

# The ISPOR Good Practices for Quality Improvement of Cost-Effectiveness Research Task Force Report

William F. McGhan, PharmD, PhD,<sup>1</sup> Maiwenn AI, PhD,<sup>2</sup> Jalpa A. Doshi, PhD,<sup>3</sup> Isao Kamae, MD, DrPH,<sup>4</sup> Steven E. Marx, PharmD, MS,<sup>5</sup> Donna Rindress, PhD<sup>6</sup>

<sup>1</sup>University of the Sciences, Philadelphia, PA, USA; <sup>2</sup>Erasmus University, Rotterdam, The Netherlands; <sup>3</sup>University of Pennsylvania, Philadelphia, PA, USA; <sup>4</sup>Keio University, Fujisawa, Japan; <sup>5</sup>Abbott Laboratories, Chicago, IL, USA; <sup>6</sup>BioMedCom Consultants Inc., Montréal, Québec, Canada

## ABSTRACT

**Objectives:** The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Health Science Policy Council recommended and the ISPOR Board of Directors approved the formation of a Task Force to critically examine the major issues related to Quality Improvement in Cost-effectiveness Research (QICER). The Council's primary recommendation for this Task Force was that it should report on the quality of cost-effectiveness research and make recommendations to facilitate the improvement of pharmacoeconomics and health outcomes research and its use in stimulating better health care and policy. Task force members were knowledgeable and experienced in medicine, pharmacy, biostatistics, health policy and health-care decision-making, biomedical knowledge transfer, health economics, and pharmacoeconomics. They were drawn from industry, academia, consulting organizations, and advisors to governments and came from Japan, the Netherlands, Canada and the United States.

**Methods:** Face-to-face meetings of the Task Force were held at ISPOR North American and European meetings and teleconferences occurred every few months. Literature reviews and surveys were conducted and the first preliminary findings presented at an open forum at the May 2008 ISPOR meeting in Toronto. The final draft report was circulated to the expert reviewer group and then to the entire membership for comment. The draft report was posted on the ISPOR Web site in April 2009. All formal comments received were posted to the association Web site and presented for discussion at the Task Force forum during the ISPOR 14th Annual International Meeting in May 2009. Comments and feedback from the forums, reviewers and membership were considered in the final report. Once Task Force consensus was reached, the article was submitted to Value in Health.

**Conclusions:** The QICER Task Force recommends that ISPOR implement the following:

- With respect to CER guidelines, that ISPOR promote harmonization of guidelines, allowing for differences in application, regional needs and politics; evaluate available instruments or promote development of a new one that will allow standardized quantification of the impact of CER guidelines on the quality of CER studies; report periodically on those countries or regions that have developed

guidelines; periodically evaluate the quality of published studies (those journals with CER guidances) or those submitted to decision-making bodies (as public transparency increases).

- With respect to methodologies, that ISPOR promote publication of methodological guidelines in more applied journals in more easily understandable format to transfer knowledge to researchers who need to apply more rigorous methods; promote full availability of models in electronic format to combat space restrictions in hardcopy publications; promote consistency of methodological review for all CER studies; promote adoption of explicit best practices guidelines among regulatory and reimbursement authorities; periodically update all ISPOR Task Force reports; periodically review use of ISPOR Task Force guidelines; periodically report on statistical and methodological challenges in HE; evaluate periodically whether ISPOR's methodological guidelines lead to improved quality; and support training and knowledge transfer of rigorous CER methodologies to researchers and health care decision-makers.
- With respect to publications, that ISPOR develop standard CER guidances to which journals will be able to refer their authors and their reviewers; lobby to establish these guidances within the International Committee for Medical Journal Editors (ICMJE) Requirements to which most journals refer in their Author Instructions; provide support in terms of additional reviewer expertise to those journals lacking appropriate reviewers; periodically report on journals publishing CER research; periodically report on the quality of CER publications; and support training and knowledge transfer of the use of these guidelines to researchers and reviewers.
- With respect to evidence-based health-care decision-making, that ISPOR recognize at its annual meetings those countries/agencies/private companies/researchers using CER well, and those practitioners and researchers supporting good patient use of CER in decision-making; and promote public presentation of case studies of applied use of CER concepts or guidelines.

**Keywords:** cost-effectiveness, guidelines, health economics, quality improvement.

## Background to the Task Force

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Health Science Policy Council recommended that the ISPOR Board of Directors establish a Task Force to critically examine the major issues related to Quality Improvement in Cost-effectiveness Research (QICER) in July 2005. The

Council's primary recommendation for this new Task Force was that it should report on the quality of cost-effectiveness research and make recommendations to facilitate the improvement of pharmacoeconomics and health outcomes research and its use in stimulating better health care and policy. The ISPOR Board of Directors approved creation of the Task Force in December 2005. An email was sent to all ISPOR members in March 2006 seeking candidates interested in serving on the leadership group or the expert reviewer group. Task Force leadership and reviewer groups were finalized by October 2006. Task Force members were knowledgeable and experienced in medicine, pharmacy, biostatistics, health policy and health care decision-making,

*Address correspondence to:* William F. McGhan, University of the Sciences, 600 South 43rd Street, Philadelphia, PA, USA. E-mail: w.mcghan@usp.edu

10.1111/j.1524-4733.2009.00605.x

biomedical knowledge transfer, health economics and pharmacoeconomics. They were drawn from industry, academia, consulting organizations, and advisors to governments and came from Japan, The Netherlands, Canada and the United States.

Face-to-face meetings of the Task Force were held at ISPOR North American and European meetings and teleconferences occurred every few months. Literature reviews and surveys were conducted and the first preliminary findings presented at an open forum at the May 2008 ISPOR meeting in Toronto. The final draft report was circulated to the expert reviewer group in March 2009 and then to the entire membership for comment in April 2009. The draft report was posted on the ISPOR web site in April 2009; 26 responses were received. All formal comments received were posted to the ISPOR Web site and presented for discussion at the Task Force forum during the ISPOR 14th Annual International Meeting in May 2009. Comments and feedback from the forums, reviewers and membership were considered in the final report. Once Task Force consensus was reached, the article was submitted to *Value in Health*.

## Introduction

Quality assessment and continuous quality improvement has long been recognized as a vital process in all societal systems and organizations. In health care, critical review of interventions and reports on the quality of outcomes can help correct deficiencies and further advance efficiency and quality. Continuous quality improvement is integral to our global efforts to improve the economics and quality of life in all health care sectors and all patient populations. There is an important role for ISPOR in macro review and examination of quality and trends in pharmacoeconomics, health care economics research, and their resulting impact on global policies and practice.

## Mission

The mission of the ISPOR Task Force on Quality Improvement in Cost-effectiveness Research (QICER) is to generate periodic quality reports and make recommendations to facilitate the improvement of pharmacoeconomics and health outcomes research, and its use in stimulating better health care and policy. This will be accomplished through periodic systematic reviews and surveys. The results and findings will be made available to ISPOR membership for comments and published as white papers and reports, including recommendations for future ISPOR initiatives, educational programs, and member services.

In this first report, the task force has focused primarily on cost-effectiveness research (CER). While broader topics in health economics and outcomes research (HEOR), such as patient reported outcomes, health-related quality of life, training, software, etc., are beyond the range of this first report, they are envisioned as targets for future work. The HEOR scope was, however, considered in our discussion of journals to capture a more holistic view of the current state of peer-reviewed publication and to position CER within a broader perspective.

As summarized in Figure 1, organizationally and individually, we embrace patients, providers, researchers, regulators, and payers to collectively advocate that scarce health care resources are allocated wisely, fairly, and efficiently. These health sector linkages are promoted through organizational services that facilitate education, communications, research, and international cooperation. Continuous quality improvement efforts are vital for improving activities and outcomes from international policies

to individual patient care. The outside ring in the diagram depicts the classic phases for quality improvement that include: developing guidelines, designing guideline implementation, conducting interventions, measuring impact, analyzing outcomes, and the feedback for improved guidelines.

## The Role of Guidelines in Quality Improvement

What role do guidelines play in promoting the quality and improvement of CER? It is usually assumed that the presence of guidelines leads to quality improvement, assuming that established guidelines increase credibility and usefulness by defining generally accepted standards and the requirements of specific users. However, in this field, there is not much evidence to support or disprove this assumption. A number of studies have evaluated the quality of research, but few have examined the relationship between the presence of guidelines and the quality of research. Two topics were examined: the availability of HEOR guidelines and the impact of guidelines on the quality of CER.

A few authors have reviewed available guidelines, comparing and contrasting them [1–3], and other resources are also available at: <http://www.ISPOR.org>; <http://www.biomedcom.org/en/resources-BMC-databases.html>. Most guidances have similar content with minor variations, but some significant differences do exist among them, most generally because of their intended purpose, the audience to be addressed, regional, cultural or political variation, or author or sponsor preferences.

How can the impact of guidelines on CER quality be measured? Most journals neither have specific guidelines or requirements for HEOR (see further discussion), nor do authors normally reveal which guidelines, if any, they observe. So despite easy accessibility of published articles, their quality, and the improvement of their quality, is not easily linked to specific guidelines. Those who measure the quality of HEOR publications [1,4–8] choose their own quality measures from those guidelines currently available and generally accepted standards.

Several formulary evaluation bodies (such as NICE in the UK [9], Canadian Agency for Drugs and Technology in Health (CADTH) in Canada [10], and PBS in Australia [11–13]) have developed specific guidances and requirements for HEOR studies submitted, but these studies are often not publicly available for evaluation in the short term. Some of these bodies have performed, or allowed, quality evaluation of studies submitted to them, which have been presented publicly [14] or published [15,16]. These often use small samples, are qualitative, and more importantly, not easily comparable across jurisdictions.

## The Evolution of Guidelines

Guideline development began in Australia in 1992, followed closely by Canada and a few academic groups in the United States [17–19]. Their form has tended to reflect their purpose, e.g., those intended for reimbursement decision-making tend to be more prescriptive, while those with more academic purposes more descriptive (discussion of the appropriateness of each will be left to a future report focused specifically on guidelines).

Over the last decade, many countries have produced their own guidances and others are in development. There are currently about 39 CER guidances from 34 countries (with multiples from some countries). These have been produced by government bodies, by academic groups, and health-care insurers, and fre-

متن کامل مقاله

دریافت فوری ←

**ISI**Articles

مرجع مقالات تخصصی ایران

- ✓ امکان دانلود نسخه تمام متن مقالات انگلیسی
- ✓ امکان دانلود نسخه ترجمه شده مقالات
- ✓ پذیرش سفارش ترجمه تخصصی
- ✓ امکان جستجو در آرشیو جامعی از صدها موضوع و هزاران مقاله
- ✓ امکان دانلود رایگان ۲ صفحه اول هر مقاله
- ✓ امکان پرداخت اینترنتی با کلیه کارت های عضو شتاب
- ✓ دانلود فوری مقاله پس از پرداخت آنلاین
- ✓ پشتیبانی کامل خرید با بهره مندی از سیستم هوشمند رهگیری سفارشات