Disclaimer

Organizations may not re-use material presented at this AMCP webinar for commercial purposes without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. Commercial purposes include but are not limited to symposia, educational programs, and other forms of presentation, whether developed or offered by for-profit or not-for-profit entities, and that involve funding from for-profit firms or a registration fee that is other than nominal. In addition, organizations may not widely redistribute or re-use this webinar material without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. This includes large quantity redistribution of the material or storage of the material on electronic systems for other than personal use.
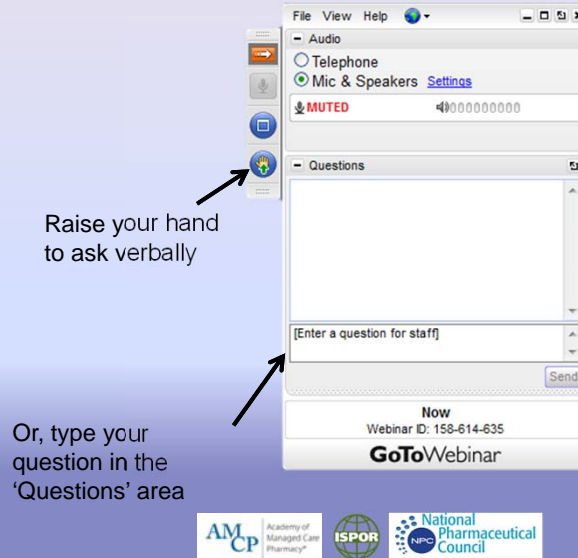
2015 AMCP Foundation P&T Committee Competition Training

Special thanks to our event sponsors:

AMCP/ISPOR/NPC

How to Ask a Question

Raise your hand
to ask verbally

Or, type your
question in the
'Questions' area

Comparative Effectiveness Research Collaborative Initiative (CER-CI)

HEALTH EVIDENCE FOR DECISION MAKING: ASSESSMENT TOOL FOR PROSPECTIVE AND RETROSPECTIVE OBSERVATIONAL STUDIES

Webinar

October 29, 2014

AMCP/ISPOR/NPC

CER-CI Interpreting Observational Studies For Health Care Decision Makers Task Force

Chair - Bradley Martin PhD, CER-CI Interpreting Retrospective Observational Studies Task Force and Professor and Division Chair, College of Pharmacy, University of Arkansas for Medical Sciences, Department of Pharmacy Practice, Little Rock, AR

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/jval

ELSEVIER

ISPOR TASK FORCE REPORTS

A Questionnaire to Assess the Relevance and Credibility of Observational Studies to Inform Health Care Decision Making: An ISPOR-AMCP-NPC Good Practice Task Force Report

Marc L. Berger, MD[1], Bradley C. Martin, PharmD, PhD[2,*], Don Husereau, BScPharm, MSc[3,4,5], Karen Worley, PhD[6], J. Daniel Allen, PharmD[7], Winnie Yang, PharmD[8], Nicole C. Quon, PhD[9], C. Daniel Mullins, PhD[10], Kristijan H. Kahler, PhD, RPh[11], William Crown, PhD[12]
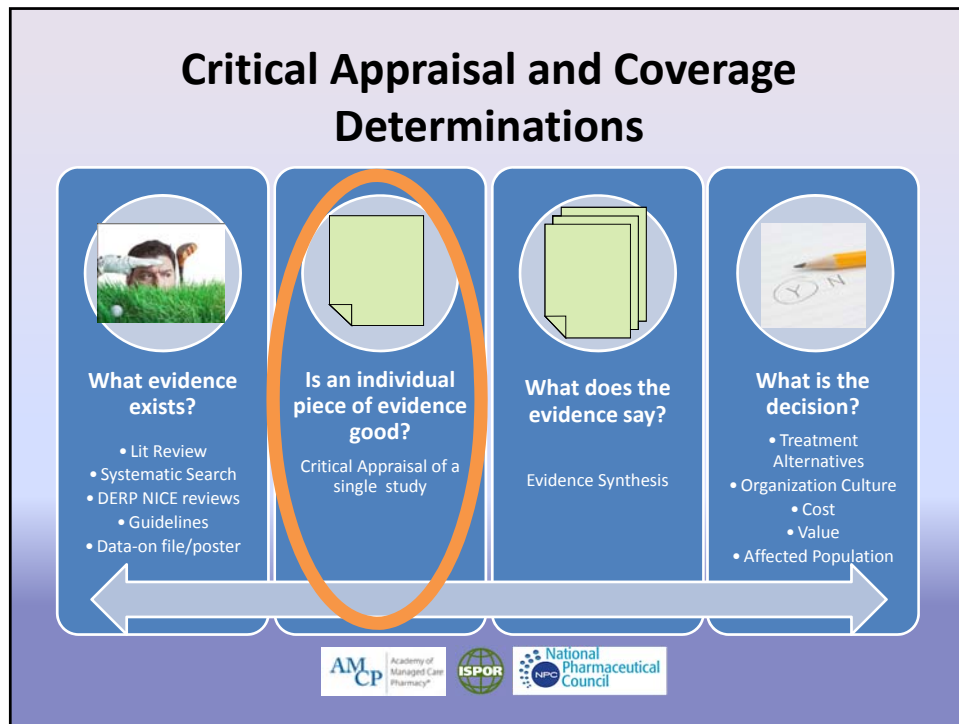
AMCP/ISPOR/NPC
CER Collaborative Initiative

- *Objective:* To enhance the usefulness of CER to improve patient health outcomes by developing assessment tools for four types of studies:
  - Prospective Observational Studies
  - Retrospective Observational Studies
  - Modeling Studies
  - Indirect Treatment Studies

Why is this tool potentially useful to decision makers around the world?

- Provides a critical appraisal tool for an individual study that can help determine whether it should be incorporated into a body of evidence
- Can be used as an educational tool to increase sophistication in the critical review of CE information

Critical Appraisal and Coverage Determinations

What evidence exists?

- Lit Review
- Systematic Search
- DERP NICE reviews
- Guidelines
- Data-on file/poster

Is an individual piece of evidence good?

Critical Appraisal of a single study

What does the evidence say?

Evidence Synthesis

What is the decision?

- Treatment Alternatives
- Organization Culture
- Cost
- Value
- Affected Population

The Issues

- Pharmacy decision makers ("users") are uncertain how to interpret retrospective observational CER studies
  - Inherent Casual Inference Challenge Due to Observational Nature
    - Counterfactual Unobserved
  - Retrospective Data are Not Routinely Collected for Research Purposes
  - Less Rigorous Regulatory Oversight
    - Variability in Approach and Conclusions
  - Complex Statistical Modeling
  - Heterogeneous Perspectives and Training
    - Epidemiology, Economics, Health Services Research, Policy, Clinical
- The issues are growing more challenging
  - More studies and more complex analytic approaches

CER-CI Part 1 – Tool Design Objectives

- As an appraisal tool:
  - easy, fast, accurate, minimal skill required…etc.
  - help end user assess the quality, credibility, and relevance of non experimental studies
- Use of the tool should result in the inclusion of more CER studies in their body of evidence and promote uniformity when appraising the quality of evidence as an educational tool

For more information:
http://www.ispor.org/TaskForces/InterpretingORSforHCDecisionMakersTFx.asp

The Task is Impossible

- A thorough evaluation requires
  - Training in mathematics, statistics, economics, epidemiology
  - Familiarity of data sources
  - Expertise in the clinical subject and its literature
- Few pharmacy decision makers will have the resources
- **Our objective: help decision makers do better than they can now**
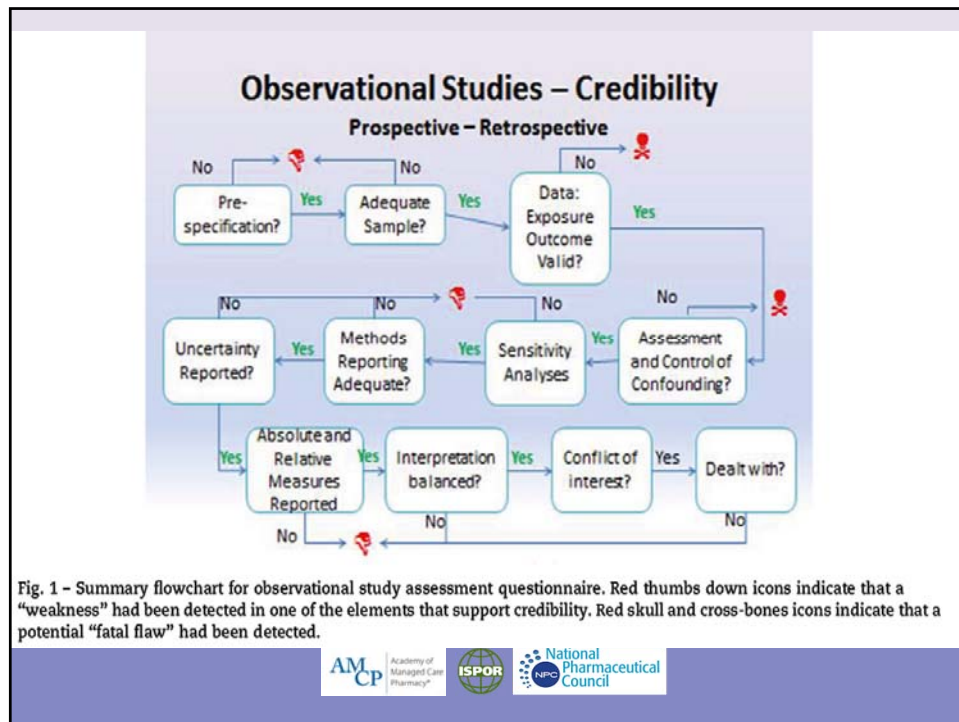
Two main questions common across all four tools

- **_Is the study credible?_**
  - Credibility is the extent to which the study accurately answers the question it is designed or intended to answer and is determined by the design and conduct of the study.
  - Addresses issues of Internal Validity; measurement, and confounding
  - Addresses issue of reporting comprehensiveness
- **_Is the study relevant?_**
  - Relevance addresses the extent to which the results of the study, if accurate, apply to the setting of interest to the decision-maker.
  - Addresses issues of External Validity (population, comparators, endpoints, timeframe) and policy-relevant differences

Checklist Organization and Content

- Relevance
  - 4 Items

- Credibility
  - Design: 9 Items
  - Data: 6 Items
  - Analysis: 3 Items
  - Reporting: 8 Items
  - Interpretation: 4 Items
  - Conflict of Interest: 2 Items

Fig. 1 – Summary flowchart for observational study assessment questionnaire. Red thumbs down icons indicate that a "weakness" had been detected in one of the elements that support credibility. Red skull and cross-bones icons indicate that a potential "fatal flaw" had been detected.

Support Care Cancer (2012) 20:941–949
DOI 10.1007/s00520-011-1165-1

ORIGINAL ARTICLE

Comparative clinical effectiveness of various 5-HT$_3$ RA antiemetic regimens on chemotherapy-induced nausea and vomiting associated with hospital and emergency department visits in real world practice

Hind T. Hatoum · Swu-Jane Lin · Deborah Buchner · David Cox

TOOL DEMONSTRATION

CER Section

Need to use:

- CERcollaborative.org
  - Students will need to register with the CER Collaborative – Registration is instant – requires password reset on first log-in.

Monograph

- General summary of reports
- Differences in assessments between team members and how they were resolved

Next Steps

- **Webinar will be posted on AMCP Foundation P&T Competition and CER Collaborative webpages**
- **Next Webinar:**
  - Friday, October 31, 2014 3pm EST