Legislating against Use of Cost-Effectiveness Information

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> The Patient-Centered Outcomes Research Institute . . . shall not develop or employ a dollars per quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.
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> — The Patient Protection and Affordable Care Act[1]

In 1996, after 2 years of deliberation, the U.S. Panel on Cost-Effectiveness in Health and Medicine, composed of physicians, health economists, ethicists, and other health policy experts, recommended that cost-effectiveness analyses should use quality-adjusted life-years (QALYs) as a standard metric for identifying and assigning value to health outcomes.[2] The recently enacted Patient Protection and Affordable Care Act (ACA) created a Patient-Centered Outcomes Research Institute (PCORI) to conduct comparative-effectiveness research (CER) but prohibited this institute from developing or using cost-per-QALY thresholds. The two events serve as revealing bookends to a long-standing debate over the role and shape of cost-effectiveness analysis in U.S. health care.

QALYs provide a convenient yardstick for measuring and comparing health effects of varied interventions across diverse diseases and conditions. They represent the effects of a health intervention in terms of the gains or losses in time spent in a series of "quality-weighted" health states. QALYs are used in cost-effectiveness analyses (termed "cost-utility analyses" when QALYs are included) to inform resource-allocation decisions: the cost-per-QALY ratios of different interventions are compared in order to determine the most efficient ways of furnishing health benefits. In contrast, other health outcomes are generally expressed in disease-specific terms, such as incidence of cardiovascular events, cancer progression, intensity of pain, or loss of function. Though useful for measuring the effects of particular treatments, these outcomes do not permit comparisons among diseases and conditions or between treatment and prevention.[3]

Researchers have published thousands of cost-utility studies in leading medical and health policy journals. Health policymakers around the world have used such analyses to inform clinical guidelines and reimbursement decisions. The U.S. government, through agencies such as the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, and the National Institutes of Health, has sponsored cost-utility analyses. Medical specialty societies have cited cost-utility studies in support of clinical guidelines.

The ACA specifically forbids the use of cost per QALY "as a threshold." The precise intent and consequences of this language are unclear. One might interpret it to mean that the PCORI, or its contractors or grantees, can still calculate cost-per-QALY ratios as long as they are not compared with a threshold (e.g., $100,000 per QALY) or used to make a recommendation based on such a threshold. Comparisons of cost-per-QALY ratios across interventions could still be useful to decision makers even without the invocation of an explicit threshold. However, the ACA suggests a broader ban on the use of cost-utility analyses — and this could have a chilling effect on the field.

The ACA's language might be seen as symptomatic of the legislation's aversion to policies that critics might see as enacting "big-government" health care or "death panels." It may reflect a certain xenophobia toward the kinds of approaches used in Britain, where the National Institute of Health and Clinical Excellence makes recommendations about technologies and services on the basis of cost-per-QALY thresholds. Reflecting this sentiment, the ACA creates a new CER institute that it labels "patient-centered" and states that the findings of PCORI-sponsored research cannot be construed as mandates for practice guidelines, coverage recommendations,

payment, or policy recommendations.

The ban on using cost-per-QALY thresholds also seems to reflect long-standing concerns that the approach would discriminate on the basis of age and disability. The worry is that the metric unfairly favors younger and healthier populations that have more potential QALYs to gain.

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To be sure, there are legitimate debates about the role of QALYs as the sole benchmark of health gains for purposes of allocating society's resources. However, acknowledging the measure's limitations, panels in the United States and Britain and at the World Health Organization have found QALYs preferable to alternative measures of health improvement.

QALYs simply give priority to interventions that offer the most health benefit in terms of measures people care about — more time spent in good health. In fact, populations with more impairment typically fare better in cost-effectiveness analyses, because they have more to gain from interventions; for example, it is generally less cost-effective to screen or treat healthier persons than persons who have poorer health at baseline or who are at greater risk for complications.

Moreover, a ban on valuing life extension presents its own ethical dilemmas. Taken literally, it means that spending resources to extend by a month the life of a 100-year-old person who is in a vegetative state cannot be valued differently from spending resources to extend the life of a child by many healthy years. Though the ACA may be seeking to avert discrimination, it instead helps to perpetuate the current system of implicit rationing and hidden biases.

The antagonism toward cost-per-QALY comparisons also suggests a bit of magical thinking — the notion that the country can avoid the difficult trade-offs that cost-utility analysis helps to illuminate. It pretends that we can avert our eyes from such choices, and it kicks the can of cost-consciousness farther down the road. It represents another example of our country's avoidance of unpleasant truths about our resource constraints. Although opportunities undoubtedly exist to eliminate health care waste, the best way to improve health and save money at the same time is often to redirect patient care resources from interventions with a high cost per QALY to those with a lower cost per QALY.[4] At a time when health care costs loom as the greatest challenge facing our country's fiscal well-being, legislating against the use of the standard metric in the field of cost-effectiveness analysis is regrettable.

The ACA states that the PCORI is intended to assist patients, clinicians, purchasers, and policymakers. Yet a ban on cost-utility analysis would leave decision makers with less information with which to compare the relative effects of interventions across diseases. The ACA states that PCORI-produced CER is intended to inform, not mandate, decisions. Why, then, be so prescriptive about costs per QALY? Better to simply develop and disseminate the information and let decision makers choose whether or not to use it and in what settings. Decision makers could consider cost-per-QALY ratios alongside other criteria, such as the priority of an intervention for vulnerable populations and concerns about equity and fairness. How can our market-driven health system work efficiently if participants lack information about the relationship between the costs and benefits of health interventions?

As the country searches for ways to curb health care spending, consideration of the cost-effectiveness of health interventions will unavoidably be part of the health care debate, alongside considerations of possible payment- and delivery-system reforms. The use of explicit, standard metrics such as cost-per-QALY ratios has the advantage of transparency and can help direct our resources toward the greatest health gains. These kinds of analyses will therefore endure as a rough benchmark of value and as a normative guide to resource-allocation decisions. It

would be unfortunate if the ACA created a barrier to their development and use.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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