

**Continuous Quality Improvement for
Cost-Effective Research (QICER):
Assessing Health Economic Methods
And Global Policy**

An ISPOR Task Force Forum

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SECTION 1

**Introduction
and
Background**



Issue Description

Continuous quality improvement is integral to ISPOR regional and global endeavors to improve the economics and quality of life in all health care sectors and all patient populations. There is a crucial responsibility for ISPOR in regularly taking a macro review and examination of overall quality and trends in pharmacoeconomics, health care economics research and the resulting impacts on global policies and practice.



Task Force Mission Statement

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 their use in stimulating more efficient and effective health care, patient care and policy.



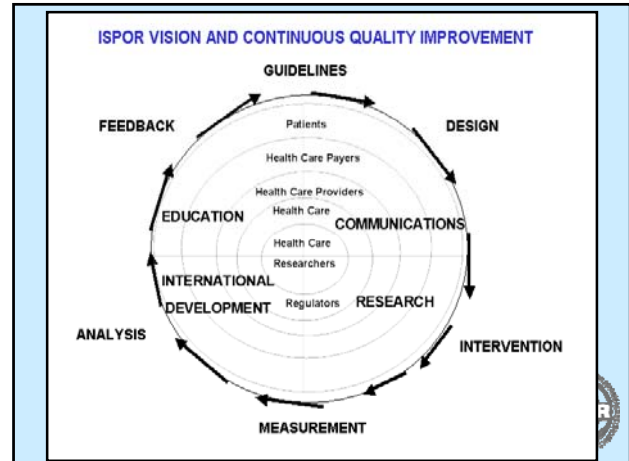
Methods

The Task Force goals are being accomplished through periodic systematic reviews and surveys. The periodic results and findings will be made available on the ISPOR website for membership comment and, after revision, published as white papers and reports that include recommendations for future ISPOR projects, educational programs, and services, both internal and external to the Society.



Sections of the Draft Report

- Section 1** -- Introduction and Overview of Issues
- Section 2** -- Guidelines around the Globe
- Section 3** -- Statistics and Science
- Section 4** -- Journals and Publication Quality
- Section 5** -- Evidence Based Practice for Decision Makers & Patients
- Section 6** -- Recommendations



SECTION 2

HEOR Guidelines and Quality Improvement



The Role of Guidelines in Quality and Improvement of HEOR

- It is assumed that the presence of guidelines leads to improvement in the quality of HEOR.
- Established guidelines are expected to increase the credibility and usefulness of HEOR. They define:
 - generally accepted standards
 - the requirements of specific audiences



The Role of Guidelines in Quality and Improvement of HEOR (2)

Two areas need to be examined

1. The quality of guidelines
 - no instrument currently available to compare or measure guideline quality
2. The impact of guidelines on the quality of HE studies
 - A number of studies have been published looking at the quality of studies submitted to guideline-producing bodies
 - None have measured the relationship between the guidelines and the studies
 - All vary on how quality is measured



Evolution of HE Guidelines

- There are currently over 32 HE guidances from more than 30 countries (multiples from the US and Canada).
- These have been produced by government bodies, academic groups, and healthcare insurers
- Many are collaborations made up of various permutations from these three groups.
- Over half currently known guidelines were prepared as part of formulary submission guidances or requirements.



Measuring Impact of Guidelines on Quality of Studies

- To assess the impact of guidelines on quality and improvement of quality of HE studies, a tool is required that is
 - Quantifiable
 - Anchored to the guidelines of interest, as well as generally accepted practices
 - Comparable across guidelines, studies and time
- There may be an instrument already available that will suit this purpose, or a new one might be developed



Summary of comments from reviewers: Guidelines(1)

- HEOR guidelines for both researchers and decisionmakers were generally considered a positive thing.
- ISPOR is considered an appropriate coordination point for the development of these.
- Most agreed that guideline quality and effectiveness are important issues and an objective measurement instrument is needed
- Should HEOR guidelines be descriptive or prescriptive? Future agenda
- Some reviewers provided updates with regard to new guidelines in development, ones not included on our list, or recently updated (Australia, France, Italy, Singapore, Taiwan). All guidelines of which we were aware were included, without regard to language.



Summary of comments from reviewers: Guidelines(2)

- Some wanted more discussion on evolution of guidelines, e.g., origins and purposes, or to see more in-depth comparison of guidelines by methods, by region, by type of health care system.. Future agenda
- Some would like to see inclusion of guidelines from bodies other than NICE, PBS etc. We felt we had included all publicly available guidelines for the conduct of HEOR, including academic and public health groups, and would appreciate receiving information about any missed.



Summary of comments from reviewers: Guidelines(3)

- Concern was expressed about quantification of the impact of HE guidelines. This stemmed from a fear that prescriptive guidelines would prevent methodological flexibility and force research into a restricted mold.
- Comment about encouraging researchers to adopt and follow HEOR guidelines. The biggest component missing from our vision was training.
- A number of reviewers suggested adding such routes as seminars, newsletters and on-line courses to promote knowledge transfer and adoption.



Future Agenda

- Promote harmonization of HE guidelines, allowing for differences in regional needs and politics
- Evaluate available instruments or promote development of one to quantify the impact of HE guidelines on the quality of HE studies
- Report periodically on countries using guidelines
- Evaluate periodically quality of studies submitted to decisionmaking bodies (as public transparency increases)



SECTION 3 Statistics and Science



Section Objectives

- What are the statistical problems in cost effectiveness research?
 - Randomized clinical trial (RCT) based economic evaluations
 - Decision model based cost-effectiveness studies
- How can we make the science better?



RCT-based Economic Evaluations: Key Issues

- Joint comparison of costs and effects and estimation of sampling uncertainty
- Analysis of cost data
- Handling of censored or missing cost data
- Sample size and power
- Evaluating transferability (generalizability) of trial results



Decision Modeling-based Studies: Key Issues

- Methods for evidence synthesis
- Probabilistic sensitivity analysis
- Value-of-information analysis
- Model validation



Key Recommendations to Improve Quality

- Need for publications of newest technical advances in applied journals, in easily understandable format
- Lack of space in journals conflicts with need for model transparency: detailed online technical appendices and models should be made available
- Peer reviewers for funding agencies and journals to be provided with a clear checklist to standardize and improve critical review of studies



Summary of Comments

- Statistical Issues
 - Generally reviewers agreed that statistical issues and challenges were comprehensively covered for RCT and model based economic evaluations
 - Few suggested expanding to issues facing other sources of economic evidence that are being increasingly used such as quasi-experimental studies, registries, and administrative data analyses.
- Recommendations to Improve Quality
 - Several suggested need for better training and education so that researchers can understand more sophisticated techniques



SECTION 4 Journals and Publication Quality



Journals have the potential to play a role in HEOR quality and improvement by..

- Establishing requirements and guidelines
- Effecting the peer review process
- Disseminating studies
- Providing peer feedback



Journals & HEOR guidelines

- This task force surveyed WAME members (World Association of Medical Editors)
- The vast majority (92%) accept some form of HEOR-type manuscripts
- BOI, systematic reviews and database studies are the most frequent



Survey results – HEOR guidelines for authors & reviewers

- None of the journals provided their own HEOR guidelines
- Most recommended either ICJME guidelines or other specific guidances.
- Only the Cochrane website had links to HEOR guidances
- ~ 58% of journals did not provide reviewers with guidelines for evaluating HEOR - for those who did, in all cases but one these were the same as author guidelines and not specific to HEOR
- 91% would consider recommending or requiring a standard set of credible HEOR guidelines



Survey Conclusions

- **Clear message that many journals accept and publish HEOR research**
- **Almost all do so without clear guidance to either authors or reviewers about quality standards**
- **Many journals have difficulty finding HEOR reviewers**
- **Almost all journals expressed interest in having a larger pool of reviewers for HEOR**



Summary of comments from reviewers: Publications

- Encouraging comments from some involved in journal development regarding need for publication guidelines.
- Emphasis that publication guidelines be easily accessible to those who need to use them, i.e., not overly sophisticated and sufficiently detailed to provide practical support.
- A few reviewers mentioned that *Value in Health* should play a role in promoting the quality of published HEOR studies.



Future plans: quality of HEOR research in the published literature

- Develop standard guidances to which journals are able to refer their authors and their reviewers
- Lobby to establish these guidances within the ICJME Uniform Requirements to which most journals refer in their Author Instructions
- Provide some form of support in terms of additional expertise to those journals without appropriate reviewers
- Periodically report on journals publishing CEA
- Periodically report on the quality of CEA publications



SECTION 5

EBM Professionals and Decision Makers



Evidence gaps are observed between researchers and EBM professionals / decision makers in interpreting...

- Full range of evidence
- Partial evidence
- Abstract
- Conclusions
- Summary for executives
- Commentary
- Translation



Common Claims

- Health-economics outcomes such as ICER and QALYs are not understood.
- Health-economics outcomes are also considered irrelevant for decision making.
- Reading only commentary rather than whole abstract is preferred.
- Studies should be scored for quality.



Conditions Causing Claims

Insufficient knowledge/skills on economic evaluations

- Lack of good-quality data.
- Lack and shortcomings of good clinical data.
- Poor connection between the clinical research and the strategy for generating economic evidence.
- Lag between the publication of the first clinical data, and the subsequent publication of the first economic study.
- Poor generalizability.
- Narrowness of research questions.
- Lack of methodological rigor at the local level.
 - inflexibility of budgets
 - large number of assumptions
 - incredibility of industry-funded studies



If decision makers do not find economic evaluations useful, then ...

Assume that they have a different and superior model.

- The way of evaluations must be changed with the constraints and the method of measuring the outcomes, but the basic approach should remain the same.
- Appraise the studies by a trusted source.
- Suggest a range of flexibility in healthcare budgets.
- Explain the practical relevance of study results, especially for generalizability.
- Continue, through the databases (eg, NHS EED), to explore the way of economic studies more accessible, without losing the key elements of critical appraisal.
- Encourage decision makers to undertake critical assessment of findings beyond quality scores.



Challenges for Decision Makers

- Recognizing the need for science of value-based medicine and health care.
- Understanding complexity of economic evaluations.
- Recognizing the gap between evidence in clinical trials and the real world.
- Improving decision processes in objective ways.
- Measuring the variability in willingness-to-pay of patients for different diseases.
- Applying incremental analyses for budget impact.
- Capturing the multi-dimensional values among patients.



Recommendations for Filling the Gaps

- Training decision makers / EBM professionals on value-based medicine and best practices.
- Building reliable databases or registries of economic studies and the evidence.
 - Developing the methods to implement economic evidence for making decisions at local level regarding budget limitations.
 - Undertaking stronger commitment to fund local studies.
 - Demonstrating usefulness of value-based approaches to improve decision-making in the real world.
 - Improving communications among the communities relevant to outcomes research such as pharmacoepidemiology, comparative-effectiveness, and health technology assessment.



SECTION 6 Recommendations and Member Feedback



Sample of Task Force Recommendations

- Promote global harmonization of HE guidelines.
- Analyze the impact of HE guidelines on the quality of HE studies.
- Evaluate studies submitted to decision making bodies.
- Promote publication of methodological guidelines in applied journals.
- Advance publication of transparent models in electronic format.
- Promote adoption of explicit best practices guidelines.
- Systematically update all ISPOR task force reports.
- Analyze the use and application of ISPOR task force guidelines.
- Develop standard guidances for outside journals.
- Continually report on the quality of CEA publications.
- Recognize annually, countries and agencies using CEA well.
- Recognize practitioners (and private companies) using CEA well.
- Recognize annually those practitioners/researchers supporting patient use of CEA in decision making.



Sample ISPOR Member Feedback on QICER Report

- Important Task Force that should continue to generate report cards.
- Patients should be in center of ISPOR CQI efforts, not just researchers.
- More evaluation is required of education and training efforts along with needs of decision makers.
- More critique needed for HEOR using patient registries and claims databases.
- Need reviews of software and analytical tools.
- Quality of life and patient reported outcomes (PRO) assessment needed in future reports.
- More critique needed on statistical issues with missing data and intension to treat, etc.
- More consideration needed for HEOR quality targets in developed countries versus developing countries.

