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# Adding Value to Evidence-Based Clinical Guidelines

Patrick J. O'Connor, MD, MPH

**C**LINICAL PRACTICE GUIDELINES (CPGs) ARE WIDELY viewed as a cornerstone of current efforts to improve the quality of clinical care.<sup>1,2</sup> At their best, CPGs articulate clear goals of care, enumerate potentially beneficial therapeutic approaches, and may reduce undesirable variation in care while supporting rational clinical management of common conditions. Clinical recommendations are often supported by evidence from well-designed randomized trials when such information is available.<sup>3</sup>

The National Guideline Clearinghouse sponsored by the Agency for Healthcare Research and Quality listed about 650 CPGs in 1999 and more than 1650 active CPGs in July 2005. In the last several years, major evidence-based recommendations from CPGs have often been proposed as measures of quality of care. For example, McGlynn et al<sup>4</sup> identified 439 disease-specific and preventive quality-of-care indicators, many of which reflect current care recommendations in CPGs. Others have proposed and federal law may soon mandate use of such quality measures to assess clinical performance for accountability purposes and for pay-for-performance initiatives.<sup>5</sup>

A wealth of evidence suggests that intensive management of diabetes, hypertension, dyslipidemias, and other chronic conditions is, on average, beneficial to broad groups of patients in terms of health outcomes.<sup>3</sup> Most data are based on studies limited to a single clinical intervention, but several clinical trials that intensively managed multiple clinical domains also have shown unequivocal benefit. In one randomized trial of adults with type 2 diabetes, simultaneous intensive management of glucose levels, blood pressure, lipid levels, use of angiotensin-converting enzyme inhibitors, and use of aspirin led to a 53% reduction in major cardiovascular events over a 7.8-year period.<sup>6</sup>

However, in this issue of *JAMA*, Boyd and colleagues<sup>7</sup> demonstrate that even the best evidence-based, disease-specific CPGs may lead to unintended consequences when used to help guide the care of elderly patients with multiple comorbid conditions. In reviewing national guidelines for 9 common chronic conditions, the authors note that 8 of the 9 CPGs failed to emphasize that benefits may vary signifi-

cantly in relation to patient factors such as life expectancy. Five of these 9 CPGs failed to address the care of patients with multiple comorbid conditions, although comorbidity is common in elderly patients. About 83% of Medicare beneficiaries have at least 1 chronic condition, and about 68% of Medicare's budget is devoted to the 23% of beneficiaries with 5 or more chronic conditions.<sup>7,8</sup>

Patients treated with multiple medications and multiple lifestyle interventions are at high risk of medical errors and nonadherence.<sup>9</sup> Many patients described by Boyd et al<sup>7</sup> would receive 10 or more distinct medications dosed at 3 to 5 times each day, along with more than a dozen nonpharmacological treatment recommendations. Such complex treatment regimens disrupt daily routines, impair social activities, and almost inevitably invite nonadherence.<sup>10-12</sup> As shown by Boyd et al, medication costs may easily exceed \$5000 per year. Even with forthcoming Part D Medicare coverage, out-of-pocket costs for many patients' medication could be nearly \$4000 per year. The cost of multiple physician visits is also high, especially if the patient does not have a primary care physician to optimize referrals and provide care for multiple conditions at each office visit.<sup>13</sup> Patients' willingness to follow complicated pharmacological regimens may further decline because of high-deductible health insurance.<sup>14</sup> Patients may become increasingly intolerant of overly complex and expensive multidrug regimens and frequent clinic visits when initial costs are paid out of pocket.

The implementation of multiple evidence-based clinical recommendations by physicians in office settings is limited both by patient preferences and by physician factors that are poorly understood.<sup>15</sup> The evidence base on which CPGs rest is limited by the number, design, and quality of the underlying clinical trials. Clinical practice guidelines have been reported to be variably flawed in terms of conflict of interest,<sup>16,17</sup> specialty turf battles,<sup>18</sup> endorsement of new<sup>19</sup> or relatively unproven pharmaceutical<sup>20</sup> agents, and focus on a single condition compared with a broader clinical focus. There is much redundancy and significant variation in recommendations across multiple CPGs for single conditions, such as the 386 diabetes-related CPGs now listed as active at the National Guideline Clearinghouse. Evidence-

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based recommendations often are embedded in lengthy documents that are not easily accessible at the point of care.<sup>21</sup> However, the most onerous problems that physicians who use CPGs now face include too many evidence-based recommendations, recommendations that are sometimes inappropriate in particular clinical situations, and recommendations that often are not ranked in terms of their clinical value. If these problems were thoughtfully addressed, the value of CPGs as a tool to improve patient health might increase substantially.

As physicians understand when applying results of clinical trials in practice, all evidence-based recommendations are not of equal clinical benefit to a patient. Benefits documented in clinical trials are “average” benefits and even within the trials the degree of benefit received from an intervention depends on many patient-specific factors. Practicing physicians care for patients with even greater patient-specific variation (because of restrictive eligibility criteria in most clinical trials), so it is not surprising to find wide variation in the benefits obtained. When treating elderly patients with multiple comorbid conditions, the complexity of care is compounded by the need to simultaneously address multiple clinical domains.

Ideally, CPGs would help physicians select from among multiple evidence-based recommendations those with the greatest potential benefit to a given patient.<sup>22</sup> With the advent of electronic medical records, the benefit of multiple evidence-based recommendations could be rapidly computed based on information available at the time of each visit, and top-priority recommendations presented to the physician at the time of the clinical encounter. When evaluated in conjunction with the patient’s personal goals for treatment (eg, reducing pain, improving function, staying independent, getting to a specific family event), such information would provide a rational starting point for discussing therapy with a patient.<sup>23</sup> For this type of fairly sophisticated decision support system to become a reality, CPGs must include information on the expected benefits of a specific evidence-based recommendation. In addition, benefit estimates ideally should take into account patient-specific factors such as age, estimated life expectancy, baseline risk of complications, and the effect of a treatment change on the complexity of a therapeutic regimen.<sup>24,25</sup>

From the perspective of a patient, value is maximized by preferentially implementing clinical actions that have maximal clinical benefit to that individual. This is especially important for frail elderly patients with multiple chronic conditions, who may be unable or unwilling to tolerate, afford, or adhere to a large number of pharmacological and lifestyle interventions over long periods. Barton<sup>3</sup> compared the clinical benefit of many evidence-based recommendations based on the number needed to treat. This simple metric estimates how many individuals with specific characteristics need to be treated for a given period to prevent 1 adverse outcome, such as a premature death or a major car-

diovascular event.<sup>22,26-29</sup> Beyond number needed to treat, other methods such as cost-benefit analysis, cost-effectiveness analysis, nonparametric measures that can accommodate multidimensional inputs and outputs, and measures of clinically preventable burden are available to rank clinical actions by their potential benefit to patients.<sup>4,12,30</sup>

As Boyd et al<sup>7</sup> point out, using evidence-based clinical recommendations as quality indicators for accountability purposes could have many unintended consequences. Holding physicians or their patients accountable for hundreds of process and outcome measures could divert clinical attention from the few key interventions that are of most potential benefit to a patient, and might multiply costs of care with minimal positive effect on health.<sup>12</sup> Depending on the specifics of how they are designed, some pay-for-performance arrangements could increase treatment with multiple medications among frail elderly patients who are most susceptible to medical errors and adverse events. Pay-for-performance arrangements could motivate some physicians to focus on specific interventions not necessarily consistent with the patient’s treatment goals or act as an incentive for physicians to care for fewer frail elderly patients with multiple comorbidities.<sup>31</sup>

Despite their limitations, evidence-based CPGs remain an important and necessary tool in the effort to improve health care quality. Strategies to address the limitations of current CPGs need to be developed and implemented, including providing recommendations based on level of evidence for particular patient groups and considering the potential economic and personal burden on the patient and caregiver as well as potential interactions with comorbid conditions. Future CPGs could be improved by including explicit information such as the number needed to treat to obtain a specified benefit, and should also be crafted more systematically to consider the influence of patient-specific factors such as age, life expectancy, and comorbidity on anticipated benefits of interventions. In addition, CPGs could include information on cost of various potential therapies, which may influence patient preferences and patient adherence to therapeutic regimens. Such modifications will increase the value of CPGs to clinicians and patients at the point of care, especially when physicians already have too much to do.

Encouraging customization of care in complex clinical scenarios respects the individuality of patients and the professional judgment of highly skilled physicians and minimizes the problem of overtreating patients most susceptible to drug interactions, drug adverse effects, and medical error. Boyd and colleagues have presented these important “in the trenches” issues in a clear and compelling way. Physicians and designers of CPGs owe it to themselves and their patients to consider these issues carefully and to craft CPGs and pay-for-performance accountability measures that will reinforce excellent clinical care while being mindful of resource use and being respectful of patient preferences and priorities.

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