical care delivery, physicians are becoming further removed from the decision-making process. They have less influence over the determination of what care should be delivered. They have become expensive workers on the assembly line of health care production [2]. Because of the empowerment of third-party payers, downward pressure is being applied to the costs of physicians' services. Cost is the driver for many payers, with quality of care only a backseat passenger. To slow this trend, physicians need to take a more active role. Who knows better what quality is and what constitutes cost-efficient health care? Physicians should be in the forefront rather than in the background as radical changes in health care occur.

The emphasis in medicine must be redirected back to its roots. Cassel [3] reminds us that medicine, at its core, is a moral enterprise grounded in a covenant of trust. The covenant has been torn apart, and the physician's responsibilities have been degraded. Physicians have capitulated to these acts, paralyzed by a lack of consensus and fear of being left out by managed care. To return to their core interest—their patients' well-being—physicians need to be mindfully assertive in their leadership in healthcare matters. Physicians must provide the paradigm for quality and discriminant reduction in services to assure that the rapid move to cost reduction does not compromise quality and result in indiscriminate reduction in services [4]. Establishment of guidelines by the medical community can provide such a paradigm and prevent cost controls from cutting the quality of medical care.

Variation: Identification of the Cost-Quality Problem

How did physicians get to this point? Was it just the high cost of medical care or was there more? In the 1970s, investigators began to identify wide variations in clinical practice across the United States. The issue of whether these wide variations were indicative of a problem in the quality of care was raised. In a further elaboration on their concept of ''small area variation,'' Wennberg and associates [5, 6] showed 10 years ago that the hospital expenditures per citizen were $889 in Boston, compared with $451 in New Haven, Connecticut [5, 6]. Yet, the outcomes of care seemed to be the same. Was this cost difference due to overuse of services in Boston or underuse in New Haven? In the same year, Chassin et al. [7] reported geographic differences in the inappropriate use of medical procedures. What accounted for all these differences? If physicians had a better understanding of these differences, perhaps they might improve the scientific basis of clinical practice as well as their ability to contain the costs of care.

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After acknowledging variations in practice and that these variations lead to significant differences in the cost of care and perhaps the quality of care, what should be done? Should physicians attempt to decrease variation or should they accept it? While Winston Churchill wryly noted, ''the dominant lesson of history is that mankind is unteachable,'' physicians should try to show that this dictum doesn't apply to them nor to their use of guidelines. In fact, as several investigators have shown, most guidelines significantly improve the process and outcome of care after they are introduced [8–10]. Critical factors in successful use of guidelines include developing or adapting the guidelines for local use, targeting a specific educational intervention, and having a specific physician reminder at the time of need.

The Infectious Diseases Society of America (IDSA) Guideline Initiative

The guideline initiative established by the Council of the IDSA is an effort to place the Society in the forefront of determining cost-efficient, quality healthcare standards in the field of infectious diseases. This effort should help place physicians back at the fulcrum, where safe, cost-effective care is delicately balanced with the highest quality of care.

The IDSA Council created a Practice Guidelines Committee composed of IDSA members who also represented allied infectious disease societies; these members initially included John McGowan, Jr., (Society of Healthcare Epidemiologists of America), Patchen Dellinger (Surgical Infections Society), Richard Sweet (Infectious Disease Society of Obstetrics and Gynecology), Peter Krause (Pediatric Infectious Disease Society), William Martone (Centers for Disease Control and Prevention), Richard Wenzel (IDSA Council), and the author. New members have recently been appointed. They are Thomas Bleck, Donald Craven, Gary Doern, Woodruff English, II, Edward Kaplan, Mary Ann Kish, Michael Polis, Joel Ruskin, Robert Salata, Maria Savoia, Stephen Schoenbaum, Thomas Yoshikawa, and the author.

Guidelines are being developed for major areas of infectious diseases. The selection of initial topics are based on the high frequency of disease occurrence, the high cost of infections, the broad impact of the disease, general agreement on the scientific evidence, evaluability of the recommendation, wide variability in practice, and usability. They will be published in *Clinical Infectious Diseases* during the latter part of 1997 and during 1998 and will be available on the IDSA Web site at www.idsociety.org.

The efforts of the many IDSA members who are participating in this endeavor will be acknowledged as each guideline is published. The panel chairpersons and their subjects are as follows: Walter Hughes, fever and neutropenia; John Bartlett, community-acquired pneumonia; Alan Bisno, acute pharyngitis; David Williams, outpatient intravenous antimicrobial therapy; Anne Gershon and Pierce Gardner, pediatric and adult immunizations; Jack Warren, urinary tract infections; Wafaa El-Sadr, tuberculosis; Ben Luft, Lyme disease; Dennis Maki, intravascular catheter infections and vancomycin use; Barth Reller, use of the microbiology laboratory; Jack Sobel, fungal infections; and King Holmes, sexually transmitted diseases and reproductive health.

Standards for quality of care with respect to surgical-site infections, bacteremia, and a measles vaccine for healthcare workers have been published [11–13]. The guidelines for opportunistic infections in patients with AIDS, a collaborative effort with the Centers for Disease Control and Prevention and the National Institutes of Health, were published in 1995 and were updated in 1997 [14].

What is a Guideline?

To better understand the derivation, uses, and problems with guidelines, it is helpful to begin with definitions. *Practice guidelines* have been officially defined by the Institute of Medicine as ''systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances'' [15]. *Standards of quality* have been defined as ''authoritative statements of (a) minimum levels of acceptable performance or results; (b) excellent levels of performance or results; or (c) the range of acceptable performance or results.'' *Medical review criteria* are ''systematically developed statements that can be used to assess the appropriateness of specific healthcare decisions, services and outcomes.'' *Performance measures* or *indicators* are ''methods or instruments to estimate or monitor the extent to which the actions of a healthcare practitioner or provider conform to practice guidelines, medical review criteria or standards of quality.''

Good guidelines should be valid, reliable, reproducible, clinically applicable, and flexible. They should also be clearly written, multidisciplinary in origin, and periodically reviewed and updated. Guidelines should be evidence based where possible, rather than simply a summary of expert opinion. Evidence-based medicine has been described as ''the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients'' [16]. The word *conscientious* indicates that the evidence should be applied consistently to each patient for whom it is relevant [17].

This is an implementation issue that will be addressed later. The term *judicious use* refers to the application of clinical experience for balancing the risks and benefits of diagnostic tests and alternative treatments for each patient and includes consideration of a patient's underlying conditions and preferences. With these caveats in the definition, it is clear that this is not just cookbook medicine. The phrase ''current best evidence from clinical care research'' underscores that practitioners need to distinguish the best evidence from the studies that have been done on a subject. To accomplish this goal, it is helpful to have an expert group cull the literature on a topic and select and distill the best evidence for drawing their conclusions.

Hence, a guideline saves practitioners an enormous amount of work in determining the best care in a given situation. When the validity of guidelines are in doubt, there are guidelines for assessing guidelines [18].

In the IDSA guidelines, statements on the quality of the evidence and the strength of the recommendation will be shown. These statements will permit clinicians to determine whether the quality of the evidence is weak (i.e., based on expert opinion alone) or strong (i.e., based on randomized controlled trials) [19]. Comments about the strength of the recommendation will indicate how strongly the guideline panel feels about their recommendation.

Since physicians or other health care workers may not be able to read the entire document at the time, executive summaries will be provided at the beginning of each IDSA guideline to give readers a brief overview.

Who Uses the Guidelines Best?

Can the IDSA guidelines be used by anyone—infectious diseases specialists as well as primary care providers—and produce the recommended care? Current knowledge and extensive experience will almost certainly be necessary to successfully apply these guidelines. Because of these needs, their use by case managers and nonphysician directors of managed care organizations will be difficult.

Issues on guideline implementation can be examined by drawing examples from infectious diseases as well as other areas of internal medicine.

First, can any physician deliver the appropriate care, given the accepted standards or guidelines of care? Recent studies suggest that primary care providers may deliver suboptimal primary HIV/AIDS care [20]. Primary care providers do not routinely inquire about their patients' sexual practices, are unlikely to provide risk-reduction counseling, and may not pick up clues from a physical examination that suggest the presence of AIDS-related infections. Primary care providers with more experience are more likely to prescribe appropriate prophylactic therapies, screen for coinfections, administer vaccinations, and properly diagnose and manage *Pneumocystis carinii* pneumonia than their less-experienced colleagues. While it may not be necessary to have subspecialty training, the major factor for providing quality care is significant prior experience in delivering care to patients with AIDS.

How Do Clinicians Implement Guidelines?

The problems associated with implementing guidelines are beginning to appear in the infectious diseases literature. Classen et al. [21] studied the relation between the timing of surgical antibiotic prophylaxis and the likelihood that postoperative wound infections would develop [21]. Despite four decades of experience indicating that prophylactic antibiotics should be given within 1–2 hours of surgery, it still isn't being done uniformly. This omission results in a significant personal and financial cost to patients. Difficulty with implementing guidelines is not unique to this side of the Atlantic Ocean; it has also occurred in the United Kingdom with respect to the use of hepatitis B immunization among cardiologists who perform invasive procedures [22]. National guidelines for protecting health care workers and patients from hepatitis B have been established in the United Kingdom. Among those involved in performing invasive procedures, 20% were never vaccinated against hepatitis B. Among those vaccinated, one-third had not completed the series or had not had themselves tested for immunity. It has been found that there is little uniformity in screening patients for hepatitis B carriage before an invasive procedure and that the level of knowledge about the risk of infection is inadequate.

Acceptance of guidelines, of course, will enhance the implementation effort. Camins et al. [23] found that a higher percentage of health care workers (HCWs) accepted tuberculosis preventive therapy when a comprehensive tuberculin skin-testing program was instituted [23]. Nonphysician HCWs were less likely to complete preventive therapy than were physician HCWs (48% vs. 74%, respectively).

Difficulty with implementation is not unique to infectious diseases guidelines. When gastroenterologists were asked if they concurred with the American Cancer Society guidelines on screening for colon cancer with occult fecal blood testing [24], 67% said they did. They were then asked how many applied the guideline to themselves; only 38% said they did.

For optimal implementation, local health care providers need to pick a guideline and adapt it to their own institution's needs. Then they will believe that they had an important role in developing the guideline and will be more likely to implement it successfully. Next, they should test for compliance with the guideline. If compliance is poor, education and such interactive measures as computer checks should be provided. A few months later, providers should retest for compliance. Only by continuously applying the Deming-Shewhart cycle of ''plan-do-check-act'' will a guideline become fully implemented [25, 26]. Once full implementation occurs, providers can move forward to another area of concern.

Indicators: A Critical Assessment and Implementation Tool

To aid implementation, IDSA guidelines will have recommended indicators or performance measures to help physicians assess implementation of key aspects of a guideline. These can be applied in physicians' own health care settings to determine if compliance is adequate. If compliance is not adequate, there will be objective, quantitative feedback for providers to help improve compliance with the guidelines.

The definition of an indicator was described above. Indicators are the instruments that the Joint Commission on Accreditation of Health Care Organizations (JCAHO) will ask physi-

cians to use to evaluate infection control programs and other aspects of care [27, 28]. The JCAHO will provide many choices of indicator sets besides its own Indicator Measurement system. For the managed care industry, the National Committee on Quality Assurance has developed its own indicators, referred to as the Health Employers Data Information Set, which was issued in a third version in January 1997. The Healthcare Financing Agency is already using its own indicator set to examine care provided to Medicare patients. Indicators are and will continue to be assembled into report cards that compare healthcare at different institutions. Thus, it is important that physicians understand what indicators are and what they are not and have input into the development of indicators as they relate to infectious diseases.

Many types of indicators have been developed by the above organizations, including structural indicators, service quality/access indicators, appropriateness (of procedure performed) indicators, basic clinical indicators, sophisticated clinical indicators, functional status indicators, prevention/screening indicators, disease management indicators, health plan enrollee health status indicators, and financial performance indicators [29]. Infection control indicators, which are considered sophisticated clinical indicators, cover such areas as surgical wound infection rates, ventilator-associated pneumonia rates, and a comparison of primary bloodstream infection rates collected via concurrent surveillance vs. medical record abstraction. Medication-use indicators are also sophisticated clinical indicators that cover individualized dosage for aminoglycosides and creatinine clearance in patients >65 years of age, as well as the timing of antibiotic prophylaxis before surgery.

Indicators that are selected should be easily measurable and based on common conditions [30]. Risk differences should be readily identifiable and quantifiable. Examples of such risk differences include rates of surgical wound infection after coronary artery bypass surgery or differences in average blood pressures among treated hypertensive patients in two managed care organizations.

Length-of-Stay Guidelines

What should clinicians do with the Milliman and Robertson length of stay (LOS) guidelines [31]? These guidelines stipulate that patients with septicemia, for example, are allowed 2 days in the hospital; those with staphylococcal endocarditis, 4 days; those with community-acquired pneumonia and shock, 2 days; and those with diabetic ketoacidosis who are comatose, 1 day. The authors claim that these guidelines are actuarial determinations based on accepted clinical practices in California. The data, however, are not available for examination. As a result, these LOS guidelines have never been clinically validated; consequently, their reliability and clinical applicability are seriously questioned. Nevertheless, despite the inability to objectively verify their validity, physicians should be aware that they are being used by Blue Cross–Blue Shield payers in almost every state in the Union.

Legal Implications of Guidelines

After all this effort to develop guidelines for the practice infectious diseases, will physicians be undone by their conscientiousness? Will guidelines be used more as inculpatory or exculpatory evidence [32]? As pointed out by Gittler and Goldstein [33], so-called concrete written guidelines or standards are not used alone in court [33]. It is the expert witness' interpretation of the standards that is critical. And it is the jury's opinion of the credibility of the expert's testimony that will establish the standard of care in an individual court case.

Consequently, physicians need to appreciate that published practice guidelines are just that—guidelines. While these guidelines should be followed most of the time in specific clinical situations, they must still be tailored to the needs of individual patients. Deviations will occur, and the reasons should be described in patients' charts as part of the current ethic of careful documentation of care provided. Guidelines will help physicians make decisions, but they will not replace good clinical judgment.

The use of evidence-based practice guidelines should improve the practice of medicine. Such guidelines will clarify the standard by which the practice of medicine is measured and will encourage explanatory documentation when exceptions are made.

In summary, although reliance on guidelines may or may not reduce the frequency of litigation, the more significant impact of guidelines will come from a reduction in unnecessary services and procedures caused by a lack of common understanding of the most effective and efficient methods of providing medical care.

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