

Free Summary



Clinical Practice Guidelines We Can Trust

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Summary

Clinicians can no longer stay abreast of the rapidly expanding knowledge bases related to health. The number of randomized controlled trials published in MEDLINE (a medical literature database) grew from 5,000 per year in 1978–1985 to 25,000 per year in 1994–2001. Furthermore, contentions that much of the literature may be biased and not applicable to important subsets of target populations have caused its quality to be suspect. Overall, clinicians increasingly are barraged with a vast volume of evidence of uncertain value. Hence, critically appraised and synthesized scientific evidence has become fundamental to clinical practice. At the same time, and particularly under conditions of uncertainty regarding optimal decisions, clinician experiential knowledge and skill (the “art of medicine”) and patient values and preferences remain essential contributors to quality healthcare practice, in a complex interplay with science.

Clinical practice guidelines (CPGs) embody and support the interrelationships among these critical contributors to clinical decision making. Rather than dictating a one-size-fits-all approach to patient care, CPGs are able to enhance clinician and patient decision making by clearly describing and appraising the scientific evidence and reasoning (the likely benefits and harms) behind clinical recommendations, making them relevant to the individual patient encounter.

Although it remains important for CPGs to be evaluated fully for their effectiveness in improving health, when rigorously developed, they have the power to translate the complexity of scientific research findings into recommendations for clinical practice and potentially enhance healthcare quality and outcomes. However, the current state of CPG development has yet to meet this potential.

CPG DEVELOPMENT CHALLENGES

Clinical practice guidelines are ubiquitous in our healthcare system. The Guidelines International Network database currently lists more than 3,700 guidelines from 39 countries. Its U.S. counterpart, the National Guideline Clearinghouse (NGC), accepted 722 guidelines to its database in 2008 alone, so that its total collection is nearly 2,700. CPG developers and users are characterized by varied organizations such as clinical specialty societies, disease advocacy groups, federal and local agencies, health plans, and commercial companies. However, CPGs suffer from shortcomings in the guideline development process, often compounding limitations inherent in their scientific evidentiary bases. Certain factors commonly undermine the quality and trustworthiness of CPGs. These include: variable quality of individual scientific studies; limitations in systematic reviews (SRs) upon which CPGs are based; lack of transparency of development groups’ methodologies (particularly with respect to evidence quality and strength of recommendation appraisals); failure to convene multi-stakeholder, multi-disciplinary guideline development groups and corresponding non-reconciliation of conflicting guidelines; unmanaged conflicts of interest (COI); and overall failure to use rigorous methodologies in CPG development. Furthermore, evidence supporting clinical decision making and CPG development relevant to subpopulations, such as patients with comorbidities, the socially and economically disadvantaged, and those with rare conditions, is usually absent.

More generally, the quality of CPG development processes and guideline developer adherence to quality standards have remained unsatisfactory and unreliable for decades. Non-standardized development results in substantial variation in clinical recommendations. At the same time, CPGs produced within a structured environment, in which a systematic procedure or “Guidelines for Guidelines” are available to direct production are more likely to be of higher quality. Furthermore, documentation of guideline development is enhanced by developer use of appraisal instruments or tools for systematically assessing and reporting the quality of guideline development processes. While uniformly endorsed standards for clinical practice guidelines development do not yet exist, there appears to be widespread agreement regarding elements basic to quality CPG development.

The concept that quality standards should inform CPG development is a pervasive concern globally, underscored by increasing calls for international standards to hasten rigorous CPG development and appraisal. Although a number and variety of guideline development appraisal tools (e.g. The Appraisal of Guidelines for Research and Evaluation [AGREE] Tool), which point to standards, are available, they inadequately reflect the full range of quality CPG development. They commonly focus on development process and form, with only a small number attending to the quality of evidence and the strength of recommendations. Furthermore, COI, the role of judgment in the derivation of recommendations, prioritization of the recommendations, development group composition, and how to assure patient-centeredness all lack sufficient attention in current standards for CPG development. These appraisal tools also are not designed for prospective application to guideline development. There are no agreed-on standards for prospective enhancement of high-quality, trustworthy clinical practice guidelines.

COMMITTEE CHARGE

In 2008, the Institute of Medicine (IOM) report *Knowing What Works in Health Care* recommended that the U.S. Secretary of Health and Human Services create a public–private program to develop (or endorse) and promote a common set of standards addressing the structure, process, reporting, and final products of systematic reviews of comparative effectiveness research and evidence-based clinical practice guidelines. Congress, through the *Medicare Improvements for Patients and Providers Act of 2008*, subsequently called on the Secretary to contract with the IOM, through the Agency for Healthcare Research and Quality (AHRQ), to undertake two studies: (1) to “identify the methodological standard for conducting systematic reviews of clinical effectiveness research on health and health care in order to ensure that organizations conducting such reviews have information on methods that are objective, scientifically valid, and consistent,” and (2) to focus on “the best methods used in developing clinical practice guidelines in order to ensure that organizations developing such guidelines have information on approaches that are objective, scientifically valid, and consistent.”

The IOM formed two committees, the Committee on Standards for Systematic Reviews of Comparative Effectiveness Research and the Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, to meet the above requests. The two committees worked independently, but in coordination with each other, because the topics were related. While the SR committee attended exclusively to methods for SR development, from formulation of the research question to derivation of the final report, the CPG committee worked from the premise that SRs reflecting the methodological standard, as defined by the SR committee, are instrumental to a trustworthy guideline development process.

The CPG committee defined “standard” as a process, action, or procedure for developing CPGs that is deemed essential to producing scientifically valid, transparent, and reproducible results. The committee examined existing standards for guidelines development, assessing whether any would ensure development of trustworthy clinical practice guidelines. Special attention was given to standards incorporating systems for appraising quality of evidence and strength of recommendations. The committee also considered methods for modifying CPGs for patients with multiple conditions; ways to reduce the number of overlapping guidelines and harmonize CPGs on the same topic; strategies to promote and evaluate adoption of development standards and trustworthy CPGs; means to distinguish trustworthy CPGs; and procedures for identifying guideline recommendations potentially appropriate for measuring the quality of healthcare systems or clinicians.

CLINICAL PRACTICE GUIDELINES: A NEW DEFINITION

The literature assessing the best methods for guideline development has evolved dramatically in the 20 years since the IOM’s first report on the subject, *Clinical Practice Guidelines: Directions for a New Program*, which defined CPGs as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” The committee saw the need to update this definition, in accordance with the AHRQ contract, and to better reflect current consensus on what constitutes a CPG, including aspects of guideline development that the committee believes are defining characteristics. The new definition is as follows: **Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.**

To be *trustworthy*, guidelines should

- Be based on a systematic review of the existing evidence;
- Be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups;
- Consider important patient subgroups and patient preferences, as appropriate;
- Be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest;
- Provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of the recommendations; and
- Be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.

The new definition provides a clear distinction between the term “CPG” and other forms of clinical guidance derived from widely disparate development processes (e.g., consensus statements, expert advice, and appropriate use criteria). Furthermore, it underscores systematic review and both benefits and harms assessment as essential characteristics of CPGs. Although the committee recognizes that other forms of clinical guidance may have value, addressing those other forms was beyond the scope of this report. Furthermore, the committee is aware that, for many clinical domains, high-quality evidence is lacking or even nonexistent. However, even giv-

en such constraints, guideline developers may still produce trustworthy CPGs if their development reflects those committee standards detailed below.

STANDARDS FOR TRUSTWORTHY CLINICAL PRACTICE GUIDELINES

As enumerated below, the committee's proposed standards reflect the latest literature, expert consensus, and public comment, and the committee hopes they represent an important advance in the newest and best practice standards for CPG development. The committee expects its standards to be assessed for reliability and validity (including applicability), and to evolve as the science and experience demand. The committee has given increased attention to aspects of COI, such as details of guideline development group exclusions; aspects of guideline group composition, including training of patient and consumer representatives in evidence appraisal; the specific nature of working relationships between systematic review teams and CPG developers; critical steps in establishing evidence foundations for clinical recommendations and rating recommendations' strength; external review of the CPG, including specified mechanisms for ensuring public stakeholder comment; and elements essential to CPG updating, including ongoing monitoring and review of the CPG-relevant scientific literature and factors indicating the need for updates. The eight standards extend across the development process from conception to completion to revision. The standards should provide sufficient flexibility to be applicable to all guideline development groups (whether evidence in a particular clinical area is lacking or abundant), unlike many development methodologies, which are specific to a particular guideline development entity and clinical problem. The committee's eight proposed standards follow.

Standards for Developing Trustworthy Clinical Practice Guidelines (CPGs)

1) Establishing Transparency

1.1 The processes by which a CPG is developed and funded should be detailed explicitly and publicly accessible.

2) Management of Conflict of Interest (COI)

2.1 Prior to selection of the guideline development group (GDG), individuals being considered for membership should declare all interests and activities potentially resulting in COI with development group activity, by written disclosure to those convening the GDG:

- **Disclosure should reflect all current and planned commercial (including services from which a clinician derives a substantial proportion of income), non-commercial, intellectual, institutional, and patient–public activities pertinent to the potential scope of the CPG.**

2.2 Disclosure of COIs within GDG:

- **All COI of each GDG member should be reported and discussed by the prospective development group prior to the onset of his or her work.**
- **Each panel member should explain how his or her COI could influence the CPG development process or specific recommendations.**

2.3 Divestment

- **Members of the GDG should divest themselves of financial investments they or their family members have in, and not participate in marketing activities or advisory boards of, entities whose interests could be affected by CPG recommendations.**

2.4 Exclusions

- Whenever possible GDG members should not have COI.
- In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the CPG.
- Members with COIs should represent not more than a minority of the GDG.
- The chair or co-chairs should not be a person(s) with COI.
- Funders should have no role in CPG development.

3) Guideline Development Group Composition

3.1 The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the CPG.

3.2 Patient and public involvement should be facilitated by including (at least at the time of clinical question formulation and draft CPG review) a current or former patient, and a patient advocate or patient/consumer organization representative in the GDG.

3.3 Strategies to increase effective participation of patient and consumer representatives, including training in appraisal of evidence, should be adopted by GDGs.

4) Clinical Practice Guideline–Systematic Review Intersection

4.1 Clinical practice guideline developers should use systematic reviews that meet standards set by the Institute of Medicine’s Committee on Standards for Systematic Reviews of Comparative Effectiveness Research.

4.2 When systematic reviews are conducted specifically to inform particular guidelines, the GDG and systematic review team should interact regarding the scope, approach, and output of both processes.

5) Establishing Evidence Foundations for and Rating Strength of Recommendations

5.1 For each recommendation, the following should be provided:

- An explanation of the reasoning underlying the recommendation, including:
 - A clear description of potential benefits and harms.
 - A summary of relevant available evidence (and evidentiary gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence.
 - An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation.
- A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation.
- A rating of the strength of the recommendation in light of the preceding bullets.
- A description and explanation of any differences of opinion regarding the recommendation.

6) Articulation of Recommendations

6.1 Recommendations should be articulated in a standardized form detailing precisely what the recommended action is, and under what circumstances it should be performed.

6.2 Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated.

7) External Review

7.1 External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (e.g., health care, specialty societies), agencies (e.g., federal government), patients, and representatives of the public.

7.2 The authorship of external reviews submitted by individuals and/or organizations should be kept confidential unless that protection has been waived by the reviewer(s).

7.3 The GDG should consider all external reviewer comments and keep a written record of the rationale for modifying or not modifying a CPG in response to reviewers’ comments.

7.4 A draft of the CPG at the external review stage or immediately following it (i.e., prior to the final draft) should be made available to the general public for comment. Reasonable notice of impending publication should be provided to interested public stakeholders.

8) Updating

8.1 The CPG publication date, date of pertinent systematic evidence review, and proposed date for future CPG review should be documented in the CPG.

8.2 Literature should be monitored regularly following CPG publication to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG.

8.3 CPGs should be updated when new evidence suggests the need for modification of clinically important recommendations. For example, a CPG should be updated if new evidence shows that a recommended intervention causes previously unknown substantial harm; that a new intervention is significantly superior to a previously recommended intervention from an efficacy or harms perspective; or that a recommendation can be applied to new populations.

The committee derived several recommendations directly relevant to the ultimate effectiveness of the eight standards in increasing the quality and trustworthiness of CPGs and enhancing healthcare quality and patient outcomes.

RECOMMENDATIONS FOR IDENTIFYING AND EVALUATING TRUSTWORTHY CLINICAL PRACTICE GUIDELINES

The committee views all eight proposed standards as essential elements in the development of trustworthy guidelines. Thus, the committee recommends that:

To be trustworthy, a clinical practice guideline should comply with proposed standards 1–8.

Optimally, CPG developers should adhere to these proposed standards and CPG users should adopt CPGs compliant with these proposed standards.

Some guideline developers will readily adapt their development process to embrace these eight standards; however, not all developers will be able to do so, and a process of evolutionary adoption overtime may be more practical. Although certain standards, such as those directed to patient and public involvement in the CPG development process and external review, may appear particularly resource intensive, strategies to increase effective public participation can minimize this burden.

The committee understands that the uniqueness of guideline development contexts may seemingly preclude certain developers from fully adhering to the standards the committee has proposed. For example, certain clinical areas (e.g., rare malignant tumors) are characterized by an exceptional dearth of scientific literature and an urgent need to deliver patient care. The committee recognizes that developers in this instance may conclude they are unable to comply with Standard 4: “Clinical practice guideline developers should use systematic reviews that meet standards set by the IOM’s Committee on Standards for Systematic Reviews of Comparative Effectiveness Research.” However, SRs that conclude there are no high-quality randomized controlled trials or observational studies on a particular clinical question would still fulfill Standard 4. In all cases, whether evidence is limited or abundant, guideline development groups should comply with the complementary Standard 5: “Establishing evidence foundations for and rating

strength of recommendations” by providing a summary of relevant available evidence (and evidentiary gaps), descriptions of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence; an explanation of the part played by values, opinion, theory, or clinical experience in deriving recommendations; a judgment regarding the level of confidence in (certainty regarding) the evidence underpinning the recommendations; and a rating of the strength of recommendations.

For certain clinical areas, such as rare diseases, there may be no disease group or clinical specialty society with resources to develop trustworthy CPGs. In these cases, outside funding assistance could spur the development of needed guidelines. The committee urges organizations desiring to produce such guidelines to coordinate their efforts and pool resources with related organizations. This could also strengthen their efforts to seek support from foundations, government agencies, and other sources without conflict. The Department of Health and Human Services (HHS) should promote the identification of best practices in CPG development, guided by the committee’s proposed standards, and should assist in training individuals in specific technical skills needed in the CPG process, particularly patient and consumer representatives.

Furthermore, to encourage the promulgation and adoption of standards, the committee recommends HHS create a mechanism to identify trustworthy guidelines. Such identification will serve three purposes, as follows:

- Promote wider adoption of the IOM standards by developers because there will be an advantage attached to CPGs publicly identified as trustworthy;
- Provide CPG users with an easy guide to identify trustworthy ones; and
- Promote adoption of trustworthy CPGs.

The committee recommends:

The Secretary of HHS should establish a public–private mechanism to examine, at the request of developer organizations, the procedures they use to produce their clinical practice guidelines and to certify whether these organizations’ CPG development procedures comply with standards for trustworthy CPGs.

Although AHRQ is not directly involved in CPG development, it does play a vital role in the dissemination and evaluation of guidelines and creation of guideline development methodologies. The NGC is a highly useful guideline dissemination tool. AHRQ should continue to operate this service, and expand its capacities to provide syntheses of recommendations by clinical topic and conduct research on best guideline development practices. As a central repository for all CPGs, the committee does not believe the NGC should be restricted to listing only those CPGs identified as trustworthy. However, the NGC’s contribution may be of questionable value when listing guidelines providing too little information for an informed reader to judge quality and trustworthiness. To be a constructive resource, the NGC should eliminate CPGs for which trustworthiness cannot be determined, and identify the trustworthiness of those retained. Further, the committee recommends that AHRQ pilot-test and assess the reliability and validity of the IOM’s proposed standards, and evaluate their effects on health care quality and patient outcomes. The committee expects its standards to evolve as science and experience regarding CPG development demand.

The committee recommends:

The Agency for Healthcare Research and Quality (AHRQ) should do the following:

- **Require the National Guideline Clearinghouse (NGC) to provide a clear indication of the extent to which clinical practice guidelines (CPGs) submitted to it adhere to standards for trustworthiness.**
- **Conduct research on the causes of inconsistent CPGs, and strategies to encourage their harmonization.**
- **Assess the strengths and weaknesses of proposed IOM standards by pilot-test; estimate the validity and reliability of proposed standards; evaluate the effectiveness of interventions to encourage standards' implementation; and evaluate the effects of standards on CPG development, healthcare quality, and patient outcomes.**

RECOMMENDATIONS FOR INDIVIDUAL AND ORGANIZATIONAL INTERVENTIONS FOR CPG IMPLEMENTATION

Promoting uptake and use of CPGs at the point of care represents a final translation hurdle to move scientific findings into practice. An important guiding principle for promoting adoption of CPGs is that attributes of the CPG (e.g., ease of use, strength of the evidence) as perceived by users and stakeholders are neither stable features nor sure determinants of adoption. Rather it is the interaction among characteristics of the CPG (e.g., specificity, clarity), the intended users (physicians, nurses, pharmacists), and a particular context of practice (e.g., in-patient, ambulatory, long-term care) that determines rate and extent of adoption. Active dissemination and adoption strategies used by implementers to promote use of trustworthy CPGs include academic detailing; audit and feedback and public reporting of performance; opinion leaders; clinical reminders and quick reference guides; payment mechanisms; and shared decision-making aides.

Organizations and health systems can also provide necessary resources, workflow modifications, and infrastructures for CPG implementation by all relevant users, and engage clinician stakeholders in the implementation process. Fundamentally, for trustworthy guidelines to affect quality of care and patient outcomes they must be implemented; hence, the committee offers the following recommendation:

Effective multifaceted implementation strategies targeting all relevant populations affected by CPGs, should be employed by implementers to promote adherence to trustworthy CPGs.

Increased adoption of electronic health records and computer-aided clinical decision support (CDS) will offer unique opportunities to rapidly move clinical knowledge from the scientific literature to the patient encounter. To achieve this goal, guideline developers should structure CPGs to facilitate ready implementation of electronic clinical decision support by health systems (e.g., clinical practices, payers, delivery systems, hospitals). Furthermore, CPG developers should specify definitive and important gaps in scientific evidence for practice recommendations, including those relevant to the target population, to facilitate understanding of potential limitations of clinical decision support. Formal organizational relationships among CPG developers, implementers, and CDS designers are encouraged to align requirements for CDS with the needs and standards of CPG developers. The committee recommends guideline developers and implementers take the

following actions to advance this aim:

Guideline developers should structure the format, vocabulary, and content of CPGs (e.g., specific statements of evidence, the target population) to facilitate ready implementation of computer-aided CDS by end-users.

CPG developers, CPG implementers, and CDS designers should collaborate in an effort to align their needs with one another.

CONCLUSION

Clinical decisions are made under uncertainty. Yet, as medical, biomedical, and health services research advance, translation of scientific evidence increasingly reduces uncertainty in clinical practice. However, requisite to this promise are clinician and patient access to trustworthy clinical practice guidelines informed by high-quality evidence and a guideline development process reflective of best practices. The committee believes the eight standards proposed herein, when embraced by guideline developers, have the capacity to increase quality and trustworthiness of CPGs and ultimately enhance healthcare quality and patient outcomes.

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Committee on Standards for Developing
Trustworthy Clinical Practice Guidelines

Board on Health Care Services

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*“Knowing is not enough; we must apply.
Willing is not enough; we must do.”*

—Goethe



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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **ENRIQUETA C. BOND** of the Burroughs Wellcome Fund, and **MARK R. CULLEN** of Stanford University. Appointed by the National Research Council and the Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

FOREWORD

Many factors enter into health care decisions. What alternatives are available? What does the evidence suggest about their potential benefits and harms? How firm is the evidence? Is there reason to adjust expectations based on a particular patient's age, gender, race, co-morbidities, or other attributes? How might different patient preferences affect the best choice for a particular patient? Are there any social, economic or other practical considerations that could affect the results of a particular care option?

Clinical Practice Guidelines (CPGs) are intended to provide a systematic aid to making such complex medical decisions. When rigorously developed using a transparent process that combines scientific evidence, clinician experiential knowledge and patient values, CPGs have the potential to improve many clinician and patient healthcare decisions, and enhance healthcare quality and outcomes.

The present state of CPG development has yet to fully meet this promise. At the request of the U.S. Congress, the Institute of Medicine (IOM) undertook this study to develop a set of standards for developing rigorous, trustworthy clinical practice guidelines. The proposed standards cover a number of elements essential to developing sound practice guidelines, including: transparency; conflict of interest; guideline development group composition; CPG–SR intersection; establishing evidence foundations for and strength of recommendations; articulation of recommendations; external review; and updating. This report and the eight proposed standards it contains are intended to reinforce the work of numerous researchers, developers and users of guidelines. This report clarifies where evidence and expert consensus buttress best CPG development practices, and where there is still much to learn. We hope and expect these standards to be pilot-tested, assessed for reliability and validity, evaluated for effectiveness, and to evolve as science and experience dictate.

I want to thank the excellent committee who conducted this work, ably led by Sheldon Greenfield, chair, and Earl Steinberg, vice chair. The committee was assisted by dedicated IOM staff led by Robin Graham. A companion report will set out standards for conducting systematic reviews of comparative effectiveness research. I hope that these reports together will advance the state of the art of systematic review and clinical practice guideline development, and contribute to a more transparent, scientifically rigorous, and patient-centered health care system in the United States.

Harvey V. Fineberg, M.D., Ph.D.
President, Institute of Medicine
February 2011

PREFACE

In the early 1990s, the Institute of Medicine (IOM) issued several reports on clinical practice guidelines (CPGs). In the ensuing years, CPGs and guideline development groups have proliferated enormously to the point that the Agency for Healthcare Research and Quality's National Guideline Clearinghouse contains nearly 2,700 CPGs. Parallel growth in CPGs has occurred in other countries; the Guidelines International Network's database currently lists more than 6,800 CPGs.

Although the numbers of CPGs and CPG developers have increased substantially, our understanding of the impact of CPGs on clinical practice and patient outcomes is limited. However, research has shown that CPGs have the potential to reduce inappropriate practice variation, enhance translation of research into practice, and improve healthcare quality and safety. CPGs also have had an important influence on development of physician and hospital performance measures. The data gathered from use of such measures have provided consumers with information on the quality of different healthcare providers and, in some instances, provided physicians and hospitals with an economic incentive to improve quality of care.

At the same time, there has been considerable concern expressed by physicians, consumer groups, and other stakeholders about the quality of the processes supporting development of CPGs, and the resulting questionable validity of many CPGs and CPG-based clinical performance measures. Specifically, this concern extends from limitations in the scientific evidence base on which CPGs rely; a lack of transparency of development groups' methodologies; conflict of interest among guideline development group members and funders; and questions regarding how to reconcile conflicting guidelines. In light of these challenges, and in response to the growing demand for insight into the quality of care being delivered in conjunction with rising healthcare costs and the strong indications of the need to improve clinical decision making and healthcare quality, a provision was included in the *Medicare Improvements for Patients and Providers Act of 2008*. It directed the IOM to form two separate, but related, committees to develop standards for systematic reviews (SRs) of comparative effectiveness research and for CPGs. If standards for development of valid SRs and CPGs were available, then clinicians and the public should have greater trust in standards-based CPGs and clinical performance measures founded on them. Standards for development of trustworthy CPGs additionally could foster the easier translation of guidelines into electronic forms of clinical decision support.

When the CPG committee was formed, we regarded the charge as more or less updating the state of the art based on accumulated experience and advances in thinking. As we delved into our work, however, we recognized that the rapid growth of CPG development efforts had resulted in substantial variation in CPG development processes. If CPGs were to have their intended impacts, there was a pressing need for standards regarding many dimensions of guideline development, including the potential for conflict of interest; the importance of transparency of the guideline development process; the appropriate type and level of patient and public input into the CPG development process; the need for clarity regarding the reasoning supporting each CPG recommendation; the approaches used to rate the quality of evidence underlying and strength of each CPG recommendation; the need to ensure that CPGs take account of patients with coexisting conditions; and the relationship between individuals who develop a guideline and those who perform SRs on topics relevant to the CPG. The committee found no existing set of standards that addressed all of the above elements or offered prospective guidance for developing high-quality, trustworthy CPGs. Thus, the committee proposes its own standards.

The diversity of talents and experiences of the committee members made our task more complicated and challenging than we had anticipated, but ultimately resulted in a highly thoughtful, rich report. Academicians from a variety of disciplines, experts from various types of stakeholder entities, and a diverse array of individuals involved in guideline development and implementation participated in our deliberations and contributed to this report. More than 2,500 publications were reviewed by staff and committee members; a public forum was conducted for organizations that develop and want to use CPGs; and several papers were commissioned to enable the committee to gain as much perspective as possible.

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The extraordinary efforts of Robin Graham, Study Director, and Michelle Mancher and Dianne Wolman made the task possible.

The two of us express our great appreciation to the committee members and staff for their commitment, effort, dedication, and wisdom. The spirited discussions during meetings and the frequent communications between meetings all contributed to this report. We hope the committee's findings and proposed standards and recommendations will foster trustworthy CPGs that increase quality of care and improve patient outcomes.

Sheldon Greenfield, *Chair*
Earl Phillip Steinberg, *Vice Chair*
Committee on Standards for Developing
Trustworthy Clinical Practice Guidelines

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