Clinical Guidelines in a Managed Care Environment

Information Paper

Executive Summary

Clinical guidelines have been created using many methodologies. Entities adopting specific guidelines must be aware of the methodology utilized in the creation of each guideline.

Methodologies employed in guideline development include: consensus panels of experts, empiric observations of one or more authors, actuarial data, opinions based on nonpatient care issues, and evidence-based guidelines grounded in clinical studies and validated in actual practice.

Many practice guidelines have not been validated in multiple practice settings prior to publication.

Guidelines developed for other specialties may not be applicable in emergency medicine without modification.

There are some clinical problems for which no clear data or expert consensus exists as to the optimal management, hence guidelines are not appropriate for these problems.

Review and modification where necessary of guidelines may be desirable in a specific practice setting. This process may enhance "buy-in" from the users and tailor the guidelines to the constraints and resources of the practice.

Evidence-based guidelines that are clear and concise with appropriate exception criteria are unlikely to increase medicolegal risk if they strengthen sound clinical decision-making.

When adopted guidelines are not adhered to in a specific clinical setting, the clinician may incur the additional burden of documenting the reasons for divergence. Failure to adequately document this deviation may increase liability in the event of unfavorable outcomes.

Many managed care organizations are evolving to a practice model where physicians share financial risk for their clinical decisions. When physicians are financially at risk for use of resources, guidelines are likely to be developed and used by provider groups rather than imposed by managed care plans or other entities.

Practitioner profiling must be based on guidelines which are clinically sound and have comparative validity for the patient population and practice setting.

The disclosure of profiling information to the individual provider can be a powerful tool in changing physician behavior.

Guidelines must allow for federal and state laws and applicable regulations including EMTALA.
Other Practical Benefits of Clinical Guidelines:

1. Guidelines may facilitate the clinician's application of current standards of practice to specific patient encounters.
2. Guidelines may enhance thoroughness in data base collection and documentation.
3. Guidelines may enhance cost savings by encouraging clinicians to eliminate unnecessary or unproven studies or procedures.
4. Guidelines may enhance reimbursement by improving documentation.
5. Guidelines may be readily incorporated into automated record keeping programs, facilitating guideline use and tracking of practice patterns.
6. Clinical guidelines, integrated with databases of current knowledge into an electronic medical record, may assist practitioners and patients in selecting the most effective and cost-conscious modalities of care.
INTRODUCTION

The American College of Emergency Physicians supports high quality patient care, ready access to health care, and patient satisfaction within reasonable cost. As the nation continues to grapple with ways to reach these health care goals, numerous strategies have been proposed. Clinical guidelines are among those strategies. Clinical guidelines, best practices, prediction rules, clinical policies, critical pathways are examples of terminology in health care delivery that reflect the growing trend to require accountability and some degree of uniformity in clinical practice.

Although the first clinical guideline was published more than 60 years ago, increased interest in clinical guidelines and their various permutations began only a decade ago, meeting with limited acceptance by the medical community. Clinical guidelines are designed to assist in the diagnosis and treatment of specific clinical entities. The goal of guidelines is to describe optimal delivery of care for patients by minimizing variations in practice.

Health policy leaders and purchasers of health care are deeply concerned with rising costs and lack of uniformity in the care process. Managed care organizations promote guidelines that focus on resource utilization and cost control. In most cases, specialty societies have developed guidelines to establish standards of care for diseases and procedures under their purview, as well as educate their members, help them become more cost-effective and competitive, and improve outcomes.

Some hospitals, hospital chains, managed care plans, and large physician practice groups have developed proprietary guidelines in an attempt to control costs and to enhance their competitiveness. Practitioner profiling is often linked with practice guidelines in these settings.

Physicians are concerned that the implementation of clinical guidelines will diminish their autonomy, while increasing clinical risk, liability and workload. In this era of increased accountability, some form of practice guidelines is likely to remain part of the strategy to meet organizational goals. The challenge is to assist physicians in understanding the benefits and pitfalls of guidelines in general, the appropriate analysis and application of specific guidelines and how to develop, modify, or utilize guidelines in their practice.

For the purposes of this document, the term “clinical guidelines” will be used as a generic term recognizing that other terms, such as “clinical policies” or “practice parameters” could be used.

CURRENT GUIDELINE UTILIZATION

The degree of penetration of clinical guidelines into the daily practice of emergency medicine is currently undocumented. ACEP has published a number of clinical policies dealing with common Emergency Department (ED) presentations such as chest pain and headache. Compliance with these policies is generally voluntary. Most emergency medicine practitioners are aware of these documents, but attempts to implement guidelines with strict adherence is uncommon.

A more typical use of guidelines in emergency practice are those that managed care organizations apply to admission decisions including those from the ED. The most commonly used criteria, from InterQual™, are utilized by over 1200 hospitals. The InterQual™ screens are based on severity of illness, intensity of service, and the availability of alternate venues for providing the same service. They are intended to be used as screening criteria followed by physician review prior to denial of any test or service.
Some tools for evaluating hospitalized patients are based on actuarial data. For instance, if the mean length of hospital stay in the US in 1997 for a colon resection patient without other significant co-morbidity is 4 days, the insurer may decide not to pay for any hospital days beyond that mean.

Several large organizations have developed proprietary ED "best practices" or "benchmarking" criteria which are implemented in their own EDs. Many of these are neither published nor externally peer-reviewed. Data regarding their usage and validity are not typically available to the medical community as a whole. There are commercial "best practice" products for ED services, some of which are linked to an electronic database and/or a computer generated template for the medical record. A key to successful implementation of any of these tools is a solid understanding of the basis on which the criteria were developed.

**BASIS AND VALIDITY OF CLINICAL PRACTICE GUIDELINES**

Important considerations for users of any clinical guideline are the motivation of the developer(s), the process or methodology utilized, and the validity of the information contained in the policy. Clinical guidelines that have cost containment or limitation of reimbursement as their driving force should be suspect.

Many early clinical guidelines were developed by expert panels and seldom required the application of scientific principles—the so-called consensus methodology. As the process matured, a number of organizations insisted upon a scientific basis for guideline development. Numerous methodologies have been employed each with specific advantages and limitations. Optimally, clinical guidelines are evidence-based, supported by randomized clinical trials, and validated by focused outcome studies. However, there is insufficient data to create evidence-based guidelines for many clinical situations. In many cases guidelines based upon common sense and clinical experience are appropriate. When there is a validated evidence-based guideline which conflicts with an opinion or consensus guideline, the evidence-based guideline should take precedence. Entities utilizing guidelines should be aware of the differences in methodology used to develop them and the outcome and validity measures, if any, which have been applied.

**DEVELOPMENT AND MODIFICATION OF CLINICAL GUIDELINES**

Most national specialty societies have developed clinical guidelines for their specialty. These guidelines can possibly be used at the local level without modification. However, there are certain advantages to having any guideline reviewed and modified to fit local practice. This process will achieve a degree of "buy-in" by those who will use the guideline and will guard against implementing a national guideline which is not appropriate for local practice conditions and available resources. Some groups may decide to develop clinical policies de novo, although to do this well will require significant commitment and effort. A poorly done clinical guideline will benefit neither patients nor providers. A clinical guideline developed for another specialty may not necessarily be applicable to the practice of emergency medicine without modification. A guideline developed in a university or research setting may not be valid in a community hospital, urgent care, or rural setting. Most well-researched and developed guidelines were intended for broad application therefore modification to the practice settings are expected.
DISEASE MANAGEMENT AND EMERGENCY MEDICINE: OPPORTUNITIES FOR INTEGRATION

As emergency medicine defines its role in the delivery systems of the future, the concept of disease management will become increasingly important. Disease management involves addressing a specific disease over its entire spectrum rather than as isolated episodes of care. Integration of prevention (primary and secondary), acute care, chronic care, hospitalization, rehabilitation, and health maintenance are part of this multi-disciplinary comprehensive approach. Clinical guidelines are an important component of disease management programs. Many organizations are adopting disease management programs as potentially an effective means of improving outcomes and controlling costs.

Disease management programs often assume that ED visits represent a failure to appropriately manage the disease. For example, one of the commonly desired outcome measures in asthma disease management programs is a reduction in ED visits. However, EDs are well positioned to deliver various types of medical care efficiently, not just true emergencies. Certain aspects of disease management may be more cost-effective and efficacious to deliver in the ED setting. For example, it is not an emergency to give a tetanus immunization or to do follow up wound care, but we do so in many cases to the benefit of the patient and health system. Emergency physicians must communicate this message to other practitioners, managed care plans, and the public. EDs should proactively investigate which aspects of disease they are best positioned to treat and insure that disease management strategies and clinical guidelines used involve significant input from emergency physicians.

LIABILITY CONSIDERATIONS

One objection often raised by practitioners regarding clinical guidelines is that their implementation will expose the provider to increased legal risk. Indeed, guidelines that lack a solid foundation in evidence and/or are poorly drafted may increase clinical and legal risks.

Guidelines that incorporate sound evidence-based clinical principles are unlikely on their own to increase risk, since plaintiff's attorneys have access to the original published evidence. Subsequent to a suboptimal clinical outcome, an appropriately crafted guideline may provide a measure of protection provided the guideline was adhered to. Failure to follow a guideline may make defense more difficult absent documentation as to the reason for the deviation. Documentation of and familiarity with the applicable guidelines are clearly very important.

Guidelines cannot be applied to all clinical situations, and exceptions to the guidelines are not unusual. The application of clinical guidelines must always be weighed in the context of the physician’s clinical judgment. Clinicians need to have a clear idea when the guideline applies. Documentation of the decision-making process contributes significantly when defending the logic of ultimate conclusions. This is true whether or not guidelines apply. There are some clinical situations and problems about which there is not a clearly established, proven basis favoring one type of treatment over another. Where evidence is insufficient to support guidelines, clinical options should be accepted.

EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA)

Institutional policies/procedures should be developed and applied in a manner that is consistent with applicable federal and state laws and other regulatory requirements. This is particularly important in a managed care environment where there may be strong incentives for health care organizations to establish policies which limit financial risk.
Under EMTALA, EDs must implement policies for the provision of appropriate screening exams and stabilizing treatment to all patients regardless of insurance status or ability to pay. This mandate places further emphasis on the need to include appropriate exception criteria in clinical guidelines, and on the need to differentiate between guidelines which are voluntary and institutional policies/procedures which may become subject to EMTALA either through their formal adoption or their routine application in clinical practice.

EMTALA compliance may be enhanced by highlighting the decision points of the screening, stabilization, and transfer processes within clinical guidelines.

ETHICAL CONSIDERATIONS

Clinical guidelines that are responsive to the inherent diversity encountered in emergency medicine may be helpful adjuncts to the practitioner in making clinical judgments, particularly if they are both cost-effective and serve to reasonably maximize patient benefit. For clinical guidelines to be both useful and ethical they must be arrived at by scientifically and statistically legitimate means. They must also make explicit the value judgments employed in determining clinical efficacy and cost-effectiveness. Clinical guidelines are, in fact, merely guidelines, not statutory requirements. They must be flexible to allow for discretionary exceptions and the interindividual variability encountered in emergency circumstances. Clinical guidelines should seek to provide maximal patient benefit within reasonable cost. In no other enterprise is morality so closely associated with the bottom line.

Ethical Principles: Balancing Beneficence and Justice

A primary ethical requirement of ED and MCO-based policies and guidelines is to help patients and protect them from life-threatening harm. This moral mandate is the embodiment of the ethical principle of beneficence: to do good for patients.

Beyond obligations of beneficence, guidelines must also promote fairness and justice. The ethical principle of justice demands that physicians treat all patients equitably, apportioning resources fairly. Health care has fast become a precious resource compelling responsible stewardship. As health care budgets are capitated and the costs of care escalate, ethical clinical guidelines must acknowledge that each discrete decision impacts on the distribution of medical resources for all patients in society. A narrow focus on individual patient's interests is unsustainable when the financial solvency of the health care system is at stake. In a closed, capitated system, physicians have duties to multiple patients who may be at risk; thus, a sensitive, just, and ethical balance must be sought. Balancing the duties of beneficence to individual patients with societal concerns of distributive justice is difficult to do at the bedside, but clinical guidelines must promote this dualistic goal. It is in attempting to balance beneficence and justice that many ethical dilemmas arise.

Blind allegiance to gatekeeper guidelines, in deciding to evaluate or admit a patient by a decision-maker who may be negatively economically impacted by the decision is fraught with pitfalls. First, guidelines may be applied by an on-call physician or gatekeeper who frequently knows less about the patient than the emergency physician. The managed care gatekeeper who has not personally evaluated the patient’s actual current condition is at a distinct medical disadvantage. Diagnosis at a distance may lack the sensitivity, specificity, and humanity of direct hands-on care.

Second, patient confidentiality is endangered every time a person other than the patient’s personal physician receives potentially sensitive information.
Third, the managed care plan's duty to individual patients may be diluted when guidelines are inspired by corporate economic interests. When hospitalization or the use of consultations or ancillary resources has a negative economic impact on the physician, the risk of dual moral agency (serving two masters) may be a substantive risk to the patient.

Fourth, guidelines must not interfere with EMTALA mandated medical screening and stabilization. Policies that routinely delay or deny such care are socially and ethically irresponsible. When fiscal concerns supervene, emergency care, screening, and stabilization may be wrongly compromised.

Since patients generally do not possess the technical ability to judge the quality of medical decision-making, it is up to the physician to act in the patient's legitimate best interests. Decisions to admit patients are usually driven by good medical science. When the science is unclear, it is the HMO that rightly bears the burden of proving that the guideline decision to use less costly care is better than, or is at least as good as, hospitalization.

Due to their powerful influence on health care decision-making and their contractual and moral duty to patients, medical businesses are morally obliged and expected to espouse guidelines and policies that primarily serve patient's interests. By assuming responsibility for the provision of health care services, managed care organizations (MCOs) also assume responsibilities of beneficence and nonmaleficence toward patients.

It is said that at their best, guidelines express the noblest aims of medicine through the continuing search for the best way to serve patients. At their worst, they can become a mindless straight jacket of outdated recipes enforced by those without any clinical expertise. Hence, physicians and policy makers must make sure that clinical guidelines reach the higher goal.

FUTURE APPLICATION AND IMPLEMENTATION OF GUIDELINES

Computerization of medical information offers potential opportunities to improve health care and reduce costs, both areas of great importance to managed care. The computerized patient record, often referred to as a CPR or EMR, (electronic medical record), offers the opportunity to quickly assemble the patient's past and present medical information for the provider. This data can then be integrated with evidence-based guidelines to assist the provider in directing the patient's treatment in the most clinically-effective and cost-conscious way. Multiple commercial and academic ventures are currently underway to develop the infrastructure necessary to support the computerized record.

Four different categories of health information are available from the computerized record:
1. health data such as prior history, medications, allergies, procedures, imaging studies, and consultations;
2. administrative data such as demographics and health plan information;
3. legal documents such as advance directives, records releases, etc.; and
4. knowledge databases with decision support systems, and applicable clinical guidelines or pathways. These guidelines where appropriate may be integrated with patient information through the computerized record.

Imagine treating a chest pain patient when you have prior records, prior EKG's, chest x-rays, and cath reports available on a computer workstation at the bedside. Assume that this hypothetical patient is having a small volume inferior infarct: the computerized record, linked to a data system, provides you with evidence-based guidelines as to treatment choices, risks involved, and outcomes.
The computerized record may potentially assist in streamlining administrative functions such as quality assurance, utilization review, risk management, workload allocation, and support for third party claims.

However, there are significant barriers to computerized record implementation. The development of these systems is in its infancy. Overcoming the socio-behavioral issues in convincing physicians to move from the traditional paper record to the electronic record will require much effort and time.

PRACTITIONER PROFILING

Practitioner profiling is a term used to describe aggregate measuring of physician performance and the tracking of compliance with organizational goals. This can include basic activity measures (utilization rates, complication rates, etc.) or more sophisticated measures such as compliance with an array of guidelines and tracking of outcomes. This trend toward quantifying or rating physician performance is likely to accelerate in response to the market forces of managed care, and with the proliferation of electronic tracking capability.

When used to support compliance with clinical guidelines, this data can be used to improve organizational performance provided that the guidelines have been demonstrated to be safe, effective, and supported by the group as a whole, and that the data are statistically significant and applied appropriately to similar patient populations and practice settings. Organizations must guard against making inappropriate credentialing decisions based solely on economic factors unrelated to quality of care.\textsuperscript{11, 12} The sharing of profiling information with individual physicians can be a powerful tool in the promotion of quality and appropriate utilization.\textsuperscript{13, 14}

SUMMARY

Many clinical guidelines have been developed and implemented over the last decade. In the emergency setting, guidelines are generally voluntary. Most managed care plans are concentrating their efforts on utilization and are using commercially available actuarial or empirically-based guidelines to control costs. Evidence-based guidelines are preferable. As other payors and stakeholders focus on costs, wider application of clinical guidelines will undoubtedly be proposed or mandated in EDs.

Some physicians tend to resist change until they are presented with compelling evidence for the modification of their practice behavior. Others may respond to economic pressure when they are at risk for their utilization decisions. Managed care and decreasing acceptance of practice variation has accelerated the change process and forced physicians to reexamine their practice patterns and compare themselves with their peers. Emergency physicians should respond to this challenge by developing guidelines that are uniquely suited to their practice environment and can be integrated into the continuum of disease management and programs for managing care.

We are at the threshold of an exciting era that will move medical care away from an empirically-based process that often used isolated data to make clinical decisions. Managing care will become a process of applying the best data available to the clinical situation.

The ultimate use of guidelines will be the development of evidence-based validated clinical tools which will be integrated with existing patient data and available to the clinician at the bedside. The gap between research and its practical clinical application in everyday practice will close. Clinical guidelines based on actuarial or cost-saving models and those based on opinion will be replaced by evidence-based guidelines adapted to the appropriate clinical situation. Rather than
fearing guidelines as a threat imposed by health plans or other outside agencies, we as physicians should be leading the development of clinically sound evidence-based clinical guidelines as decision support tools rather than rigid recipes. Hopefully, these tools will help us to provide more efficient service and better care for our patients.

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REFERENCES


