Guidelines and Algorithms: Perceptions of Why and When They Are Successful and How to Improve Them

Joseph H. Keffer

Medicine is increasingly complex, a reality created by the explosion of knowledge during the last 50 years. The cost of applying this knowledge creates a daunting economic challenge. As a result, there has been a profusion of guidelines intended to influence medical practice. This report explores the interrelated issues and concepts that impact the value and success of guidelines. These include medical quality and error, compliance, and the impact on outcomes in an evidence-based medicine context. Lessons learned from previous guidelines must be understood in relation to human behavior. Legal implications of the guidelines must be considered because both an increase and a decrease in liability can be anticipated. Many products have been labeled “advocacy guidelines” with a negative context. They are believed to express motivation rather than optimizing care. The ideal of professionalism is challenged, and there is potential for the growing use of guidelines in enforcing punitive actions. Constructive experience has emphasized the appropriate required elements for practice guidelines: a systematic review of the literature, an assessment of the volume and level of the evidence, and development of a review process by an appropriate multidisciplinary group for consistency, clinical impact, and resource implications leading to clearly stated and reasonable recommendations. The dissemination of guidelines, beyond conventional publication in a journal, will impact the success of the intended outcomes. The exploitation of electronic avenues, including the Internet and the evolving interactive electronic medical record, seems to be essential for future success in these endeavors.

Clinical practice guidelines (CPGs), fostered as the likely solution to achieve improved quality of care while reducing the ever-increasing costs of healthcare, have proliferated at a furious rate from the 1980s to the present. They have also been touted as a protection from malpractice litigation. As with most early enthusiastic assessments of new trends, the reality has been somewhat less satisfying. This report represents a modest attempt to address some of what we have learned with regard to the successes, failures, impacts, and implications of guidelines. In addition, projections for the future are offered, based on integration of the relevant literature. Describing CPGs as the “new tower of Babel” (1), one report identified 855 publications of guidelines targeted for the general practitioner alone, as “68 cm high, and weighing 28 kilos”. Obviously, a comprehensive review of all published guidelines would be as impossible and unproductive for this review as it has been for the general practitioner. It is no wonder that most practitioners have disdained the majority of guidelines. Nonetheless, they remain a hope. There is much to be learned from a review of our experiences to date because guidelines will continue to play a role of increasing importance.

Origin of Guidelines

Faced with the daunting diversity of new publications of medical advances, the National Institutes of Health Consensus Conferences proposed guidance with regard to the adoption of new technology and optimal treatment. The outcome of these efforts, the “NIH Consensus Guidelines”, originated in efforts begun in 1978 (2). Major efforts to achieve a respected product from these deliberations have included careful selection of both presenters and attendees, public discourse, hearing of scientific

1 Nonstandard abbreviations: CPG, clinical practice guideline; AHCPR, Agency for Health Care Policy and Research; CHF, congestive heart failure; ACE, angiotensin-converting enzyme; and ERISA, Employee Retirement Income Security Act.
Definitions of Guidelines and Algorithms

Although guidelines have evolved to address quality and costs, there are a variety of perspectives revealed by the differing attempts to define them. It is instructive to consider the emphasis shown in various definitions.

Schwartz et al. (4) offer a set of four definitions from standard sources as follows:

1. "A related set of generalizations derived from past experience arranged in a coherent structure to facilitate appropriate responses to specific situations" [28th Bethesda Conference, quoted from Schwartz et al. (4)].
2. "Guidelines (compared to textbooks) are more concerned with specifying treatment strategies for certain patient types, with healthcare quality, and the reduction of unjustifiable clinical variability and costs" [B. Hurwitz, as quoted from Schwartz et al. (4)].
3. "Guidelines—like overviews—gather, appraise and combine evidence. Guidelines, however, go beyond most overviews in attempting to address all the issues relevant to a clinical decision and all the values that might sway a clinical recommendation. Like decision analysis, guidelines refine clinical questions and balance trade-offs" [From the Evidence Based Medicine Working Group, quoted from Schwartz et al. (4)].
4. "Systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific clinical circumstances" [Institute of Medicine, quoted from Schwartz et al. (4)].

According to the Agency for Health Care Policy and Research (AHCPR), practice guidelines are “systematically developed statements to assist health care providers, consumers, payers, and policy makers in making decisions on how specific health conditions can be most effectively and appropriately prevented, treated, and managed” (5). A preferred variation of the AHCPR definition is concise and highlights the essential constituent elements as follows: “Practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” (6). The essential elements of this definition are (a) systematic development, (b) appropriateness, and (c) specific applications. We shall see the importance of these in reviewing the success and failures of guidelines to date and the projected future of guidelines. The AHCPR, a government creation, is targeted toward policy development.

Providing a historical perspective, the concept of guidelines has been related to a 4th century BC philosophical discourse in which Plato “set up a thought experiment: doctors would be stripped of their clinical freedom . . . [no longer allowed unchecked authority] . . . but would form themselves into councils to determine majority views about how to practice medicine in all situations” (7). Hurwitz (7) reports that Plato concluded “important hallmarks of expertise include flexible responsiveness and ‘improvisatory ability’—an approach to practice endangered, he believed, by use of guidelines”. The validity of this lesson has been substantiated by modern experience with guidelines. An essential element of the practice of medicine continues to require exceptions to guidelines. Learning this lesson has been essential to the application of CPGs to the law and to audit and payment issues, all of which continue to perplex those who conceive of guidelines as algorithms.

Algorithms

In contrast to guidelines, algorithms are intended to be simplistic and to address a single option, i.e., they are limited and not suitable for complex decision making in which multiple choices may be more or less appropriate. Derived from mathematics, algorithms may be described as a systematic rule set for solving a particular problem with unambiguous alternatives and having a clear stopping point. A clear example would be a baking recipe [Author’s synthesis of multiple sources, dictionaries, and the web]. Algorithms have been likened to a decision tree and of value because they “are logical and sequential, can be automated using a computer . . . , are incorporated into software programs . . . ” (8). An oft-quoted example is the application to thyroid function, but even here the expert is
concerned with rare disease variations such as pituitary resistance to thyroid hormone, which causes results to be misleading in simplistic algorithms. There are few strict alternatives in medical care with unambiguous alternatives. As such, algorithms are confined within larger care plans in well-defined situations. The emphasis on “either/or” thinking is uncomfortable for physicians unless all of the details are clear and unequivocal. As such, most algorithms, such as chest pain triage with its multiple complexities and options, must be considered as soft guidance, addressing limited issues within a larger context, the guideline. Contrasting algorithms with CPGs, one requires that the guideline be comprehensive and offer multiple options. Inherently, there must be an option to deviate from the guideline, as experience has shown and as will be discussed below in both clinical and legal lessons.

As with CPGs, algorithms are too numerous to review. Recently, when I entered the term in MEDLINE and confined it to “human” and the English language, the search listed 184 entries that had been published in the prior 90 days.

**Need for CPGs**

There is no substantive argument that denies the need for CPGs to assist the physician in the modern and increasingly challenging practice of medicine. One need only cite the burgeoning medical literature reflecting the ever-expanding knowledge base, along with an appreciation of the level of detail that influences medical decisions. There are a host of alternatives open to individual medical decisions. Any reasonable individual will acknowledge the need for tools that facilitate optimal practice. As such, we have heard more and more of the evidence-based medicine movement, outcomes analysis, decision analysis, and technology assessment. In addition, we have come to appreciate that we must match these academic efforts with an improved understanding of physician behavior, human error, the contribution of medical informatics, and the influence of health policy and political science on social policy. All of these must be considered in the successful deployment of CPGs and will be alluded to in the subsequent discussions.

**Experience with Practice Guidelines to Date**

Among successful guideline implementations, one need not look beyond the revolution in neonatal screening for unequivocal progress. An excellent example is the screening for hypothyroidism at birth, a well-documented, cost-effective, and humanistic intervention. Factors essential to the program include mandatory adoption in all 50 of the United States, tracking and treatment of the affected individuals, and follow-up academic documentation of the effectiveness of the guideline (9). Recent, more germane reports of successful implementation of a key guideline relevant to wide clinical practice have involved diabetes (10) and unstable angina (11). However, evaluations such as these are too few, in contrast to the many published guidelines.

Learning from failed experience is also a path to success. As such, guideline evaluations, although all too few, have much to teach. A series of reports from 1989 (12, 13) and subsequently have labeled practice guidelines as “cookbook medicine”. This often-restated appellation, although doubtlessly issued with professional motivation, has hindered well-intentioned efforts to advance the effectiveness of guidelines. Physicians guard their autonomy, as well they should. The reality, both in practice and in the courts, is that cookbook medicine is never justifiable and that no guideline is acceptable if such is the intention or expectation. In an encouraging recent survey of attitudes of faculty and house staff toward guidelines, the allegation of cookbook medicine persisted, particularly among junior physicians. What was more notable was the much greater favorable significance given to the guidelines by faculty compared with junior house staff, providing evidence that this hollow charge may be overcome in the future (14).

More substantive reviews of CPGs have revealed more concrete limitations. In a study of CPGs issued by specialty societies, which might be expected to be of high caliber, one study reported 431 guidelines eligible under the criteria for the review (15). The authors provided a checklist for review, which stands today as a generally accepted set of standards (Table 1). Most did not meet the criteria: 67% failed to report the stakeholders; 88% provided no information regarding the searches for published studies encompassed by the guideline; and 82% did not grade the recommendations according to the quality of the evidence. Moreover, this report documented that recommendations originating from different groups can be conflicting, and in the opinion of some reviewers, “they are invalid, unreliable, and irrelevant”. In an accompanying editorial (16), there was a reminder that many guidelines were thinly disguised “advocacy guidelines”. They have been given this label because they are so self-serving and reflect a single group in isolation rather than being the product of multidisciplinary effort reflecting many perspectives. We now recognize that this is counterproductive. The authors indicated that such a design generally reflects the GOBSAT (Good Old Boys Sat At Table) methodology of guideline development, a statement that is all too true. Rather, we are moving toward evidence-based medicine to replace “eminence-based medicine”.

<table>
<thead>
<tr>
<th>Table 1. Checklist to assess the quality of guidelines endorsed by specialty societies.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Description of the type of professionals and other stakeholders involved in developing the guideline</td>
</tr>
<tr>
<td>2. Description of the sources of information used to retrieve the relevant evidence</td>
</tr>
<tr>
<td>3. Explicit grading of the evidence in support of the main recommendations</td>
</tr>
<tr>
<td>*Adapted from Hibble et al. (1).</td>
</tr>
</tbody>
</table>
Failed guidelines reflect a variety of issues. Unforeseen circumstances may invalidate an apparently excellent document. For example, the authors of a review of the CPG issued by the AHCPR for heart failure found that there is emphasis on early treatment for congestive heart failure (CHF) attributable to reduced ventricular systolic function (17). Initiation of treatment in asymptomatic patients with angiotensin-converting enzyme (ACE) inhibitors impacts the quality of life and costs of care in a favorable fashion. Although admittedly sound, the authors of the review noted that, lacking the requisite tools, the general physician cannot screen for the asymptomatic diagnosis of failure without a consultation. They identified these as echocardiography or radionuclide scanning (17). Similarly, the Canadian Association of Radiologists determined that a single national standard for practice was deterred by the varying circumstances, including funding by the various provincial agencies.

Beyond question, the first and most essential element for a valid CPG is the evidence underlying it. In one survey of 95 published guidelines in cardiology, the authors of a recent report found that only 13% of cardiology guidelines graded the evidence using defined scales and that few documented a reproducible search strategy, essential for qualifying the evidence (21). On the other hand, the upper respiratory syndrome guideline was solidly based on good evidence but failed, as mentioned above (19). In a thoughtful consideration of the success and limitations of evidence-based medicine, Larson (23) emphasizes not only the fallibility of the evidence and the inherent bias in any human effort, but identifies a series of “critical factors of success” for the evidence-based medicine program. In effect, these are very much like a CPG: they include local clinician involvement, a unified or closed medical staff, protocols, and physician extenders and financial incentives and “academic detailing” (discussed later).

### Human Error

There currently is extensive debate with regard to the extent of error and adverse consequences of medical practice in the United States (24, 25). There is the hope, reminiscent of the Platonic discourse, that the application of guidelines can interrupt patterns of human error by incorporating “systems” that will ensure error-free practice. Superficial study of patterns of human error may lead one to propose that CPGs could eliminate the majority of these problems. Although it may be agreed that error is the fault of inadequate systems, the current literature is limited at best in supporting the notion that CPGs, in their present stage of development, can reverse our existing error rate. Major augmentation of the guidelines, as discussed in the section on means of improving them, will be requisite.

### Physician Behavior and the Guidelines

In a summary of numerous studies of the subject of physician compliance with guidelines, there is the reminder that “Despite wide promulgation, clinical practice guidelines have had limited effect on changing physician behavior. Little is known about the process and factors involved in changing physician practices in response to guidelines” (26). The conclusions reached emphasize the...
variability of reports in the literature and that reports of successful implementation may not be generalizable because obstacles in one setting may not exist in another. Smith (27) reports an exhaustive review of the relevant literature stimulated by the failure of guidelines to change behavior. He reports the accumulation of 4127 publications in a MEDLINE search of “practice guideline” (3969 since 1989). Referring to the “special feature of Physician Behavior”, the author provides insight for the nonphysician into the long educational process that produces the firm imprint observed in patterns of physician behavior and why this is not readily altered. “As human beings, physicians are motivated by multiple interests: the patient’s interests, their own interests, society’s interests, and, increasingly, the payor’s interests” (27). In this statement, we are reminded of reality.

Various analyses of the efficacy of CPGs have focused on a variety of explanations for the limited success they have achieved. Physician behavior appears to be the single most likely obstacle to greater impact. As such, it is now getting the attention it deserves. The issue is not new; in a studied analysis of the known factors involved in changing physicians’ practice patterns, Greco and Eisenberg (28) reviewed the six general methods for altering physician behavior, which reflect the current wisdom of the time: education, feedback, participation by physicians in efforts to bring about change, administrative rules, financial incentives, and financial penalties. Although they presented their results optimistically, the authors acknowledged the existence of few randomized controlled studies that could be relied on and advocated the combination of at least two interventions to achieve a particular goal. Laboratorians are long familiar with these issues because the literature is replete with efforts to change laboratory usage patterns and with failures when the interventions are suspended (29). Illustrative of the problems and potentially successful methods of approaching the issue of behavior modification is an outcome-based guideline implementation presented in the recent literature (30). Among the noteworthy recommendations in this report were encouraging meaningful involvement by clinicians, appealing to their desire for a good reputation, peer pressure, paying attention to financial issues and rewards, and identifying the means by which the physician’s well-being will be enhanced. Achieving this goal achieves compliance. It should come as no surprise that physicians are quite human. In a departure from the usual gentle persuasion approach, Katterhagen counsels: “When implementing a guideline, don’t be too democratic” (30).

It should also come as no surprise to us that the concept of “academic detailing” is given high grades for effectiveness, if not efficiency (27). As reported here, it is possibly the most effective strategy, although it has not been evaluated in controlled studies. This tool is a concept taken from drug detailing as successfully carried out in the model used by the pharmaceutical industry. An accepted authority or opinion leader in a face-to-face educational meeting with office-based physicians discusses the guideline or revision of behavior that is sought. In concept, it is reported to derive from “social learning, innovation, and social influence/power theories such as diffusion of innovation” (27). Smith discusses the importance of valid, well-researched guideline content, followed by conventional education and then the detailing, reminders, audit and feedback, and economic incentives stated to clearly influence physician behavior. Smith’s summary statement follows and characterizes the state of our knowledge all too well: “There is no unifying theory of physician behavior change tested among physicians in practice. Attempts to affect individual physician’s performance have often met with failure. Mixed results are found for almost all interventions reviewed. Multiple interventions yield better results” (27). This conclusion is in sobering contrast to the naive expectation that “if you publish it, they will follow it.”

**Opportunities for Laboratory Medicine Contributions**

Fundamental to guidelines and their audit and feedback is the need for objective, computer-accessible data. Laboratory data often are the key to successful classification of patients, to branching of the algorithms associated with their implementation, and to subsequent audit for compliance and efficacy of the guideline. As such, professional laboratorians are highly appropriate members of the multidisciplinary teams constructing local adaptations and implementing CPGs. No better example can be offered than the recent American College of Cardiology/American Heart Association guideline for the diagnosis and treatment of unstable angina and myocardial infarction (31). The essential focus on troponin as the discriminator of myocardial injury and the complexities of the troponin issues compellingly identify the importance of the role of the laboratorian. Another example is the recent guideline for the application of exercise testing, which precludes this technique unless troponin testing is negative in two serial samples (32).

Analytical considerations may critically bias the application of valid guidelines. A clear example includes the varied meanings and the imprecision of differing prostate-specific antigen determinations (33). Dialysis guidelines for chronic renal failure clearly relate the administration of expensive erythropoietin therapy to complex issues of measurements of ferritin, iron, and transferrin saturation, which differ in these patients. A recent analysis of the guideline and its economic feasibility illustrates the need for expert clinical chemistry guidance (34).

In one final example of the need for a clinical chemist’s contribution, consider CHF. One can see the fulfillment of the need expressed in the guideline for screening of asymptomatic patients discussed above. The dilemma faced by the primary care physicians was that the guideline called for initiation of treatment in asymptomatic patients with left ventricular failure, but reported the lack
of available tools to do so, referencing echocardiography or nuclear scans to screen potential patients. Now the need is fulfilled by the use of assays for the natriuretic peptides (35). It is clear that the contribution of the professional laboratorian can enhance and enlighten guideline development, monitoring, and continual improvement.

**Legal Aspects Related to Guidelines**

An appealing concept is the expectation that if physicians adhere to a relevant guideline, it would likely protect them from subsequent malpractice litigation. In 1991, Brennan (36) thoughtfully analyzed the legal implications of CPGs with specific reference to malpractice litigation. He predicted that they would be used for both inculpatory and exculpatory purposes. Inculpatory refers to the use of the guideline to bring about or confirm malpractice by the plaintiff. Exculpatory evidence is the reverse. It is the use of the guideline to defend the physician from charges of malpractice. Brennan (36) further predicted that courts would not be revolutionized by the existence of guidelines. Four years later, he and his colleagues systematically catalogued the available experience and searched for evidence of the impact of the many guidelines (37). They reviewed litigation files at two insurance companies and surveyed malpractice attorneys. The yield of information was extensive. Although exculpatory applications of the guidelines were twice as common as inculpatory applications, clearly guidelines are a two-edged sword. Equally important and unquantified is the impact of the guidelines in deterring either the defendant or the plaintiff from proceeding to trial after a lawsuit reveals compliance with or deviation from a relevant guideline. Although clear exceptions exist for abandoning a guideline, physicians must identify the justifiable reason in the medical record.

As to the rigidity of the law with regard to the physician’s duty to adhere to a guideline, the courts agree with Plato. Just as he recognized in the 4th century BC, physicians must be free to exercise individual judgment for the individual patient (9, 38). A clear summary is the following: “The legal status of a guideline turns on whether its development, and application have statutory backing, and whether the guideline embodies clinical practices accepted as proper by a responsible body of doctors” (38). In another corroborating opinion, Matthews (39) summarizes as follows: “The structure of legal reasoning focuses on the particular facts in the case at hand rather than appealing to abstract decision procedures”. It is clear that the guidelines have not replaced expert witnesses. Rather, both plaintiff and defendant continue to require experts to study “this case in these circumstances”, not unlike the argument that individual patients must be treated according to an individual set of facts. However, it is clear that a trend is developing in which the guidelines are expected to play a greater role in influencing the testimony of experts called in for the proceedings. This is reflected by the increasing number of cases settled on the basis of guidelines before going to trial (9, 37, 38). As contradictory guidelines are progressively replaced by more thoroughly developed, evidence-based CPGs that are aggressively implemented, the expectation is that the weight of the evidence that is provided to the court will grow in acknowledged importance. The guidelines will more truly represent the standard of practice. So too will their impact on jurisprudence.

A different aspect of guidelines and their impact on the law involves the interaction between the Employee Retirement Income Security Act (ERISA) and managed care, and the impact of this interaction on the practitioner. It is clear that physicians are under pressure from managed care organizations to limit care by following certain guidelines adopted and encouraged by the managed care organization. The ERISA law exempts managed care organizations from lawsuits related to the denial of care under provisions that identify healthcare as a retirement benefit, a law conceived to protect pensions. Currently, political debate centers around reversing this application of the law, which was clearly intended for a different purpose and predated the extension of managed care to the extent seen in the United States today (40).

**Disease Management and Guidelines**

Disease management, as a concept, may be best described as “Guidelines on Steroids”. This dramatizes the detailed application of a set of guidelines to a particular area of medicine. Ellrodt et al. (41) provided a capsule summary of this movement, which they defined as “an approach to patient care that coordinates medical resources for patients across the entire health care delivery system”. They identified four ambitious but essential components of disease management: “1) An integrated health care delivery system capable of coordinating health care across the continuum, 2) a comprehensive knowledge base of the prevention, diagnosis, treatment, and palliation of disease, 3) sophisticated clinical and administrative information systems that can be used to analyze practice patterns, and 4) continuous quality improvement methods”. Alternatively, disease management may be defined as a “rapidly growing movement focusing standardized multidisciplinary approaches to a limited population with a uniform problem” (42, 43). This is a very significant and growing movement creating major change in the delivery of healthcare in the United States.

An example of the glowing reports of successful disease management can be seen in CHF. Here, in spite of continuing publication of strong guidelines for improved management, changes in practice patterns to conform to these advances have occurred at a rate that is deemed inappropriate. Ramahi et al. (44) reported the significant improvement of clinical outcomes and the implications for cost reduction by applying disease management principles to CHF. In an accompanying editorial, leading academic cardiologists conceded the gross shortcomings
of the medical community, who continue to fail in applying significantly improved medical practices to the enormous field of CHF (45). These authors excuse practitioners to some extent by blaming reimbursement system patterns and urge the Medicare program to introduce financial incentives that encourage appropriate visits, monitoring of laboratory values, and adjustment of doses of ACE inhibitors and other drugs. This is not a convincing defense of poor medical practice.

Other applications are to diabetes, asthma, osteoporosis, coronary risk management (lipid lowering), hypertension, and a growing list of other conditions and diseases; all of these applications progressively seek to extract entire groups of patients from the conventional physician–patient relationship. Common to most of these is the application of systematic guidelines with the promise of improved outcomes and lowered costs. Although clearly achieved in some analyses, improved outcomes and lowered costs are not always demonstrable but are cited in defense of the concept. In reality, they deal in chronic diseases, which often show poor clinician compliance with established, unarguably valid, and desirable guidelines. In effect, they target areas of the practice of medicine in which the single doctor–single patient relationship often is limited. In making policy, the limitations of the science may be overcome by the “technocratic wish” (40).

According to this view, the shortcomings of the desired social and political attraction may be deemphasized, whereas the attractiveness may shape what is desired as scientific. The disease management movement may be in this category until evidence of its effectiveness in practice is shown more widely and by controlled, well-designed studies. Given the entrepreneurial influences that currently dominate medicine in the United States, however, disease management organizations may be expected to continue to expand their influence.

Although debate will proceed with regard to the value of disease management, Bodenheimer (43) expressed concern for the commercialization of this form of care by the pharmaceutical industry, which may be primarily interested in controlling market share by capturing the target customer base. Areas of incursion by commercial sources include diabetes, hypertension, and oncology. The transparent goal of pharmaceutical concerns is to control the selection of therapies in an obviously competitive market by controlling the guidelines applied to the organization. In this report (43), Merck, Astra-Zeneca, and Eli Lilly are identified as having major interests in “Merck-Medco”, “Salick Health Care”, and “Control Diabetes Services”, respectively, each of which is a disease management firm. As stated by Bloor and Maynard (46), “A pharmaceutical company that chooses to forward integrate into healthcare provision may stabilize the market for its own products. Thus, a company with a drug for treating asthma can ensure that this drug is used by its own healthcare providers, so avoiding prescribers’ substitution of rival branded drugs or generics”. Bodenheimer (43) counters that disease management should be performed “within healthcare institutions and be integrated with primary care rather than being outsourced to specialized commercial entities”. This is an argument heard before with regard to commercialization of the laboratory industry, imaging, hospital ownership, and other aspects of medicine. It seems unlikely that the movement in a commercial direction will not continue, but the burden is great to assure scientifically valid outcomes and reasonable cost reduction.

In summary, the disease management movement is progressing rapidly. It will continue to do so as long as the critical mass of individual practitioners fails to adopt needed guidelines. This leads not only to poor outcomes, but also to high costs.

**Strategies to Improve Guideline Quality and Effectiveness**

Short of implementing wholesale disease management practices, what evidence is there that guidelines can be made more effective? The following phrase aptly portrays the essence: “The complexity of the task cannot be underestimated and must be recognized and addressed if guidelines and research are to be successfully implemented” (47). The guideline must first be of high quality and reflect the best evidence available. In their recent editorial, Miller and Petrie (16) provide an excellent summary of the method required (Fig. 1). This draws on a detailed analysis of the quality of published specialty guidelines (15). Miller and Petrie (16) emphasize systematic literature review and evaluation of the quality of the evidence, the generalizability and clinical impact, and resource implications with judgment exerted in development of the guideline by a multidisciplinary group. Finally, they stress graded recommendations. In addition to the education of physicians, by extending this process to paramedical staff, office staff, and administrators, guideline implementation will greatly improve the probability

---

**Fig. 1.** Rational procedural sequence for the development of a quality guideline to increase the probability of achieving effective change in physician practices.

Adapted from Miller and Petrie (16).

---

**Derivation of Guideline Recommendations**

1. **Evidence level=study type=quality assessment**
2. **Evidence Table of Validated studies**
3. **Volume of evidence Consistency of evidence Generalizability Clinical Impact Resource Implications**
4. **Considered judgment of multidisciplinary guideline-development group**
5. **Graded recommendation**
of success (48). This practice is also well known to drug
detailing and must be recognized if academic detailing is
to be effective.

Every change requires a champion. Whether in medi-
cine or in other endeavors, identification of a respected
leader to lead the project, to be a source of consultation,
and to continue the advocacy in the face of resistance
remains a fact of life (47). This reality has been recognized
for many years, as discussed by Borbas et al. (47) in the
context of innovation research, adult learning theory, and
social influence. They provide the insight that often the
key clinical leader may not be in a formal position of
leadership but is identified by the medical staff as the
individual to whom they go for information. These phy-
sicians not only possess clinical expertise, but also have
“the innate skills for engaging others to creatively solve
problems” (47). By contrast, the formal leaders often do
not possess “the other necessary traits [i.e., communica-
tion skills and humanism] necessary to be effective”.

There is a consensus among authors that to success-
fully implement guidelines, the following are needed, as
presented well by Roberts (49). There should be a reason
for using CPGs, mainly to improve clinical practice. Cost
flows from poor practices. The executive team and med-
ical leadership must understand CPGs, how they work,
and what they can and cannot do. The roles of the Chief
Executive Officer and the Chief Financial Officer are
critically required to provide the commitment and sup-
port required for implementation. Development of a CPG,
although drawing on nationally respected sources, must
be adapted locally with active physician involvement.
Although the documents may be placed in the medical
record to facilitate adoption, there must be explicit en-
dorsement of the right of the treating physician to exert
ultimate decision making in applying the guideline or
deviating from it. A physician-champion who is estab-
lished, respected, and influential among the doctors and
who is diplomatic is essential to the success of the
program (49). The impacted physicians require a clear
understanding of the benefits they will experience from
the program. Meetings must be held at times convenient
to the physicians, not the hospital staff. Implementation
must involve in-service education around the clock to
introduce the concepts to the staff. Monitoring and fol-
low-up to identify noncompliance is necessary but should
be identifiable as by an educator rather than auditor.
Academic detailing may be described as “an innovation to
cajole, coerce, and convince ... peers to accept the new
way”. One such example of successful implementation of
these elements has been described with regard to the use
of β-blockers in acute myocardial infarction, and empha-
sizes most of these same points (50). The guideline must
be of high quality, must require expert educational train-
ing and placement of the guideline in patient charts, and
must include recommendations for appropriate consulta-
tions. In short, a multifaceted implementation is essential.

Some expert specialty societies now recognize the
limitations of simply publishing a state-of-the-art guide-
line and stopping with that effort. No longer expecting
automatic adoption or accepting noncompliance, these
groups are evolving a new sense of responsibility to
ensure adoption, especially in view of the rapidly devel-
op ing global impact of improvements in quality care (51).
In addition to stressing the value of cooperation across the
Atlantic Ocean, these societies have become aware that to
alter the rate of noncompliance with excellent guidelines,
more must be done. Bassand (52) reported on an official
document of the European Society of Cardiology written
to address the development of positions on various sub-
jects, such as guidelines. Promoting awareness of the
guidelines, disseminating them, and encouraging their
use are taking on a new importance in overcoming the
barriers to implementation. There is intense activity to
exploit electronic publishing through the Internet,
through increasing access to complete published docu-
ments, and through developing aids, including executive
summaries, flyers, slides, web-casts, and cyber confer-
ences (52).

One cannot avoid emphasizing the great contribution
that still awaits widespread deployment, namely com-
puter reminders at the point of care. Typical of this
concept is the report of improved use of preoperative
antibiotic prophylaxis when administered at appropriate
times (53). Although others continue to struggle with this
clearly valid principle, the Salt Lake City group demon-
strated ideal compliance in a subsequent report 4 years
later, made possible entirely by the use of an advanced
computerized system that impacts the moment of medical
decision making (54). Tierney et al. (55) provide an
excellent instruction for the successful computerization of
guidelines. A simple but clear study shows the dramatic
improvement in compliance that can be achieved com-
pared with manual reminders (56). Although few institu-
tions currently have the sophisticated integrated informa-
tion systems required for applied computerization (57),
implementation, and audit of guidelines, most hospitals
are moving in that direction. They should be strongly
couraged to expedite achievement of those goals.

There is hope that, aided by improved insight into the
reasons for poor adoption of the guidelines and with
newer tools available, CPGs will soon fulfill the promise
that has been anticipated for so long. They will do so,
however, only if the lessons have been learned well. These
include evidence-based medical validation, multidisci-
plinary development, local adaptation, understanding
physician motivation, incorporation of proper incentives,
and possibly most importantly, embedding them in real-
time computer systems as aids to practice. The private
practice of medicine has changed greatly in recent de-
cades. Unless there is accelerated progress to achieve the
numerous improved outcomes that are available and the
associated cost savings, one can expect much more heavy-
handed intervention by third-party payers. To illustrate,
one need only review the opportunities identified to
impact Medicare by the further extension of disease management (58). The case to do so is a credible one. The medical profession owes a duty to the patient and to society. There is room for improvement.

References

35. Ramahi TM, Longo MD, Rohlies RN, Sheynberg N. Effect of heart


