In the Literature

DEVELOPING A CENTER FOR COMPARATIVE EFFECTIVENESS INFORMATION

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The United States spends far more per capita on health care than any other developed nation, but this spending does not produce correspondingly better health outcomes. Moreover, the long-term growth of health care spending—which has been about 2.5 percentage points faster than the economy overall—will present many challenges if it continues indefinitely.

Finding acceptable ways of limiting spending can be difficult, both fiscally and politically. The typical approach involves cutting payments for health care services without addressing the growth in the volume of services used. A more direct and effective approach would be to improve the way decisions are made about the type, frequency, and volume of treatments. This requires a better way of comparing the clinical effectiveness of medical treatments, so that both payers and providers of health care can make more informed coverage, payment, and patient-care decisions. Doing so could control costs and improve outcomes.

In "Developing a Center for Comparative Effectiveness Information" (*Health Affairs* Web Exclusive, Nov. 7, 2006), Gail R. Wilensky, Ph.D., senior fellow at Project HOPE, assesses the feasibility of an agency devoted to comparative clinical effectiveness research, and examines various options for structure, placement, financing, and functions. According to Wilensky, such a center could provide independent reviews of the comparative effectiveness of therapies and procedures so that health plans, hospitals, and public health programs can "spend smarter" on health care.

Current Efforts

The Food and Drug Administration currently requires clinical trials of new drugs or medical devices, but the trials typically focus on efficacy relative to a placebo, and not the effectiveness of new therapies compared with existing, alternative therapies. What's more, most health care spending is allocated to medical and surgical procedures, not pharmaceuticals. To be most useful, Wilensky says, effectiveness research needs to focus on the full range of new and existing medical therapies that have come on the market over the past several decades.

International Models

In many other countries—including Australia, Canada, Germany, and the United Kingdom—clinical and economic assessments of medications or medical therapies are required as a prerequisite for coverage. These countries, which all have national payer systems, house their comparative effectiveness research within government agencies. The review processes differ in terms of levels of transparency, whether the decisions are mandatory or advisory, and whether results are subject to appeal. In Australia, for instance, the health minister cannot list a drug without a positive recommendation from the review agency. There is no formal appeal process. The final decision is made public, but not the rationale for the decision or the relevant clinical or cost data.

Options for Comparative Effectiveness in the U.S.

The multipayer system in the United States presents political and other challenges. Most important, a comparative effectiveness center must be regarded by all payers, clinicians, and patients alike as an objective and credible source of information. Otherwise, says Wilensky, the information it produces will ultimately be of little use.

One possible location for such a center would be within the federal Agency for Healthcare Research and Quality (AHRQ), which focuses on health services research, including some comparative effectiveness studies. But AHRQ primarily performs systematic reviews and retrospective analyses of administrative electronic health record data. While the review of existing research is important, Wilensky stresses that the production of new information will be the focus of the comparative effectiveness center. AHRQ could be augmented by an independent external board, along with a panel of experts to advise on research priorities, provide oversight, and disseminate results.

The center might also be housed within another agency in the Department of Health and Human Services (HHS), or it could exist as an independent board with appointed members, similar to the Federal Reserve. Placing it within the government, Wilensky warns, limits any opportunities for private sector funding and increases the possibility of industry pressure.

Alternatively, the center could be part of a quasi-governmental entity, such as the Institute of Medicine (IOM). The IOM is generally highly regarded by leaders in government and industry. Yet, its consensus process might prevent generation of information in a timely manner. The center could also be created as a federally funded research and development center (FFRDC). FFRDCs are typically linked to a federal agency and operate as private, nonprofit organizations that can only accept 30 percent of funding from private sources. This would allow private sector involvement while providing a direct link to the federal government.

Wilensky also considers placement within a public foundation or the private sector, as a freestanding nonprofit institution or one affiliated with a university. Having the center in the private sector could minimize concerns that its decisions were subject to political pressure. In addition, it could maximize funding and involvement by private sector stakeholders. Still, the lack of a government role might raise questions about the objectivity of the findings.

In terms of financing options, Wilenksy states that congressional appropriation is the "most obvious and direct" way to fund the center. Another financing alternative is the Medicare Trust Fund, since Medicare would be an important beneficiary. Other financing options include underwriting by the private sector, voluntary contributions, or levying a small fee on all users of the service, including health plans and providers.

Conclusions

Wilensky concludes that the placement of a comparative effectiveness center within a quasi-governmental entity is the most attractive option. In particular, she points to the benefits of establishing a FFRDC, linked to either AHRQ or a newly established HHS agency. "Despite many different views, there is widespread agreement on the attributes that need to be associated with a comparative effectiveness center: objectivity in the selection of what is studied, credibility in the findings, and independence—from political pressures generated either by government or by private-sector stakeholders," Wilensky concludes. How best to achieve this set of outcomes, however, will surely differ among the various players.