

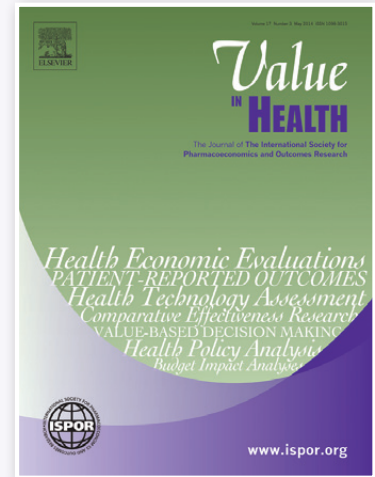
## Value in Health Volume 19, Issue 1

### The following articles will be included in the January/February 2016 issue of *Value in Health* (Volume 19, Issue 1):

The high costs of recently launched drugs are currently attracting considerable media coverage in the US. In this issue of *Value in Health*, a paper by Christine Leopold et al. explores whether this is a watershed moment, or merely a rehashing of an often-revisited grievance that will be quickly forgotten. In addition, we publish the first part of the ISPOR Emerging Good Research Practices Report on multicriteria decision analysis (MCDA), recognizing that this technique is being increasingly used in priority setting and reimbursement decisions in health care. Finally, a paper by Koonal Shah et al. provides empirical evidence on whether the values for health states the EQ-5D-5L instrument are greatly affected by whether the upper anchor in the time trade-off study is defined as 'full health' or the best health state in the descriptive system.

Kind regards,

**Michael F. Drummond, MCom, DPhil** and **C. Daniel Mullins, PhD**  
Co-Editors-in-Chief, *Value in Health*



### FEATURED ARTICLES:

#### Thirty Years of Media Coverage on High Drug Prices in the US – A Never-Ending Story or a Time for Change?

The introduction of a number of breakthrough, highly effective and high-cost specialty medicines over the past years has stoked the fire of the long-running drug price debate.

#### Multiple Criteria Decision Analysis for Health Care Decision Making – An Introduction: Report 1 of the ISPOR MCDA Emerging Good Practices Task Force

This initial task force report presents an overview of the principal methods of MCDA and provides examples of its use in different kinds of decision making. (See page 25 for summary)

### ISSUE HIGHLIGHTS:

#### ECONOMIC EVALUATION

##### The Cost of Increasing Physical Activity and Maintaining Weight for Mid-Life Sedentary African American Women

In this article, Tricia Johnson et al. evaluate the marginal costs of increasing physical activity and maintaining weight for a lifestyle physical activity program targeting sedentary African American women. (See page 47 for summary)

#### PATIENT-REPORTED OUTCOMES

##### Changes in Quality Of Life Associated With Complications of Diabetes: Results from the ADVANCE Study

Alison Hayes et al. use patient-reported outcomes to measure the impact of complications on summary measures of health-related quality-of-life among people with type 2 diabetes.

#### PREFERENCE-BASED ASSESSMENTS

##### An Empirical Study of Two Alternative Comparators for Use in Time-Trade off Studies

In this study, Koonal Kirit et al. assess differences in time trade-off valuations using two different comparators (full health and 11111). (See page 47 for summary)

#### COMPARATIVE EFFECTIVENESS RESEARCH / HTA

##### The "Efficacy-Effectiveness Gap": Historical Background and Current Conceptualization

The objectives of this study by Clementine Nordon et al. were to

understand the historical background in which the concept of the Efficacy-Effectiveness Gap (EEG) has emerged and to describe the conceptualization of EEG.

#### POLICY PERSPECTIVES

##### The Parity Paradigm: Can Legislation Help Reduce the Cost Burden of Oral Anticancer Medications?

In this policy perspective piece, Sheetal Kircher et al. discuss the history, opportunities, and limitations of drug parity laws in oncology.

#### SYSTEMATIC REVIEWS

##### The Reporting of Treatment Non-Adherence and Its Associated Impact on Economic Evaluations Conducted Alongside Randomised Trials: A Systematic Review

The objectives in this review by Samuel Brilleman et al. were to examine trial-based economic evaluations and to identify: 1) the proportion reporting adherence; 2) methods for assigning intervention costs according to adherence; 3) participants who were included in the economic analysis; and 4) the statistical methods to estimate cost-effectiveness in those who adhered. (See page 47 for summary)

For all articles in this issue, and to see what services *Value in Health* provides for its authors see: [http://www.ispor.org/valuehealth\\_index.asp](http://www.ispor.org/valuehealth_index.asp).

## Spotlight on Value in Health

Value in Health hopes by summarizing key aspects of highlighted articles, readers will be able to identify research that is most relevant to their fields. We also recognize that many ISPOR members may wish to be kept abreast of the most salient points of articles that are outside their areas when they are not able to read each issue of Value in Health in its entirety.

Value & Outcomes Spotlight would like to thank the authors for contributing their overviews.

**From Volume 19, Issue 1 (January/February 2016):**

### Preference-Based Assessments

#### **An Empirical Study of Two Alternative Comparators for Use in Time Trade-off Studies** (pp. 53-59)

Studies to produce value sets for preference-based measures of health require an upper anchor to be defined if the values are to be used to calculate quality-adjusted life years. Two different upper anchors have been used in time trade-off (TTO) studies to elicit values for the EuroQol Group's EQ-5D-5L instrument: 'full health' and health state 11111. The latter is the best health state in the EQ-5D-5L descriptive system. It describes having 'no problems' on each of the five dimensions of health. However, it is unclear how the specification of the comparator health state affects the TTO valuations elicited. This paper therefore assesses differences in TTO valuations using these two alternative comparators. Stated preference data were collected from a broadly representative sample of the UK general public (N=443). Respondents were randomly allocated to one of two arms, each using a different comparator health state. The differences in mean values across arms were found to be mostly small and non-significant. The two arms produced data of similar quality. Respondents who were allocated to the 'full health' comparator arm were asked to value health state 11111 – 98.2% of these respondents gave 11111 a value of 1. Based on these results, the Koonal Shah et al. conclude that EQ-5D-5L values elicited using TTO are not greatly affected by whether full health or 11111 is used as the comparator health state.

#### **The Cost of Increasing Physical Activity and Maintaining Weight for Mid-Life Sedentary African American Women** (pp. 20-27)

This paper reports the marginal costs of increasing physical activity and maintaining weight for a lifestyle physical activity program targeting sedentary African American Women. The Women's Lifestyle Physical Activity Program is a 48-week walking program that includes six group meetings with behavioral strategies for increasing physical activity designed for sedentary mid-life African American women.

Physical activity has been shown as an effective strategy for preventing and managing chronic conditions, including hypertension, heart disease, diabetes and obesity, and for improving depressive symptoms. Programs to improve physical activity in African American women are particularly important, since they have a higher prevalence of hypertension, diabetes, obesity and depression symptoms compared with White women. Few studies have evaluated the cost-effectiveness of physical activity programs from a societal perspective, and none have focused specifically on African American women. We found that the cost to increase moderate to vigorous intensity physical activity and

maintain weight in previously sedentary African American women is relatively low. We found a cost of \$1.50 per minute per week (min/wk) (95% CI 1.28 – 1.87) for walking, \$1.73/min/wk (95% CI 1.41 – 2.18) for moderate to vigorous intensity physical activity and \$1.94/min/wk for leisure-time moderate to vigorous physical activity. The cost to increase steps per week was \$0.46 per step (95% CI 0.30–0.85), and the cost to maintain weight was \$412 (95% CI 399 – 456).

While the total cost of a group-based physical activity program is relatively low, the participant opportunity costs represent a substantial share of these costs. It is critical that decision makers include participant opportunity costs when considering the costs of implementing a physical activity program. We found that participant opportunity costs represent nearly half of total costs of Women's Lifestyle Physical Activity Program. Opportunity costs have historically been excluded from other cost effectiveness analyses of physical activity interventions, although they may be a significant barrier to continued participation.

#### **The Reporting of Treatment Nonadherence and Its Associated Impact on Economic Evaluations Conducted Alongside Randomized Trials: A Systematic Review** (pp. 99-108)

In this paper, Sam Brilleman et al. systematically review published trial-based economic evaluations and, based on their findings, provide recommendations for improved handling of nonadherence to allocated treatment. The review highlights the need for improvements in the collection and reporting of adherence and suggests published guidance on adherence measure reporting should also be followed when reporting trial-based economic evaluations. Given there has been little discussion about the unique challenges presented by nonadherence in trial-based economic evaluations we make recommendations on analysis approaches which should be taken. They recommend a CONSORT diagram be included with all trial-based economic evaluations and recommend that if nonadherence is prevalent then trial-based economic evaluations aimed at informing policy should report primary ITT analyses based on the net monetary benefit (NMB) rather than on the incremental cost-effectiveness ratio (ICER). Under plausible assumptions, the ICER is invariant to the rate of nonadherence, whereas the NMB is influenced by changes in adherence and recommend that trial-based economic evaluations report sensitivity analyses which aim to estimate cost-effectiveness in participants who adhere to treatment. Finally, Brilleman et al. discuss reasons why such an estimate is desirable and, furthermore, highlight that per-protocol analyses will not provide an unbiased estimate. Therefore, that alternative approaches such as instrumental variable analysis should be explored.