

Barriers Between Guidelines and Improved Patient Care: An Analysis of AHCPR's Unstable Angina Clinical Practice Guideline

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Objectives. To describe common barriers that limit the effect of guidelines on patient care, with emphasis on recommendations for triage in the Agency for Health Care Policy and Research (AHCPR) Unstable Angina Clinical Practice Guideline.

Data Sources. Previously reported results from a prospective clinical study of 10,785 patients presenting to the emergency department (ED) with symptoms suggestive of acute cardiac ischemia.

Study Design. Design is an analysis of the AHCPR guideline with regard to recognized barriers in guideline implementation. Presentation of hypothetical scenarios to ED physicians was used to determine interrater reliability in applying the guideline to assess risk and to make triage decisions.

Principal Findings. The AHCPR guideline's triage recommendations demonstrate (1) poor interobserver reliability in interpretation by ED physicians; (2) limited applicability of recommendations for outpatient management (applies to 6 percent of patients presenting to the ED with unstable angina); (3) incomplete specifications of exceptions that may require deviation from guideline recommendations; (4) unexpected effects on medical care by significantly increasing the demand for limited intensive care beds; and (5) unknown effects on patient outcomes. In addition, analysis of the guideline highlights the need to address organizational barriers, such as administrative policies that conflict with guideline recommendations and the need to adapt the guideline to conform to local systems of care.

Conclusions. Careful analysis of guideline attributes, projected effect on medical care, and organizational factors reveal several barriers to successful guideline implementation that should be addressed in the design of future guideline-based interventions.

Key Words. Practice guidelines, unstable angina, risk assessment, triage

Despite generally favorable effects of guidelines on patient care, guidelines often fail to achieve their objectives (Grimshaw et al. 1995; Worrall, Chaulk, and Freake 1997). The major problems with guidelines can be characterized

as follows: (1) excessive complexity and difficulty in testing the guideline in practice, (2) limited applicability, (3) failure to capture subtle clinical nuances that may make a guideline inappropriate, (4) poor-quality scientific evidence, (5) unexpected effects on other aspects of medical care, (6) organizational inefficiencies that impede guideline effectiveness, and (7) unpredictable effects of local adaptation (Weingarten 1997; Institute of Medicine 1990; Grilli and Lomas 1994). Items 1, 2, and 3 apply to specific attributes of guidelines; items 4 and 5 relate to "knowledge-based" factors pertaining to the clinical impact of guidelines; and items 6 and 7 relate to "structural and organizational" factors that must be addressed in implementing guidelines.

This article discusses the forementioned barriers that limit the impact of guidelines on patient care. It focuses on the results of a recent evaluation of the Agency for Health Care Policy and Research (AHCPR) Unstable Angina Clinical Practice Guideline and other selected studies from the practice guideline literature.

OVERVIEW OF THE AHCPR UNSTABLE ANGINA CLINICAL PRACTICE GUIDELINE

This guideline was developed to define diagnostic and management strategies likely to maximize therapeutic benefit for patients with unstable angina, which is broadly defined as a clinical syndrome that falls between stable angina and acute myocardial infarction (AMI) in the spectrum of presentations of coronary artery disease. An important element of the guideline is its recommendation for the initial triage of patients with unstable angina based on risk factors for poor short-term outcome: (1) high-risk patients: admit to an intensive care bed, (2) intermediate-risk patients: admit to a telemetry or intensive care bed, (3) low-risk patients: outpatient management with close follow-up (Braunwald et al. 1994). It was believed that use of the guideline would reduce unnecessary hospitalizations and use of CCU beds primarily by discouraging the admission of low-risk patients.

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Evaluation of the AHCPR Unstable Angina Guideline

The decision to conduct a formal evaluation of the guideline was motivated by two factors. First, the guideline's recommendation to pursue outpatient management for low-risk unstable angina patients represents a departure from current clinical practice. As failure to diagnose AMI remains the most frequent cause of malpractice suits in emergency medicine (Karcz 1990; Hill 1989), risk avoidance dominates triage behavior in the emergency department (ED) setting and a substantial fraction of low-risk patients are hospitalized. Second, the triage of patients with symptoms suggestive of unstable angina is highly controversial, and the consequences of incorrect clinical decision making are costly in terms of morbidity, mortality, and/or resource use.

This evaluation was aimed at determining the clinical applicability of the AHCPR Unstable Angina guideline in a consecutive series of ED patients diagnosed with unstable angina and at projecting the potential effect of implementing the guideline on triage decisions. To address these questions, we examined data from five hospitals that participated in a prospective clinical trial of the triage of patients with possible acute cardiac ischemia, just prior to release of the AHCPR guideline. The Acute Cardiac Ischemia Time Insensitive Predictive Instrument (ACI-TIPI) Clinical Trial was a prospective study in 10,785 patients presenting with symptoms suggestive of acute cardiac ischemia to the EDs of ten hospitals during the period May 10, 1993 to December 10, 1993 (Selker, Beshansky, and Griffith 1995). The procedures for subject enrollment, data collection, follow-up, assignment of final diagnosis, and classification of patients into guideline risk groups have been described (Katz et al. 1996).

Demonstration of Barriers to Guideline Implementation

Complexity and Trialability. A guideline might be ignored or misapplied, especially if it is overly complex or difficult to put to the test in clinical practice. In their review of compliance studies in the guideline literature, Grilli and Lomas reported that recommendations involving more complex procedures had significantly lower compliance rates than recommendations involving less complex procedures (41.9% vs. 55.9%, $p = .05$); similarly, those recommendations that were difficult to pretest on a limited basis had lower compliance rates than recommendations judged to be high on trialability (36.8% vs. 55.6%, $p = .03$) (Grilli and Lomas 1994).

Use of the AHCPR guideline to triage patients with suspected unstable angina is highly complex and difficult to pretest because of the challenging

task of integrating the relevant criteria required for risk stratification of these patients. In the course of evaluating this guideline, a group of emergency physicians at one of the participating study sites was consulted to discuss the guideline's recommendations for triage. After an overview of the guideline, these physicians were presented with clinical vignettes that were characteristic of intermediate and low-risk groups (see appendix) and were asked to ascertain the patient's level of short-term risk based on the guideline's criteria. The results, shown in Table 1, demonstrate that there was considerable disagreement in this sample of ED physicians in interpreting the guideline's risk stratification algorithm (combined kappa = 0.08). One strategy to improve the reliability of guideline interpretation is to present the guideline in an alternative format, such as a clinical algorithm or critical pathway. These formats require explicit analysis of the logic structure and careful attention to the language used in guidelines (Barak, Margolis, and Gottlieb 1998).

Applicability. The definition of the target population should be clearly stated, and the size of this population and its burden of disease should warrant the substantial effort required to implement a guideline. In a guideline study of hospitalized patients with chronic obstructive pulmonary disease (COPD), implementation of the guideline did not result in significant reduction in length of stay for intervention versus control periods (3.7 days vs. 4.3 days, $p = .11$). One explanation for this finding is that the guideline, because of its restrictive inclusion and exclusion criteria, was applicable to only 24 of 124 (19 percent) COPD patients who were correctly identified as low-risk and eligible for early discharge (Kong, Belman, and Weingarten 1997).

The AHCPR Unstable Angina guideline clearly defines the target population and provides useful evidence-based recommendations regarding the management of unstable angina patients, who account for 570 thousand

Table 1: Interrater Agreement of ED Physicians in Rating Three Hypothetical Scenarios Based on the AHCPR Unstable Angina Guideline (The criterion rating of each scenario is shown in column 1)

Scenario	ED Physicians' Rating of Short-Term Risk of Adverse Outcomes		
	High	Intermediate	Low
Intermediate-risk	2	8	1
Low-risk (a)	0	5	6
Low-risk (b)	0	4	7
Kappa	0.04	0.01	0.16

hospitalizations annually (Graves 1993). However, our evaluation of the triage component of the AHCPR guideline revealed that only 6 percent of patients who were suspected of having unstable angina in the ED were at low risk for adverse cardiac outcomes during 30-day follow-up (range: 5–8% across different hospital types—tertiary care university, urban municipal teaching, university-affiliated community) and were eligible for outpatient management. This suggested that the effect of the guideline in reducing the hospitalization of patients seen with unstable angina in the ED setting was likely to be modest, although the potential savings from reduced hospitalization of low-risk patients could be substantial on a national level.

Failure to Capture Subtle Clinical Nuances. The AHCPR unstable angina guideline captures many subtleties in clinical presentation that portend short-term outcome, such as the presence of dynamic ECG changes in association with angina. It fails, however, to account explicitly for the influences of other medical, psychiatric, or social problems that may necessitate deviation from its triage recommendations. In a study of risk stratification of unstable angina patients, Reilly and colleagues found that 30 percent of patients predicted to be at very low risk of adverse outcomes (and suitable for outpatient workup) required continuing hospitalization for a variety of medical comorbidities (Reilly et al. 1998). In addition, visual cues may also convey essential information that is germane to the initial management of patients with suspected acute cardiac ischemia (McNutt et al. 1993). Thus, good guidelines should demonstrate clinical flexibility, in that they should identify the specifically or generally expected exceptions to their recommendations (Institute of Medicine 1992).

Unexpected Effects on Other Aspects of Medical Care. In our evaluation of the AHCPR guideline, we compared the triage disposition observed in practice versus that recommended by the guideline for each risk group (Table 2). We found that current triage patterns differed from guideline triage recommendations in that 60 percent of high-risk cases were triaged to telemetry (instead of to a coronary care unit, CCU). Strict adherence to the guideline would have led to CCU admission for these patients, although there was no compelling reason to admit the patient to a CCU bed in most of these cases. It is noteworthy that the levels of monitoring and therapy in telemetry and coronary care units may differ significantly across different hospitals, and that the benefit of admitting all high-risk cases to a CCU is questionable with regard to patient outcomes (Selker et al. 1987). Thus, while the guideline was intended to reduce unnecessary hospitalizations, its implementation could lead paradoxically to a significant increase in demand for limited intensive care unit beds.

Table 2: Triage Disposition for Patients in Each Guideline Risk Group ($N = 453$) (Shaded Cells Indicate Triage Disposition Orders in Agreement with Guideline Recommendations)

Guideline Risk Group	Triage Disposition		
	Home	Telemetry	Intensive Care
Low	1	25	1
Intermediate	5	219	22
High	1	107	72
Total	7	351	95

Note: Does not include four patients who were admitted to unmonitored beds (1 low; 1 intermediate; 2 high-risk).

Comparable examples can be found in other guideline studies. In an intervention trial of guidelines to promote a two-day hospital stay for low-risk patients with chest pain, patients in the intervention group had significantly lower costs of initial hospitalization but had a significantly higher all-cause hospital readmission rate (including readmission for cardiac conditions), compared to the control group (Weingarten et al. 1994). In an evaluation of the American Thoracic Society's guidelines for treatment of community-acquired pneumonia (CAP), Gleason and colleagues examined patient outcomes and costs for patients who were managed in agreement with the guidelines versus those who were not. Compliance with recommended antibiotic therapy in the subgroup of patients with advanced age and/or comorbidity substantially increases the costs of therapy without evidence of improvement in any patient outcomes; however, the number of patients in this subgroup limited the power to detect important differences in outcomes such as mortality (Gleason et al. 1997). In another study, application of the AHCPR guideline for acute low back pain would have increased sensitivity in detecting the occasional patient with significant low back pathology (spinal fractures and tumors); however, use of the guideline would have dramatically increased the use of lumbar x-rays in patients with acute low back pain at the time of the first visit by 31 percent (Suarez-Almazor et al. 1997). These studies demonstrate an important role for pretesting guideline recommendations by explicitly quantifying the risks and benefits of standardizing medical practice in a particular clinical domain.

Poor-Quality Scientific Evidence. Although it is still unclear from the existing literature whether evidence-based guidelines work any better than consensus-based guidelines in general (Worrall, Chaulk, and Freake 1997),

guidelines may not improve care when the underlying evidence base is poor and may formalize unsound practice (Rice 1995). For example, guidelines for ED triage, based on expert opinion, initially suggested that non-emergent ED patients could be safely referred to off-site clinics without significant adverse consequences (Derlet and Nishio 1990). A subsequent validation study suggested, however, that the triage guidelines were not sufficiently sensitive to identify patients whose condition justified ED care (Lowe, Bindman, and Ulrich 1994).

The recommendations for triage in the AHCPR unstable angina guideline were based largely on observational studies and expert opinion. Despite this limitation, our evaluation indicated that the guideline effectively stratified patients with unstable angina across multiple dimensions (Katz et al. 1996). Low-risk patients had a very low risk of adverse short-term outcomes (0 percent had cardiovascular complications or death; 4 percent required revascularization). Similarly, high-risk patients were more likely to have had AMI than low-risk or intermediate-risk patients (15 percent versus 0 and 5 percent, respectively). However, the risk groups specified by the guideline did not improve discrimination in patients with suspected acute cardiac ischemia when compared to clinician judgment, and the guideline's impact on patient outcomes has yet to be demonstrated. This is currently the focus of ongoing research.

The evidence base of guidelines, including their demonstrated impact on patient care, is a major determinant of acceptance by physicians. In a recent survey of faculty and housestaff at a university teaching hospital, we found that the need for evidence on the clinical impact of practice guidelines was rated as the most important factor related to their usage. In addition to evidence, other factors that were rated highly were (in order of importance): (1) more ready access to guidelines in daily practice, (2) a good explanation from clinical leaders and subject experts on the rationale for using guidelines, and (3) evidence that guidelines reduce health care costs. In a survey of medical directors of managed care physician groups, the availability of national or local data was rated as an important influence in the development and implementation of clinical guidelines (Fang, Mittman, and Weingarten 1996). Existing databases with detailed clinical data can provide a less costly means of assessing the impact of guidelines without conducting effectiveness trials.

The process of behavior change in physicians occurs in stages, sometimes over a period of years, with knowledge-related influences (i.e., scientific evidence pertaining to clinical effectiveness) playing a relatively greater role early on in the process of adoption (Putman and Campbell 1989). Thus,

providing physicians with high-quality evidence that guidelines improve care, coupled with baseline data that compares current practice versus practice expected according to the guideline, can serve as a powerful motivation for change in clinical practice.

Organizational Inefficiencies that Impede Guideline Effectiveness. Compliance with guidelines may be significantly compromised by multiple organizational problems, including time constraints, inadequate staff, lack of sufficient resources to provide initial or follow-up treatment, and funding restrictions (Carter, Belcher, and Inui 1981). The importance of visit duration in compliance with preventive care guidelines was suggested in a recent observational study of 138 community-based family physicians; in this study, the duration of visits during which preventive services were delivered was significantly longer than those visits without preventive services (10.9 vs. 8.8 minutes, $p < .0001$) (Stange, Locke, and Goodwin 1998). Similarly, the use of non-physician staff, in addition to the designation of follow-up time for preventive services, reduces the burden on physicians and improves compliance with guidelines for smoking cessation (Duncan, Stein, and Cummings 1991). Finally, organizational policies or funding restrictions on recommended services may limit compliance with guidelines; an example is the widespread lack of insurance coverage of smoking cessation services among health plans (Parkinson et al. 1992).

The successful implementation of complex acute care guidelines, such as the AHCPR Unstable Angina guideline, requires the involvement and coordination of multiple inpatient and outpatient departments (e.g., emergency medicine, cardiology, family medicine, general internal medicine, nursing, nuclear medicine, medical administration) and requires the alignment of management objectives and clinical policies of these departments. Organizational strategies such as continuous quality improvement may be particularly useful in implementing complex guidelines that cut across multiple departments if there is strong leadership and commitment to the principles of total quality management (Weiner, Shortell, and Alexander 1997).

With regard to low-risk ED patients, the AHCPR guideline encourages hospitals to discharge these patients and to provide for outpatient follow-up within 48–72 hours of initial presentation. In our evaluation of the guideline, we found that policies of the study hospitals recommended admission for patients presenting to the ED with stable angina (classified as low-risk by the guideline); only one of 28 low-risk patients was discharged to home. With regard to the high-risk group, successful implementation of the guideline requires that hospitals provide adequate intensive care resources to

accommodate these patients. In our evaluation, a CCU bed was unavailable at the time of triage for 26 percent of those high-risk patients who were admitted to a telemetry bed (instead of to a CCU bed, as recommended) (Katz et al. 1996). Thus, in attempting to explain the lack of adherence to guidelines in current practice, we uncovered significant organizational barriers to their implementation.

Unpredictable Effects of Local Adaptation. The effects of modifying the guideline to conform to local beliefs and the local system of care are often unpredictable, and few studies have specifically addressed this topic. The Institute of Medicine Committee on Clinical Practice Guidelines expressed concern about local adaptation efforts because of the increased potential for conflict and inconsistency, particularly if local processes involve unsystematic, arbitrary approaches to guideline modification (Institute of Medicine 1992).

In one study, local adaptation of the AHCPR Depression guideline by an health plan review committee resulted in a document that was shorter, more user-friendly, and stronger in its emphasis on screening compared to the AHCPR guideline; the revised guideline made recommendations for each step in the diagnosis and management of depression that were customized for clinical use in a large health maintenance organization (Brown, Shye, and McFarland 1995). The participation of members of the target group in reviewing the scientific evidence of the guideline, determining its applicability to their practice setting, and modifying parts of the guideline as needed is a useful social influence strategy for guideline implementation (Mittman, Tonesk, and Jacobson 1992). While participatory guideline review entails high levels of effort, the process allows physicians to exchange views, assumptions, and beliefs; to compare the guideline against their own standards; and to gain a sense of ownership over the guideline and the process of quality improvement (Mittman, Tonesk, and Jacobson 1992; Wise and Billi 1995). When the adaptations are major, then the collection of pilot data before and after implementation of the guideline is recommended.

CONCLUSION

This article reviews several common barriers that may limit successful implementation of guidelines in clinical practice, as illustrated by evaluating recommendations for triage in the AHCPR Unstable Angina Clinical Practice Guideline. A major limitation to adoption of this guideline is insufficient

evidence on the beneficial impact of the triage guidelines on ED decision making and patient outcomes relative to current practice. This evidence is critical in motivating a change in physicians' management of suspected ACI and in providing physicians with a scientific basis for setting clinical policy.

Experience over the past decade has indicated that developing sound, evidence-based guidelines is not enough to improve the quality of health care. Careful attention to both knowledge-based factors and organizational factors in the implementation process will maximize the likelihood that guidelines fulfill their promise in improving patient care. Health services researchers can play an important role by evaluating the impact of guidelines on patient care outcomes (thus improving the evidence base for guidelines prior to their dissemination), as well as by advancing our understanding of the organizational variables and social influence strategies that promote successful implementation.

APPENDIX

Hypothetical Low-Risk Scenario Presented to Emergency Department Clinicians

62 year old male with history of hypertension who presents to ED with new onset angina lasting 5–10 minutes, which occurred two days ago.

- Patient is currently pain-free; he did not receive nitroglycerin.
- The episode was associated with prolonged exertion; his normal activities are not limited.
- No history of nocturnal angina.
- No other known cardiac risk factors.
- Examination is negative for mitral regurgitation murmur, S_3 , rales, or hypotension.
- ECG shows 1 mm T-wave inversion in leads III and a VF (no change since prior ECG).

Using the AHCPR guideline, how would you classify this patient in terms of his short-term risk of death or non-fatal MI?

- High-risk _____
- Intermediate-risk _____
- Low-risk _____
- Unknown _____

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