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#### **Editorial**

## "Back to the Future" With Value in Health



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For the 20th anniversary issue of *Value in Health*, we wanted to reflect on how "value" has been defined, measured, and debated since the journal started. At the same time, *Value in Health* continues to be forward-looking. We are grateful to the 2 former Editors-in-Chief, Joel W. Hay, PhD, and Josephine Mauskopf, PhD, MHA, for setting the trajectory for excellence in peer review, and we are proud of the impact that *Value in Health* has made on the field of health economics and outcomes research (HEOR) as we celebrate the journal's achievements over the past 20 years.

In planning this special anniversary issue, we issued a call for papers to attract submissions on value-related topics that have been widely discussed in *Value in Health* over the past 2 decades and for which there remain current debate and an exciting future agenda. More than 60 articles were submitted for this 20th anniversary issue, and we selected 17 articles on the basis of our peer-review process. The selected articles discuss various topics, which we have categorized under 3 main themes: *Notions of "Value" in Healthcare, Decision-Analytic Modeling,* and *HEOR in the Broader Context of Health Technology Assessment (HTA) and Comparative-Effectiveness Research.* 

#### Notions of "Value" in Healthcare

The journal's title is a good reminder that the notion of "value" has different connotations and reflects clinical, economic, and health-related quality-of-life components. Certainly, the debate surrounding the use of cost per quality-adjusted life-year remains a highly controversial and at times political concern. The notions of value are interdependent on measurement and so regardless of how value is defined, there remain controversies regarding both the numerator (ie, measurement of costs) and the denominator (ie, measurement of effectiveness or benefits). The articles grouped under the *Notions of "Value" in Healthcare* section discuss those components, as well as the role of patient-reported outcomes as one of the central notions of defining and assessing value.

Many governments around the world have also been interested in knowing how to assess value in healthcare. There are several international agencies that are responsible for value assessments and their approaches have been debated in both academic and policy arenas. The "reference case" also has been widely debated from both a scientific and a pragmatic lens. Some of the controversies that were being debated 20 years ago have been resolved

to a large extent, whereas other notions of value remain as controversial in 2019 as they were at the turn of the century.

The science of HEOR has certainly evolved over the past 2 decades and ISPOR has been a major driver of some of that scientific advancement. *Value in Health* remains committed to publishing the best methodological and empirical HEOR articles, including reports by ISPOR task forces that aim "to develop expert consensus guidance reports on international good practice standards for HEOR and on the use of this research in healthcare decision making."<sup>1</sup>

## **Decision-Analytic Modeling**

Decision-analytic modeling is a central feature of HEOR and has been a major theme in the journal since its inception. We have published numerous empirical studies in all fields of medicine, but perhaps the major contribution to the literature has been in the development of methodological standards. The journal has published a number of articles discussing the pros and cons of different modeling approaches and published the outputs of the 2 ISPOR Good Research Practices task forces on modeling, <sup>2,3</sup> the second jointly with the Society for Medical Decision Making, <sup>3</sup> which have outlined the standards to which all analysts should aspire.

For this anniversary issue, we commissioned articles from the journal's 2 previous Editors-in-Chief, both of whom focused on the modeling theme. The article from our founding Editor-in-Chief, Joel W. Hay, stresses the need for more transparency in modeling if it is to gain sufficient credibility, especially among decision makers in the United States. The article by our second Editor-in-Chief, Josephine Mauskopf, analyzes the journal's contribution to the literature on guidelines for multivariable and structural uncertainty in cost-effectiveness analyses. She argues that, in the future, we can expect more consideration of different methods for combining multivariable and structural uncertainty analyses, as part of a continued evolution of uncertainty analyses in published studies, consistent with the goal of providing more useful information to decision makers.

Looking to the future, we see no diminution in the role decision-analytic modeling will play in the journal. In the case of pharmaceuticals, the existence of accelerated approval has led to products being approved with less mature clinical data, and the growth in specialty pharmaceutical products has led to a greater

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need for evidence synthesis and a greater role for data collected postapproval. In addition, there is a growing interest in the evaluation of medical devices and procedures, which, because of a different approach to regulation, are less likely to have well-controlled clinical studies and consequently have a greater reliance on observational data to demonstrate their clinical effectiveness. All these developments suggest a strong role for modeling going forward, with a particular emphasis on new methods to analyze real-world data.

An important development, which is just beginning, is the increased role of machine learning and artificial intelligence in decision-analytic modeling. This is likely to be particularly important in the analysis of large, real-world data sets and should lead to increased efficiency in modeling and in the provision of healthcare itself. We expect to publish many more articles on these topics in the future.

# HEOR in the Broader Context of HTA and Comparative-Effectiveness Research

Throughout the journal's history, we have published a number of articles discussing the role of HEOR in the broader context of HTA and comparative-effectiveness research, including the contribution of all these subdisciplines to informing clinical decision making and health policy. As in the case of decision-analytic modeling, the journal has published a large number of empirical studies. In addition, we have contributed to the literature on developing methodological standards and on good practice, including improving transparency and increasing stakeholder involvement. The journal has also published a number of articles that compare the practice of different HTA bodies in their use of cost-effectiveness data. Over the years, it has become apparent that there are key national differences that influence the extent of the use of HTA and how it is practiced. We expect to publish more articles exploring these issues as the use of HTA spreads to other countries and regions worldwide.

In the future we also expect to receive more submissions discussing the methodological and practical challenges of using HEOR in decisions about the reimbursement of health technologies. The changes in the regulation of new medicines, including the aforementioned accelerated approval processes, mean that

early dialogue between regulators, manufacturers, and HTA bodies is increasingly important and that the balance of data collection on clinical and cost-effectiveness will shift more toward post-launch and include a greater role for real-world data.

In addition, the increased uncertainty about clinical effectiveness and cost-effectiveness suggests that the current interest in managed entry agreements is unlikely to be reduced. In fact, with the advent of more new therapies with curative intent, having the potential for high initial budgetary impact, there is an even greater need to develop innovative approaches for the adoption of these therapies. Therefore, we expect to publish more articles discussing the various types of managed entry schemes in the future.

## **Looking Forward to the Future**

As the current Editors-in-Chief, we are proud of what *Value in Health* has achieved over the past 20 years. Nevertheless, like the individual researchers whose articles it receives, the journal is only as good as the next article it publishes. Therefore, we see our role as maintaining the high standards that the journal has already established, and hopefully improving on them. A key part of this task is to anticipate the changes we are likely to see in the field of HEOR as the environment for healthcare products and services changes in the future. The changes will be partly reflected in the articles we receive, but we also intend to use our themed sections to make the journal content as relevant and as current as we can. If we can achieve that, *Value in Health* will continue to deliver "value" to its readers and its authors well into the future.

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