Clinical Practice Guidelines and Recommendations: Room for Dissent?

In this issue of Mayo Clinic Proceedings, an article by Musher asks “Should committees that write guidelines and recommendations publish dissenting opinions?” Although he raises important concerns—using examples from both the development of practice guidelines in general and the more specific guidelines for pneumococcal vaccination—I disagree with his conclusion that it is important for committees to publish dissenting opinions alongside new or updated guidelines and recommendations.

Musher likens practice guidelines to United States Supreme Court decisions. He argues that such guidelines become the law of the land in terms of medical practice. From there, he proposes that, like the Supreme Court, those committees that publish guidelines ought to publish alongside their majority decision any minority opinions of its members.

I disagree with Musher’s analogy in 3 ways. First, committees that write guidelines and recommendations are not writing mandates enforceable by law, which is in stark contrast with the Supreme Court. For example, the committee at issue in Musher’s commentary, the Advisory Committee on Immunization Practices (ACIP), does not write vaccination requirements—neither for schools and day care centers nor for any other group or program. What the ACIP writes are recommendations. The ACIP is the only federal body that makes recommendations for the routine and special vaccination of civilian children and adults. Organized and supported by the Centers for Disease Control and Prevention, the Committee is comprised of 15 volunteers: 14 are experts in immunization practices and public health, and 1 is a lay representative. Other groups, academies, and colleges certainly can write and have written guidelines and recommendations that differ from, and even oppose, ACIP opinions. School and day care requirements for vaccinations are determined by the states and vary widely as a result.

Second, we can test the outcomes of practice guidelines and recommendations empirically; this is not the case with judicial decisions regarding constitutional law. The best appeal against a practice recommendation is when evidence emerges that the recommendation is failing to achieve the outcomes intended. Musher’s own example with the 2014 ACIP recommendation offers a case in point. That recommendation concerned routine pneumococcal vaccination and called for a major change in practice. Previously, adults turning 65 years of age were to receive a single dose of 23-valent pneumococcal polysaccharide vaccine. Now, adults turning 65 years of age are to receive instead a single dose of 13-valent pneumococcal conjugate vaccine and then 1 year later receive a single dose of 23-valent pneumococcal polysaccharide vaccine. Musher points out that the greatest reductions of pneumococcal disease in this age group have occurred only when we began routinely vaccinating infants and toddlers against pneumococcal disease, thus greatly reducing those strains from circulating among those 65 years and older. Thus, he doubts that the new recommendation will achieve the outcomes anticipated. However, his concerns are testable through study. This ability to test recommendations empirically in clinical practice contrasts sharply with Supreme Court decisions. All the opposing jurists in the minority can do is voice their opinions as their only recourse. Lawmakers may subsequently pass new laws to accommodate the minority opinions, but until such actions are taken, the majority opinion stands as the only legal interpretation. Going forward, clinical studies of the occurrence rates of serious pneumococcal disease in those aged 65 years and older will reveal the success or failure of the 2014 ACIP recommendations. Indeed, the recommendations specifically note that the strength of the evidence for this change is only moderate and state that the Committee will revisit the evidence and its recommendations in 2018.
reference to the strength of the evidence alludes to the ACIP’s adoption in 2010 of an explicit framework of making evidence-based decisions using the Grading of Recommendations Assessment, Development and Evaluation system of evaluating recommendations, including evidence regarding disease epidemiology; vaccine immunogenicity, efficacy, effectiveness, safety, and reactivity; and vaccination feasibility, acceptability, and cost. No clinical practice guideline or recommendation is immutable, never to be revisited. Indeed, the ACIP routinely revises its recommendations to follow the evidence.

Third, the role of a minority opinion as Musher envisions it would play a different role in practice guidelines and recommendations than in Supreme Court judicial decisions. In the latter, although the simultaneous publication of minority opinions may lead to legislation, they officially exist only as the rejected wisdom of the Court. In considering Musher’s analogy, we need to recognize that these Supreme Court minority opinions do not support alternative legal practice. Further, they do not serve to diminish the force of the Supreme Court decisions. The majority opinion is still the law of the land. Indeed, most of the public have no idea of the number of Supreme Court justices who joined in minority opinions with even the most well-known of decisions: Roe v Wade (410 US 113 [1973]) or Miranda v Arizona (384 US 436 [1966]) (it was 2 and 4 justices, respectively, by the way). Those minority opinions have no impact on the legality of abortion or the rights of the accused, but Musher argues explicitly that minority opinions published alongside practice guidelines and recommendations would facilitate alternative approaches in care. This view is very different from the intent and outcomes of minority opinions published with Supreme Court decisions, and, as I will argue, is counterproductive to the goals of practice guidelines and recommendations.

A primary goal of practice guidelines and recommendations is to standardize practice. For those who question the value of standardization of clinical practice as a necessity, consider what investigators do when executing a randomized controlled trial. Those performing the interventions to be compared in the trial will adhere to standard protocols to eliminate variation. Eliminating variation not only facilitates study but also reduces confusion and failure. Consider the success that the ACIP has had over the years through its intentional efforts to broaden its reach by working with numerous organizations to develop and harmonize those recommendations with the positions of the American Academy of Pediatrics (AAP), American Academy of Family Physicians, American College of Physicians, and American College of Obstetricians and Gynecologists.

Before the ACIP’s efforts to harmonize recommendations with leading academies and colleges, the AAP recommended a second measles-mumps-rubella vaccination at 11 to 12 years of age, whereas the ACIP recommended the second vaccination at 4 to 6 years of age. The disparate recommendations in 1995 led to misunderstandings and under-vaccination. Similar problems arose during the same decade when the ACIP, AAP, and American Academy of Family Physicians offered 3 different options to clinicians and parents on the use of the live oral polio vaccine and the enhanced inactivated polio vaccine; the options were difficult to communicate and apply. A single recommendation solved the problem. The ACIP’s efforts do not simply align different schedules regarding the age at which vaccines are to be given; they directly address popular yet false vaccine contraindications and provide clarity on valid minimal ages and intervals as well as proper dosing and routes. Even the abbreviations that we use in writing about vaccines are the result of the ACIP’s standardization. Standardization works.

Dissenting opinion has a role, of course, in driving science forward, but we should not confuse the work of writing guidelines and recommendations with the legal practice of simultaneously publishing Supreme Court majority and minority opinions. In summary, guidelines and recommendations are not legal mandates. Their impact can be tested empirically, unlike Supreme Court decisions. Requiring committees to publish dissenting opinions alongside their recommendations, however, would diminish their intent and encourage practice variation, unlike Supreme Court minority opinions. Indeed, guidelines and recommendations such as those promulgated by the ACIP have been tremendously successful...
in improving practice by reducing needless variation and addressing disagreement.

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Potential Competing Interests: Dr Jacobson serves on a data monitoring committee for a series of Merck & Co, Inc--funded studies of a pneumococcal conjugate vaccine and on 2 safety review committees for Merck & Co, Inc--funded studies of human papillomavirus vaccines.

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REFERENCES