

Clinical Practice Guidelines: the More, the Better?

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Clinical practice guidelines are supposed to be evidence based and unbiased. High quality guidelines have the potential to promote the use of effective clinical services, minimize undesirable practice variation, and reduce the use of unnecessary services. Unfortunately, most of the guidelines produced thus far are flawed and untrustworthy. High quality guidelines may still have the intrinsic limitation of being too disease-focused rather than patient-focused, and lack applicability and validity when dealing with patients with multiple comorbidities or diseases. When applicable, clinical practice guidelines may serve as a relative guidance, rather than the absolute standard. Physicians need to be critical and vigilant when faced with a plethora of guidelines as following flawed practice guidelines may result in harm to patients. The use of clinical practice guidelines as the “standard of care” as well as for pay-for-performance based on guideline adherence is unjustified.

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INTRODUCTION

Clinical practice guidelines are “statements that include recommendations intended to optimize patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care option.”¹ Guidelines are widely considered evidence based, unbiased, and valid. High quality guidelines have the potential to promote the use of effective clinical services, minimize undesirable practice variation, and reduce the use of unnecessary services.²

In 1990, the Institute of Medicine (IOM) proposed guideline developments to reduce undesirable health care variation by assisting health care providers in decisions-makings. In the following years, guideline productions proliferated at an astonishing speed, so that by 2008, more than 350 guideline development groups had produced several thousand practice guidelines.² National Guideline Clearinghouse (NGC) accepted 722 guidelines to its database in 2008 alone.¹ It reached the point that any group of individuals could designate itself a guideline group to come up with guidelines on diseases/conditions; and different guideline groups could review the same disease/condition and reach different conclusions.³

It is not surprising that many practitioners and health care administrators started to question the validity of these guidelines that were mass produced in such a manner.^{4,5} The

concerns expressed included limitations in the scientific evidence on which the guidelines relied, a lack of transparency of the guideline development groups' methodologies, and conflict of interest among guideline development group members and funders, as well as questions regarding how to reconcile conflicting guidelines.¹

Apparently, the current use of the term, “guidelines”, has strayed from the original intent of being unbiased and evidence based. It is not uncommon to see bias in the development of guidelines, involving the reviewed research, misrepresentation of the data, or failure to assess the quality of the evidence supporting the recommendations. Inadequate or weak evidence may lead to conclusions based on value judgments, organizational preferences, or opinion. In addition, practice guideline authority and influence usually comes from the sponsoring organization and status of the publishing journal. Specialty and subspecialty societies can use guidelines to enlarge their area of expertise in a competitive medical field. Federal guideline agencies usually focus on cost saving approaches, while committees influenced by industry are more likely to shape recommendations in accord with industry needs.

Besides, the validity of systematic reviews and meta-analyses may also be negatively affected by bias. For example, several practice guidelines on long-term opioid therapy for chronic pain were published between 2008 and 2011. Although each guideline was based on analysis of essentially the same body of published research, the guideline conclusions differed significantly.

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Frequently, when one looks deeper, he/she may find issues pertaining to the source of funding or the sponsorship, and other materials that tied the authors to certain industry, organization, or agency. This has led to skewed reporting of findings and conclusions geared towards interests or agenda of the particular industry involved.⁶ Additionally, one may find problems in the quality of evidences used to substantiate a recommendation of certain medical procedures or medical products. Among the problems, particularly, there is use of weak evidence as definitive proof. Finally, the sources of "evidence" vary significantly depending on whether the authors solely used published studies; and whether the studies used were industry funded.⁶

Faced with the chaos of the pervasive proliferation of practice guidelines and the widespread concern expressed by physicians, consumer groups, and other stakeholders regarding the quality of the processes supporting development of practice guidelines, US Congress mandated IOM to develop a set of standards for developing rigorous, and trustworthy clinical practice guidelines.¹ In 2011, IOM published the report, "Clinical Practice Guidelines We Can Trust," in which it proposed eight standards/recommendations, deemed essential to developing sound practice guidelines. These include transparency establishment, management of conflict of interest, guideline development group composition, guideline-systematic review intersection, establishing evidence foundations for and rating strength of recommendations, articulation of recommendations, external review, and guideline updating.¹

Reames et al. evaluated the recent oncology practice guidelines by using IOM standards as a benchmark.⁷ The authors chose to study clinical guidelines and consensus statements addressing the screening, evaluation, or management of the four leading causes of cancer-related mortality in the United States (lung, breast, prostate, and colorectal cancer), published between 2005 and 2010. They performed a systematic MEDLINE search and identified 593 potentially eligible oncology practice guidelines. Following their defined inclusion criteria resulted in the exclusion of 424 documents, resulting in 169 practice guidelines for review, among which 47 publications were labeled as consensus statements. The authors concluded that there was not a single practice guideline that fully met all IOM standards.

Another recent study by Kung et al. also evaluated the performance of 130 randomly selected clinical practice guidelines from the National Guideline Clearinghouse (NGC) with regard to the IOM standards.⁸ The overall findings were similar to that of Reames and colleagues. There was not a single guideline that met all IOM standards. Both evaluations of practice guidelines found that there was poor adherence to IOM standards, particularly with regard to conflict of interest management. Lastly, Choudhry et al. showed, in their cross-sectional survey of 44 guidelines, that 87% of the guideline authors had some form of industry tie,⁹ and therefore failed to measure up to IOM standards.

A study named "Are the Institute of Medicine's Trustworthiness Guidelines Trustworthy?" was conducted, aimed at investigating whether IOM standards were trustworthy by their own criteria.¹⁰ Ironically, Young and Greenberg found that even the IOM document itself passed only two of its own standards, partially passed two standards, and failed four. It can be argued that the IOM document is not a practice guideline and thus cannot be evaluated as such. However, given that the IOM document purports to be a blueprint for developing guidelines to optimize care, Young and Greenberg felt that the same standards should apply to the IOM document. Additionally, it is probably premature to recommend clinical practice guidelines to meet all eight IOM standards. Further studies are needed to determine the best criteria for evaluating practice guidelines, in view of the IOM standards being perceived as inflexible or being set too high, a viewpoint shared by others.¹¹

WHAT LIMITATIONS DO CLINICAL PRACTICE GUIDELINES HAVE?

1. Practice guidelines, even if unbiased and valid, are often too narrowly focused on single diseases and are not patient focused. Patients seldom have single diseases, and few if any, guidelines help clinicians in managing complexity.¹² Most practice guidelines address single diseases in accordance with modern medicine's focus on disease and pathophysiology.¹³ The aging of the population and the increasing prevalence of chronic diseases pose challenges to the development and application of clinical practice guidelines. In 1999, 48% of Medicare beneficiaries aged 65 years or older had at least three chronic medical conditions and 21% had five or more. Health care costs for individuals with at least three chronic conditions accounted for 89% of Medicare's annual budget.¹⁴ Most guidelines did not modify or discuss the applicability of their recommendations for older patients with multiple comorbidities.¹²
2. Paradoxically, guidelines are often too comprehensive, covering every possible intervention that could be appropriate for a patient with that single disease.⁴ Guidelines are not patient-specific enough to be useful and rarely allow for individualization of care. Most guidelines have a one-size-fits-all mentality and do not build flexibility or contextualization into the recommendations.^{12,15}

WHAT ARE POTENTIAL HARMS GUIDELINES MAY CAUSE?

The greatest danger of flawed clinical practice guidelines is to patients. Recommendations that are not based on evidence, or based on weak, skewed, or wrong evidence, can result in suboptimal, ineffective, or harmful practices.

1. Even if the guideline is of high quality and thus valid (rarely), the frequently advertised benefit of guidelines: more consistent practice patterns and reduced variation, may come at the expense of reducing individualized care for patients with special needs. Because the specific

elements of care are based on single-disease clinical practice guidelines, pay-for performance may create incentives for ignoring the complexity of multiple comorbid chronic diseases and dissuade clinicians from caring for individuals with multiple comorbid diseases. Quality-of-care standards based on these guidelines also may lead to unfair and inaccurate judgments of physicians' care for this population.¹²

2. Lay versions of guidelines, if improperly constructed and worded, may mislead or confuse patients and disrupt the doctor-patient relationship.¹⁶ Clinical guidelines can adversely affect public policy for patients. Recommendations against an intervention may lead providers to drop access to or coverage for services. Imprudent recommendations for costly interventions may displace limited resources that are needed for other services of greater value to patients. The tendency of guidelines to focus attention on specific health issues is subject to misuse by proponents and advocacy groups, giving the public (and health professionals) the wrong impression about the relative importance of diseases and the effectiveness of interventions.¹⁶
3. Flawed clinical guidelines harm practitioners by providing inaccurate scientific information and clinical advice, thereby compromising the quality of care. They may encourage ineffective, harmful, or wasteful interventions. Clinical guidelines can also hurt clinicians professionally. Flawed guidelines are not only used by physicians, they can also be used by insurers, quality assessment organizations, and malpractice lawyers, who can misinterpret such recommendations as defining quality of care and mistakenly punish or reward physicians.^{4,17} Auditors and managers may unfairly judge the quality of care based on criteria from invalid guidelines. Algorithms that reduce patient care into a sequence of binary (yes/no) decisions often do injustice to the complexity of medicine and the parallel and iterative thought processes inherent in clinical judgment. Words, numbers, and simplistic algorithms can be used by those who judge clinicians to repudiate unfairly those who, for legitimate reasons, follow different practice policies.¹⁶ Guidelines are also potentially harmful to doctors as citable evidence during malpractice litigation and because of their economic implications.^{18,19} Guidelines that conclude that a procedure or treatment lacks evidence of benefit may be misinterpreted by funding bodies as grounds for not investing in further research and for not supporting efforts to refine previously ineffective technologies.

WHAT ARE THE SOLUTIONS TO CLINICAL GUIDELINE PROBLEMS?

Unfortunately, there is no simple solution, and there probably will never be, in view of the perpetual conflict between the overgeneralization of single-disease-centered guidelines and the ever increasing call for individualized/personalized medicine. The applicability of clinical guidelines may be easily challenged when caring for patients with multiple co-

morbidities, or when other factors such as patient preferences, care burden, insurance coverage plan, etc., become deciding factors. It is necessary to keep in mind that practice guidelines are suggestive not compulsory. Practice guidelines should allow individualization and flexibility when dealing with individual patient as one size certainly does not fit all. Recommendations should vary based on patient comorbidities, the health care setting, and patient values and preferences.⁴

Also, it seems that IOM may need to allow some deviation from the eight standards it previously set for guideline development, considering the fact that its own document failed to meet its own standards.¹⁰ Indeed, two decades have passed since IOM proposed the development of clinical guidelines to reduce inappropriate health care variation by assisting patient and health care provider decisions. Since then little improvement in clinical guidelines has been made with regard to meeting the eight new standards of IOM.⁸ Perhaps, it's more sensible for IOM to reset its guideline standards to a level that is reasonably achievable and applicable. In the meantime, the guideline development groups must strive to minimize conflict of interest, because the lack of guideline control in individuals and organizations has become the greatest threat to create trustworthy clinical practice guidelines.²⁰

Guideline development groups may never be able to completely eliminate the problem of conflict of interest, due to the dichotomy in seeking "experts" who participate in guidelines being the same individuals who are typically sought for industry-based collaborations.²¹ It is necessary that guideline development groups make painstaking effort in curbing it before government agencies take central control of guideline productions. At this point, the utility and validity of many clinical guidelines in providing useful guidance in clinical practice remain to be debatable, despite the fact there have been numerous calls and recommendations made in an attempt to make guidelines more "trustworthy".^{4,5,17,21}

WHAT OPTIONS DO HEALTH CARE PROVIDERS HAVE?

1. Clinicians should reject guidelines that were mass produced without solid scientific foundation because these flawed, biased guidelines may do more harms to patients. Unless there is evidence of appropriate changes in the guideline process, clinicians must reject calls for adherence to guidelines. Physicians would be better off making clinical decisions based on valid primary data.^{4,22}
2. For valid guidelines that have been updated, appraised using IOM standards, and clinically applicable, physicians may use them as practice guidance, realizing guidelines have their own limitations. As stated previously, practice guidelines are often too narrowly focused on single diseases and are not patient focused. Ironically, practice guidelines can also be generalized, having a one-size-fits-all mentality and do not build flexibility or contextualization into the recommendations.^{4,12}

3. For the practice of mingling guideline adherence with pay-for-performance, physicians should speak up together in a unified voice of objection. Payment to physicians in pay-for-performance programs, based on their meeting quality-of-care standards created for single diseases, can create financial incentives for physicians to focus on certain diseases and younger or healthier Medicare patients. These initiatives perpetuate the single-disease approach to care and fail to reward physicians for addressing the complex issues that confront patients with several chronic diseases. Standards that define quality of patient care, regardless of a patient's health status and preferences, by placing emphasis on attaining high rates of adherence to practice guidelines rather than the more difficult task of weighing co-morbidity burden, risks, and benefits of complex therapies in shared decision making could ultimately undermine the quality of care.²³
4. For the increasing practice of introducing clinical practice guidelines into the courtroom, to be used as de facto standards of care, physicians should stand together and voice our opposition, as these will hamper physicians' discretion in determining what course of treatment is the best under specific circumstances, and thus conceivably compromise the quality of care that a patient deserves, in light of the aforementioned limitations and various of problems of practice guidelines.

In summary, although clinical practice guidelines are supposed to be evidence based and unbiased, the current use of the word "guidelines" has shifted from the original intent of IOM. Most of the guidelines produced thus far are flawed, biased, and untrustworthy. High quality guidelines may still have the intrinsic limitation of being too disease-focused rather than patient-focused, and lack applicability and validity when dealing with patients with multiple comorbidities or diseases. When applicable, clinical practice guidelines may serve as a relative guidance only, rather than the absolute standard. Physicians need to be critical and vigilant when faced with a plethora of guidelines as following flawed practice guidelines may result in harm to patients. The use of clinical practice guidelines as the "standard of care" as well as for pay-for-performance based on guideline adherence is unjustified.

CONFLICT OF INTEREST

The authors have no conflict of interests to disclose.

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