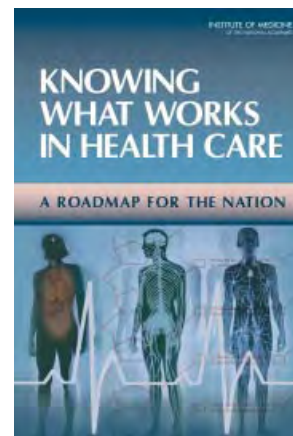


REPORT BRIEF • JANUARY 2008

DEVELOPING TRUSTED CLINICAL PRACTICE GUIDELINES

SELECTED FINDINGS FROM KNOWING WHAT WORKS IN HEALTH CARE: A ROADMAP FOR THE NATION



Clinical practice guidelines are an important means for interpreting and translating research evidence for clinical practice and health care decision making in general.

Decisions about the care of individual patients should be based on the conscientious, explicit, and judicious use of current best evidence. This means that individual clinical expertise should be integrated with the best information from scientifically-based, systematic research and applied in light of each patient's values and circumstances. Clinical practice guidelines are an important means for interpreting and translating research evidence both for clinical practice and for health care decision making in general. Guidelines can be especially helpful to individuals who want to be more engaged in managing their own care when confronted with serious illness.

The development of clinical practice guidelines in the United States involves the coordination of many public and private organizations such as medical professional societies, patient advocacy groups, health plans, government agencies, proprietary firms, and others. While some guidelines have been developed with scientific rigor, the reliability of many current guidelines is questionable because the underlying methods are neither transparent nor based on a systematic and comprehensive assessment of all available evidence. Importantly, it is often difficult to discern whether or not the clinical recommendations are biased due to financial or other types of conflict of interest. Moreover, there is a plethora of guidelines for some conditions and sometimes the guidelines have conflicting and confusing advice. For example, the National Guideline Clearinghouse currently contains 471 practice guidelines just for managing hypertension.

At present there are no protections against the proliferation of poorly developed clinical practice guidelines. Nor is there an infrastructure or process for encouraging the development of objective, trustworthy clinical advice.

WHAT ARE CLINICAL PRACTICE GUIDELINES?

Clinical practice guidelines are systematically defined statements that are designed to help clinicians and patients make decisions about appropriate health care for specific clinical circumstances. They are not intended to



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supplant the independent judgment of clinicians in responding to particular clinical situations.

If it is developed in a way that ensures transparency, scientific rigor, and high standards for accountability and objectivity, a clinical practice guideline can be a trusted resource for information on the effectiveness of health services. Scientifically-based guidelines also have the potential to reduce undesirable practice variation by discouraging the use of services with minimal or questionable value while encouraging the use of services that are known to be effective.

Groups that measure provider performance frequently look at adherence to clinical practice guidelines as a basis upon which to evaluate the quality of care, and many payers are now moving toward the use of pay-for-performance strategies that establish differential payments on the basis of adherence to quality measures. Guidelines are likely to become increasingly influential in clinical practice as health information technology and direct decision support are used at the point of care.

THE GUIDELINE DEVELOPMENT PROCESS

The process for developing guidelines is distinct and separate from conducting systematic evidence reviews. A well-conducted systematic review will delineate what is known and not known about the effectiveness of a health intervention. The guideline panel then faces the significant challenge of translating the findings presented in the systematic review into specific care recommendations. The challenge is often exacerbated by the absence of high quality evidence reviews or an altogether insufficient evidence base. As a consequence, guideline panels must consider the best way to trade-off between rigor and pragmatism, and between adherence to evidence and broader clinical utility. Sometimes, by necessity, a consensus of expert opinion fills in the gaps between areas supported by scientific evidence.

The clinical recommendations embedded in practice guidelines should be systematically developed by panels of experts who have access to the available evidence, an understanding of the clinical problem and the relevant research methods, and sufficient time and resources to absorb the information and make considered judgments.

The process should incorporate two separate grading systems: one for connoting the quality of the available evidence and another for connoting the strength of the clinical recommendation. The grade representing the quality of the evidence should reflect the level of confidence that, if the recommendation is followed, the anticipated outcomes will occur. The grade representing the strength of the recommendation should reflect the balance of benefits and harms that are associated with the intervention and the guideline panel's conclusion about the importance of adhering to the recommendation. For example, recommendations are considered strong when the benefits clearly exceed the harms or when the harms clearly exceed the benefits. Lower-level recommendations (sometimes referred to as clinical options) are made when the balance of anticipated benefits and harms is unclear.

Clinicians should be able to discern when guidelines are based primarily on expert opinion rather than empirical evidence. Often, however, it is not clear which parts of guidelines are evidence based and which are not. The guidelines should explicitly disclose the role of expert opinion particularly when the relevant evidence is sparse.

POTENTIAL SOURCES OF BIAS IN CLINICAL PRACTICE GUIDELINES

- Members of the guideline panel have a material interest in the recommendations, e.g., stock ownership, royalties, or other returns.
- Members of the guideline panel have indirect financial interests, e.g., they could be paid for the health service under consideration or receive honoraria for promoting or discussing it in an academic setting.
- The guideline panel is primarily or exclusively made up of individuals from one specialty with only limited participation by other types of providers, patients, plans, methodologists, etc.
- Members of the guideline panel have intellectual biases, e.g., prior research, strongly held opinions, or professional specialty that might compromise their objectivity or bring it into question.
- The organization producing the guideline receives funding from companies with a material interest in the recommendations.
- The guideline panel does not allow participation from members of the public.

Often, however, it is not clear which parts of guidelines are evidence based and which are not. The guidelines should explicitly disclose the role of expert opinion particularly when the relevant evidence is sparse.

Key Attributes of Trusted Guidelines

Guideline development should reflect the following attributes to ensure that the recommendations are trustworthy and relevant to the concerns of patients and clinicians:

- **Objectivity** — Instituting balanced panel participation and governance will help to ensure that the clinical guidance that is produced is objective and trustworthy.
- **Transparency** — Open deliberations that encourage public participation help ensure a balance of viewpoints. Methods should be explicitly defined, consistently applied, and available for public review. Conflicts of interest should be publicly disclosed.
- **Efficiency and timeliness** — The process should be responsive to the needs of patients and clinicians at the point of care. Timeliness is crucial; health care decisions must be made whether or not a relevant guideline is available.
- **External review** — Peer review by outside experts helps ensure the quality of guidelines. Guideline panels should incorporate peer review into their processes and also allow public comment on draft guidance. There should be in-

To minimize bias due to conflicts of interest, guideline panels should include a balance of competing interests and diverse stakeholders, publish conflict of interest disclosures, and prohibit voting by members with material conflicts.

dependent oversight of the peer review process to ensure that well-supported criticism informs the final recommendations.

- **Currency** — Guidelines have limited shelf lives. Medical practice is dynamic and evidence is constantly expanding. Guideline developers must be ever-vigilant in monitoring the research literature. Organizations should not develop guidelines unless they are willing to maintain their currency.
- **Overlaps and gaps** — Guidelines often conflict; groups that develop or sponsor guidelines should be willing to participate in the reconciliation of their work with that of other groups when appropriate. In addition, a process for identifying and addressing the absence of guidelines for rare diseases and other clinical areas is needed.

FINDINGS

This report brief summarizes key findings from one chapter in the IOM report *Knowing What Works in Health Care: A Roadmap for the Nation*. The full report recommends that the U.S. Secretary for Health and Human Services designate a National Clinical Effectiveness Assessment Program with responsibility for producing unbiased information on clinical effectiveness, including rigorous standards for ensuring unbiased, trustworthy clinical guidelines. It further recommends the following:

- Groups developing clinical guidelines or recommendations should use the standards of the National Clinical Effectiveness Assessment Program, document their adherence to the standards, and make this documentation publicly available.
- To minimize bias due to conflicts of interest, guideline panels should include a balance of competing interests and diverse stakeholders, publish conflict of interest disclosures, and prohibit voting by members with material conflicts.
- Providers, public and private payers, purchasers, accrediting organizations, performance measurement groups, patients, consumers, and others should preferentially use clinical guidelines developed according to the standards of the National Clinical Effectiveness Assessment Program.

FOR MORE INFORMATION . . .

Copies of *Knowing What Works in Health Care: A Roadmap for the Nation* are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, www.nap.edu. The full text of this report is available at www.nap.edu. This is the third of three Report Briefs on this publication.

This study was supported with funds from the Robert Wood Johnson Foundation. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the organizations or agencies that provided support for this project.

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