IfPA Institute for Patient Access

The Physician's Perspective:
A Health Policy Brief from the Institute for Patient Access

MARCH 2016

Clinical Practice Guidelines and Patient Access

By David Charles, MD and Mary Ann Chapman, PhD

Clinical Practice Guidelines: Recommendations, Not Limitations

David Charles, MD

When patients experience health problems, they trust their physicians to recommend the best possible treatments, taking into account their medical history, symptoms, and preferences. Physicians rely on their training and experience to make these important decisions. To assist physicians and help promote evidence-based health care, clinical practice guidelines have been developed for a variety of health conditions and procedures.

Clinical practice guidelines can substantially influence medical practice and patient access to treatment. For these reasons, it is essential that organizations follow a transparent, inclusive, and evidence-based process for guideline development. Moreover, guideline recommendations were never intended to apply to all patients or to replace physician judgment. Consequently, clinical practice guidelines should not be used to force one-size-fits-all health care.

Clinical practice guidelines are designed to help optimize patient care.

Guidelines need input from a broad range of stakeholders, including a multidisciplinary group of experts and patients or advocates.

Clinical practice guidelines' influence on treatment decisions and health insurance/reimbursement requires that their development entail transparent processes and unbiased, thorough reviews of the evidence.

The application of guidelines must permit flexibility in the care of individual patients when deemed necessary by their physician.

Standards for Guideline Development

Due to the increasing number of guidelines (>2,700), some of which may be contradictory or perceived as untrustworthy, the Institute of Medicine (IOM) developed standards for clinical practice guidelines in 2011.[1,2] These standards are summarized in the following table.[1]

Institute of Medicine Standards for Developing Trustworthy Clinical Practice Guidelines[1]

- **Transparency:** Guideline development and funding should be transparent.
- **Conflicts of interest:** Conflicts of interest should be disclosed and managed.
- **Guideline development group composition:** Group should be multidisciplinary and include those affected by the guideline.
- **Systematic reviews:** Systematic reviews used in guideline development should meet IOM's Standards for Systematic Reviews of Comparative Effectiveness Research.
- **Evidence foundation and strength of recommendation:** Underlying rationale and strength of evidence should be provided.
- **Articulation:** Recommendations should be articulated in a standardized format that includes the action to be performed and the relevant circumstances.
- **External review:** Guidelines should undergo external review by a broad group of relevant stakeholders.
- **Updating:** Guidelines should be updated based on new evidence.

Guideline Development Processes

Medical Professional Societies

The exact methods of guideline development vary among different medical professional societies, but they generally include several common features. A committee is formed to develop the guidelines, typically comprising a multidisciplinary group of clinical experts and other stakeholders such as patients, advocates, and policymakers.[3] The group typically formulates the guideline objectives and clinical questions, and defines the patient population(s). The group may then determine the type of evidence and outcomes to include, and define the analytic framework.[4] Both the Agency for Healthcare Research and Quality (AHRQ) and the IOM require guidelines to be evidence based, as opposed to opinion or experience based,[1,5] and many medical professional societies grade the strength of the underlying evidence. Once the evidence is reviewed, it is translated into recommendations and often subjected to external review.[6]

Government Organizations

Government organizations sometimes publish clinical practice guidelines. For example, the Centers for Disease Control and Prevention (CDC) has recently developed guidelines for the prescription of opioids (painkillers) for the treatment of chronic pain in primary care settings.[8] In the development of these guidelines, the CDC followed the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method (http://www.gradeworkinggroup.org/), which specifies the systematic review of scientific evidence and promotes the transparent grading of evidence quality and recommendation strength.[8] The resulting recommendations were considered by a core expert group that included CDC scientific staff, subject matter experts, state agency representatives, and an expert in guideline development methods. Later, the guidelines were reviewed and commented on by a variety of stakeholders, including professional medical organizations, community groups, and the public.[9]

Health Insurance Organizations

Most large health insurance organizations adopt selected guidelines from medical professional organizations.[10-13] However, others adapt existing guidelines or develop their own.[14,15] Health insurance organizations do not typically describe the process of guideline development on their websites, but may state that the guidelines are evidence based and are developed by staff physicians in consultation with practicing clinicians.[14,15]

Controversy in Guideline Development

Unfortunately, not all organizations that develop guidelines adhere to the standards set by the IOM. This can lead to substantial controversy over the legitimacy of the guideline committee, conflicts of interest, quality/interpretation of the evidence, and potential limits to patient care.[7] Clinical practice guidelines can be extremely influential, not only in determining which therapies and procedures physicians recommend to their patients, but also in determining health insurance coverage policies.[3] It is therefore important that guideline development groups follow standards designed to promote transparent, inclusive, impartial, and evidence-based recommendations.

Transparency

Transparency is the first principle described in the IOM Standards for Developing Trustworthy Clinical Practice Guidelines.[1] Although many guideline development groups do use transparent processes, transparency is not universal.

For example, some have questioned the process by which the CDC selected the committee to develop their recent guidelines for the prescription of opioids for the treatment of chronic pain in primary care settings. In response to claims that they preferentially selected experts favorable to their position, the CDC broadened their request for input to include numerous external groups, including professional medical organizations, community groups, and the public.[9,18]

Who Develops Clinical Practice Guidelines?

Type of organization	*Examples*
Medical professional societies	American Academy of Neurology American Academy of Pediatrics
Non-profit alliances	National Comprehensive Cancer Network® (NCCN®)
US government	Centers for Disease Control and Prevention (CDC)
Health insurance companies	Unity Health Insurance

Conflict of Interest

A second principle outlined by the IOM is the disclosure and management of conflicts of interest. The most knowledgeable and relevant experts may have conflicts of interest, such as physicians who practice medicine in the area described in the guideline.[1] Often, it is important to include these individuals despite their potential conflicts of interest. In recognition of this, the IOM recommends that a majority of guideline group members, as well as the committee chair and co-chair, should be free from conflicts of interest.

Most importantly for guideline development, group members must disclose any potential conflicts of interest. These potential conflicts of interest must then be adequately examined and managed. When this doesn't occur, insurers may inappropriately restrict coverage as demonstrated by a 2008 finding of the Connecticut Attorney General that the Infectious Disease Society of America failed to review the conflicts of interest of group members who developed an influential 2006 guideline on Lyme disease.[19]

Evidence Base

The IOM standards indicate that guidelines should include a summary of relevant available evidence (including evidence gaps) and an assessment of the

quality, applicability, completeness, and consistency of the evidence.[1] Although many guideline developers do attempt to thoroughly and objectively evaluate the available evidence, the evidence base is often incomplete, and multiple interpretations may be possible.

An example of this is in the 2014 revised guidelines issued by the American Academy of Pediatrics Committee on Infectious Diseases for the use of a prophylactic medication for infants at increased risk for hospitalization due to infection with respiratory syncytial virus.[20] The revised guidelines have been criticized for the data utilized in drawing their conclusions.[21]

Participation from Relevant Stakeholders

Per the IOM standards, guideline development groups should be multidisciplinary and include populations expected to be affected by the guideline. Although it can sometimes be challenging to include patients in guideline development groups, many different methods of involving patients have been successfully implemented.[3] Moreover, patient advocates may be a good fit for guideline development groups given their representation of a broad patient perspective, as well as their understanding of medical terminology and the structure and importance of clinical evidence.[3]

Patient and advocate representation is particularly important for guideline development by organizations whose members may be divorced from patient concerns, such as the government and health insurers. In the absence of patient involvement, health insurers may be inclined to weigh cost too heavily and government organizations may develop guidelines that lack the patient perspective.

Use of Clinical Practice Guidelines

Clinical practice guidelines can be extremely useful to physicians in helping to determine proven, evidence based treatments. For patients, guidelines can help engender confidence that they are receiving the best medical care. However, guidelines were never intended as absolutes, and problems can arise when a patient's individual situation necessitates deviation from the recommendations. Patients given treatments that are not aligned with clinical practice guidelines may wonder why, leading them to question their physician's judgment and interfering with the patient-physician relationship.

> Guidelines were never intended to ration patient care or replace physicians' judgment.

Physicians may feel pressured by health insurance companies and even their employers to follow the guidelines in most or all situations. Indeed, guidelines can be, and often are, used to restrict patient care even if they were not developed according to the IOM standards. Ultimately, it is essential that physicians have the latitude to provide individualized patient care that may not fit a particular practice guideline, as deemed necessary in their professional judgment.

Conclusions

Clinical practice guidelines can be useful to both physicians and patients, helping to promote consistent, evidence based medical care. The guidelines can also be extremely influential, not only in shaping physician behavior, but also in determining health insurance coverage and reimbursement. For these reasons, the methods used to develop clinical practice guidelines must be transparent, inclusive, thorough, and systematic. Diligent efforts should be employed to guard against bias while including the most relevant experts, as well as patients and advocates who provide an important perspective. Guidelines were never intended, and should not be used, to ration patient care or as a replacement for physicians' judgment.

References

1. Institute of Medicine. Clinical Practice Guidelines We Can Trust. March, 2011. Available at: www.iom.edu/cpgstandards. Accessed February 9, 2016.
2. Ransohoff DF, Pignone M, Sox HC. Development of trustworthy practice guidelines--reply. JAMA. May 8 2013;309(18):1890-1891.
3. Eccles MP, Grimshaw JM, Shekelle P, Schunemann HJ, Woolf S. Developing clinical practice guidelines: target audiences, identifying topics for guidelines, guideline group composition and functioning and conflicts of interest. Implement Sci. 2012;7:60.
4. Woolf S, Schunemann HJ, Eccles MP, Grimshaw JM, Shekelle P. Developing clinical practice guidelines: types of evidence and outcomes; values and economics, synthesis, grading, and presentation and deriving recommendations. Implement Sci. 2012;7:61.
5. Agency for Healthcare Research and Quality. National Guideline Clearinghouse. Inclusion criteria. Available at: https://www.guideline.gov/about/inclusion-criteria.aspx. Accessed February 16, 2016.
6. Rosenfeld RM, Shiffman RN. Clinical practice guideline development manual: a quality-driven approach for translating evidence into action. Otolaryngol Head Neck Surg. 2009;140(6 Suppl 1):S1-43.
7. Guallar E, Laine C. Controversy over clinical guidelines: listen to the evidence, not the noise. Ann Intern Med. 2014;160(5):361-362.
8. Centers for Disease Control and Prevention (CDC). Draft CDC Guideline for Prescribing Opioids for Chronic Pain. Updated January 28, 2016. Available at: http://www.cdc.gov/drugoverdose/prescribing/guideline.html. Accessed February 17, 2016.
9. Centers for Disease Control and Prevention. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. Available at: http://www.asam.org/docs/default-source/advocacy/cdc-draft-guideline.pdf?sfvrsn=0. Accessed February 19, 2016.
10. Humana®. Clinical practice guidelines. Available at: https://www.humana.com/provider/support/clinical/clinical-practice. Accessed February 16, 2016.
11. United Healthcare®. Clinical guidelines. Available at: https://www.unitedhealthcareonline.com/b2c/CmaAction.do?channelId=accaca74f198e110VgnVCM2000002cc0dc0a. Accessed February 16, 2016.
12. Cigna HealthSpring®. Clinical practice guidelines. Available at: http://www.cigna.com/iwov-resources/medicare-2015/docs/clinical-practice-guidelines.pdf. Accessed February 16, 2016.
13. Anthem® Blue Cross. Clinical practice guidelines. Available at: https://www.anthem.com/wps/portal/ahpprovider?content_path=provider/noapplication/f2/s0/t0/pw_b132861.htm&label=Clinical%20Practice%20Guidelines&state=me. Accessed February 16, 2016.
14. Unity Health Insurance. Clinical practice guidelines (CPGs). Available at: https://unityhealth.com/practitioners/clinical-guidelines. Accessed February 16, 2016.
15. Medica®. Clinical guidelines. https://www.medica.com/providers/policies-and-guidelines/clinical-guidelines. Accessed February 16, 2016.
16. Rochwerg B, Schunemann HJ, Raghu G. Idiopathic pulmonary fibrosis - clinical management guided by the evidence-based GRADE approach: what arguments can be made against transparency in guideline development? BMC Med. 2016;14(1):22.
17. Washington Legal Foundation. Letter to the Centers for Disease Control and Prevention, November 17, 2015. Available at: http://www.wlf.org/upload/litigation/misc/CDCComments-Opioids.pdf. Accessed February 28, 2016.
18. Samp R. CDC bows to demands for transparency and public input on draft opioid-prescribing guidelines. Forbes. December 15, 2015. Available at: http://www.forbes.com/sites/wlf/2015/12/15/cdc-bows-to-demands-for-transparency-and-public-input-on-draft-opioid-prescribing-guidelines/#558b51d31122. Accessed February 28, 2016.
19. Connecticut Attorney General's Office. Press Release. Attorney General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees To Reassess Guidelines, Install Independent Arbiter. May 1, 2008. Available at: http://www.ct.gov/ag/cwp/view.asp?a=2795&q=414284. Accessed February 17, 2016.
20. American Academy of Pediatrics. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. July 28, 2014. Available at: http://pediatrics.aappublications.org/content/early/2014/07/23/peds.2014-1665 and http://pediatrics.aappublications.org/content/134/2/e620. Accessed February 19, 2016.
21. Domachawske JB. The 2014 AAP COID update on palivizumab. Pediatric News. February 25, 2015. Available at: http://www.pediatricnews.com/columnists/single-view/the-2014-aap-coid-update-on-palivizumab/3c76ea3404b6ca7257a56682320acdac.html. Accessed February 19, 2016.

About the Author and the Institute for Patient Access

David Charles, MD, is a neurologist practicing and conducting clinical research in Nashville, Tennessee. Dr. Charles has chaired both the Public Policy Committee of the American Neurological Association and the Government Relations Committee of the American Academy of Neurology. Dr. Charles has served as a Health Policy Fellow in the United States Senate on the staff of the Labor Subcommittee for Public Health and Safety, and is National Chairman of the Alliance for Patient Access.

Mary Ann Chapman, PhD, is a scientific communications writer based in Mead, Washington.

The Institute for Patient Access is a physician led nonprofit 501(c)(3) research organization promoting the benefits of the physician-patient relationship in the provision of quality healthcare. To learn more visit www.AllianceforPatientAccess.org.