

This is a repository copy of *International Society for Pharmacoeconomics and Outcomes Research Comments on the American Society of Clinical Oncology Value Framework*.

White Rose Research Online URL for this paper:

<https://eprints.whiterose.ac.uk/101882/>

Version: Accepted Version

Article:

Malone, Daniel C, Berg, Nancy S, Claxton, Karl orcid.org/0000-0003-2002-4694 et al. (8 more authors) (2016) *International Society for Pharmacoeconomics and Outcomes Research Comments on the American Society of Clinical Oncology Value Framework*. *Journal of Clinical Oncology*. pp. 2936-2937. ISSN 1527-7755

<https://doi.org/10.1200/JCO.2015.64.4328>

Reuse

Items deposited in White Rose Research Online are protected by copyright, with all rights reserved unless indicated otherwise. They may be downloaded and/or printed for private study, or other acts as permitted by national copyright laws. The publisher or other rights holders may allow further reproduction and re-use of the full text version. This is indicated by the licence information on the White Rose Research Online record for the item.

Takedown

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.

ISPOR Comments on ASCO Value Framework

Daniel C. Malone, Ph.D.
Professor, College of Pharmacy, Associate Professor, College of Public Health
University of Arizona
Tucson, Arizona

Nancy S. Berg, B.Sc.
Chief Executive Officer
International Society for Pharmacoeconomics and Outcomes Research
Lawrenceville, New Jersey

Karl Claxton, Ph.D.
Department of Economics and Centre for Health Economics
University of York
Heslington, York, UK

Louis P. Garrison, Jr., Ph.D.
Professor, Pharmaceutical Outcomes Research & Policy Program
Adjunct Professor, Departments of Global Health and Health Science
University of Washington School of Pharmacy
Seattle, Washington

Maarten Ijzerman, Ph.D.
Professor, Chair of Health Technology & Services Research
University of Twente
The Netherlands

Kevin Marsh, Ph.D.
Senior Director
Evidera
London

Peter Neumann, Sc.D.
Professor, Tufts University School of Medicine
Director, Center for the Evaluation of Value and Risk in Health
Institute for Clinical Research and Health Policy Studies
Tufts Medical University

Mark Sculpher, Ph.D.
Professor, Centre for Health Economics
University of York,
Heslington, York, UK

Adrian Towse, M.Phil.

Director, Office of Health Economics
London, UK

Carin Uyl-de Groot, Ph.D.
Professor,
Chair, Department of Health Technology Assessment
Institute of Health Policy & Management
Director, Institute for Medical Technology Assessment/
Erasmus University Rotterdam
The Netherlands

Milton C. Weinstein, Ph.D.
Henry J. Kaiser Professor of Health Policy and Management
Harvard T.H. Chan School of Public Health
Boston, MA

Dear Editor,

As members of International Society for Pharmacoeconomics and Outcomes Research (ISPOR), we read with great interest the new ASCO conceptual framework to assess the value of cancer treatment options.¹ We applaud the Value in Cancer Care Task Force for proposing a conceptual framework to support clinicians and patients to assess the value of new cancer treatments. We acknowledge the challenges facing clinician-patient decision making, particularly concerning cancer treatments. Like ASCO, we recognize that the cost of treatments is increasingly being placed on the patient through cost-sharing, and that engaging patients as part of individual treatment decisions is of high importance. ASCO's framework highlights the growing tension among patients, insurance companies, and product manufacturers in a very dynamic healthcare environment. In that light, the framework deserves a field test, and we look forward to seeing the outcome of that experience. We also appreciate the opportunity to offer comments and suggestions on the ASCO framework at this early stage, and our membership stands ready to support ASCO in future enhancements.

In our view, the proposed framework focusing on the patient-physician dyad is an interesting approach and has some desirable elements, but also some important limitations. It would be helpful to clarify differences between a value framework to support the physician-patient individual-level decision-making, and a framework that would operate more at a broader societal level. Indeed, the two perspectives are linked in that decisions made at the individual level, when aggregated, affect the resources available to the health care system, the overall cost of health care, and ultimately, access and health outcomes that can be delivered to all patients. This reflects the need for health systems to consider cost-effectiveness appropriately in decisions about funding, pricing, and reimbursement. The European Society of Medical Oncology (ESMO), for example, created the Magnitude of Clinical Benefit Scale in a similar effort to ASCO's task force, but that approach takes into account whether benefit is curative or palliative and only applies to solid tumor types.² Furthermore, validated measures of health-related quality of life are explicitly incorporated into the ESMO approach.

While the focus of the ASCO value framework is on the patient perspective, the paper also notes that the physician "has a responsibility to be a good steward of health care resources." Clinical treatment guidelines that consider cost-effectiveness, and reflect differing health state valuations among patients, can provide clinicians with a way to help resolve what might appear to be a conflict in these roles. We encourage ASCO to consider expanding its perspective, giving consideration to this broader framework when developing treatment guidelines. Such an approach would be consonant with recent recommendations by the American College of Cardiology/American Heart Association to incorporate cost-effectiveness analysis into clinical treatment guideline development.³ Patients with serious cardiac disease face many of the same issues that cancer patients face:

severe limitations in functional status and quality of life, high mortality, and burden of treatment.

In its conceptual framework, the task force did not embrace the use of quality-adjusted life years (QALY). The authors noted concerns that the QALY may not fully capture all of the relevant attributes sufficiently, that there is no consensus on thresholds for ICERs, and that “health care rationing” is implied. While recognizing these points, the health economics and outcomes research field is substantially invested in using both QALY and cost-effectiveness analysis as tools to support the difficult health care resource allocation decisions that societies face. For example, the Tufts Medical Center Cost-Effectiveness Analysis (CEA) Registry (www.cearegistry.org) catalogs over 4300 cost-utility analyses with valuations of patient health-related quality of life in over 10,000 health states. While we recognize that the direct usefulness of these tools for individual patients may be limited, we have suggestions concerning definition of value criteria and the methods used to derive the weights and the resulting outcomes in the ASCO value framework. We would encourage that future research engage experts in multi-criteria decision analysis (MCDA) to validate and revise the weights, and if necessary, and to incorporate individual patient preferences into the framework.

In summary, we applaud the efforts by ASCO to incorporate value assessments in an environment of constrained resources. As a leading society of health economists and outcomes researchers, ISPOR has developed over 40 good practice guidelines related to health technology assessment. We invite ASCO and other societies to engage our members in the creation and validation of value assessment tools.

Sincerely,

Daniel C. Malone, Ph.D.
Professor, College of Pharmacy, Associate Professor, College of Public Health
University of Arizona
Tucson, Arizona

Nancy S. Berg, B.Sc.
Chief Executive Officer
International Society for Pharmacoeconomics and Outcomes Research
Lawrenceville, New Jersey

Karl Claxton, Ph.D.
Department of Economics and Centre for Health Economics
University of York
Heslington, York, UK

Louis P. Garrison, Jr., Ph.D.
Professor, Pharmaceutical Outcomes Research & Policy Program
Adjunct Professor, Departments of Global Health and Health Science

University of Washington School of Pharmacy
Seattle, Washington

Maarten Ijzerman, Ph.D.
Professor, Chair of Health Technology & Services Research
University of Twente
The Netherlands

Kevin Marsh, Ph.D.
Senior Director
Evidera
London

Peter Neumann, Sc.D.
Professor, Tufts University School of Medicine
Director, Center for the Evaluation of Value and Risk in Health
Institute for Clinical Research and Health Policy Studies
Tufts Medical University

Mark Sculpher, Ph.D.
Professor, Centre for Health Economics
University of York,
Heslington, York, UK

Adrian Towse, M.Phil.
Director, Office of Health Economics
London, UK

Carin Uyl-de Groot, Ph.D.
Professor,
Chair, Department of Health Technology Assessment
Institute of Health Policy & Management
Director, Institute for Medical Technology Assessment/
Erasmus University Rotterdam
The Netherlands

Milton C. Weinstein, Ph.D.
Henry J. Kaiser Professor of Health Policy and Management
Harvard T.H. Chan School of Public Health
Boston, MA

References:

1. Schnipper LE, Davidson NE, Wollins DS, et al. American Society of Clinical Oncology statement: a conceptual framework to assess the value of cancer treatment options. *J Clin Oncol* 2015; 33(23):2563-77.
2. Cherny NI, Sullivan R, Dafni U, et al. A standardized, generic, validated approach to stratify the magnitude of clinical benefit that can be anticipated from anti-cancer therapies: the European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS). *Ann Oncol* 2015;25(8):1547-73.
3. Anderson JL, Heidenreich PA, Barnett PG, et al. ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2014;63(21):2304-2322