



PRESS RELEASE

For Immediate Release

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ISPOR RELEASES NEW TASK FORCE RECOMMENDATIONS FOR THE DEVELOPMENT OF CLINICIAN-REPORTED OUTCOME ASSESSMENTS

**New Report Fills Long Standing Guidance Gap and
Will Help Standardize ClinRO Assessments**

Princeton, NJ—February 13, 2017—The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) published a new Task Force Report, "[Clinician-Reported Outcome Assessments of Treatment Benefit: Report of the ISPOR Clinical Outcome Assessment Emerging Good Practices Task Force](#)," in the January 2017 issue of *Value in Health*. This new ISPOR Good Practices for Outcomes Research Task Force Report fills a long-standing gap in guidance recommendations, setting forth measurement standards for clinician-reported outcome assessments.

Clinician-reported outcomes (ClinRO) assessments measure a medical treatment's impact on how patients feel or function in their daily lives. ClinRO assessments involve trained health care professionals (clinicians) evaluating a patients' health status, making judgments on the measurements, and then interpreting and reporting them. ClinRO assessments are frequently used to evaluate patient outcomes (endpoints) in clinical trials. These endpoints often inform the regulatory review and approval of new medical treatments. The guidance recommendations from this new ISPOR Task Force Report will help standardize ClinRO assessments to: 1) improve outcomes measurement in trials, 2) provide clarity on treatment benefit, and 3) improve the overall drug development process.

"Accurate measurement of patient outcomes in clinical trials is essential," noted lead author John H. Powers, III, MD, George Washington University School of Medicine, Washington, DC, USA. "We need to answer the question, 'Do interventions provide added benefits to patients compared to the current standard of care; and if so, how much?'" ClinRO assessments are also important to payers because



efficient and accurate measurement of a treatment’s effect can provide justification for reimbursement.”

Stressing the importance of defining patient-relevant treatment benefits, coauthor Laurie Burke of the University of Maryland’s School of Pharmacy, Baltimore, MD, USA and former US Food and Drug Administration (FDA) Director of Study Endpoints and Labeling Development stated, “Developing valid and reliable ClinRO assessments helps to decrease variability and errors in measurement and provides better information for regulatory review of a treatment’s benefit versus harm.”

ISPOR has published eight patient-reported outcome [Good Practices for Outcomes Research Task Force Reports](#) based on the FDA’s “[2009 Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims](#)” before embarking on [Clinical Outcome Assessments: Conceptual Foundation](#) and this ClinRO Good Measurement Practices Task Force Report.

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ABOUT ISPOR

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) is a nonprofit, international, educational and scientific organization that promotes health economics and outcomes research excellence to improve decision making for health globally.

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ABOUT ISPOR GOOD PRACTICES FOR OUTCOMES RESEARCH TASK FORCE REPORTS

ISPOR has earned an international reputation for research excellence based, in part, on its [Good Practices for Outcomes Research Task Force Reports](#). These highly cited reports are expert consensus guideline recommendations on good practice standards for outcomes research (clinical, economic, and patient-reported outcomes) and on the use of this research in health care decision making. [ISPOR Task Forces](#) are comprised of subject matter experts representing different stakeholders from diverse work environments (i.e., regulators, payers, manufacturers, technology assessors, etc. from research, government, academic, and industry sectors around the world). All ISPOR Good Practices for Outcomes Research Task Force Reports are published in the Society’s scientific journal, [Value in Health](#), and are made freely available as open access articles as part of the Society’s mission.

ABOUT VALUE IN HEALTH

[Value in Health](#) (ISSN 1098-3015) is an international, indexed journal that publishes original research and health policy articles that advance the field of health economics and outcomes research to help health care leaders make evidence-based decisions. The journal’s 2015 impact factor score is 3.824. [Value in Health](#) is ranked 3rd out of 74 journals in health policy and services (social sciences), 8th out of 87 journals in health care sciences and services, and 10th out of 344 journals in economics (social sciences). [Value in Health](#) publishes 10 issues a year and circulates to more than 10,000 readers around the world. Web: www.ispor.org/valueinhealth | Twitter: [@ISPORjournals](http://bit.ly/ISPORjournals-T)