

CLINICAL JUDGMENT AND CLINICAL PRACTICE GUIDELINES

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Abstract

Clinicians make judgments under conditions of uncertainty. Decision research has shown that in uncertain situations individuals do not always act rationally, coherently, or to maximize their expected utility. Advocates of clinical guidelines believe that these guidelines will eliminate some of the cognitive biases that the practitioner may introduce into the medical decision-making process in an attempt to reduce its uncertainty. Other physicians have grave doubts about guidelines' application in practice. Guideline implementation lags well behind their development. Studies of practicing physicians and a survey of clinicians in one specialty and setting indicate that experienced clinicians may be implementing guidelines selectively. Many clinicians are concerned that guidelines are based on randomized trials and do not reflect the complexity of the real world, in which a decision's context and framework are important. Their reluctance also may be due to the difficulty of applying general guidelines to specific clinical situations. The problem will only increase in the future. The patients of the 21st century will be older and have more complex disease states. Physicians will have more patient-specific therapies and need to exercise more sophisticated clinical judgment. They may be more willing to use guidelines in making those judgments if research can demonstrate guidelines' effectiveness in improving decision making for individual patients.

Keywords: Clinical judgment, Practice guidelines, Decision making, Cognitive bias

Opinions regarding the extent to which guidelines should be implemented are split between guideline advocates and clinicians who have grave doubts about their application in practice. The goal for both views is improved clinical decision making.

Guideline advocates believe that the practice of medicine is evolving into an increasingly rational discipline that ultimately can be broken down into a series of algorithmic approaches (guidelines), formulated by panels of experts who will base their conclusions primarily on the results of randomized controlled trials. The experts will abstract the most up-to-date knowledge, suggest how it applies to clinical practice, and present clinicians with strategies that they can implement in their practice.

Beside assembling and disseminating information, guidelines may serve another function. They may help the clinician make more rational judgments. Clinicians make judgments under conditions of uncertainty (5;13). In assessing a patient, making a diagnosis, and deciding on a treatment, they must judge not only each possible outcome's desirability but also its probability of occurrence. Clinicians use their experience, training, knowledge, and consultations with colleagues to manage this uncertainty. Decision research has shown that

when individuals make decisions in uncertain situations, they do not always act rationally, coherently, or to maximize their expected utility. Human inference does not always follow the laws of probability. It tends to be systematically biased and error-prone (20). A small number of heuristics (i.e., aids to problem solving or “helpful rules of thumb”) (37) mediate judgments and interfere with rational decision making (31). Common heuristics include being “influenced by what is similar (representativeness), comes easily to mind (availability) and comes first (anchoring)” (19).

From the standpoint of the decision researcher, clinical guidelines may serve to remove some of the uncertainty in the medical decision-making process. At the same time, they may eliminate some of the common heuristics and biases that the practitioner may unwittingly introduce into the situation in an attempt to reduce its uncertainty. A reduction in uncertainty may have cost as well as outcome implications. A study of resource use in a Medicare health maintenance organization (HMO) found that each standard deviation increase in anxiety due to uncertainty on the part of physicians corresponded to a significant 17% increase in mean charges (1).

A second group of clinicians has a very different outlook. These clinicians believe that since each patient is unique, the practice of medicine is as much an art as it is a science and cannot be reduced to a finite number of directives. Practicing clinicians generally believe that they possess, by virtue of their training and experience, a degree of clinical judgment that allows them to attend to each patient’s unique set of problems, to get to the heart of each clinical problem, and to process simultaneously a multitude of variables that a guideline would address in a clumsy and stilted manner. They believe that guidelines are often helpful to beginners and the inexperienced and can be useful to experienced clinicians when they encounter a patient outside their area of expertise. On the other hand, guidelines do not cover every situation. If inexperienced physicians do not recognize that a guideline does not apply to a particular patient or to complex disease states or to patients with multiple comorbid conditions, the guideline may send them off on the wrong tack. Clinicians are worried that in spite of these concerns, medical societies, HMOs, and governmental agencies, by applying subtle and not-so-subtle pressures to ensure compliance, will force practicing physicians to follow guidelines in all but the most extraordinary circumstances.

For guidelines to counteract judgment biases, clinicians must use them consistently. Research on implementation appears to indicate that when not forced by external constraints to adhere to medical guidelines and practice parameters, many physicians ignore them (6;11;18;35). Studies of actual physician decision making raise the question of what factors underlie clinicians’ reluctance to follow guidelines. Is it attributable to a nonrational approach to decision making or the converse, a rational recognition by practicing clinicians that most of their real-world situations are not addressed in the guidelines? Most physicians are fiercely independent and do not like to be regimented or to be told that there is only one acceptable approach to treatment. Are those who do not follow guidelines acting from a conviction that the guidelines are not applicable, are they acting from a desire to craft their own approach to each patient and not follow the dictates of an impersonal panel that cannot know the specifics of the case, or are they unaware of the guidelines and would follow them if guideline dissemination was improved?

This paper will first review some of the cognitive biases that have been shown to interfere with rational decision making in general and medical decision making in particular. It will then consider implementation issues through a review of the literature and an informal survey of practitioners. The survey assessed reasons for nonadherence to the guidelines as well as their degree of implementation. The results of the review and survey will serve as a basis for discussion of the question of why—when guidelines are designed to help clinicians make more informed and rational decisions—many physicians seem to ignore them. Finally, the

implications of conflicts between clinical judgment and practice guidelines for the practice of medicine in the 21st century will be addressed.

COGNITIVE BIASES AND MEDICAL DECISIONS

Some of the situations that lead to biases and that have been shown to influence medical judgments include:

- The framing of the problem (10;33);
- The tendency to ignore unspecified possibilities (39);
- The inclination to respond with inaction when faced with multiple options (40);
- The tendency for additional options to shift preferences among the original options (41); and
- The tendency to neglect the base rate of the disease in the population (42).

These biases will be discussed in more detail below.

Framing

Framing refers to the context in which an issue or problem is presented. A framing effect is an “induced shift in reference level” (43). Although the concept of rational choice implies that decisions should not alter with changes of frame, relative desirability of options frequently does change with a change in perspective. Framing is a frequently studied problem in medical decision making (43). A literature review reported finding 44 relevant papers and 12 trials (32). Preferences often depend on the method used to report data (4). In six of seven articles (32), presenting treatment benefits in terms of the relative instead of the absolute risk reduction was significantly more likely to result in a “treat” response, and presenting adverse treatment effects in relative terms resulted in their being viewed more negatively (32). In a study that presented the same trial results in five different formats, as if they were from different drug trials, clinicians were more likely to say they would prescribe the drug when the results were reported in a relative risk format (4).

Presenting information in terms of gain or loss also influences physician judgment. One study presented the outcomes first in terms of the probability of dying and then in terms of the probability of living. Nearly twice as many subjects chose the therapy in the mortality frame (42% versus 25%), and this distinction held for graduate students, patients, and physicians (33). Another study of framing showed that physician choice of a therapy to prolong life expectancy may be influenced by the format in which the life expectancy information is presented. The physicians rated more highly a therapy that was presented as extending life expectancy for 2 years for 15% of their patients and not extending life for the other 85%, compared to an equivalent therapy that on average extended life by 15 weeks (29).

The effects of experience on framing are mixed. Presenting options in a positive frame (survival) instead of a negative frame (mortality) influenced less experienced physicians to choose a more aggressive or risky therapy (10). No differences were found between physicians who had been in practice for less than 10 years and those who had been in practice longer (4). In another study, more experienced physicians and those who worked in public hospitals were less susceptible to framing (32). In a study of the intentions of family physicians to prescribe hormone replacement therapy, the presence of serious potential adverse treatment effects also minimized the effects of framing (36).

Unspecified Possibilities

Theory states that the probability of a hypothesis and of its complement must add to unity. Therefore, the probability of a hypothesis should not be changed if it has a single alternative

or five, but when five alternatives were bundled together and labeled “none of the above” to create a single alternative, the decision maker was more likely to overestimate the likelihood of the original alternative (39). When physicians were given brief clinical scenarios and asked for probability assessments, they tended to minimize possibilities that were not described. Specifying what was the complement of the first hypothesis, as opposed to bundling it in a category called none of the above, may have served to remind the physicians of alternatives that they overlooked (39).

Multiple Alternatives

A study of medical decision making in situations with no easy answers compared choices between two options and then between these same options expanded to three (40). The investigators found that even when the third option was not chosen, adding a third alternative increased the difficulty for the decision maker. In many cases, having a third alternative served to shift the decision maker’s preferences between the original two options or increased the tendency to choose one distinctive option or even delay making a decision. A third alternative may lead a physician to maintain the status quo and not offer any treatment (40).

Base Rate of Disease in the Population

In another study of physician decision making, pediatricians’ lack of knowledge of epidemiologic facts, such as the prevalence of a particular disease, the probability of a patient having the disease, and the effectiveness of a particular treatment, did not explain deviations from “rational” strategies. The authors hypothesized that the clinicians may have had difficulty applying general epidemiologic knowledge to decisions about individual patients. This difficulty was an example of the cognitive bias of base rate neglect (42), in which decision makers do not incorporate the prevalence of the condition in the general population into their assessments of the probability of a specific patient having the condition. In Bayesian terms, the decision makers were insensitive to prior probabilities (44). For instance, 10 patients of 1,000 may have had the symptom of a disease and 8 of those 10 may have had the disease, while 95 of the 990 patients without the symptom may have had the disease. The probability of a patient having the disease and having the symptom was not 8 of the 10 who had the symptom or 80%, but 8 of all 103 who had the disease, or 7.8% (21). Another researcher points out that the base rate of a condition in the general population may be different from the base rate in a particular practice. For example, while the base rate in the population in the previous example was 103 of 1,000, or 10.3%, the base rate in a physician’s practice could be 1% or 20%. On the other hand, if the physician’s recent experience was 20% and the rate in his practice was 20%, he would not be ignoring local population base rates if he assumed a 20% prevalence as opposed to 10%. Physicians may be responding to their practice base rate as opposed to the population base rate, and their recent experiences may be similar to the practice base rates but not the population base rates. To measure whether a decision is unduly influenced by a physician’s recent experiences, it is necessary to know the base rate in his or her practice as well as recent experiences (38).

ARE GUIDELINES FOLLOWED IN PRACTICE?

Dissemination

For guidelines’ implied promise of reducing physician uncertainty during clinical decision making to be fulfilled, a physician must at least be willing to consult them. Unfortunately, guideline implementation lags well behind development (45). Dissemination involves such passive activities as publication in specialty journals and direct mailings to the members of the organizations that developed the guidelines. A survey of 55 organizations participating

in a workshop on clinical practice guidelines found that over half did not try to ensure implementation, while a third delegated the task to committees. Most dissemination, 85%, was through direct mailing to members and publication in journals or newsletters. These methods are the least effective means of dissemination. Without follow through, guidelines may be disseminated but not implemented. Other popular forms of dissemination were through organizing conferences or workshops (74%), sponsorship of research (49%), and training of influential educational leaders (44%). Only a third of the organizations disseminated guidelines through computer technology and only a quarter used such active tactics as face-to-face visits and audits, feedback, reminders, and prompts (8). These last measures are the most effective forms of implementation (12;25;35).

Implementation

Once guidelines are disseminated, the next question is whether physicians use them and, if so, what effects the guidelines have on practice. A survey of 3,000 Canadian physicians found that, while they were positive about guidelines developed by clinicians, they had not yet integrated them into their practices (27). A 1993 review of 59 published evaluations of clinical guidelines found that in general they improved clinical practice, but the size of the improvement varied from very small to, at most, moderate (22). A more recent survey of a random sample of practicing pediatricians from the AMA master list found that awareness of four different pediatric guidelines was not consistent. It ranged from 66% for hyperbilirubinemia in the newborn to 16% for preventive services. In those aware of the guidelines, reported rates of changing behavior to follow guidelines were much lower, ranging from 19% to 36% (9).

A cross-sectional study using unannounced standardized patients who presented themselves to family practices in Ontario found that prevention guidelines were incompletely integrated into clinical practice (28). In contrast, a prospective intervention study measuring implementation of pneumonia practice guidelines in an emergency department (ED) found much greater use and acceptance of the content of the guideline. Using a validated prediction rule, a study nurse risk-stratified patients presenting with pneumonia and gave this information to the ED physicians. In 52% of the cases, the physicians rated their patients' mortality risk the same as the guidelines. Over 70% of the physicians found the mortality and triage information in the guidelines helpful and had positive opinions about the guideline's value, but these favorable attitudes did not generalize to other guidelines (24). The article did not discuss whether the presence of the study nurse and her activities could have increased awareness of the guidelines and biased the results.

Physicians' Reasons for Nonadherence to Guidelines

There are many published surveys of physicians' attitudes or reasons for nonadherence to medical guidelines. Only a few studies have explored in detail why physicians do not adhere to specific clinical practice guidelines when they treat individual patients. A primary reason may be that physicians disagree with the recommendations. For example, the Joint National Committee and the World Health Organization guidelines for treatment of uncomplicated essential hypertension recommended diuretics and beta-blockers as first-line therapy, but a meta-analysis of studies on the use of beta-blockers in the elderly found, despite lower average blood pressure in the treated groups, little benefit compared to placebo or other therapies. Recent studies of diuretic therapy found an association with renal cell carcinoma, particularly among women (34).

Guidelines may not be implemented for other reasons. One retrospective study examined charts to determine why, for 34% of the patients with low-risk chest pain, physicians did not follow a guideline to reduce hospital length of stay. It found that 42% of these

patients were misclassified, 14% were due to the hospital's failure to record a patient's departure within time limits specified by the guidelines, 9% had their status changed to high risk during their hospitalization, and 19% had a higher severity of illness than patients discharged under the guidelines. In only 16% of these patients might the result have been due to *a priori* physician refusal to follow the guidelines (14). In this study of actual practice, most physicians followed the guidelines or exercised what could be deemed good clinical judgment even on retrospective evaluation. Guidelines may be more likely to be followed when they do not require practitioners to change their current practice. A clinical audit of general practitioners in the Netherlands found that guideline recommendations were followed on average 61% of the time, but recommendations that required changing existing practice routines were followed 44% of the time, and nonspecific recommendations were followed only 36% of the time (23).

Another reason that clinicians may appear to reject guidelines is that the guidelines' purpose is different from that of the clinician. Two studies of the difference between recommendations by decision analytic models and clinical decisions by practicing pediatricians and general practitioners illustrate this point. The authors stated that lack of acceptance of the recommendations of two decision analyses could not be explained by imperfections in the data, or differences in weighting of clinical information or in evaluation of outcomes. In one case, pediatricians paid most attention to interpretive factors, such as impression of illness and body temperature, rather than to factors given more weight by the researchers from their review of the literature. The authors concluded that the researchers and clinicians had different starting points. The goal of the researchers was to detect the disease at an earlier stage, whereas the focus of clinicians was to prevent the development of serious secondary disease states. Clinicians' training is primarily focused on curing diseases, not preventing them (42). In another study, general practitioners and patients disagreed with guidelines on prevention that suggested discontinuing annual check-ups. Both the practitioners and the patients placed high value on the check-up as a means of detecting insidious diseases, even without proof that the check-ups were effective, whereas the guidelines authors were comparing the effectiveness of the check-up with other forms of prevention and screening (3).

Experience and Implementation of Practice Guidelines

Some studies examined who adhered to guidelines and suggested that the more inexperienced physicians were the ones who found the guidelines most useful (17;24). In fact, one commentator stated that originally guidelines were intended to inform junior doctors and physician assistants of "the right thing to do" (15). They were not intended for use by more experienced physicians, who presumably would be familiar with the content of the guidelines and would not need them.

For inexperienced physicians, guidelines may also remove cognitive biases. In a study of the effects of positive (survival) and negative (mortality) framing, residents' choice of therapy was more likely to be influenced by the frame of a problem than that of physicians who had an average of over 15 years' experience. The residents were influenced for 42% of the cases, while the more experienced physicians were influenced in only 9% of the cases. The investigators speculated that the latter's preferences were based on stable habits that were not as easily swayed by the framing manipulations (10). However, the review of framing studies found that three of four studies showed no effect of practice experience on susceptibility to framing effects (32).

Implementation Survey

To further examine implementation, we conducted a survey in the anesthesia department of a large teaching hospital. In this survey, residents and staff with differing levels of experience

were queried as to their awareness and familiarity with two anesthesiology guidelines (the difficult airway algorithm and blood component therapy) that had been developed with expert clinical input as well as from a review of the published literature. These guidelines had been disseminated through professional society publications and communications with members. It was assumed that, because of the teaching and research mission of the hospital and its medical school affiliation, both the staff and residents would be more aware of the guidelines and more familiar with the guidelines' contents than clinicians in the community. In addition, it was anticipated that one of these guidelines (the difficult airway algorithm) would be considered tantamount to a specialty standard and that the respondents would all agree with it and report using it almost all the time. The blood component therapy guideline was considered to be more controversial and therefore less apt to be strictly followed.

As predicted, most respondents were aware of or familiar with the guideline on managing the difficult airway. The newer residents and fellows were somewhat less likely to have read it (21%), but 65% reported that they were familiar with its contents. All the staff level physicians were aware of the guideline, and 64% had read it. With the exception of those physicians with the most experience (21 or more years), the extent of guideline use was similar for physicians at all levels of experience. Half of the most experienced physicians reported deviating from the airway guideline most of the time.

The responses were more variable for the guideline on blood components. Only 37% of the first year residents were aware of the guideline, and only 12.5% had read it while another 37% were familiar with its contents. All the less experienced staff had read the guideline, but only about half the staff with over 5 years of experience had read it. All the physicians, particularly the less experienced residents and staff, reported less use of the blood components guideline than of the difficult airway guideline.

Over half the physicians surveyed indicated that one of their reasons for not using a guideline was that it was inappropriate in some of the clinical situations they encountered, while less than 10% thought the guidelines were too rigid, unwieldy, or required facilities that they did not have. Less than 3% indicated that they did not use a guideline because they did not believe it. Although we have no data as to the extent of compliance to these specific guidelines by anesthesiologists in private practice, few of the respondents (8%) in the survey population stated that they did not believe in the guidelines and did not use them in their practice at all. Almost two-thirds (61%) used them more than half the time.

DISCUSSION: WHY ARE GUIDELINES OFTEN IGNORED?

The implementation reviews and the survey demonstrate that it is not necessarily a valid assumption that clinical practice guidelines are widely implemented throughout the medical community. Physicians are not applying guidelines uniformly, but are utilizing them selectively. The least experienced physicians, who need guidelines the most, may be the least likely to be familiar with them. The very experienced physicians may be substituting their own techniques and knowledge in individual situations. In the survey of academic anesthesiologists reported here, half the most experienced staff reported not following guidelines most of the time. This finding is similar to that of a study at a university teaching hospital examining the use of glucose colony-stimulating factor in chemotherapy patients. In that study, the physicians who were most knowledgeable about the guidelines, the oncologists and hematologists, felt the most qualified to override them when they believed that the guidelines did not apply (7).

Critiquing the Use of Guidelines

Critiques of guidelines include the fear that evidence-based medicine does not reflect the complexity of the real world, in which a decision's context, framework, and setting are

important (30). Commentators raise serious questions about the adoption and applicability of guidelines in clinical practice (16;26). One of the major concerns is that the data used in the meta-analyses that form the basis for most of the recommendations come from randomized trials and do not include many treatments and patients who are seen in real-life practice. Older, experienced clinicians often view guidelines as a set of directives issued by panels composed of physicians who are out of touch with real patients. Most clinical trials exclude patients with comorbid conditions, while many patients in clinical practice have other features that influence diagnosis and treatment. The guidelines apply to the patients who are similar to those studied in large clinical trials, not the outliers and many clinical subgroups with complex disease entities that are not easily categorized, let alone managed. Clinicians place less faith in guidelines in complex situations that are not easily resolvable by decision trees. Even when every conceivable diagnostic alternative is presented in a highly detailed guideline, actual diagnosis may be different than that suggested by a guideline. One or more comorbid conditions or a patient-specific context could invalidate the guideline's assessment. Proceeding down the wrong algorithmic pathway in such cases may lead to inappropriate and dangerous treatments, particularly when patients have comorbid conditions and disease states that masquerade as other entities. Examples include patients with sexually transmitted diseases (i.e., syphilis and AIDS), auto-immune diseases (i.e., systemic lupus erythematosus), and chronic sublethal toxic exposure (e.g., to carbon monoxide), conditions whose symptoms are notorious because they often mimic a number of diseases. An inexperienced practitioner following a guideline could misinterpret signs or symptoms. Guidelines can give the practitioner a false sense of security. Without guidelines, the inexperienced physician may be more likely to get a consultation in ambiguous situations from more experienced colleagues who can supplement the collective experience of their profession with their intuition and "clinical judgment." In addition, most clinical trials use intention-to-treat analyses that do not reflect post-randomization events that cause alterations in treatment (16). When physician behavior in clinical practice was studied, many clinicians who did not seem to be following a guideline were responding to changes in their patients' status during the course of treatment (14). Many experienced clinicians are worried that in a guidelines-driven medical practice, individuals who differ from "average" patients will get lost and their needs will be ignored (16).

These concerns are paralleled in the decision-making literature by the fears of researchers that rational decision making does not reflect the conditions of real-life decisions, such as those in which clinicians have imperfect information and are under time pressure and other stresses. Overly elaborate guidelines, particularly those containing a multitude of decision trees in an attempt to cover every possible combination and permutation, may be impractical in situations of great time pressure, when seconds count. In these circumstances, clinicians may operate under a "take the best" paradigm in which they choose the first solution that matches their needs, without examining all solutions and integrating them. In this approach, clinicians use "limited knowledge to make fast inferences" and judge results by outcomes rather than by consistency (20). The clinicians are not making irrational decisions due to biased judgments; they are using a different process to arrive at their conclusions. They draw upon their personal database of clinical experiences as well as their training and knowledge of the medical literature. Because they can summon this information in milliseconds, they can arrive at conclusions that leapfrog over a complex guideline. They believe that this clinical acumen is an intuitive window to the heart of the patient's condition.

On the other hand, in a time-sensitive situation in which the alternatives are clear-cut, guidelines may be very effective. When a stereotyped yet medically appropriate response to a small number of yes-no variables can be implemented in seconds by a relatively

unsophisticated practitioner, such as an emergency medical technician, a rapid “cookbook” solution is preferred. For instance, when a patient has a cardiac arrest, simple low-level algorithmic approaches, such as the Advanced Cardiac Life Support guidelines, are universally acknowledged to be effective instruments.

Guidelines in the 21st Century

Given the state of knowledge at the end of the 20th century, the selective use of guidelines may be a positive component of medical practice. Until guidelines become more specific to individual variations in clinical problems or at least to clinical subgroups, and are updated more routinely, they probably cannot serve as a template for more rational decisions for all patients, nor can they serve to eliminate cognitive biases in decisions made under uncertainty. Many clinicians fear that in the 21st century, guidelines will cease to become suggested practice and will become standards or norms with severe consequences for those who deviate from them and for patients who do not fall within the guideline specifications or profiles. Guidelines will become the all-encompassing solution to diagnostic and treatment issues and will produce a two-tier system of physicians rather than a medical community who view each other as colleagues and who in most instances defer to the experience of practicing clinicians. At a time when a larger proportion of patients will require physicians who can think independently, most physicians will cease to think for themselves. For instance, guidelines appear to be most effective for disease states that are easy to characterize and have well-defined modalities of treatment with discrete endpoints. This type of guideline may be inapplicable for the elderly. In the 21st century, the elderly will comprise a much higher proportion of the population than in the last century. The elderly have complicated disease states and multiple chronic conditions that do not always have discrete endpoints. With their complex multisystem diseases, the elderly will be difficult to fit into preselected categories based on clinical trials that exclude patients with comorbid conditions. Molecular medicine and pharmacogenetics, which hold so much promise for the practice of medicine in the 21st century, are still in their infancy. Perhaps in the future they will produce applications that can be reduced to guidelines. At this state of their development, it appears that their application to individual patients in actual practice will demand complex and sophisticated judgments on the part of the physician. A professional group that conducts most of its practice by following a series of guidelines may not be equipped to utilize these new therapies to their best advantage.

At the beginning of the 21st century, more research is needed on how guidelines are implemented in actual practice (2) before they are offered as a standard of care. In addition, much more research on the application of guidelines to medical decisions needs to be conducted. This research would determine whether guidelines improve patient outcomes and help physicians exhibit “good clinical judgment.” More studies of the basis of clinical judgment that characterize how experienced physicians arrive at their intuitive conclusions also are needed. Incorporating the results of these studies into guidelines may make them more palatable to clinicians. Before a guideline becomes a standard, it is important to evaluate whether it reduces the uncertainty in medical decisions, eliminates decision-making biases, applies to complex cases, and improves patient outcomes.

The difference between the theoretical use of guidelines and their actual use in practice is analogous to the difference between use of a new therapy in a clinical trial and use in actual clinical practice. In a clinical trial, a therapy shows its efficacy. In practice, the therapy demonstrates its effectiveness. By setting out what is known from clinical trials and expert opinion, guidelines may appear to improve physician decision making, but until the guidelines are tested, in practice or at least in simulations, by comparing the outcomes for

cases in which physicians were constrained to follow guidelines to the outcomes for cases that physicians managed by their own clinical judgment, it is not possible to assess their effectiveness in improving physician judgments. Until provisions for implementation and evaluation research are built into their production and promotion, guidelines may continue to be ignored or at least not considered to be the foundations for good clinical judgment by a large proportion of practicing clinicians.

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