

# Virtual Mentor

American Medical Association Journal of Ethics  
January 2013, Volume 15, Number 1: 51-55.

## POLICY FORUM

### Evidence-Based Guidelines and Quality Measures in the Care of Older Adults

Erika Ramsdale, MD, and William Dale, MD, PhD

Discussion of health care utilization, costs, and quality continues to pervade the public and political discourse. The basic message is that we have an unsustainable, dysfunctional system, with costs spiraling out of control and a poor return on our investment. Among 19 industrialized countries, the United States has the highest rate of preventable deaths despite the highest per capita expenditure on health care, mostly attributable to poorly controlled chronic conditions [1]. Health care reform initiatives aim to simultaneously increase access, improve quality, and contain costs. The most recently enacted iteration, the Patient Protection and Affordable Care Act of 2010, extends insurance coverage, promises to lower costs through the work of the Independent Payment Advisory Board, and (beginning in 2015) to cut payments to providers who do not report on selected quality measures.

In any year, approximately 10 percent of Americans account for more than two-thirds of health care costs [2]. Forty percent of this group are older than 65, and many of them have multiple chronic conditions. For these older patients with complex conditions and multimorbidity, how should “quality care” be defined? Is it possible to standardize quality measures for these patients based on the best current evidence? Should the measures be linked to provider incentives? Will taking these steps improve outcomes and quality of life for this group of patients?

#### What Counts as Evidence?

The dominant paradigm guiding current medical practice is evidence-based medicine (EBM) [3]. The gold standard for “evidence” in EBM is the blinded, prospective randomized clinical trial (RCT), which eliminates bias by: (1) random assignment of participants to interventions to control for confounding variables, and (2) concealing outcomes from data evaluators to allow them to assess the efficacy and effectiveness of interventions objectively. EBM based on RCTs has largely supplanted other forms of clinical evidence, such as individual expertise, anecdotal case series, case-control studies, and observational cohort studies. Ideally, EBM advocates the “conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” [4]. Indeed, guidelines are preferentially based upon evidence from prospective RCTs and represent a systematic application of EBM to practice.

Detractors maintain that this approach encourages a defensive, algorithmic medical practice in an attempt to adhere to overly standardized, reductive guidelines [5]. In many cases, clinical trials fail to enroll subjects representative of patients seen in

practice. In fact, the most complex patients—elderly patients with multimorbidity—are typically excluded from RCT participation. Even when older patients are included, trials tend to enroll only the healthiest, generally excluding those with significant numbers of comorbid conditions, functional impairments, and cognitive dysfunction [6]. In cancer therapeutic trials, for example, elderly patients represent only 25 percent of trial participants, despite comprising greater than 60 percent of cancer cases overall [7], and rigorous exclusion criteria permit only the healthiest older patients to enroll.

### **Can EBM Be Used to Individualize Care for Older Patients?**

This process of developing EBM-based guidelines and applying them to clinical care highlights the tension between generating unbiased knowledge based on statistical aggregation and the application of this information to individual patients. RCTs are designed to eliminate the “noise” of population heterogeneity from the measurement of true effects between an intervention and an outcome. Clinical practice, however, must respond to the specificity of the individual patient’s condition, and clinical heterogeneity increases with age and multimorbidity.

Many older adults remain robust and clinically similar to their younger counterparts, but others are more vulnerable to stressors and still others are frail, generating a broad spectrum of older patients. Applying data from narrowly defined clinical trials that enroll mostly younger and healthier patients to the entire spectrum of older patients is inappropriate and possibly even harmful in many situations.

### **What about Quality Measures?**

Should EBM-based clinical practice guidelines form the basis for quality and cost containment measures for older adults with complex conditions? Attractive as it might be for standardizing health care, there are pitfalls to this approach. Such a strategy both fails to account for the uniqueness of older individuals and dismisses the role of the physician as a judicious user of evidence. Encouraging defensive and algorithmic medical practice diminishes the “art of care” that has been a cornerstone of medicine. EBM-based practice was never intended to be a static, one-size-fits-all mandate, but a highly dynamic process that includes a trained physician’s judgment in applying multiple sources of evidence to complex, emergent systems (i.e., the irreducible totality of the patient). Linking EBM to quality measures and pay-for-performance threatens to co-opt this process, eliminating the step between the measuring of population-based evidence and the weighing of its merit for specific individuals.

Furthermore, there is no definitive evidence that using EBM clinical guidelines as quality measures improves outcomes. Most quality measures focus on structures or processes, rather than directly on outcomes [8]. Outcomes are what really matter, but they can be heavily influenced by factors outside the health care system (e.g., poverty, education level, lifestyle choices). Processes, such as screening for cancer, giving aspirin after a heart attack, or giving adjuvant chemotherapy to stage III colon cancer patients, are easily measured and directly ascertain what is being done to the

patient in the health care setting. Processes are then “linked” to outcomes based on RCTs showing, for example, that aspirin improves mortality when given after an MI [9], or that adjuvant chemotherapy improves survival following resection of a stage III colon cancer [10]. Still, these linkages between process and outcome may not be generalizable, particularly to complex clinical situations. Little data exist showing that process measures definitively improve outcomes in many cases, and they may prove quite harmful for many older patients.

Furthermore, using aggregate evidence may lead to denial of reimbursement for the treatments deemed most useful for a particular patient. The debates that have raged the last few years over the use of mammography (especially in women ages 40-50) and prostate-specific antigen (PSA) screening for men illustrate this point; using these guidelines as a basis for insurance reimbursement, under the rubric of “quality care,” often ignores individual risk-benefit ratios.

### **Conclusions**

The substitution of overly simplistic guidelines for nuanced clinical judgment attuned to individual patient complexity can be dangerous. Unless we focus more on clinical judgment, care cannot be said to be “individualized” or “patient-centered.” It is often said that we are shifting toward a “patient-centered” model of health care, one that involves patients in medical decision making and treats the “whole patient” [11]. The reality for many physicians can be very different: hemmed in by decreasing payments, increasing demands for reporting and documentation, and growing interference by insurers, doctors can scarcely afford to educate patients during their increasingly abbreviated clinic visits, elicit their opinions and insight, or have conversations about their goals.

The patients who account for the largest share of our health care dollars—older adults with multiple chronic diseases—are also those for whom EBM guidelines least often apply. In fact, applying EBM guidelines to such individuals can be an onerous or impossible challenge [12]. Our older patients with chronic conditions are the most vulnerable in a health care model driven solely by EBM-based quality measures, and perhaps have the most to gain from a truly patient-centered model of health care. Algorithmic guidelines sufficiently flexible to account for the wide heterogeneity of older adults are unlikely to be created. Bluntly applied guidelines may cause as much harm as good. Instead, we need to find better ways to support thoughtful, well-trained clinicians in applying evidence in a shared decision with patients. Reimbursing physicians for spending more time with and thinking harder about these patients, rather than checking off “quality” boxes, is one genuine way to improve quality in health care. This approach is more likely to produce more ethically sound, as well as more individualized, outcomes for older adults.

## References

1. Nolte E, McKee CM. Measuring the health of nations: updating an earlier analysis. *Health Aff (Millwood)*. 2008;27(1):58-71.
2. Cohen S, Yu W. Statistical Brief #354: The concentration and persistence in the level of health expenditures over time: estimates for the U.S. population, 2008-2009. Agency for Healthcare Research and Quality. [http://meps.ahrq.gov/mepsweb/data\\_files/publications/st354/stat354.shtml](http://meps.ahrq.gov/mepsweb/data_files/publications/st354/stat354.shtml). Accessed December 13, 2012.
3. Guyatt G, Cairns J, Churchill D, et al. Evidence-based medicine. A new approach to teaching the practice of medicine. *JAMA*. 1992;268(17):2420-2425.
4. Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ*. 1996;312(7023):71-72.
5. Feinstein AR, Horwitz RI. Problems in the "evidence" of "evidence-based medicine". *Am J Med*. 1997;103(6):529-535.
6. Zulman DM, Sussman JB, Chen X, Cigolle CT, Blaum CS, Hayward RA. Examining the evidence: a systematic review of the inclusion and analysis of older adults in randomized controlled trials. *J Gen Intern Med*. 2011;26(7):783-790.
7. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. *JAMA*. 2004;291(22):2720-2726.
8. Donabedian A. Evaluating the quality of medical care. *Milbank Mem Fund Q*. 1966;44(3 Suppl):166-206.
9. Antithrombotic Trialists' Collaboration. Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high risk patients. *BMJ*. 2002;324(7329):71-86.
10. Andre T, Boni C, Mounedji-Boudiaf L, et al. Oxaliplatin, fluorouracil, and leucovorin as adjuvant treatment for colon cancer. *N Engl J Med*. 2004;350(23):2343-2351.
11. Agency for Healthcare Research and Quality. Expanding patient-centered care to empower patients and assist providers. *Research in Action*. 2002;(5):1-11. <http://www.ahrq.gov/qual/ptcareria.pdf>. Accessed December 13, 2012.
12. Boyd CM, Darer J, Boult C, Fried LP, Boult L, Wu AW. Clinical practice guidelines and quality of care for older patients with multiple comorbid diseases: implications for pay for performance. *JAMA*. 2005;294:716-724.

Erika Ramsdale, MD, is in the final year of her hematology/oncology fellowship at the University of Chicago. She has also completed fellowships in geriatric medicine and clinical medical ethics and is planning to pursue a career in geriatric oncology. Her research focuses on clinical decision making in older adults with cancer, particularly those with complex comorbidities or frailty.

William Dale, MD, PhD, is the section chief of Geriatrics and Palliative Medicine at the University of Chicago, where he established the Specialized Oncology Care and

Research in the Elderly (SOCARE) clinic. He has published more than 50 articles on medical decision making, geriatric oncology, and quality of life for older adults, particularly older adults with cancer. Dr. Dale is a board-certified geriatrician with a PhD in health policy.

**Related in VM**

[The Limitations of Evidence-Based Medicine—Applying Population-Based Recommendations to Individual Patients](#), January 2011

[A Call to Integrate Ethics and Evidence-Based Medicine](#), January 2013

[The Debate over Prostate Cancer Screening Guidelines](#), January 2011

[N-of-1 Trials: Individualized Medication Effectiveness Tests](#), January 2013

*The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.*

Copyright 2013 American Medical Association. All rights reserved.