

## Section 3.9 Design

# Introduction to Clinical Guidelines

This tool describes the use of evidence-based guidelines in caring for patients, encourages community-based care coordination (CCC) programs to gain consensus for using evidence-based protocols, and provides a plan for implementing clinical guidelines.

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**Time needed:** 2 hours

**Suggested other tools:** Physician Engagement; Technology Tools and Optimization for CCC; Assessment of Data Needs for Clinical Quality Measures (CQMs); Quality Scores Monitoring and Reporting; CCC Program Evaluation

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## How to Use

1. **Understand** the range of terms used to describe evidence-based guidelines.
2. **Recognize** that in many practice settings there is a gap between guidelines and clinical practice.
3. **Describe** the benefits of and challenges in using evidence-based guidelines.
4. **Plan** for implementing a convergence toward a common set of evidence-based guidelines within the CCC program community.
5. **Monitor** the use of clinical guidelines within the CCC program and across the industry as new guidelines and new strategies for adoption come into place.

## Evidence-based Guideline Terminology

Evidence-based medicine has been defined as the application of a more scientific, data-driven approach to healthcare decision-making. A number of terms have been used to describe this approach. Although they may often be used synonymously, some modest distinctions can be made:

- **Clinical guidelines** is the term most commonly used by the federal government in its value-based purchasing initiatives as well as by the Agency for Healthcare Research and Quality (AHRQ) National Guideline Clearinghouse.<sup>1</sup> The Institute of Medicine defines clinical practice guidelines as “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 options.”<sup>2</sup> The term *clinical guidelines* also tend to be the preferred term among providers (as distinguished from care pathway or care map which are terms more often used by nursing professionals) or clinical policies or practice parameters which are more commonly referenced in managed care environments.
- **Clinical policy** or **practice parameters** are terms which tend to denote proprietary development or use of clinical guidelines within a specific hospital, hospital chain, managed care plan or other organized setting. Such policies or parameters are often used to control cost and enhance their competitiveness. Practitioner profiling is often linked with use of such policies or parameters in these settings.<sup>3</sup>
- **Care pathways** or **care maps** are terms used to describe a predetermined written guide for a plan of care for a specific health situation generally used by nurses to develop specific care plans for patients. These terms are also used when referencing a medical management or utilization guide.<sup>4</sup>

It is also important to appreciate the difference between **clinical guidelines** and **clinical quality measures** (CQMs). CMS describes CQMs as tools that help measure and track the quality of healthcare services within the healthcare delivery system. They measure health outcomes, clinical processes, patient safety, efficient use of healthcare resources, care coordination, patient engagement, population and public health, and adherence to clinical guidelines.<sup>5</sup>

For CQMs required by the CMS Meaningful Use of EHR incentive program, the Medicare Shared Savings Program and other initiatives, the measures are comprised of definitions, measure logic, data elements, and value sets.<sup>6</sup> AHRQ, CMS, the National Library of Medicine (NLM), and the Office of the National Coordinator for Health Information Technology (ONC) provide these components in various formats.

In addition to their availability, CQMs undergo a thorough, consensus-based process to be designated national voluntary consensus standards. The National Quality Forum (NQF) is a not-for-profit membership organization created to develop and implement a national strategy for healthcare quality measurement and reporting and is the standards organization that endorses quality measures as national voluntary consensus standards. Many of the CQMs adopted by CMS are endorsed by NQF. These are available from the AHRQ National Quality Measure Clearinghouse (NQMC) which, much like the National Guideline Clearinghouse, is a public resource for evidence-based quality measures and measure sets. A section of NQMC is devoted to NQF-endorsed measures.<sup>7</sup> (For more information, see *Assessment of Data Needs for CQMs and Quality Scores Monitoring and Reporting* in this Toolkit.)

## Current Clinical Guideline Utilization

The degree of usage of clinical guidelines in daily practice is unknown despite that the National Guideline Clearinghouse lists close to 10,000 guidelines. In addition, there appears to be significant variability in successful implementation by type of guidelines with more success generally in cancer guideline and for certain chronic illnesses, such as diabetes and COPD. However, overall utilization is not at the desired point given the many published articles on how to implement such guidelines.

## Benefits and Challenges in Use of Clinical Guidelines

Although formalization of clinical guidelines is relatively new, it is based on work that began in the late 1960s that identified the need and initiated development of guidelines. In general, clinical guidelines arose out of the recognition that there is too much waste in healthcare delivery, higher-quality care is needed, and that science and clinical best practice ought to play a role in the overall solution.<sup>8</sup> Consider the list of benefits and challenges provided below to prepare to make the case for implementing clinical guidelines in the CCC program.

### Specific benefits of clinical guidelines include:

1. *Definition of consistent standards of care* for a specific condition, event or process based on scientific evidence that may improve quality.
2. *Delineation of process and expected outcome* that can be measured.
3. *Identification of performance expectations* so that all providers across a community are operating at a level of value necessary by the whole.
4. *Definition of accountability and reduction in variation in care* that may reduce cost, such as by aiding emergency providers in determining appropriateness for hospitalization, addressing patient needs to avoid readmission, and incorporating case management guidelines for level of service utilization.
5. *Improvement in communications* among healthcare professionals, especially when guidelines address care planning, care coordination, and resource use.
6. *Improvement in documentation*, especially when guidelines can be incorporated into electronic health record (EHR) software.

### Challenges in gaining adoption include:

1. *Basis and validity of clinical guidelines.* The ACEP Information Paper previously cited notes that “optimally, clinical guidelines are evidence-based, supported by randomized clinical trials, and validated by focused outcome studies.” However, the ACEP Information Paper notes that such evidence is not available for many clinical situations and that when driven strictly by actuarial data, limitation of reimbursement should be suspect.

It is important to assess the quality of such guidelines and their applicability in various settings. In fact, various systems have been used to stratify the quality of evidence and to assign grades for recommended usage. The most common of these, originally published in 1986 and updated in collaboration with the AHRQ, are from the U.S. Preventive Services Task Force.<sup>9</sup>

**a. *Stratification of Evidence Quality:***

- i. Level I: Evidence from at least one properly designed randomized controlled trial.
- ii. Level II-1: Evidence obtained from well-designed controlled trials without randomization.
- iii. Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- iv. Level II-3: Evidence obtained from multiple time series designs with or without the intervention. Dramatic results in uncontrolled trials.
- v. Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

**b. *Grades for Recommending a Clinical Service:***

- i. Level A: Good scientific evidence suggests that benefits of the service substantially outweigh risk; clinicians should discuss service with eligible patients.
  - ii. Level B: At least fair scientific evidence suggests that the benefits of the service outweigh the risk; clinicians should discuss service with eligible patients.
  - iii. Level C: At least fair scientific evidence suggests that there are benefits to the service, but the balance between benefits and risks are too close for making general recommendations; clinician need not suggest this service unless there are individual considerations.
  - iv. Level D: At least fair scientific evidence suggests that risks of the service outweigh benefits; clinicians should not routinely offer service to asymptomatic patients.
  - v. Level I: Scientific evidence is lacking, of poor quality, or conflicting, such that the risk versus benefit cannot be assessed; clinicians should help patients understand the uncertainty surrounding the service.
2. *Liability considerations* are often raised by providers who have the concern that clinical and legal risks may be increased by implementation of guidelines that do not have a solid foundation in evidence and/or are poorly drafted. This concern – which is not a concern when sound, evidence-based principles are implemented and adhered to – is so strong that a bill introduced in Congress in March 2014 (Saving Lives, Saving Costs Act) would grant providers increased liability protection (i.e., cause a suspension in a malpractice proceeding allowing for an independent medical review panel investigation) if they demonstrate they followed established guidelines.<sup>10</sup>

3. *Ethical considerations* must balance what seems to be good with what is right. Guidelines cannot be applied to all clinical situations and exceptions to guidelines are not unusual. Every patient presents a unique situation which may not have been controlled in a clinical trial. The application of clinical guidelines must always be weighed in the context of the provider's clinical judgment. However, when there is a validated evidence-based guideline which conflicts with an opinion or consensus guidelines, the evidence-based guideline should take precedence.

## **Plan for Implementing Clinical Guidelines**

Merola and Hopkins recommend a series of steps to move a community forward in adopting evidence-based guidelines. Such steps may include:

### **1. Select evidence-based guidelines.**

From the volume of guidelines published in the National Guideline Clearinghouse (and other sources) as well as the discussion of challenges, there are many to choose from and their selection process must be driven by critical needs of the setting and providers' confidence in the guidelines. Although the task of selecting guidelines may seem daunting, the process is often more likely to be one of reaffirming the value of existing guidelines and gaining consensus for use. With various health reform and incentive programs in existence, at least a starting point on selection is in place.

It is recommended that:

- a. *A multi-disciplinary selection committee* should be formed that represents all stakeholders. While some guidelines may be specific to a specialty, a multi-disciplinary selection committee can help with critical review and will garner trust in a CCC program where there is heightened dependency among providers to treat patients with multiple chronic conditions.
- b. *Initial screening criteria* should be established (e.g., quality evidence and grades; whether the evidence in the guideline is current; whether the guideline addresses care planning, care coordination, and resource use; and how easy the guideline is to use, deploy in current software, and share with patients) and a clinician, clinical team, or teams be given the task of culling through the guidelines to select the most likely candidates.
- c. *Selection committee should engage community members* to make them aware of the process, introduce them to evidence-based guideline concepts, allay concerns, and generally keep the community informed of all steps in the implementation process.
- d. *Selection committee should recommend a set of guidelines* based on thorough review of each recommended guideline. This may be an iterative process wherein an initial pass at available guidelines may not yield a desirable guideline for a given type of patient.

**2. Establish a priority for use of guidelines within the CCC program.**

As communication and building trust are vital to the success of a CCC program, it is essential that each stakeholder organization in the program buy into adoption of evidence-based guidelines, leadership communicates to their staff members their commitment to using evidence-based guidelines, sufficient funding for implementation is allocated, and monitoring appropriate usage is ensured.

**3. Plan for multidisciplinary use of evidence-based guidelines.**

Just as the selection was made from a multidisciplinary perspective, so must their use be made by providers, nurses, and all others as applicable. Guidelines may need to be deconstructed so that each discipline uses the portion applicable or have narrative translated into a checklist format, flow diagram, or algorithm. Any guideline must include the ability to exercise autonomy and clinical judgment, respond to patient preferences, and document the decision making process.

**4. Test clinical guideline usage on a sampling of providers to ensure that the guideline is clear and usable.**

Such testing may be paper-based or automated depending on the level of EHR adoption in the community. If paper-based, there should be an expectation that ultimately the best way to make such guidelines accessible is via automation. Use results of the test to make any modifications as necessary and to prepare to fully implement.

**5. Ensure that software in use within the CCC program can deliver the guideline to clinicians as desired.**

EHRs already in place may have guidelines already embedded in clinical decision support components. If so, a selection committee should still review the guidelines, determine their acceptability and utility, and plan for adoption. If there are issues with any of the guidelines, these should be discussed with the vendor and changes accommodated. If a certain guideline desired is not embedded in the EHR, a discussion with the vendor should assess the feasibility of incorporating the guideline. Utilizing clinical guidelines on paper should be a last resort as it is not conducive to analyzing results, benchmarking, or obtaining variance reports.

**6. Train all those who are expected to use evidence-based guidelines.**

How training is conducted should reflect the multiple ways staff members learn. If appropriate groundwork has been laid in advance of the training, there should be no surprises and all stakeholders should be ready to accept the training. Of course, reality is often less than ideal and part of the training will necessarily be reassurance of the community's commitment to using such guidelines in a transparent manner. Once again, leadership must support the training as well as the use of the guidelines themselves. Sufficient time must be allotted for acclimation, and ongoing monitoring and support for the change is essential.

**7. Establish measurements and share results.**

Measuring and sharing results is an essential part of every quality improvement initiative. In order to determine the impact of evidence-based guidelines, pre- and post-implementation measures should be taken. These should include both quality and cost

considerations. Clinical quality measures required for the CMS Meaningful Use of EHR incentive program, CMS Physical Quality and Reporting System, Medicare Shared Savings Program, and other initiatives as well as the Joint Commission and other accrediting bodies may serve as measures for quality. Cost reports from payers or organizational tracking of costs may serve as measures for cost. It is important to present findings by relating them to evidence-based guidelines. It is also necessary to make any applicable adjustments for clinical acuity variations.

Cost reduction must also be considered in light of reimbursement, with strategies deployed to share savings and not reduce pay. If the CCC program resides in a community where feedback on performance is new, such feedback should be as carefully planned as the implementation of the guideline itself. Feedback on performance, however, is known to be an important component to any behavior change and must not be avoided simply because it is new to the community.

#### **8. Implement performance improvement as necessary.**

Use of evidence-based guidelines may require an understanding of root cause for less-than-desired outcomes. Once known, steps can be taken to make adjustments in workflow, to retrain, to modify technology or to implement other change management strategies.

### **Monitor Evidence-based Guideline Strategies**

Just as medicine itself is constantly changing with new and emerging research, so should evidence-based guidelines be expected to change. Use of clinical guidelines must be a dynamic process. Updates in guidelines themselves must be identified and implemented. Feedback on performance must be considered in modifying guideline usage. Health reform initiatives by governmental and commercial payers will factor into what guidelines may be used while bearing in mind the admonition that guidelines must be evidence-based.

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### **References**

<sup>1</sup> Agency for Healthcare Research and Quality (AHRQ), National Guideline Clearinghouse. Available at: <http://www.guideline.gov/>

<sup>2</sup> <http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx>

<sup>3</sup> American College of Emergency Physicians (ACEP), Clinical Guidelines in a Managed Care Environment, Information Paper. Available at: [www.acep.org](http://www.acep.org)

<sup>4</sup> Powel, S.K. and D. Ignatavicius. *Case Management Society of America, Core Curriculum for Case Management*, Lippincott, Philadelphia, 2001.

<sup>5</sup> CMS.gov Clinical Quality Measures Basics. Available at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures.html>

<sup>6</sup> Office of the National Coordinator for Health Information Technology (ONC) Standards and Regulations, Clinical Quality Measures portal. Available at: <http://www.healthit.gov/policy-researchers-implementers/clinical-quality-measures>

<sup>7</sup> Agency for Healthcare Research and Quality (AHRQ), National Quality Measure Clearinghouse, NQF-Endorsed Measures. Available at: <http://www.qualitymeasures.ahrq.gov/>

<sup>8</sup> Merola, P. and R. C. Hopkins. (April 2010). How Hospitals Can Successfully Implement Evidence-based Guidelines. Milliman Healthcare Reform Briefing Paper. Available at: <http://www.milliman.com/insight/healthreform/How-hospitals-can-successfully-implement-evidence-based-guidelines/>

<sup>9</sup> U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services: Report of the U.S. Preventive Services Task Force*. Stratification available at: <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/Grades> available at: <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/appendix-a.html>

<sup>10</sup> Crane, M. (March 6, 2014). Law Would Grant ‘Safe Harbor’ to Docs Who Follow Guidelines. Available at: [http://www.medscape.com/viewarticle/821588\\_print](http://www.medscape.com/viewarticle/821588_print)

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