

DEVELOPING GUIDELINES TO SUPPORT QUALITY IMPROVEMENT OF HEALTH ECONOMIC PUBLICATIONS

Presented by the multi-organizational Health Economic Publication Guidelines (HEPG)
Task Force
9 November 2010
8:30-9:30 am

Presenters: Donna Rindress--Dan Greenberg--Federico Augustovski

Overview of today's forum

- Leadership team
- Background
- Mandate & objectives
- Timetable
- Work to date
 - Systematic review of literature & public domain
 - Delphi exercise
- Upcoming plans
 - Delphi con't
 - Face to face consensus meeting
 - Consultation with stakeholders
 - Finalize guidelines & acceptance by participating orgs
 - Dissemination plan

Leadership team

- **Federico Augustovski**
Instituto for Clinical Effectiveness and Health Policy & U. Buenos Aires, Buenos Aires Argentina.
- **Chris Carswell**
Editor Pharmacoeconomics, Auckland, New Zealand
- **Michael Drummond**
University of York, York England & Editor Value in Health
- **Dan Greenberg**
Ben-Gurion University of the Negev, Beer-Sheva, Israel
- **Wolfgang Greiner**
University of Bayreuth, Bayreuth Germany & Editor European Journal of Health Economics
- **Stan Heimberger**
Franklin Lakes NJ
- **Mark Helfand**
CSPH, Portland OR & Editor Medical Decision Making
- **Don Huseureau**
CADD, Ottawa, ON, Canada & HTAI representative
- **Angela Hutchinson**
Centers for Disease Control, Atlanta GA
- **Gordon Liu**
Peking University, Guanghua School of Management, Beijing, China
- **Josephine Mauskopf**
RTI International, Research Triangle Park, NC, & former Editor Value in Health
- **Kathy McDonald**
Stanford University, Stanford, CA & SMDM representative
- **David Moher**
Children's Hospital of Eastern Ontario Research Institute, Ottawa ON, Canada & EQUATOR network representative
- **Peter Neumann**
Tufts Medical Center, Boston MA
- **Donna Rindress (Chair)**
BioMedCom Consultants, Montreal QC Canada
- **Joanna Siegel**
ARIC Research Initiative in Clinical Economics, Bethesda MD

Organization

- The task force leadership team is a small group made up of 16 people with prior interest and experience in this field coming from more than one HE related professional organization
- *Participating organizations: ISPOR, SMDM, HTAI*
- *Participating journals: Value in Health, Pharmacoeconomics, Medical Decision Making, Eur J Health Economics*
- Work facilitated mostly through email and teleconferences.
- ISPOR provides support to coordinate
- At least 2 face-to-face meetings each year at ISPOR with others under discussion with SMDM and HTAI
- Later phases will also require external communications with regard to dissemination/communication with ICMJE, WAME, other journals

Background

- Concept originated from results of survey of medical journal editors (WAME) performed by the ISPOR QICER Task Force in 2008
- Although respondents accepted and published some or all types of health economic and outcomes research, the vast majority of them had no guidelines, requirements, or checklists for health economics (HE) or outcomes research (OR)(HEOR), for the use of either their submitting authors or their reviewers
- The few times any sort of guidelines or requirements were provided, these were most commonly the Uniform Requirements for Biomedical Publication published by the International Committee for Medical Journal Editors (ICMJE)

Background

- Uniform Requirements gold standard for biomedical publishing. They do include some links to discipline-specific reporting guidelines* but not for HE
 - *e.g., observational epidemiology studies, meta-analyses of observational studies, RCTs, studies of diagnostic accuracy, and systematic reviews and meta-analyses
- Most respondents said they would use/incorporate HE guidelines if made available by a credible professional association
- One recommendation of the QICER task force was that ISPOR help make HE reporting guidelines available to authors and reviewers to support the quality, consistency and transparency of HE research reporting

Background

- Although there are a number of guidelines and checklists already available, they are not generally used in publishing
- Possible explanations :
 - Existing guidelines too broad or comprehensive
 - Existing guidelines may be difficult to use by the average biomedical researcher/reviewer community
 - Certain guidelines may not be known outside a very specialized HE community
 - Because certain guidelines were specifically developed for a single journal (e.g., BMJ guidelines) other journals may be reluctant to recommend or use

Background

- However,
 - fairly broad consensus among available recommendations and guidelines
 - considerable stability of content for several years with regard to reporting
- We proposed reviewing and consolidating HE guidelines already available
- This is a trend in several other biomedical disciplines
- Common denominator=EQUATOR network

The EQUATOR approach

INITIAL STEPS

- (Identify need: review literature/evidence)

PRE-MEETING

- (Identify participants, conduct Delphi, generate items for consideration, prepare for face to face meeting)

FACE TO FACE CONSENSUS MEETING

- (discuss results of review, Delphi, evidence for inclusion of items in guidance, plan document production, discuss knowledge translation strategy)

POST MEETING ACTIVITIES

- (develop guidance & explanatory document, pilot test, develop publication strategy)

POST PUBLICATION ACTIVITIES

- (seek & address feedback, promote endorsement of and adherence to guidelines, evaluate guideline impact, develop website, translate, update)

Mandate

- To support and improve the quality, consistency and transparency of HE research reporting in the health economics and biomedical literature by reviewing and consolidating guidelines and recommendations
- To develop clear, easy to use guidelines explicitly for reporting HE research
- To work collaboratively with other relevant HE organizations

Mandate

- TF to focus on reporting guidelines for core HE analyses/studies
- Not focus on details of conduct or methodology, but on necessary content, format and approach to effective presentation of such studies (except to enhance understanding of reporting recommendations)
- Future work may be undertaken in other areas relevant to HEOR

Objectives

- Primary objective of guidelines would be to provide guidance to authors and reviewers of HE publications
- Possible secondary benefits:
 - Education---academic colleagues have expressed desire for tools to train students to read and evaluate health economic publications
These could serve as such a tool with the benefit of being ratified by a number of professional organizations and ICMJE endorsed
 - Quality improvement--- comprehensive measurement tool developed using standard global HE publication guideline could provide consistent mechanism for quantitative evaluation and longitudinal comparisons

Timetable

Activity	Timeframe
TF approved by ISPOR BOD	Nov 2009
Identify & recruit leadership team	Jan-Aug 2010
Build collaborations	
Systematic review of HE guidelines and QA	May-Aug 2010
Develop Delphi exercise	Aug-Nov 2010
Conduct Delphi exercise	Nov-Dec 2010
Organize consensus meeting to determine final content	Mar-Apr 2011
Develop draft guideline	Apr-May 2011
Circulate among membership	
Final guideline to BODs of participating organizations	May-Jul 2011
Publish ratified guidelines	Aug-Dec 2011
Lobby ICMJE/journals	May-Dec 2011
Follow up	May 2011 →

Work to date

Leadership team assembled

- 16 members:
 - Editors of HE journals
 - Experience developing reporting guidelines (EQUATOR network)
 - Experience developing HE guidelines
 - Research focus on HE reporting quality or HE quality assessment
 - Representatives from organizations with HE as part of their discipline
 - Global perspective (US, Canada, UK, Germany, Israel, Argentina, New Zealand, China)

Work to date

Systematic reviews (May-Aug 2010)

- HE guidelines and HE quality assessment studies retrieved from public domain sources, including PubMed, Centers for Reviews and Dissemination, the EQUATOR network, and web pages/reports from bodies/institutions issuing any type of guidelines for economic evaluation (e.g., NICE, CADTH, etc.).
- PubMed searched from inception using the search terms "health economic guidelines, quality assessment, cost-benefit analysis/standards, cost-effectiveness analysis/standards" as well as by employing "related citations" function.

Work to date

Systematic reviews (May-Aug 2010)

- Abstracts from recent conferences of ISPOR, SMDM, HTAI, ASHE and IHEA searched for relevant posters and presentations, e.g., assessment of quality of HE reporting
- Scope of searches limited to core HE research, i.e., cost-effectiveness, cost-utility, cost-benefit, and cost-minimization analyses
- Led to identification of 74 HE guidelines and 66 studies assessing the quality of published economic evaluations

Work to date

Data extraction, synthesis and analyses:

- Template developed to extract data
- **HE guideline** data extracted from 74 papers to populate 35 fields
- Data synthesized highlighting common themes, areas of agreement and disagreement
- Data links maintained to original source(s)

Work to date

- Similar approach for studies assessing the quality of published economic evaluations
 - percentages of studies citing an issue as a problem in HE reporting based on review of 66 relevant papers
 - For quantitative studies assessing quality, any item reported as a problem in 20% or more of the HE studies reviewed was included in quantitative calculations
- Stats on frequency of recommendations and QA issues compiled and provided to support questions throughout survey
- *(Larger reports on both reviews developed for use as discussion material at consensus meeting)*

Work to date

The Delphi exercise (Aug-Nov 2010)

- Delphi survey designed:
 - to identify key items to be addressed in the development of HE reporting guidelines
 - to highlight areas of consensus
 - To highlight issues needing further discussion
- Survey consists of 51 items selected based on review of HE guidelines
- Design also informed by quality assessment studies
- A highly distilled summary of findings provided for each item including frequency of specific issues seen in the OA literature

Upcoming plans

- Ongoing: Delphi survey soon to be circulated (2 iterations)
- Consensus meeting to be convened (~Jan-Feb 2011) to review findings, discuss controversies and issues and determine final content of guidelines
- First draft of guidelines to be developed and circulated among participating org members & second draft incorporating member input (Mar-Apr 2011)
- Ratification of guidelines by the BODs of each participating organization to be sought (Apr-May 2011)

Phase 2: dissemination & follow up

- Once guidelines ratified by BODs of participating organizations:
 - SHORTER TERM:
 - Publication (simultaneous?) of core guidelines and descriptive companion paper
 - Discussions initiated to embed a link to these in the Uniform Requirements
 - Promote biomedical journals publishing HE studies to adopt and encourage use of guidelines for authors & reviewers
 - Develop mechanism for feedback
 - LONGER TERM
 - Evaluate impact of guidelines
 - Update guidelines

Questions or Comments?

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Or any of the taskforce members

More information:
Web:
<http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp>