Commentary

Should Cost Be Formally Incorporated into Clinical Practice Guideline Recommendations?

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Abstract

There is increasing discussion worldwide on explicitly including cost as part of the clinical practice guideline development process. While this could enhance our understanding of value-based care and improve resource utilization, there are many practical challenges for cost inclusion. This commentary explores this issue, examining it from multiple angles and giving pros and cons to inclusion in future guidelines.

Keywords

clinical practice guideline, cost, value-based care

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With accelerating health care costs, there is increasing interest in explicit and transparent assessments of health care value. Cost is commonly left out of clinical practice guideline (CPG) development. There is growing discussion, however, from guideline developers and at Guidelines International Network meetings for incorporation into future guidelines. Therefore, the question surfaces, should the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) formally factor cost into the guideline development process?

As one may expect, there is no simple answer to that question. If we take a step back, the first question becomes, how do we assess costs? The US multipayer system is the first hurdle in looking at the reality of this idea. The ever-changing technology landscape leads to changing costs as new technology arises, patents expire, and generics become available. Cost-effective analysis (CEA) studies are often not standardized and can be difficult to assess for broadened applicability.

Furthermore, there is the more theoretical discussion of recommendations for best patient care versus best value-based care, and many people will sit on both sides of that long-standing debate. The pros and cons for these questions are explored here, examining the scientific process behind guideline development as well as what other specialties have done to incorporate cost.

The United States has the highest health expenditures without the greatest outcomes and life span. We do need to recognize that there is a finite level of health care resources and that many patients, even those insured, may have high out-of-pocket expenses, cost-prohibitive deductibles, and other financial concerns.

Cost considerations in CPGs must be consistent and transparent. There is little high-quality evidence on cost-benefit in the otolaryngology literature, and data become out of date quickly. This is probably the biggest hurdle to inclusion in our guideline methodology. The methodology set forth by the AAO-HNSF to govern and standardize its CPG development is highly acclaimed. Per the guideline development manual by Rosenfeld et al, “selection of key action statements is driven by opportunities to promote best practices, reduce variations in care and minimize inappropriate care or resource utilization.” Currently, the AAO-HNSF does incorporate a place for costs in the evidence profile. There is a section labeled “harms, benefits, and costs.” This has been used to identify cost outliers. There is no formal consideration of cost in determining whether a key action statement is an option, recommendation, strong recommendation, and so on.

Some groups have explicitly included costs in methodology. The most substantial efforts for cost inclusion have come from 2 groups: the National Institute for Health and Care Excellence (NICE) in the United Kingdom and the American College of Cardiology/American Heart Association. NICE explicitly incorporates economic considerations into CPG development and has a health economist on every CPG development panel. The role of the health economist is to systematically review available CEA data and de novo economic analysis where cost-effectiveness data are not available or adequate. There are, of course, fundamental differences in the United Kingdom’s single-payer nationalized health insurance with respect medical

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treatment cost identification. A NICE guideline development typically takes 2 years (approximately 1 year longer than AAO-HNSF guideline development process).8

The American College of Cardiology/American Heart Association (ACC/AHA) have been developing guidelines for 30 years and are one of the recognized leaders in US subspecialty guideline development. In 2014 the group published a “statement on cost/value methodology in clinical practice guidelines and performance measurements,”9 developing formal methodology to evaluate existing CEA literature and incorporate it into CPG recommendation and strength. Existing literature was evaluated by the Quality of Health Economic Studies Instrument.10 An assigned “level of value” is given to an intervention, ranging from “high value” (better outcome at a lower cost) to “low value” (greater cost) (QALY gained). There are also categories of “uncertain value” (when data are insufficient) and “not assessed.” These categories are then combined with the level of evidence evaluating efficacy. For example, a class I recommendation would be that therapy is an “A” level of evidence and a “high” level of value. The ACC/AHA statement also incorporates room for exceptional cases when a “resource-intensive therapy” provides the only treatment of a condition.9

While these numbers may seem arbitrary—and in many respects are—they are commonly used to determine heath care value. Interestingly, the level of <$50,000 reflecting lower cost comes from a historical Medicare decision to cover dialysis in renal failure.9

QALY is a standard measure of outcomes and generally the preferred measure of clinical effectiveness in health economics.9 It reflects years of survival adjusted for quality of life. Much controversy exists around the use of such thresholds, which is beyond the scope of this commentary.4

If we return back to what future CPGs of the AAO-HNSF might include, we can consider multiple options moving forward. A health economist is likely not practical; creating multiple de novo analyses would greatly lengthen the guideline development process and increase the costs of production. A better option is continuing to assess available CEA literature on each key action statement topic and use costs as part of the evidence profile, ensuring that this portion is given careful consideration by the group. Outliers can be noted (ie, a particularly effective yet expensive medication). Last, including CEA research needs at the end of each guideline would be helpful to strengthen available data, promoting stronger evidence of cost and value for future guidelines.

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