Comparative Effectiveness—Looking Under the Lamppost

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Despite the accomplishments and purported value of the US health system, the United States still lags behind other developed countries in the health outcomes it produces.[1] Clinical care consumes 95% of the health dollar but accounts for only about 20% of the determinants of health.[2] The other 80% is determined by behaviors and the health of communities: the social and physical environments. The United States compares unfavorably with other nations on many of those determinants.[3] Failure to understand how those determinants can be improved will result in paying extraordinary costs for interventions to treat the illnesses and injuries that are their natural outcome. Regardless of how much more sophisticated the US medical care system becomes, without fundamentally changing health improvement strategies, including using what already is known to modify underlying determinants as well as conducting research to improve this understanding, the health gap that exists between the United States and other nations will remain.

The Patient-Centered Outcomes Research Institute (PCORI), created under health reform's Patient Protection and Affordable Care Act (ACA) to foster comparative effectiveness, was the logical vehicle for learning what works to improve health and understanding the relative value of alternative strategies[4] to enable wise investment of resources. Yet an enormous opportunity to do so has been largely squandered and needs to be rectified.[5]

Comparative effectiveness studies have great potential to identify the most effective interventions to significantly improve health outcomes. However, to maximize the value of these investments, interventions with the greatest potential need to be included. Yet ACA expressly limits PCORI to evaluation of clinical interventions, remarkably eliminating from consideration interventions that can address the greatest causes of preventable morbidity and mortality.

The Institute of Medicine Committee on Comparative Effectiveness Prioritization has defined comparative effectiveness research as "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care."[6] It further defined that the purpose of comparative effectiveness research is "to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels."[6] While consistent with the intent of the PCORI, the Institute of Medicine definition also appears to exclude population-based policies and programs.

To its credit, and recognizing the importance of systems of care, many of the highest priorities of the Committee on Comparative Effectiveness Prioritization were health system interventions that seek to understand and improve processes of care for specific conditions managed within the clinical care system, thus stretching the narrow boundaries in ACA. Although limited to clinical settings, the committee implicitly recognized that comparative effectiveness is not just about how specific technologies and care practices compare but also about system-level practices, ie, the way in which care practices are organized, managed, and optimized.

There is value to be gained by reducing overuse, underuse, and misuse by improving medical care practices and technologies. Yet the comparative effectiveness agenda is hampered by the legislative restrictions on use of economic evaluations. Economic assessments are essential to increase the efficiency of the clinical care system and curb the runaway costs that are a primary driver of the national debt to date and going forward and will continue to limit economic competitiveness. Moreover, focusing on comparisons of technologies for highly focused conditions can at best lead to small incremental improvements in health and even in the aggregate cannot efficiently have a major effect on the overall health of the population. For instance, compare the effectiveness, population benefit, and efficiency of pharmacogenomic tests for lung cancer with policy initiatives to reduce tobacco use.

Perhaps the greatest flaw in the funded comparative effectiveness agenda is the missed opportunity to assess interventions that can improve the underlying determinants of health. It is important to understand the effectiveness of policies and programs as well as how they compare with each

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other and with clinical interventions in terms of their effects on downstream consequences. For instance, how do bariatric surgery or intensive behavioral management of obesity compare with initiatives to increase access to healthy foods, financial disincentives for sugar-sweetened beverages, and menu labeling? These are clearly not either/or decisions but require comparative insights to understand the synergies of multiple interventions and the incremental value of additional ones and to help inform real-world decisions based on realistic investment constraints.

The current comparative effectiveness agenda is looking under the lamppost, where the greatest expenditures actually lie but not where there are the greatest opportunities for health improvement and potential reductions in expenditures. Not only do the confines of the legislated agenda exclude a full examination of the efficiency of those clinical care expenditures, they fail to examine the very interventions that have the potential to obviate the need for clinical care.

The end result is that the focus of the PCORI on clinical care may yield improvements in clinical management but can only have a modest effect on population health because it has removed perhaps as much as 80% of the opportunity from consideration.[2] In short, the PCORI will fail to provide the information necessary to understand the tradeoffs among the full range of health-improvement strategies.

That PCORI was heralded as the key approach to assessing comparative effectiveness to improve health care incorrectly suggests to policy makers that the issue of comparative effectiveness has been adequately addressed legislatively and that this initiative can significantly contribute to slowing the increases in medical care spending. These false impressions can only further contribute to increases in the already incomparable percentage of the US gross domestic product spent on medical care.

Although it is unlikely that Congress will change the scope of the work undertaken by the PCORI in the near term, other resources should be identified to address this broader agenda. Without doing so, the United States will continue to overinvest in clinical care, underinvest in the upstream determinants of health, and fall farther behind other nations in terms of health, spiraling medical care costs, and competitiveness. Under the guidance of the recently created Public Health National Prevention, Health Promotion and Public Health Council, the National Institutes of Health and the Centers for Disease Control and Prevention are both well positioned to fund and oversee this research in conjunction with intersectoral federal partners, such as the Department of Transportation on public transportation and bikeable communities; the US Department of Agriculture on healthy food policies; and the Department of Housing and Urban Development on healthy homes and urban design.

If no additional research funds are available, readjusting the research portfolio to identify effective interventions that address the underlying determinants of health is imperative. Even in complex behavioral areas like alcohol abuse, appropriate policy interventions can have relatively rapid effects. For example, studies examining the relationship of blood alcohol levels greater than 0.8% to motor vehicle fatalities, the value of ignition interlocks in reducing crashes, and the association of reducing the density of stores and businesses that sell alcohol with harm reduction, demonstrate the feasibility of these studies and their importance to both improving health and reducing the need for clinical care for potentially devastating outcomes.

Realigning the comparative research portfolio to address the underlying determinants of health and identify effective and efficient policies and programs is necessary to help slow the endless spiral of medical care costs and the deterioration of US health indices compared with those of other countries.

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