The Patient Not in the Room

In their article, Vanness and colleagues (1) explore the best way to establish a cost-effectiveness threshold for policy considerations. This may seem an arcane matter in cost-effectiveness analysis that is of interest to few beyond health economists. However, there are several reasons why this work may profoundly affect everything from clinical guidelines to insurance coverage policies to Medicare negotiation of drug prices.

The U.S. health care system continues to prove itself incapable of providing affordable, high-quality care to all Americans. Since 2009, the amount that workers pay for health insurance has increased 71% while wages have increased 26% (2). In addition, more than 80% of workers must pay a deductible before insurance kicks in, and the average deductible has doubled over the past decade to $1655, although many pay far more.

Consequently, for a growing number of Americans who do not qualify for Medicaid or adequate subsidies through state health insurance exchanges, unaffordable insurance premiums and deductibles lead them to abandon health insurance. During 2017 to 2019, the number of Americans without insurance increased by 2 million, and 27 million Americans had no health insurance at any time throughout 2019 (3). These figures were from before coronavirus disease 2019 (COVID-19) decimated jobs and the employer-based insurance of tens of millions more Americans.

What happens to people who lack insurance or have high out-of-pocket costs? A 2019 Gallup poll reported that one quarter of adults have put off treatment of a serious medical condition because of the cost—the highest figure since Gallup began asking the question 3 decades ago (4). Another Gallup and West Health survey found that 34 million people knew at least 1 friend or family member who had died over the past 5 years after forgoing treatment because of costs (5).

Here, we come to the real issue driving the importance of the study by Vanness and colleagues: Although every added dollar the United States spends on health care may generate added health, at least for those directly benefiting from that extra spending, it also puts more pressure on health insurance premiums, harming patients not in the room. We must face this challenge head-on and structure clinical guidelines, insurance coverage, pricing, and payment mechanisms to mobilize resources to support the best care possible for each patient while also ultimately doing more good than harm for the population. In other words, our efforts to ensure *primum non nocere* for the patient in front of us must apply equally to patients not in the room whose suffering and needs are just as real.

Vanness and colleagues' approach to estimating a cost-effectiveness threshold enables us to determine whether we are doing more good than harm. Cost-effectiveness analysis uses the best available evidence for alternative care options to simulate outcomes and costs for hypothetical cohorts over time. The additional cost required per unit of "health gain" for one option versus another is used to compare the cost-effectiveness of alternative care options. This metric can focus on a single clinical outcome, such as the cost per additional stroke prevented by one anticoagulant versus another. More helpful is a measure of health gain that can apply across all conditions, such as the commonly used quality-adjusted life-year (QALY), with cost-effectiveness expressed as "cost per QALY."

The upper boundary for the cost per QALY can help policymakers determine at what price an intervention becomes too costly for its added benefits—that is, when the amount spent on that intervention would be better spent on other health interventions or would better serve society if spent outside the health system on such services as education and housing. But what should the cost-per-QALY threshold be?

Health economists have advanced myriad methods to answer this question, which fall into 2 camps (6). "Willingness to pay" approaches use surveys, analyses of previous funding decisions, or more normative estimates linked to societal wealth to unearth how much society is—or should be—willing to pay for added health. The contrasting approach identifies a threshold by measuring the "opportunity cost" of resources spent in health care systems. This is feasible in systems with explicit budgets in which aggregate spending and outcomes can be compared at the margin (7). In these settings, the opportunity cost of a new intervention is the health forgone when other interventions cannot be delivered because of the fixed budget. This approach is exemplified by pathbreaking work in the United Kingdom and elsewhere (8). Barriers to implementing opportunity cost methods in a health system without a fixed budget have thwarted similar efforts in the United States—until now.

Vanness and colleagues (1) had the novel insight to try to estimate an opportunity cost threshold for the U.S. health system, despite its elastic budgets, by linking the threshold to the adverse health effects of losing insurance when rising premiums become unaffordable. Their estimate requires multiple assumptions, most notably the likelihood of dropping insurance at any given level of premium increase and the associated increased mortality. Yet, their work is logically elegant, and rigorous sensitivity analyses show the robustness of their principal findings.

They estimate a U.S. cost-effectiveness threshold of $104 000 per QALY. That this is higher than thresholds suggested by opportunity cost research in other countries is unsurprising given higher health care spending and higher average income in the United States. Yet, this threshold lands remarkably close to the findings of recent research using willingness-to-pay methods (9) and to the range used by the Institute for Clinical and

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Economic Review to recommend fair pricing benchmarks that support evidence-based negotiation of drug prices by insurers and health systems in the United States (10). Vanness and colleagues' work will strengthen these and other efforts to apply cost-effectiveness analysis more broadly in the U.S. health care system.

There are, of course, caveats. The idea that a single threshold is applicable across the diverse landscape of U.S. health care will be challenged. Some will criticize assumptions about the magnitude of harm associated with insurance loss. Others may believe that this work underestimates the adverse effects of increasing costs because the model considered only insurance loss and not the harmful effects of delaying or skipping care to manage costs while insured. Also, cost-effectiveness is but a single element in judging value. Coverage and pricing decisions must include careful consideration of potential broader benefits of treatment beyond health and awareness of situations in which cost-effectiveness may undervalue treatments for certain conditions.

These caveats aside, this work moves us in the right direction. It is time for a renewed push to get policymakers, clinicians, and the public to recognize that when prices for services exceed a threshold in relation to their benefits, real harm comes to American patients. A "homegrown" U.S. threshold for cost-effectiveness that is rooted in evidence will facilitate a more honest public dialogue about value and fairness. It is time to advance the use of cost-effectiveness analysis to inform a system that takes care of everyone, including those patients not in the room.

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