Clinical Guidelines

Clinical practice guidelines (CPGs) are often the basis and justification for clinical quality measures (CQMs). Clinicians may not have the justification for CQMs at their fingertips even though clinicians are expected to keep up with the latest medical science literature. The number of randomized controlled trials published annually has grown exponentially[1] making it impossible for a clinician to keep up with the literature. This literature is extensive and requires additional research to uncover bias or application to target populations. CPGs seek to close the gap between the clinician and relevant literature by providing information, recommendations, and/or best practices on healthcare for specific circumstances, diagnostic and treatment options, or patient management. While CPGs are not meant to dictate care, and in some cases still require rigorous evaluation, they are guidelines clinicians can consider, translating complex research findings into practical information and justification for CQMs that can ultimately enhance healthcare quality and outcomes. However, over the years, CPG development has received attention and scrutiny to ensure that bias is reduced, and quality and validity are maintained or even improved.

The Institute of Medicine (IOM), now the National Academy of Medicine, has been studying CPGs for almost 30 years beginning with a report in 1990 entitled *Clinical Practice Guidelines: Directions for a New Program*. Drivers for this report were "perceived health and economic consequences of inappropriate medical care" (p. 2) resulting from a variety of sources such as escalating healthcare costs and variations in practice. It was determined that, while there were good processes in place to develop CPGs, there were deficiencies in scope, substance, and method. The report provided a definition of CPGs and identified attributes of good guidelines.

Fast forward twenty years and IOM was again asked to assess CPG development. The 2011 report, *Clinical Guidelines We Can Trust*, noted that, despite the benefit that CPGs offer to clinicians in information and ease of access, challenges remain in CPG development. CPGs may inadvertently include poor quality information with questionable validity. During the guideline development process, deficiencies may arise, such as[2]

- Variable quality of individual scientific studies used in the development of the CPG
- Limitations in systematic reviews upon which the CPG is based
- Lack of transparency in the development methodology

[1] Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Graham, R., Mancher, M., Miller Wolman, D., Greenfield, S., & Steinberg, E. (Eds.). (2011). *Clinical Guidelines We Can Trust*. Washington (DC): National Academies Press. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK209538/

[2] Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Graham, R., Mancher, M., Miller Wolman, D., Greenfield, S., & Steinberg, E. (Eds.). (2011). *Clinical Guidelines We Can Trust*. Washington (DC): National Academies Press. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK209538/

- Failure to utilize multi-stakeholder, multi-disciplinary guideline development groups
- Non-reconciliation of conflicting guidelines
- Unmanaged conflicts of interest
- Overall failure to utilize scientifically-rigorous methodologies in CPG development.

Quality standards for CPGs must be rigorous and widely adopted, and existing guideline development tools must be improved. The development of CPGs must rely on shared standards to ensure that they are trustworthy and of high quality. In 2011 the committee revised the 1990 definition of CPGs and developed items to assist in identifying trustworthy guidelines (p. 5)[3]

- 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
- Be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.

Since 1997, the Agency for Healthcare Research and Quality (AHRQ) has provided an online National Guideline Clearinghouse (NGC) of over 2,000 guidelines from multiple sources and countries. CPGs are available for many clinical specialties such as allergy and immunology, cardiology, family medicine, gastroenterology, men's health, neurology, oncology, and women's health. There are also separate summaries and sources available not on the NGC for individual clinical specialties. These are usually found on the specialties' website or in their professional journal. CPGs are also developed by organizations such as disease advocacy groups, federal and local government agencies, health plans, and commercial companies. Using the NGC, clinicians and other CPGs users can search based on target population characteristics (e.g., age or gender), clinical specialty, organization, guideline category, intended users, methods used, and implementation tool. The NGC also allows users to compare various guideline summaries to help identify the most appropriate CPG for their use. As a result of the 2011 IOM report, the criteria for inclusion in the NGC was revised. Numerous CPGs were removed or modified because of the criteria revision.

As mentioned previously, CPGs are often the basis for CQMs. For example, the 2017 National Quality Forum Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement notes that the methods used to develop CPGs are very similar to what should be used to develop appropriate use criteria. Discussion of pertinent CPGs is expected as part of the NQF Evidence Attachment.

[3] Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Graham, R., Mancher, M., Miller Wolman, D., Greenfield, S., & Steinberg, E. (Eds.). (2011). *Clinical Guidelines We Can Trust*. Washington (DC): National Academies Press. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK209538/

Per the Blueprint, measure developers are expected to review any pertinent CPGs as part of information gathering for de novo and respecified measures, and as part of the maintenance process. A review of and updates to CPGs may be the reason for respecifying a measure. A summary of pertinent CPGs is part of the Information Gathering report. When discussing gaps, the lack of CPGs or inconsistent CPGs should be discussed. Measure developers should review CPGs for currency and address if new studies are not incorporated in the CPG. Since most of the CPGs are disease or condition specific and clinical trials used for the basis of CPGs usually exclude persons with multiple chronic conditions (MCCs), use of CPGs in development of measures for MCCs need to be assessed carefully as disease-specific guidelines may conflict and/or present unintended consequences.

CPGs are expected to continue to be an important aspect of CQM development and maintenance. CQM developers need to be aware of the positive aspects and potential shortcomings of CPGs and consider all the evidence when developing and maintaining CQMs.

For more information on this topic, please visit our Overview of the Conceptualization Phase of Measure Development on the CMS website.