



PRACTICE MANAGEMENT GUIDELINES FOR TRAUMA

EAST AD HOC COMMITTEE ON

GUIDELINE DEVELOPMENT

(Unabridged - Revised 1/23/98)

Introduction

There is growing interest in the use of clinical practice guidelines as a means of reducing inappropriate care, controlling geographic variations in practice patterns, and making more effective use of health care resources. Developments at the national health policy level, as well as managed care imperatives, suggest that clinical practice guidelines will play an increasingly prominent role in the practice of medicine. Such guidelines can contribute to medicine as an aid in clinical decision making, a research tool, and an educational resource. We, as trauma surgeons, should participate in such endeavors in an effort to improve trauma care and guide future research.

The Agency for Health Care Policy and Research (AHCPR) has led the way in guideline development methodology and currently has published 20 guidelines addressing a variety of topics.³ Their initial work has led others to develop an evidence-based approach to care.

The American Medical Association and the Council of Medical Specialty Societies have endorsed clinical practice guidelines and are organizing specialty societies to set forth policies on the subject.

Evidence continues to accrue that management guidelines improve clinical practice.^{1,2} Evidence-based guidelines have been published on intravenous analgesia, sedation, and sustained neuromuscular blockade in the ICU.^{3,4} The Brain Trauma Foundation has published evidence based guidelines for management of severe head injury.⁵ Clinical computerized bedside protocols have improved outcome in ARDS and hypoxia.^{6,7} National literature/consensus-based guidelines have also been published for stress ulcer prophylaxis and albumin transfusion and are currently in development for antibiotic usage and fever work-up in the ICU.^{8,9} The role of EAST and other national organizations will be to provide a series of national consensus-based guidelines from which institutionally-specific clinical management protocols (CMPs) and/or pathways can be developed (see Figure 1). To a limited extent, these guidelines can be utilized to develop protocols and pathways.

Guideline Development

A step-by-step process to practice management guideline development, largely adapted from AHCPR recommendations has been derived.¹⁰ This process ensures a combination of rigorous methodology and practical feasibility that can be adapted to clinical decision making at any institution. In essence, the model used consists of development, implementation, measurement, and revision stages.

Step 1: Topic selection--Historically, AHCPR has developed guidelines for areas where there was evidence of variation in practice for a clinical problem, in comparable patient populations. With respect to trauma, it is felt that topics should be selected based on volume, associated hospital costs, and implications for quality improvement or quality assurance. In general, guidelines will be disease, problem, or process specific.

Step 2: Selection of a panel--Members of the panel may include physicians, nurses, pharmacologists, methodologists, health economists, and representatives from other disciplines. Such a multidisciplinary panel should be tailored to the particular topic being addressed and represent those that will be affected by the particular guideline.

Step 3: Clarification of purpose and scope of the guideline--Objectives of the guideline need to be defined clearly and concisely, and should specify the condition, type of patient, and clinical presentation for which the guideline is intended. Appropriate inclusion and exclusion criteria would then target the patient population and the clinical setting in which the guideline was to be used.

Step 4: Listing of the goals--A list of goals should be prepared in conjunction with clarification of the purpose and topic selection. Prior to the literature search, the panel would identify the goals of the guideline. Identification of anticipated health outcomes such as lowering morbidity, changing practice behavior and delivery patterns, and lowering costs also need to be listed. Along with this an assessment of clinical benefits and potential harms should be outlined based on what is best for the patient.

Step 5: Assessment of scientific evidence--All relevant empirical data should be evaluated for clinical benefits and harms of the various interventions. Attempts should be made to collect as much quality scientific data as possible, utilizing existing national consensus-based guidelines. Proper methods, including a variety of databases and cross checking of citations, need to be used to ensure that these standards are met and biases avoided. It has been proposed that the scientific evidence assessment methods employed by the Canadian and U. S. Preventative Task Force be applied when looking at levels of evidence. Levels of evidence are graded based on the strength of the scientific evidence. For purposes of practice management guidelines for trauma, data will be classified as follows:

Class I evidence: Prospective randomized controlled trials (PRCTs) - the gold standard of clinical trials. Some may be poorly designed, have inadequate numbers, or suffer from other methodological inadequacies, and thus may not be clinically significant.

Class II evidence: Clinical studies in which the data were collected prospectively, and retrospective analyses which were based on clearly reliable data. These types of studies include observational studies, cohort studies, prevalence studies and case control studies.

Class III evidence: Most studies based on retrospectively collected data. Evidence used in this class includes clinical series, databases or registries, case reviews, case reports, and expert opinion.

Technology assessment: The assessment of technology, such as ICP monitoring devices, does not lend itself to classification in the above-mentioned format. Thus, for technology assessment, the devices were evaluated in terms of their accuracy, reliability, therapeutic potential, and cost-effectiveness.

Once the evidence has been classified it should be utilized to make recommendations. The correlation between the evidence and the recommendations is as follows:

Level 1: This recommendation is convincingly justifiable based on the available scientific information alone. It is usually based on Class I data, however, strong Class II evidence may form the basis for a level 1 recommendation, especially if the issue does not lend itself to testing in a randomized format. Conversely, weak or contradictory Class I data may not be able to support a level 1 recommendation.

Level 2: This recommendation is reasonably justifiable by available scientific evidence and strongly supported by expert critical care opinion. It is usually supported by Class II data or a preponderance of Class III evidence.

Level 3: This recommendation is supported by available data but adequate scientific evidence is lacking. It is generally supported by Class III data. This type of recommendation is useful for educational purposes and in guiding future studies.

Step 6: Drafting and validation of the document--A final document should be drafted by the panel presenting a synthesis of the literature review and opinions of the panel members. The draft document would be submitted to all members of the panel for review and modification. Subsequent to this, the guidelines would be presented for review to members of the committee on guideline development as well as any other interested parties. A separate companion comprehensive document containing the summary data, collection of expert opinions and references would be made available as well. This approach will enhance the scientific rigor of practice management guideline development. Proceeding in such a manner provides for formal assessment of scientific evidence, panel meetings, and open forum sessions that seek broad input on relevant issues.

Step 7: Presentation--After presentation to the membership, any further recommendations will be made, and a final document will be prepared with plans for implementation. It is important at this juncture to assure "buy-in", as any undermining of the guidelines before implementation can be extremely detrimental. Plans for implementation, i.e. inservicing, pretesting, date of start-up, and reevaluation, should be outlined. Any concerns should be addressed, and consensus should be obtained by majority opinion. Minority opinions may be reported along with the majority consensus statement.

Step 8: Implementation--Implementation involves extensive education and inservicing of nursing, resident, and attending staff members and has one important guiding principle: The guidelines must be available to the clinicians and nurses in real time while they are actually seeing the patient. After appropriate inservicing, a pretest of the planned guideline should be performed on a limited patient population in a clinical setting. This will serve to identify potential pitfalls. The pretest should include written documentation of experiences with the protocol, observation, and suggestions. A nurse manager should be appointed to oversee the process.

Step 9: Evaluation--Evaluation is necessary to determine whether the guidelines have altered practice patterns, improved efficiency and health outcomes, maintained quality of care, and met the goals set forth. Each guideline should be reviewed within a designated time period after which they can be updated and revised based on new evidence and technology. Changes are expected as they will provide a focused, rather than random, curriculum for training programs and continuing education.

Step 10: Research--Guideline development can lead to research opportunities, particularly with regard to practice parameters and outcomes analysis.

A current limitation on the concept of guideline development is the paucity of prospective, randomized Class I data for the development of more secure evidence-based guidelines. Another limitation is the relatively immature information systems that can incorporate these guidelines into the bedside computer. Both of these limitations should be short-lived, however, it will not obviate the need for each institution to develop a process to obtain local, clinical "buy-in".

Utilizing the process described, four practice management guidelines were developed by the EAST Ad Hoc Committee for the Development of Practice Management Guidelines for Trauma. A consensus conference of 20 trauma surgeons interested in guideline development was held and initial topics were selected for development. Each member of the conference selected topics that they felt were important for development. Four topics were then selected by majority consensus. Each topic was assigned a chairperson, and the chairperson was then responsible for selecting his/her committee members. The individual committees were given latitude on how to approach their topics but all were expected to conform to the above described process. Once completed, the guidelines were reviewed by the committee chairperson and the chairperson of the guideline committee and returned for revision. The revised guidelines were submitted to the members of the EAST program chairman and the president of EAST. The guidelines were presented at the annual EAST meeting in 1997, and revisions were made based on comments and suggestions from the organization. These recommendations are summarized on the following pages. A more extensive, unabridged version, including evidentiary tables and discussion of relevant literature (too lengthy for journal publication), is available at the following address:

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