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VALUE HEALTH. 2019; 22(9):975–976

Commentary

Yes, Improve the US Value Frameworks, But Recognize They Are Already in Prime Time

Peter J. Neumann, ScD*, *Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, Boston, MA, USA*

Given their ever-growing visibility, US value assessment initiatives warrant close attention. Therefore, the commentary by DuBois et al[1] is to be welcomed. The piece raises a number of valuable points; above all that each value framework offered to date has strengths and limitations, and all have opportunities for improvement.

The authors usefully enumerate a set of key principles that they believe should underlie every framework. These principles are reasonable, and in the main, not terribly controversial. Most would agree that frameworks should be transparent and reproducible; that evaluations of interventions should be revisited over time; that there is merit in taking a broad perspective; that assessments should incorporate elements important to patients; and that a diversity of approaches reflecting the needs of diverse stakeholders should be considered. Finally, the article aptly raises various concerns (eg, about the lack of transparency, the absence of a societal perspective, and the need for more attention to patient preferences) with some of the existing frameworks. Arguments such as these should encourage the field to improve its methods and help the larger medical and policy communities find common ground about what constitutes value.

I'd add several comments. First, we should not be surprised by variation among the frameworks, and even that some frameworks do not adhere to all of the key principles. As the recent ISPOR Special Task Force (STF) on US Value Assessment Frameworks (of which I was a member and co-chair) noted, the frameworks have different missions, take different perspectives, and address different decision contexts.[2] Some, such as the approach used by the Institute for Clinical and Economic Review (ICER), are geared toward coverage and reimbursement decisions, whereas others, such as the American Society of Clinical Oncology (ASCO) framework, are intended to support shared clinical decision-making between physicians and patients. Although a broader societal perspective is useful as a general principle, we should not expect all stakeholders—and all value frameworks—to embrace that view; for example, although patient preferences are a crucial component of any value framework, a tension can exist between the perspective of an insured individual patient—who, when ill, may desire all potentially beneficial healthcare regardless of cost because they pay only a fraction of that cost—and the payer who seeks to efficiently allocate available resources to improve overall population health.[3] As another example, the US Medicare program, a social program funded in part by general tax revenues, has reason to consider a broad societal perspective, but also has fiscal responsibilities to manage its health resources and thus motive to consider a narrower payer perspective.

Second, the idea that value assessments should be separate from budget considerations needs context. On the one hand, as Dubois et al observe, value and budget impact are different concepts. Reflecting this sentiment, the ISPOR STF stated, "We do not recommend considering budget impact as an integral part of value assessment itself or structuring/requiring an automatic discount linked to budget impact, or introducing an inverse relationship between value and budget impact."[3] Nevertheless, the concepts are related if one is explicit about available budgets and opportunity costs. As the Second Panel on Cost-Effectiveness in Health and Medicine (on which I served as a member and co-chair) has noted, "To say that an intervention 'is cost-effective but not affordable' must mean that the criteria used to judge cost-effectiveness do not reflect the scale and value of the opportunity costs."[4] The cost-effectiveness threshold being used to judge value may be too high (ie, insufficiently stringent).

Finally, I'd dispute the idea that none of the value frameworks are ready for prime time. To be sure there is room to improve the frameworks on methodological and process grounds. Moreover, many important conceptual and empirical issues remain for the field of economic evaluation.[4] Nevertheless, one can always cultivate a sense of uncertainty about, and opposition to, the frameworks by calling them imperfect and not fully matured. This seems unfair, particularly for some of the frameworks, such as those promulgated by ICER and the American College of Cardiology/American Heart Association, which rely primarily on established methods of cost-effectiveness analyses that researchers and policy makers have used for decades.

Suggesting that the frameworks are unready for prime time perpetuates an idea that one day we'll get the frameworks right if we only work harder at it and make necessary adjustments. In reality, even as the frameworks improve, the field will never have ideal and universally accepted value measurement approaches given different perspectives and decision contexts, as well as diverse patient preferences about health, and widely varying ideologies about how society should organize its health system. Saying, as the article does, that "more progress is needed before widespread adoption and use" reflects a status quo bias (a

* Address correspondence to: Peter J. Neumann, ScD, Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research, Health Policy Studies at Tufts Medical Center, 35 Kneeland St 7th floor, Boston, MA 02111, USA. Email: pneumann@tuftsmedicalcenter.org

https://doi.org/10.1016/j.jval.2019.04.1929

penchant for the current state of things). But any processes in place before the advent of the frameworks lacked transparency and had their own flaws. The better question is not whether the new frameworks are ready for prime time, but whether the benefits of having the frameworks outweigh their costs. I'd answer yes, despite limitations and a need for further work.

Although much work remains, we should also be reassured by the progress the value frameworks have made. The National Comprehensive Cancer Network has introduced preference categories into its guidelines (as DuBois et al, acknowledge). ASCO has updated its framework once (eg, adding quality of life to its attributes of value)[5] and is reportedly working on further revisions. ICER has taken important steps to improve its approach—for example, amending the manner in which it assesses affordability, and developing modifications for ultra-rare disease treatments.[6,7] The entry of the Innovation and Value initiative is encouraging in that it makes its models, including model source code, fully transparent.[8]

The emergence of multiple frameworks in the private sector, developed and funded by different sources, is a response to a clear need and, moreover, shows diversity in the marketplace of ideas about value assessment. Although ICER has emerged as a kind of US National Institute for Health and Care Excellence–like organization, notably, it is a private, nonprofit group that disseminates information rather than possessing regulatory or reimbursement authority. As is appropriate, and as Dubois et al would have it, its information provides one input that payers use to inform a complex decision-making process. Going forward, as the ISPOR STF underscores, society would benefit from the exploration and testing of novel elements of benefit to improve value measures that reflect the perspectives of both plan members and patients.[3] Even as this research moves ahead, we should recognize that the value frameworks are already in prime time.

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