Stakeholder-Driven Quality Improvement: A Compelling Force for Clinical Practice Guidelines

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Abstract

Clinical practice guideline development should be driven by rigorous methodology, but what is less clear is where quality improvement enters the process: should it be a priority-guiding force, or should it enter only after recommendations are formulated? We argue for a stakeholder-driven approach to guideline development, with an overriding goal of quality improvement based on stakeholder perceptions of needs, uncertainties, and knowledge gaps. In contrast, the widely used topic-driven approach, which often makes recommendations based only on randomized controlled trials, is driven by epidemiologic purity and evidence rigor, with quality improvement a downstream consideration. The advantages of a stakeholder-driven versus a topic-driven approach are highlighted by comparisons of guidelines for otitis media with effusion, thyroid nodules, sepsis, and acute bacterial rhinosinusitis. These comparisons show that stakeholder-driven guidelines are more likely to address the quality improvement needs and pressing concerns of clinicians and patients, including understudied populations and patients with multiple chronic conditions. Conversely, a topic-driven approach often addresses “typical” patients, based on research that may not reflect the needs of high-risk groups excluded from studies because of ethical issues or a desire for purity of research design.

Keywords

quality improvement, clinical practice guidelines, evidence-based medicine

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M ost guideline developers would agree with the substance of an Institute of Medicine report stating that rigorous methods should drive clinical practice guideline development—not the preferences of individuals or medical societies—if the products are to be trustworthy.\(^1,2\) What is less clear, however, is where quality improvement (QI), as driven by measures of quality and performance, enters the process. Should it be the priority-guiding force in formulating recommendations, or should it enter only after recommendations have been finalized?

Guidelines and QI both began in an age when scientific rigor and trustworthy methodology took a backseat to opinion-based development. Whereas the methodological standards for guidelines have improved,\(^1,2\) QI methods have yet to be similarly upgraded despite prominent requests.\(^3-5\) The overlap between QI and clinical recommendations is obvious and unmistakable. Hence, as we applaud the progress made in bringing rigorous tools of research evaluation and synthesis to bear on guideline development, we also hope that an analogous movement gains traction within the world of QI.

The 2011 Institute of Medicine report on standards for guidelines\(^1\) went beyond a mandate for trustworthy methodology, calling for much greater emphasis on stakeholder engagement, especially patients and health consumers, as requisites for effective implementation and for stringent efforts to manage conflicts of interest. Effective approaches to realizing these objectives may ultimately prove more challenging than the upgrading of methods for bringing clinical research to bear on guideline development and yet may be particularly important for implementation and real-world impact. In this context, a stakeholder-driven approach to guideline development\(^6\) emphasizes pragmatic concerns expressed directly by the deliverers and recipients of care in defining scope, purpose, and content (Table 1). Such concerns are best articulated through a multidisciplinary guideline development group with effective, dynamic engagement of consumers and other nonphysician stakeholders as well as from working clinicians.\(^2\) A multistakeholder group is most likely to focus on issues important and meaningful for
patients (rather than providers and health care systems) and is advantaged to identify the gaps between knowledge and practice for which formal recommendations are most needed and likely to be effective.

**Some Illustrative Examples**

The impact of the approach to guideline development—stakeholder driven versus topic driven (Table 1)—on guideline relevance is illustrated by 4 guidelines on otitis media with effusion (OME), thyroid nodules, sepsis, and acute bacterial rhinosinusitis.

An early attempt at an OME guideline, developed by the Agency for Health Care Policy and Research using a topic-driven approach (Table 1), defined the target patient as “an otherwise healthy child age 1 to 3 years with no craniofacial or neurologic abnormalities or sensory deficits.”8 This definition corresponds to entry criteria in OME randomized controlled trials, which can have limited generalizability because of design bias, imprecision, inconsistency, indirectness, and reporting bias. Beyond these limitations, however, the utility of the guideline was ultimately questionable because OME is self-limited in most “otherwise healthy children” and rarely requires intervention. Most pediatricians already knew this at the time.

More recently, a guideline development group organized by the American Academy of Pediatrics included a broader mix of multidisciplinary clinicians and allied health professionals and began by discussing gaps in care perceived by stakeholders. The group changed the target patient to a child “aged 2 months through 12 years with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae.”9 At the same time that it established “at risk” criteria for developmental delays, this stakeholder-driven approach (Table 1) allowed the resulting guideline to focus on a population of children with OME who might benefit most from intervention. Subsequently, the American Academy of Pediatrics guideline was updated by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) to include substantial new information for patient engagement and shared decision making, driven largely by QI opportunities identified early on by consumer members of the development group.10 This new information enhances the impact and relevance of older recommendations regarding a

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**Table 1. Comparison of 2 Approaches to Clinical Practice Guideline Development.**

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<tr>
<th></th>
<th>Stakeholder-Driven Approach</th>
<th>Topic-Driven Approach</th>
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<tbody>
<tr>
<td>Underlying focus</td>
<td>Stakeholder perception of needs, knowledge gaps, and clinical uncertainties</td>
<td>Topic-related evidence, especially randomized trials and systematic reviews</td>
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<tr>
<td>Process driving development</td>
<td>Clinical relevance and pragmatism with an overriding goal of QI</td>
<td>Epidemiologic purity and rigor of evidence selection and synthesis</td>
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<tr>
<td>Determining the guideline</td>
<td>Based on practice variation, clinical concerns, and knowledge gaps in a specific population</td>
<td>Based on a need to develop guidelines for large homogeneous populations similar to those selected for randomized trials and in systematic reviews</td>
</tr>
<tr>
<td>scope</td>
<td>with the most to gain from helpful guidance</td>
<td></td>
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<tr>
<td>Composing the guideline</td>
<td>Includes broad, multidisciplinary stakeholder representation, including patients and</td>
<td>Includes primarily specialists and content experts who are best suited to interpret the research literature; may or may not include other disciplines, allied health providers, consumers, or patients</td>
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<tr>
<td>development group</td>
<td>consumers; promotes capacious, unconstrained thought about real-world QI needs; content experts are a minority</td>
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<td>Ideal qualities for the</td>
<td>Someone who understands QI and relevant guideline methodology and has group facilitation</td>
<td>Someone with extensive experience and content expertise in the guideline topic</td>
</tr>
<tr>
<td>development group chair</td>
<td>skills that engage all stakeholders</td>
<td></td>
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<tr>
<td>Prioritizing ideas for key</td>
<td>Explicit ranking of ideas by the guideline development group based on the perceived clinical gaps and the potential QI impact</td>
<td>Self-evident process of prioritizing ideas with the highest level of evidence and de-emphasizing those with low-level evidence</td>
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<td>questions</td>
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<td>Identifying key questions for</td>
<td>Formulated to address QI needs and pressing concerns of clinicians and patients, including understudied special populations, high-risk subgroups, and patients with multiple chronic conditions</td>
<td>Formulated to address needs of “typical” patients, based on research that may not reflect the needs of at-risk groups excluded from studies because of ethical issues or desire for purity of research design</td>
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Abbreviation: QI, quality improvement.
lack of efficacy for antibiotics, corticosteroids, antihistamines, and decongestants, which remain valid.8,9 In other words, in this case, the 2 approaches yielded sets of recommendations that can be considered complementary rather than contradictory.

Another relevant contrast is found in guidelines for thyroid nodules and cancer. Although thyroid surgery has a 10% incidence of postoperative dysphonia11 and may cause permanent hoarseness, a widely cited guideline12 from the American Thyroid Association, written by endocrinologists and surgeons, does not include the word “voice,” and the terms “hoarseness,” “laryngoscopy,” or “vocal cord paralysis” appear 1 time each. Recognizing an important unmet need, a later guideline effort by the AAO-HNSF, with a diverse multidisciplinary development group (including nurses, consumers, allied health specialists, and primary care clinicians), produced a guideline entitled “Improving Voice Outcomes after Thyroid Surgery,” with recommendations for laryngoscopy, patient education, and surgical techniques to minimize dysphonia.11 This alternate approach by the AAO-HNSF, driven by stakeholder concerns about voice outcomes and their importance to patients, identified an entirely new focus for the guideline developers. As in the first example, the American Thyroid Association and AAO-HNSF guidelines coexist and provide complementary information on managing thyroid nodules and cancer.

The Surviving Sepsis Campaign guideline13 provides an example of why rigorous methodology and attention to stakeholder-driven perceptions and concerns must coexist for a clinical guideline to be accepted as trustworthy. The guideline recommendations for the use of activated protein C and an invasive catheter for measuring central venous oxygen saturation as part of a multifaceted bundle of interventions followed a highly publicized clinical trial.14 Both recommendations attracted scrutiny because of substantial industry support.15 The trial, the trialists, most of the principal authors of the corresponding guideline, and the initial edition of the guideline itself were funded by the manufacturers of the recommended interventions. However, other factors beyond simple conflicts of interests likely played equally or more important roles in limiting adoption.

From a methodological standpoint, the Surviving Sepsis Campaign team failed to base its approach on systematic reviews of relevant prior research, a requirement of the 2011 Institute of Medicine standards.1 A meta-analysis of sepsis trials16 demonstrated that the potential impact of care on sepsis survival was likely due to early initiation of the emergency department rather than any specific hemodynamic monitoring formula. Subsequent research, driven by the perspective of working clinicians, demonstrated that early fluid resuscitation and antibiotics yielded the same outcomes as the surviving sepsis formula.17,18 Second, the surviving sepsis guideline development group was heavily weighted toward researchers and academicians. Working clinician stakeholders (including nurses), had they been adequately represented, would likely have voiced their skepticism regarding practicality and the need for expensive and sophisticated central monitoring in the emergency phase of

Table 2. Alignment of Quality Strategy with Guideline Development.

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<th>National Quality Strategy Priority</th>
<th>Guideline Principle or Practice</th>
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<tr>
<td>Making care safer by reducing harm caused in the delivery of care</td>
<td>Recommending against ineffective or harmful therapy; promoting measuring, tracking, and reporting of adverse events and complications</td>
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<td>Ensuring that each person and family are engaged as partners in their care</td>
<td>Facilitating stakeholder engagement with tools to support shared decision making (eg, option grids) and by stating explicitly the role of patient preference</td>
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<tr>
<td>Promoting effective communication and coordination of care</td>
<td>Recommending counseling; facilitating action with fact sheets, teaching aids, frequently asked questions, and plain language summaries; and promoting opportunities to coordinate and improve access to care</td>
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<td>Promoting the most effective prevention and treatment practices for the leading causes of mortality</td>
<td>Recommending and promoting awareness of effective interventions for treating and preventing illness; tailoring recommendations to patients with multiple chronic conditions (multimorbidity)</td>
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<td>Working with communities to promote wide use of best practices to enable healthy living</td>
<td>Crafting clear and actionable guideline statements and derivative products that facilitate dissemination, implementation, and performance measures</td>
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<tr>
<td>Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models</td>
<td>Convening multidisciplinary guideline development groups that include consumers and patients (or patient advocates) and that explicitly consider how cost and access might affect each guideline recommendation</td>
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care. In summary, had the Surviving Sepsis Campaign guideline followed the stakeholder-driven approach being advocated here, available evidence would have been properly valued and frontline practitioners from relevant disciplines would have been involved at an early stage thereby yielding recommendations much more likely to be adopted in clinical practice. Instead, it was not until the publication of the fourth edition of the guideline in 2017 that the recommendations came into alignment with the evidence and the perspectives of practitioner stakeholders.

A final example, concerning acute bacterial rhinosinusitis in adults, illustrates how group composition may influence guideline outcomes and yield conflicting results. One group of content experts, which excluded consumers and allied health professionals, developed a guideline for the Infectious Disease Society of America, whose recommendations largely address antibiotic selection, dosing, and duration of therapy.\(^{20}\) The guideline does not, however, endorse watchful waiting or discuss management without antibiotics, even though 85% of acute sinusitis improves without antibiotic therapy.\(^{21}\) In contrast, a stakeholder-driven group convened by the AAO-HNSF with broad stakeholder participation, including generalists, consumers, and a nurse, recommends antibiotics and watchful waiting as appropriate initial strategies for managing acute bacterial rhinosinusitis.\(^{22}\) Only 2 of the 12 key recommendations in the AAO-HNSF guideline relate to antibiotic therapy, the emphasis instead focusing on supportive therapy, patient education, and minimizing adverse events through judicious antibiotic use. The stakeholder-driven approach resulted in a more patient-centered guideline with a large role for watchful waiting, as opposed to the topic-driven approach (Table 1), which yielded a narrower focus on antibiotics and the nuances of drug selection.

**National Quality Strategy Priorities**

An additional advantage of a stakeholder-driven approach is the ability to focus on National Quality Strategy priorities (Table 2) of communication, care coordination, and engagement of persons and families, in addition to priorities more often covered in topic-driven guidelines, such as prevention, treatment, and harm reduction.\(^{23}\)

Consider, for example, a key recommendation from a stakeholder-driven guideline from the AAO-HNSF on tympanostomy tubes,\(^{24}\) which constitute the most common ambulatory surgery for children in the United States. The guideline recommends that “clinicians should educate caregivers [emphasis added] of children with tympanostomy tubes regarding the expected duration of tube function, and also recommends follow-up schedule, and detection of complications.”\(^{22}\) This commonsense statement, intended to empower caregivers during the 12 to 24 months that the ear tube typically remains in place, was prompted by caregiver and nursing concerns and by observational studies about the benefits of education outcomes and adherence to follow-up.

Communication and care coordination are important quality goals that need to be articulated in guidelines alongside rigorous methods but often are not. By way of exception, one quality-driven guideline makes a strong recommendation that “The surgeon should inform the anesthesiologist [emphasis added] of the results of abnormal preoperative laryngeal assessment in patient who have had laryngoscopy prior to thyroid surgery.”\(^{11}\) Whereas adherence to this recommendation is difficult to measure with existing claims data, the recommendation could lead to new billing codes or to standardized data fields in electronic health records that facilitate future measurement. This recommendation for communication may be seen as a voice of QI interpolated into the fabric of a clinical guideline. It is 1 of only 13 recommendations in the guideline, thereby serving to emphasize its importance as a quality metric and potential performance measure.

**Challenges to Putting Stakeholders in the Driver’s Seat**

Our goal in calling explicit attention to stakeholders as a driving force for guideline development (Table 1) is to highlight the ultimately problematic role that a topic-driven focus may come to play when the process of guideline development is not appropriately steered, potentially resulting in the wrong questions about the wrong patients. Addressing outcomes that are meaningful and important to patients is facilitated by a multidisciplinary development group, with engaged clinicians and consumers\(^{1,2}\) driven by stakeholder needs and QI opportunities. Implementing such a group, however, is difficult: qualified consumers are hard to find; clinicians are often academic specialists with industry ties; and important stakeholders (eg, primary care, nursing, allied health) may be deemed unimportant and therefore excluded.

Maintaining a disciplined, stakeholder-centered focus during guideline development requires a chairperson skilled in group facilitation. A good facilitator strives to enable discussion, encourage understanding, ask open-ended questions, promote group dynamics (giving everyone a chance to speak), and provide feedback that bolsters the group.\(^{6}\) Keeping QI at the forefront requires encouraging all stakeholders, including consumers and other nonphysicians, to contribute, while preventing specialists and content experts from dominating discussions because of strong opinions or intellectual bias. Engaging diverse stakeholders in guideline development, however, does not necessarily ensure uptake and implementation of the resulting guidance.\(^{25}\) Continued efforts and surveillance are therefore needed beyond the development stage, which could be facilitated through qualified clinical data registries.

A particular challenge is to avoid making recommendations for important QI issues with a limited evidence base unless the development group has reasonable confidence in the associated benefits, harms, and costs that would result from implementation. Needing to improve care does not ensure a knowledge base sufficient to define how it should...
be done, and in the case of QI, a temptation may exist to circumvent traditional models of evidence. Integration of guideline development with stakeholder-driven QI approaches can only result in a “win-win” enhancement of both spheres. Trustworthy guideline methodology that emphasizes confidence in evidence as a key factor in determining recommendation strength is a requisite to such integration.

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**References**


