

Michigan Medicine Quality Department Clinical Care Guidelines: Purpose and Methods

Overview

Michigan Medicine (MM) charged the Guideline Development unit within the Quality Department to work with primary care physicians, specialists, and subspecialists to produce collaborative clinical care guidelines. These guidelines assist MM physicians in providing optimal care for patients in a cost effective manner. The guidelines focus on important clinical decisions and actions in the context of overall case management. Described below are the multiple purposes of the guidelines, some of their features, and the methods for their development, review and institutional endorsement.

Purpose

The guidelines help MM and its clinicians accomplish several interrelated clinical and institutional goals:

- Assure optimal clinical outcomes
- Identify appropriate, high quality, cost effective care
- Help assure provision of this care across physicians
- Establish standards to minimize variation in practice across clinicians
- Facilitate collaborative practice between primary care physicians and specialists for both ambulatory and inpatient care settings
- Facilitate planning and coordination between physicians and units providing ancillary services
- Support the teaching mission of MM by providing the basis for teaching modules for practicing physicians, house staff, and medical students
- Demonstrate MM clinical leadership in the processes of developing and implementing explicit clinical guidelines
- Demonstrate MM clinical leadership in enhancing clinical care based on results of ongoing assessments of the impact of guidelines
- Establish recommendations that others can use to:
 - Develop operational measures to evaluate and report performance of MM clinicians
 - Guide MM leadership in prioritizing and planning Quality Improvement (QI) initiatives
 - Develop decision tools incorporated into electronic medical records to assist clinicians in providing recommended care.

Guideline Characteristics

Several characteristics differentiate these guidelines from those developed by many other groups.

- **Product:** practical guidelines for busy clinicians.
- **Clinical conditions:** focus on selected conditions within primary care and within inpatient care where care quality is likely to be improved or care delivered more cost effectively.
- **Empirical base:** primarily based on important current trials and reviews of secondary sources (e.g., other guidelines and their evidence, review articles), not necessarily a comprehensive review of all literature. Expert consensus is used to apply research findings to the context of daily practice.
- **Systematic development:** systematic processes are used to develop guidelines to assure consistency in content and relevance.
- **Scope:** address the overall clinical care process, including ambulatory, inpatient, and transitional areas (including the Emergency Department).
- **Format:** information is presented in a format that facilitates use and quick reference by busy clinicians.
 - **Key points** relevant to improving practice are summarized along with “Level of Evidence” and “Strength of Recommendations.”
 - **Flow diagrams** (or tables) illustrate the overall sequence of major decision and action steps.
 - **Clinical background** for the recommended actions is presented, organized in the sequence of clinical activities.
 - **Extent of empirical support** for key points is summarized.
 - **Deviations from national guidelines**, if present, are highlighted and explained.
 - **References** provide supporting evidence and more detailed discussions of the clinical topic.

Methodology for Developing the Guidelines

The development and approval of clinical guidelines is a complex process involving a number of steps at various institutional levels. A general outline of the methods followed in developing these guidelines is presented below. The specific procedures for an individual guideline may vary somewhat to meet circumstances unique to it.

The Guideline Development unit within the Quality Department has direct responsibility for the following processes

1. Identify guideline topic

- a. Assemble suggestions for possible guideline topics from clinical leaders.
- b. Assess priority using information regarding potential need, usefulness, and feasibility of potential topics.
- c. Select topics for guideline development with advice from the leadership in partnership with OCA.

2. Establish guideline team

- a. Identify a clinical leader for the guideline team who is knowledgeable about the clinical topic and, to the extent possible, also knowledgeable about guideline development processes. For topics that focus on the practice of primary care physicians, the team leader is usually a primary care physician.
- b. Identify other team members with expertise in the clinical areas likely to be relevant to the guideline content. Team members are selected in consultation with the guideline team leader and relevant clinical leaders. Individual's knowledge about guideline development is also considered when selecting team members.

The Guideline Development unit oversees the following processes:

3. Activities of the guideline team

- a. Orientation of team leader. A member of the Guideline Development unit meets with the team leader to explain the objectives, roles, and processes the team will follow in developing guidelines for use by other physicians, as well as the management of content-area experts.
- b. Team leader outlines draft of issues. The team leader, with assistance from the member of the Guideline Development unit, develops an initial outline of the key questions and the scope of clinical activity to be addressed.
- c. Orientation of team members. The Guideline Development unit (or other core personnel) and the team leader meet with the team members to explain the objectives, roles, and processes, including the explicit methodology.
- d. Team establishes guideline objectives and scope. Using the outline prepared by the team leader as a starting point for discussion, the team identifies the key questions and the scope of clinical activity to be addressed.
- e. Team defines issues. The team identifies the outcomes to be addressed, the processes of clinical care by which they are addressed, and the key questions of evidence pertaining to those outcomes and processes.

- f. Assignment of specific clinical topics to team members. Specific topics are assigned to individual team members.
- g. Team members review information and prepare "issue" drafts. For their assigned topics(s), team members use defined search strategies to search current literature (including other relevant guidelines, review articles, and important recent trials) and prepare an initial draft based on literature meeting the agreed-upon inclusion criteria. The team members also list the information they have reviewed and characterize the strength of the evidence.
- h. Initial guideline draft prepared. The team leader and supporting technical personnel assemble and edit the drafts on individual issues into an initial draft guideline.
- i. Team reviews draft. The entire team reviews and discusses the draft guideline, identifying areas of disagreement or uncertainty and areas where the document can be improved through more detailed review of specific literature, changes in scope of content, or changes in presentation. Assignments are made to team members to address specific issues.
- j. Team evaluates impact on patient and system. Cost issues are identified and cost differences between alternative processes of care estimated. Areas where patient values differ along cultural, gender, age, or individual lines are identified and recognized in the treatment recommendations.
- k. Revision and review by team continues until a draft is supported by all. The process of preparation of revised drafts, their review, and change continues until a draft can be supported by all team members. Team members are encouraged to share working drafts with others to obtain external feedback for improvements and to be sure that their individual perceptions are shared broadly by their peers.
- l. Patient education materials. When relevant, the team either creates or reviews and updates MM online patient education materials to be consistent with recommended practice.
- m. Online CME self-study. The team leader develops a knowledge application test so the guideline can be used for online CME self-study.
- n. Suggestions for implementation. The team reviews their final guideline draft, identifies clinical activities and areas likely to be affected by guideline recommendations, and offers suggestions on ways to implement the key points of the guideline to facilitate the delivery of recommended care. The discussion of operational issues may result in modifications to guideline wording.

4. Guideline review and approval

- a. Peer review. Team members share the draft guideline with physicians and others whose practice is related to the guideline content for their peer review and comment. The guideline draft is revised based on these comments.

- b. Medication review. Medication recommendations in guidelines for ambulatory care are reviewed by a Doctor of Pharmacy who has special expertise in the clinical area. The individual is identified by MM Pharmacy Services. Medication recommendations in guidelines for inpatient services are reviewed by the UMHHC Pharmacy and Therapeutics Committee.
- c. Endorsement by UMHS Clinical Practice Committee (CPC) of the University of Michigan Medical Group. The CPC reviews the guidelines produced by all teams. Concerns are referred back to the guideline team to address in a revision of the guideline. CPC endorsement establishes the guideline as generally expected practice by MM physicians wherever they practice.
- d. Approval and endorsement by the UM Hospitals and Health Centers (UMHHC)
- If the guideline involves pediatric care, the C&W Operations Sub-Committee and the C&W Executive Committee reviews the guideline.
 - If the guideline involves care of women, the Perinatal Joint Practice Committee reviews the guideline.
- Following the above reviews, if applicable, the UMHHC Executive Committee on Clinical Affairs (ECCA) reviews and institutionally endorses the guidelines. ECCA endorsement establishes the guideline as generally expected practice within UMHHC.

5. Guideline implementation and measurement

The Guidelines Development unit has the lead responsibility for disseminating approved guidelines, making them easily accessible. It can advise operational units on implementing guideline recommendations into practice. The focus is on implementing the key points of a guideline. Assistance is sought from all of the organizational units affected by implementing the guidelines. The diverse content means that implementation efforts will vary from guideline to guideline.

The Guideline Development unit assists MM units that measure practice performance with the development of measures of actual practice related to guideline recommendations. For aspects of practice that are institutional priorities, units responsible for measuring performance report variations between actual practice and guideline recommendations. The reports are provided to clinical leaders and to clinicians to help them understand their own practices in order to improve clinical practice, improve the guideline, or both.

6. Guideline updating

- a. Major updates. At most, four years from the approval of a guideline, the Guideline Development unit will reconstitute a guideline team to review current literature, review available data regarding actual practice, and determine whether the existing guideline needs to be revised. The guideline team will be reconstituted with as many of the original members as is feasible. Revisions will follow the processes described above.
- b. Interim revisions. Between major updates the guideline team lead reviews the guideline annually to assess

whether the content remains substantively current, needs minor interim revisions, or a major update should be initiated early. If team members or the Guideline Development Unit become aware of a substantive change in recommended care, they ask the team leader to perform a similar review of the current content of a guideline and to recommend the extent of change that should be initiated.

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