

## **PART IV. PROMOTING AND IMPLEMENTING SAFETY PRACTICES**

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## Chapter 51. Practice Guidelines

### **Robert Trowbridge, MD**

University of California, San Francisco School of Medicine

### **Scott Weingarten, MD, MPH**

University of California, Los Angeles School of Medicine

### **Background**

Practice guidelines are among the most widely employed methods of modifying physician behavior. Defined as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions,”<sup>1</sup> guidelines may affect both the process and the outcome of care. Although guideline development and implementation have traditionally focused on ensuring a perceived standard of care, increasing emphasis has been placed on patient outcomes and patient safety. In this regard, thousands of guidelines have been promulgated on a great variety of clinical topics ranging from the prevention of falls in the elderly to the proper use of bone marrow transplantation.<sup>2,3</sup>

### **Practice Description**

Guidelines vary greatly in terms of both method of development and format. Some consist of relatively straightforward statements that advocate a particular clinical practice, whereas others represent a series of complex algorithms that require the input of multiple clinical variables. Many guidelines are developed by specialty and advocacy organizations with attention paid to rigorously conducted systematic reviews.<sup>4</sup> Others may simply reflect a local standard of care.

Guidelines should only be considered a potential source of information and are effective at modifying physician behavior only when coupled with appropriate implementation strategies. Guidelines disseminated using a multifaceted approach that provides for peer influence and management support, for example, are more likely to be successful in influencing provider behavior than strategies that depend solely on the passive dissemination of printed materials.<sup>5</sup>

### **Prevalence and Severity of Target Safety Problem/Opportunities for Impact**

Practice guidelines have the potential to greatly impact patient safety as they may facilitate widespread dissemination of practices that effectively reduce medical errors. It is well established in other medical fields that known tenets of effective health care are not practiced on a universal basis despite overwhelming evidence supporting their use. According to an audit of Medicaid charts in Connecticut, for example, only 50% of patients presenting with an acute myocardial infarction received aspirin and beta-blockers on the day of admission despite substantial evidence that these practices reduce mortality.<sup>6</sup> A second report estimated that 3500 infarctions would be averted and 4300 lives saved annually if beta-blockers were appropriately prescribed in patients with coronary artery disease.<sup>7</sup> Guidelines could help rectify similar shortcomings in the field of patient safety with corresponding reductions in medical errors.

## Study Design

There are no well-designed studies that specifically evaluate the effect of practice guidelines on patient safety. However, research regarding their effectiveness in modifying physician behavior and improving patient outcomes is plentiful. The most comprehensive review evaluating general utility of guidelines involved an extensive search of MEDLINE and other electronic databases, the gray literature and the bibliographies of pertinent articles. Its analysis included 59 reports consisting of both controlled time series and before-after studies in addition to randomized trials.<sup>8</sup>

A second systematic review, limited to computer-based guidelines, reported the results of a search of several electronic databases (MEDLINE and CINAHL) complemented by a limited bibliography search. It included 25 studies detailing the use of 20 guideline systems. In this group, there were 10 time series studies (all without external controls) and 10 controlled trials, 9 of which were randomized.<sup>9</sup>

A final systematic review, limited to the primary care setting, also searched MEDLINE and several other electronic databases and included a limited bibliography search.<sup>10</sup> This review included only randomized trials that reported clinical outcomes associated with the treatment of patients with established diagnoses and identified 13 studies for inclusion. In keeping with these criteria, trials of the use of guidelines to promote preventive health care and proper diagnostic evaluations were excluded.

Several studies not represented in the above systematic reviews also provide valuable information on the effectiveness of practice guidelines. Two multicenter studies, for example, evaluated the impact of guidelines on the treatment of patients admitted for pneumonia and certain surgical procedures, respectively. Both of these were prospective before-after trials.<sup>11,12</sup> A prospective controlled trial of the implementation of a diabetes guideline using problem-based learning was also completed,<sup>13</sup> as were 2 randomized controlled trials of the local implementation of nationally developed guidelines.<sup>14,15</sup> Other recently completed works include an evaluation of a guideline for the outpatient treatment of cystitis with concurrent and historical controls, and a prospective before- after investigation of a guideline for the treatment of upper gastrointestinal hemorrhage.<sup>16,17</sup>

## Study Outcomes

Very few of the reviewed studies report outcomes specifically linked to patient safety. Those that do (such as guidelines to prevent falls in the elderly (Chapter 26) and to promote hand washing (Chapter 12)) are of less than robust design.<sup>2,18,23</sup> A few of the studies included in the systematic reviews do report the effect of guidelines on surgical site infections and vaccination rates, but results are reported in terms of the process of care rather than the outcome of care. The systematic review from Worrall et al is an exception, as it only analyzed studies that reported direct clinical variables.<sup>10</sup> Among the other studies, however, the most commonly reported variables were length of stay, rates of provider adherence to guidelines, complication rates and the rates of the appropriate use of diagnostic testing.

## Evidence for Effectiveness of Practice

Despite the inherent methodologic problems of many of the cited studies, there is substantial evidence that practice guidelines may be effective in influencing provider behavior and patient outcomes. In the seminal review from Grimshaw and Russell, 9 of 11 studies reporting clinical outcomes noted some degree of improvement while the process of care was found to improve in 55 of 59 studies.<sup>8</sup> This review did include several trials with marginal study design, but the authors argued for the inclusion of the time series and before-after studies on the premise that the magnitude of effect seen in many of the studies overwhelmed any potential bias that may have been attributable to study design. They additionally noted that the randomized trial may not represent the best method for evaluating practice guidelines.

The systematic review investigating the utility of computer-based guidelines is similarly encouraging.<sup>9</sup> Fourteen of 18 studies found guidelines increased provider adherence to the tenets of care promoted by the guidelines. Of the 8 studies that evaluated patient outcomes, 3 found improvements. These results mirror those of Grimshaw and Russell and reinforce the supposition that guidelines, at least in the studies completed to date, are more effective at influencing the process rather than the outcome of care.

The systematic review of controlled trials reporting clinical outcomes in the primary care setting is significantly less optimistic.<sup>10</sup> Only 5 of the 13 trials analyzed showed improvements in the defined clinical outcomes. None did so across all of the study groups or for an extended period of time. These results cast doubt on the utility of guidelines, particularly since this paper only included rigorously conducted trials reporting clinical outcomes, in contrast to the larger review by Grimshaw and Russell. However the authors correctly assert that many of these studies likely used guidelines that were not evidence-based and which may not have been sensitive enough to discern small improvements in clinical outcomes. In addition, it is likely that improvements in the process of care represents a reasonable surrogate endpoint for clinical outcomes given the size of the studies that would need to be conducted to show a beneficial outcomes effect of guidelines. To exclude all studies using this surrogate endpoint may be an extreme and unnecessary measure.

The studies of guidelines that have been published since the completion of the above systematic reviews are similarly conflicting. The multicenter study of the pneumonia guideline, for example, showed no effect on the length of stay or complication rates whereas the study of the postoperative surgical guidelines showed a significant decrease in the length of stay in 2 of the 3 groups.<sup>11,12</sup> Additionally, studies of the implementation of nationally developed guidelines yielded conflicting results, perhaps as a function of the implementation strategies used in each study. The study of the Agency for Healthcare Policy and Research (AHCPR, now the Agency for Healthcare Research and Quality, AHRQ) guideline for cessation of smoking in pregnant woman, which was a rigorously conducted randomized controlled trial, used extensive implementation strategies and showed a marked and statistically significant increase in the smoking cessation rate in the intervention group.<sup>15</sup> In contrast, the trial using continuous quality improvement measures and academic detailing to promote the AHCPR depression guideline showed little effect.<sup>14</sup> Yet several other studies, all of reasonable design and well-controlled, demonstrated improvements in the process of care<sup>13,16,17</sup> with one also reporting a marked clinical benefit in improving glycemic control in diabetics.<sup>13</sup>

## Potential for Harm

It has been theorized that practice guidelines, if improperly developed or implemented, could actually be detrimental to the process of care or worsen clinical outcomes. A study of guidelines in the use of neurodiagnostic testing in patients with low back pain found the tests were more frequently utilized in an improper fashion than at baseline when clinicians were given a set of guidelines that were relatively narrow in focus.<sup>19</sup> Another study of patients treated for congestive heart failure found the guidelines actually increased the length of stay beyond that which was clinically necessary.<sup>20</sup> Although neither of these studies revealed worsened patient outcomes due to the guidelines, that potential certainly exists. In addition, the promulgation of guidelines with imprudent advice could also result in widespread harm to patients.

## Costs and Implementation

Developing and implementing practice guidelines is expensive. When developed for a complex clinical problem by a national organization, for example, they consume tremendous resources, often tens of thousands of dollars.<sup>21</sup> In addition, some of the more successful implementation strategies, such as academic detailing (Chapter 54), also require a substantial measure of effort and financial outlay.

The manner in which practice guidelines are implemented is at least as important as the content of the guidelines themselves. Several systematic reviews have investigated both the strategies that are associated with successful institution of guidelines and the specific barriers to implementation.<sup>5, 22, 23</sup> These reviews concluded that the deterrents vary by practice location and that strategies to circumvent these barriers must be devised on an individual and local basis. In general, however, the number and intensity of the implementation strategies employed generally corresponds with the ultimate success of the guideline.

## Comment

There is convincing but by no means overwhelming evidence that practice guidelines are effective in positively influencing the process and, to a lesser extent, the outcome of care. Many of the completed studies are plagued by methodologic shortcomings that reflect the difficulty inherent in studying the impact of guidelines. Although evidence specific to the use of guidelines in patient safety is scanty, they are likely to be as effective in this area as any other. It thus appears that well-constructed guidelines could play a significant role in ensuring patient safety and reducing medical errors. The effectiveness of guidelines, however, is dependent on many factors outside of their content. In particular, specific attention must be focused on utilizing appropriate implementation strategies if the full potential of guidelines is to be realized.

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