The ICER Value Framework: Integrating Cost Effectiveness and Affordability in the Assessment of Health Care Value

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A B S T R A C T

What should be the relationship between the concepts of cost effectiveness and affordability in value assessments for health care interventions? This question has received greater attention in recent years given increasing financial pressures on health systems, leading to different views on how assessment reports and decision-making processes can provide the best structure for considering both elements. In the United States, the advent of explicit value frameworks to guide drug assessments has also focused attention on this issue, driven in part by the prominent inclusion of affordability within the value framework used to guide reports from the Institute for Clinical and Economic Review. After providing a formal definition of affordability for health care systems, this article argues that, even after using empirical estimates of true health system opportunity cost, cost-effectiveness thresholds cannot by themselves be set in a way that subsumes questions about short-term affordability. The article then presents an analysis of different approaches to integrating cost effectiveness and budget impact assessments within information to guide decision making. The evolution and experience with the Institute for Clinical and Economic Review value framework are highlighted, providing lessons learned and guiding principles for future efforts to bring measures of affordability within the scope of value assessment. Keywords: affordability, budget impact analysis, cost-effectiveness analysis thresholds, drug pricing.

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Introduction

Introduced for use in 2013, the drug Sovaldi (Sofosbuvir, Gilead Sciences, Inc., Foster City, California) forced health systems around the world to confront a stark contrast between the concepts of “cost effectiveness” and “affordability.” The drug was effective: most patients treated were effectively cured of the virus that causes chronic hepatitis C. And, even at an initial list price of $84,000 in the United States, cost-effectiveness analyses by academics and health technology assessment (HTA) agencies concluded that it represented good value for money over the long-term [1,2]. But even though competitive entry and insurer negotiating brought the price down significantly, the large numbers of infected patients needing treatment forced health systems to confront a potentially crushing short-term budget impact. As a result, patient access to Sovaldi in many countries was delayed, and even when made available it was often funded only for patients with advanced disease [3,4]. Apparently, Sovaldi was cost-effective but unaffordable.

This divergence between a drug’s cost effectiveness and its perceived affordability will have come as no surprise to those health economists who have long criticized the use of incremental cost-effectiveness ratios as a guide to decision making [5]. They would argue that Sovaldi’s incremental cost effectiveness at the time of entry provides little insight into whether Sovaldi represents a wise use of available resources for health care. Other health economists and policymakers, however, believe that cost effectiveness is a useful input to resource allocation decisions and are more likely to see in the case of Sovaldi a demonstration that current thresholds for decision making are unrealistically high, untethered from what should be their empirical source: the true marginal opportunity cost of new expenses within the health system [6]. A final set of observers views Sovaldi as demonstrably cost-effective and therefore a good value for the health system, the problems paying for it being nothing more than a demonstration of the failure of health system managers and governmental leaders to plan ahead so that they can eliminate low-value services and re-allocate the resources to effective new services [7].

Views on the lessons to be taken from Sovaldi therefore differ widely. All observers, however, would agree that since the world-wide economic crisis of 2007 to 2008, the debate over the relationship between cost effectiveness, affordability, and a broader concept of value in health care has greatly intensified. Before that time many health systems in the developed world had become accustomed to adding resources year after year, with budgets usually rising faster than the underlying rate of growth of national economies [8]. With growth assumed, questions about
whether health systems could afford to fund all new “cost-effective” interventions were relatively muted. But over the past 8 years the landscape has shifted, with health systems around the world now facing strict dictates to shed costs or at best to grow no faster than the national economies in which they are embedded. As a consequence, substantial additional funding can no longer be assumed to be forthcoming to pay for new services. It is within this chastened fiscal environment that the question of whether all cost-effective interventions are affordable has become much more acute.

As a reflection of this new reality, Germany, Japan, and England are among many countries that have recently proposed measures to help moderate spending on new drugs—even those with favorable long-term cost effectiveness—if they exceed or threaten to exceed specific budget impact thresholds [9-11]. In the United States, concerns about rising drug expenditures have triggered a vigorous public policy debate and highlighted the question of how the value of drugs should be assessed. In the absence of a centralized governmental HTA agency in the United States, clinical specialty societies and independent groups have developed several “value frameworks” intended to guide decisions by individual patients and clinicians or to inform price negotiations and coverage determinations by insurers [12,13]. Most of these value frameworks include multiple domains of value, but only one, the framework developed by the Institute for Clinical and Economic Review (ICER), includes a measure of affordability for new drugs within the conceptual core of an assessment of value to the health system. To guide deliberation on affordability, ICER performs a potential budget impact analysis at the national level with a suggested threshold that, if exceeded, signals to policymakers that the amount of added health care costs associated with a new service may be difficult for the health system to absorb over the short-term without displacing other needed services or contributing to unsustainable growth in health care insurance costs [14].

Does this approach create more problems than it attempts to solve? How should information on cost effectiveness and budget impact be considered and by whom? Pressure groups representing drug companies and some health economists have criticized ICER’s approach by asserting that information on budget impact should be held apart from any process of evaluating a treatment’s value to avoid creating a bias against the long-term perspective on value [15,16]. Given the debate over the ICER value framework, which is set amid the growing global concern regarding drug costs, the goal of this study was to examine the conceptual and practical relationship between cost effectiveness and affordability as components of the assessment of the value of drugs and other health services. Ultimately, this analysis will argue that a measure of affordability is necessary and complementary to the information provided by cost-effectiveness analysis, and that both should be included in any deliberative process intended to support sustainable access to high-value care for all patients.

A Definition of the Affordability of New Health Services

Affordability is not a simple concept, whether within or outside health care settings. As long as the cost for a good or service does not outstrip the entire amount a potential buyer has available, then what constitutes an ‘affordable’ cost cannot be determined empirically [17]. But this does not make it impossible to define affordability nor to design empirical measures of affordability that can inform deliberations on the value of new health services.

The affordability of a new service can be defined most usefully through a negative framing in which affordability is assumed unless funding would cause a net harm through one or more of the following four mechanisms:

1. By requiring cuts or other changes to existing health care services that cause a greater loss of benefits, to the same or different patients, than the corresponding gains anticipated from the new service;
2. By absorbing available new resources that could be spent on other identifiable services that would provide greater overall benefit to the same or different patients;
3. By increasing the amount that must be paid by individual patients to an extent that would require unreasonable individual sacrifice;
4. By requiring the re-allocation of spending from other social goods (e.g., education) or an increase in new revenues (e.g., taxes) that would cause a greater loss of benefits to society than the benefits anticipated from the adoption of the new service.

At the root of all these criteria lies the basic idea of opportunity cost: a new service that adds costs to the health system to help some patients always means that there are benefits foregone to the same or other patients, or to society more generally. The resources available for health are never a truly fixed amount given the ability to shift resources from other spending over time. Decision makers trying to judge affordability need to consider this temporal flexibility but must still make judgments of whether the benefits foregone from spending on a new service are likely to be greater than the benefits to be gained; if so, the service should be considered unaffordable. This does not mean that a health system could not pay for it, just that the health system (or the broader society) would end up “poorer” for having done so. There is some affinity in this approach with the medical maxim of “first, do no harm.” We will return later in this article to consider empirical measures that can help identify when the potential budget impact of a new service raises a significant risk of excessive opportunity cost. First, however, we must address the question of whether cost-effectiveness thresholds themselves can serve this purpose.

Can Cost-Effectiveness Thresholds Subsume Questions about Affordability?

There are four basic ways of thinking about how to identify the most appropriate threshold for incremental cost-effectiveness ratios: 1) the willingness to pay (WTP) of a health system (or society) demonstrated by past positive and negative funding decisions; 2) societal WTP based on normative ideals of what a society should be willing to pay for health care; 3) societal WTP based on extrapolation from the answers individuals (either healthy or ill) give when asked hypothetically how much money they would be willing to give up from their own salary to avoid a certain health loss or receive a health gain; and 4) the opportunity cost based on empirical efforts to estimate the cost effectiveness of services already in the health system that would be displaced at the margin if new services are introduced.

Can any of these methods for setting an incremental cost-effectiveness ratio threshold eliminate the potential tension between cost effectiveness and affordability? It may seem self-evident that the first three methods are particularly insensitive to the dynamic between cost effectiveness and affordability. Whether derived from past funding decisions, normative ideals, or individual trade-off decisions, single incremental cost-effectiveness ratio thresholds, or even incremental cost-effectiveness ratio ranges, cannot reflect the scale of spending on different health services given the number of patients involved. Therefore,
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