



**UMHS Clinical Care Guidelines:
Purpose and Methods**

Purpose

The University of Michigan Health System charged the Guideline Development unit within the UM Faculty Group Practice's Quality Management Program to work with primary care physicians and other relevant specialists and subspecialists to produce clinical care guidelines. These guidelines are to assist UMHS 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. The guidelines are based on empirical evidence, other evidence based guidelines prepared by nationally recognized groups, and expert consensus about practical considerations in providing care. The guidelines are presented in a format that helps busy practitioners incorporate recommendations into practice.

The guidelines are needed to help the UMHS 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
- Address instances of substantial variation in practice across clinicians
- Facilitate collaborative practice between primary care physicians and specialists
- Facilitate planning and coordination between physicians and units providing ancillary services.
- Support the teaching mission of the UMHS by providing the basis for teaching modules for practicing physicians, house staff, and medical students.
- Demonstrate UMHS clinical leadership in the processes of developing and implementing explicit clinical guidelines
- Demonstrate UMHS clinical leadership in enhancing clinical care based on results of ongoing assessments of the impact of guidelines

Several objectives were established regarding the guidelines to be developed. The objectives differentiate these guidelines from guidelines developed by many other groups.

- **Product:** practical guidelines for busy clinicians.

- **Clinical conditions included:** focus on selected conditions within primary care or on boundary between primary care and other specialists, particularly on high volume areas 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 a comprehensive review of all literature. Expert consensus is used to apply research findings to the context of daily practice.
- **Systematic development:** guidelines developed to the current state of the art using the explicit clinical policies development method.
- **Scope:** address the overall care process for the clinician. Areas with strong empirical support are identified, but must be described in the overall context of care.
- **Format:** information is presented in a format to facilitate its utilization and 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 then presented, organized in the sequence of clinical activities.
 - **Extent of empirical support** for key points is summarized.
 - **Deviations from national guidelines** if present, is highlighted and explained.
 - **References** are provided for representative reports of 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 process of guideline development is managed through an administrative structure involving (1) GUIDES within the Quality Management Program and (2) a UMHS steering committee representing institutional units likely to be affected by guidelines.

Functions of GUIDES, the UMHS Guidelines Steering Committee are described in the steps below.

1. Identify guideline topic

- a. Assemble suggestions. GUIDES assembles suggestions for possible guideline topics from UMHS Steering Committee members and other sources.
- b. Assess priority. GUIDES assembles information regarding potential need, usefulness, and feasibility of potential topics.
- c. Select topics. GUIDES, with advice from the UMHS Steering Committee selects topics for guideline development.

2. Establish guideline team

- a. Identify the team leader. GUIDES, with advice from Steering Committee and clinicians knowledgeable about the topic, identifies 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. GUIDES and the team leader identify the areas of clinical expertise likely to be relevant to the guideline content and, with advice from the Steering Committee and others, identify team members to represent those clinical areas. Individual's knowledge about guideline development is also considered in selecting team members.

3. Activities of the guideline team

- a. Orientation of team leader. A GUIDES member meets with the team leader to explain the objectives, roles, and processes, including the explicit clinical policies development method and the management of content-area experts in developing guidelines for use by primary care physicians.
- b. Team leader outlines draft of issues. The team leader, with assistance from the GUIDES member, develops an initial outline of the key problems and the scope of clinical activity to be addressed.
- c. Orientation of team members. GUIDES (or other core personnel) and the team leader meets 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

problems and the scope of clinical activity to be addressed.

- e. Team defines issues. Using its choice of problem-structuring methods, 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 issues to team members. Specific clinical issues are assigned to individual team members to produce initial information according to the group's defined literature search and inclusion strategies.
- g. Team members review information and prepare "issue" drafts. For their assigned issue(s), team members use defined search strategies to search current literature (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, using input from management information systems and cost accounting consultants as necessary. 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. The team reviews UMHS online patient education materials to be consistent with recommended practice.
- m. Online CME self-study. The team leader develops a knowledge appreciation test so the guideline can be used for online CME self-study.
- n. Suggestions for implementation. The team reviews their final guideline draft and offers suggestions on

ways to implement the key points of the guideline. The discussion of operational issues may result in modifications to guideline wording.

4. Guideline review and approval

- a. Peer review. The guideline is circulated among volunteer faculty physicians and other clinicians, administrators, and methodologists who were not involved in its development, for peer review and commentary.
- b. Review by UMHS Guideline Steering Committee. A formal external review is provided by the Guideline Steering Committee, which reviews the guidelines produced by all teams. Concerns are referred back to the guideline team to address in a revision of the guideline.
- d. UMHS administrative approval. If the guideline involves pediatric care, the Mott Executive Committee reviews the guideline. The UMHS Executive Committee on Clinical Affairs reviews and institutionally endorses all guidelines.

5. Guideline implementation and measurement

GUIDES has the lead responsibility for seeing that approved guidelines are broadly implemented into practice. 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 focus is on implementing the key points.

To the extent possible, inexpensive methods will be identified to measure actual practice in comparison with guideline recommendations. Variations between actual practice and guideline recommendations will be provided to clinicians to help them understand their own practices and can serve as a baseline for improving clinical practice, improving the guideline, or both.

6. Guideline updating

Approximately two to three years from the approval of a guideline, GUIDES 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. Additionally, GUIDES may initiate the guideline review process anytime that new information suggests that the current guideline needs substantive modification.

Personnel

GUIDES

Guideline Oversight

Connie J. Standiford, M.D.
Associate Medical Director, Ambulatory Care
Division of General Medicine
Department of Internal Medicine

Grant M. Greenberg, M.D., M.A., M.H.S.A.
Department of Family Medicine

R. Van Harrison, Ph.D.
Department of Medical Education

Measurement Oversight

Steven J. Bernstein, M.D., M.P.H.
Division of General Medicine
Department of Internal Medicine

UMHS Steering Committee

Ambulatory Care
Department of Internal Medicine
Division of General Medicine
Connie J. Standiford, M.D., Committee Chair

Clinical Affairs
John E. Billi, M.D.

College of Pharmacy
James Stevenson, PharmD

Department of Family Practice
Jean M Malouin, MD

Department of Internal Medicine
Division of General Medicine
Barbara C. S. Soyster, M.D

Department of Obstetrics & Gynecology
Margaret Punch, M.D.

Department of Pediatrics
Division of General Pediatrics
Kelly A. Orringer, M.D.

Department of Medical Education
R. Van Harrison, Ph.D.

Nursing Administration
Candia B. Laughlin, M.S., R.N., C.S.

Further Information

For further information contact:
Ellen Patrick-Dunlavey, M.A.
Quality Management Program, Faculty Group
Practice

University of Michigan Health System
2500 Green Road Suite 700
Ann Arbor, MI 48105 – 5748
Phone: (734) 936-9771
Fax: (734) 232-2484
Email: gdlnoversight@umich.edu