Dear ISPOR Member,

In this issue, Faulkner et al. report on behalf of the ISPOR Personalized Medicine Development and Reimbursement Working Group and identify five key areas in which health economics and outcomes research best practices could be developed to improve value assessment, reimbursement and patient access decisions for personalized medicine. Also, Thokola and Duenas analyse the possible applications of multi-criteria decision analysis (MCDA) in health technology assessment and compare MCDA approaches with the health technology appraisal process used by the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom. In addition, Lis et al. report on behalf of the ISPOR Risk Management Working Group, comparing the risk management approaches of the Food and Drug Administration and European Medicines Agency in recent drug approvals.

Kind regards,

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

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FEATURED ARTICLE

Challenges in the Development and Reimbursement of Personalized Medicine - Payer and Manufacturer Perspectives and Implications for Health Economics and Outcomes Research: A Report of the ISPOR Personalized Medicine Development and Reimbursement Working Group

In this paper, the Personalized Medicine Special Interest Group of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) evaluated key development and reimbursement considerations from the payer and manufacturer perspectives.

ISSUE HIGHLIGHTS

ECONOMIC EVALUATION

The Use of Qualitative Methods in Developing the Descriptive Systems of Preference-Based Measures of Health-Related Quality of Life for Use in Economic Evaluation

In this article, the authors describe how qualitative methods can be used in the development of descriptive systems of preference-based measures (PBM) of health-related quality of life.

PATIENT-REPORTED OUTCOMES

Work Productivity in Relapsing Multiple Sclerosis: Associations with Disability, Depression, Fatigue, Anxiety, Cognition, and Health-Related Quality of Life
The aim of this article was to characterize work productivity in relapsing multiple sclerosis (MS) using a work productivity scale and to identify associations between work productivity and disability, depression, fatigue, anxiety, cognition, and health-related quality of life.

PREFERENCE-BASED ASSESSMENTS

*Comparison of Generic, Condition-Specific, and Mapped Health State Utility Values for Multiple Myeloma Cancer*

As resource allocation informed by cost-utility analysis requires that the benefits are comparable across patient groups and interventions, the authors analyse the comparability of generic, condition-specific and mapped utility values for a multiple myeloma cancer patient dataset.

HEALTH POLICY ANALYSIS

*Comparisons of Food and Drug Administration and European Medicines Agency Risk Management Implementation for Recent Pharmaceutical Approvals: Report of the International Society for Pharmacoeconomics and Outcomes Research Risk Benefit Management Working Group*

The objectives of this article are to compare the Food and Drug Administration’s (FDA) Risk Evaluation and Mitigation Strategies (REMS) and European Medicines Agency’s (EMA) Risk Management Plan (RMP) guidances, and compare REMS and RMPs for specific chemical entities and biological products.

METHODOLOGICAL ARTICLES

*Whole Disease Modeling to Inform Resource Allocation Decisions in Cancer: A Methodological Framework*

This article presents a methodological framework for developing health economic models of whole systems of disease and treatment pathways to inform decisions concerning resource allocation - an approach referred to as "Whole Disease Modeling."

POLICY PERSPECTIVES

*Multiple Criteria Decision Analysis for Health Technology Assessment*

The authors of this paper analysed the possible application of MCDA approaches in health technology assessment (HTA) and described their relative advantages and disadvantages.

ALSO IN THIS ISSUE:

ECONOMIC EVALUATION

*Patient-Level Hospital Costs and Length of Stay After Conventional Versus Minimally Invasive Total Hip Replacement: A Propensity-Matched Analysis*

*Cost-Effectiveness of Using a Molecular Diagnostic Test to Improve Preoperative Diagnosis of Thyroid Cancer*

*A Multigene Prognostic Assay for Selection of Adjuvant Chemotherapy in Patients with T3, Stage II Colon Cancer: Impact on Quality-Adjusted Life Expectancy and Costs*

*Budget Impact Analysis of HIV Testing in the VA Healthcare System*
Demonstrating the Burden of Hypoglycemia on Patients’ Quality of Life in Diabetes Clinical Trials: Measurement Considerations for Hypoglycemia

Development of the Shortness of Breath with Daily Activities Questionnaire (SOBDA)

Measuring Health-Related Quality of Life in Leukemia: The Functional Assessment of Cancer Therapy - Leukemia (FACT-Leu) Questionnaire

Preferences for Managing Symptoms of Differing Severity: A Discrete Choice Experiment

Contingent Valuation Scenarios for Chronic Illnesses: The Case of Childhood Asthma

Using the Multiple Sclerosis Impact Scale to Estimate Health State Utility Values: Mapping from the MSIS-29, Version 2, to the EQ-5D and the SF-6D

Measuring and Valuing Health Benefits for Economic Evaluation in Adolescence: An Assessment of the Practicality and Validity of the Child Health Utility 9D in the Australian Adolescent Population

Comparing 15D and SF-6D Performance in Fragility Wrist and Hip Fracture Patients in a Two-Year Follow-Up Case-Control Study

Inquiry into the Relationship between Equity Weights and the Value of the QALY

Rank Reversal in Indirect Comparisons

Unidimensional 12-Item Zarit Caregiver Burden Interview for the Assessment of Dementia Caregivers’ Burden Obtained by Item Response Theory

The Use and Performance of Productivity Scales to Evaluate Presenteeism in Mood Disorders

What is Wrong with Orphan Drug Policies?

What is Wrong with Orphan Drug Policies? Suggestions for Ways Forward
In addition to the above topics, *Value in Health* also published articles on Comparative Effectiveness Research (CER) and Health Technology Assessment (HTA).

The mission of *Value in Health* is to set a high scientific standard using editorial review and peer review, not just to screen articles, but also to foster communication within the research community and between the outcomes research community and health care decision-makers. Using this underlying premise and with attention to detail, the editors of *Value in Health* hope to enhance the validity, reliability and transparency of pharmacoeconomics and outcomes research and its real world applicability. For additional information, please see: http://www.ispor.org/valueinhealth_index.asp. Please send questions or comments to: viheditor@ispor.org. Be sure to follow us on Twitter: @ValueinHealth.