Value in Health Regional Issues (ViHRI): Writing Quality Manuscripts for Success

Presented by the *ViHRI* Asia Editorial Board

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CEA, CBA, Outcomes Research & Health Policy

- Cost-effectiveness analysis
- Markov modeling for decision making
- Cost-benefit analysis
- Patient centered outcome research
- Pharmacoepidemiology & drug safety
- Public health
- Health policy

Topics for CEA, CBA and Markov modeling

- Cost-effectiveness of colonoscopy in screening for colorectal cancer
- Cost-effectiveness of population Helicobacter pylori screening and treatment
- Cost-effectiveness of new treatments for overactive bladder
- Cost-effectiveness of bronchodilator therapy for COPD patients
- Cost-effectiveness of hepatitis B immunization in low-income country
- Cost-benefit analysis of educational program for general practitioners in China for the prevention and treatment of depression
- Cost-benefit analysis of childhood vaccination against chickenpox (varicella vaccination)
- Cost-benefit analysis of immunization for pneumococcal pneumonia

Example#1

Available online at www.sciencedirect.com
ScienceDirect
journal homepage: www.elsevier.com/locate/jval

Cost-Effectiveness of a Collaborative Care Depression and Anxiety Treatment Program in Patients with Acute Cardiac Illness

Christopher M. Celano, MD[1,2,*], Brian Healy, PhD[1,3], Laura Suarez, MD[1], Douglas E. Levy, PhD[1,4], Carol Mastromauro, LICSW[1], James L. Januzzi, MD[1,2], Jeff C. Huffman, MD[1,2]

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ABSTRACT

Objective: To use data from a randomized trial to determine the cost-effectiveness of a collaborative care (CC) depression and anxiety treatment program and to assess effects of the CC program on health care utilization. **Methods:** The CC intervention's impact on health-related quality of life, depression-free days (DFDs), and anxiety-free days (AFDs) over the 24-week postdischarge period was calculated and compared with the enhanced usual care (EUC) condition using independent samples *t* tests and random-effects regression models. Costs for both the CC and EUC conditions were calculated on the basis of staff time, overhead expenses, and treatment materials. Using this information, incremental cost-effectiveness ratios were calculated. A cost-effectiveness acceptability plot was created using nonparametric bootstrapping with 10,000 replications, and the likelihood of the CC intervention's cost-effectiveness was assessed using standard cutoffs. As a secondary analysis, we determined whether the CC intervention led to reductions in postdischarge health care utilization and costs. **Results:** The CC intervention was more costly than the EUC intervention ($309.86 vs. $34.93; $z = -11.71$; $P < 0.001$), but was associated with significantly greater increases in quality-adjusted life-years ($\beta = -2.43$; $P = 0.01$) and DFDs ($\beta = -2.13$; $P = 0.05$), but not AFDs ($\beta = -1.92$; $P = 0.09$). This translated into an incremental cost-effectiveness ratio of $1887.04 per quality-adjusted life-year saved, $13.36 per DFD, and $15.74 per AFD. Compared with the EUC intervention, the CC intervention was also associated with fewer emergency department visits but no differences in overall costs. **Conclusions:** The CC intervention was associated with clinically relevant improvements, was cost-effective, and was associated with fewer emergency department visits in the 24 weeks after discharge.

Keywords: anxiety, cardiovascular disease, collaborative care, cost-effectiveness, depression.

Example #2

Good Research Practices for Cost-Effectiveness Analysis Alongside Clinical Trials: The ISPOR RCT-CEA Task Force Report

Scott Ramsey, MD, PhD (cochair),[1] Richard Willke, PhD (cochair),[2] Andrew Briggs, DPhil,[3] Ruth Brown, MS,[4] Martin Buxton, PhD,[5] Anita Chawla, PhD,[6] John Cook, PhD,[7] Henry Glick, PhD,[8] Bengt Liljas, PhD,[9] Diana Petitti, MD,[10] Shelby Reed, PhD[11]

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ABSTRACT

Objectives: A growing number of prospective clinical trials include economic end points. Recognizing the variation in methodology and reporting of these studies, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) chartered the Task Force on Good Research Practices–Randomized Clinical Trials—Cost-Effectiveness Analysis. Its goal was to develop a guidance document for designing, conducting, and reporting cost-effectiveness analyses conducted as a part of clinical trials.

Methods: Task force cochairs were selected by the ISPOR Board of Directors. Cochairs invited panel members to participate. Panel members included representatives from academia, the pharmaceutical industry, and health insurance plans. An outline and a draft report developed by the panel were presented at the 2004 International and European ISPOR meetings, respectively. The manuscript was then submitted to a reference group for review and comment.

Results: The report addresses issues related to trial design, selecting data elements, database design and management, analysis, and reporting of results. Task force members agreed that trials should be designed to evaluate effectiveness (rather than efficacy), should include clinical outcome measures, and should obtain health resource use and health state utilities directly from study subjects. Collection of economic data should be fully integrated into the study. Analyses should be guided by an analysis plan and hypotheses. An incremental analysis should be conducted with an intent-to-treat approach. Uncertainty should be characterized. Manuscripts should adhere to established standards for reporting results of cost-effectiveness analyses.

Conclusions: Trial-based cost-effectiveness studies have appeal because of their high internal validity and ratchet. Improving the quality and consistency of these studies will increase their value to decision makers who consider evidence of economic value along with clinical efficacy when making resource allocation decisions.

Keywords: cost effectiveness, economic, guidelines, randomized clinical trial.

Example#3

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VALUE IN HEALTH

Cost–Benefit Analysis of Preventing Nosocomial Bloodstream Infections among Hemodialysis Patients in Canada in 2004

Zhiyong Hong, MD, DrPH,[1] Jun Wu, MD, PhD,[1] Clem Tisdell, PhD,[2] Crystal O'Leary, BHSc,[1] James Gomes, PhD,[3] Shi-Wu Wen, MD, PhD,[4] Howard Njoo, MD[5]

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ABSTRACT

Objectives: Hemodialysis-associated bloodstream infection (BSI) is a significant public health problem because the number of hemodialysis patients in Canada had doubled from 1996 to 2005.Our study aimed to determine the costs of nosocomial BSIs in Canada and estimate the investment expenses for establishing infection control programs in general hospitals and conduct cost–benefit analysis.

Materials and Methods: The data from the Canadian Nosocomial Infection Surveillance Program was used to estimate the incidence rate of nosocomial BSI. We used Canadian Institute of Health Information data to estimate the extra costs of BSIs per stay across Canada in 2004. The cost of establishing and maintaining an infection control program in 1985 was estimated by the US Centers for Disease Control and Prevention and converted into 2004 Canadian costs. The possible 20% to 30% reduction of total nosocomial BSIs was hypothesized.

Results: A total of 2524 hemodialysis-associated BSIs were projected among 15,278 hemodialysis patients in Canada in 2004. The total annual costs to treat BSIs were estimated to be CDN$49.01 million. Total investment costs in prevention and human resources were CDN$8.15 million. The savings of avoidable medical costs after establishing infection control programs were CDN$14.52 million. The benefit/cost ratio was 1.0 to 1.8:1.

Conclusion: Our study provides evidence that the economic benefit from implementing infection control programs could be expected to be well in excess of additional cost postinfection if the reduction of BSI can be reduced by 20% to 30%. Infection control offered double benefits: saving money while simultaneously improving the quality of care.

Keywords: bloodstream infection, costs and benefits, health economics, infection control program.

Topics for patient centered outcomes research

- Health care with individual's preferences, autonomy, and needs
- Treatment outcomes related to patient's survival, function, symptoms, and health-related quality of life;
- Individual differences and access barriers in various health care settings
- Health disparity between ethnicities, urban/rural areas, etc.
- Optimize health outcomes while addressing burden to individuals, technology, and personnel, and other stakeholder perspectives.

Topics for pharmacoepidemiology & drug safety

- Drug adverse event (or adverse drug reaction)
- Drug use evaluation
- Drug utilization pattern
- Pharmacotherapy and medication therapy management
- Risk and benefit of preventive, diagnostic, therapeutics and health delivery system

Example#4

A Review of Quantitative Risk–Benefit Methodologies for Assessing Drug Safety and Efficacy—Report of the ISPOR Risk–Benefit Management Working Group

Jeff J. Guo, PhD,[1] Swapnil Pandey, MS,[2] John Doyle, PhD,[3,4] Boyang Bian, MS,[1] Yvonne Lis, PhD,[4] Dennis W. Raisch, PhD[5]

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ABSTRACT

Objective: Although regulatory authorities evaluate the risks and benefits of any new drug therapy during the new drug-approval process, quantitative risk–benefit assessment (RBA) is not typically performed, nor is it presented in a consistent and integrated framework when it is used. Our purpose is to identify and describe published quantitative RBA methods for pharmaceuticals.

Methods: Using MEDLINE and other Internet-based search engines, a systematic literature review was performed to identify quantitative methodologies for RBA. These distinct RBA approaches were summarized to highlight the implications of their differences for the pharmaceutical industry and regulatory agencies.

Results: Theoretical models, parameters, and key features were reviewed and compared for the 12 quantitative RBA methods identified in the literature, including the Quantitative Framework for Risk and Benefit Assessment, benefit-less-risk analysis, the quality-adjusted time without symptoms and toxicity, number needed to treat (NNT), and number needed to harm and their relative-value-adjusted versions, minimum clinical efficacy, incremental net health benefit, the risk–benefit plane (RBP), the probabilistic simulation method, multicriteria decision analysis (MCDA), the risk–benefit contour (RBC), and the stated preference method (SPM). Whereas some approaches (e.g., NNT) rely on subjective weighting schemes or nonstatistical assessments, other methods (e.g., RBP, MCDA, RBC, and SPM) assess joint distributions of benefit and risk.

Conclusions: Several quantitative RBA methods are available that could be used to help lessen concern over subjective drug assessments and to help guide authorities toward more objective and transparent decision-making. When evaluating a new drug therapy, we recommend the use of multiple RBA approaches across different therapeutic indications and treatment populations in order to bound the risk–benefit profile.

Keywords: drug safety, incremental risk–benefit ratio, multicriteria decision analysis, number needed to treat, risk–benefit assessment, risk–benefit plane, stated preference method.

Topics for public health & health policy

- Immunization program evaluation
- Rare disease treatment and policy
- Insurance coverage and accessibility
- Reimbursement policy
- Drug pricing
- Hospital formulary
- Chronic diseases and impacts for society

Example#5

Drug Safety Surveillance in China and Other Countries: A Review and Comparison

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ABSTRACT

Objective: Drug safety and postmarketing surveillance have become important public health issues in China. This study reviews the relatively new drug safety surveillance system in China and compares it with the systems in the United States and Europe.

Methods: An extensive literature review was conducted in the following four areas: 1) the organizational structure of the State Food and Drug Administration (SFDA) in China; 2) the development of an adverse drug reaction (ADR) monitoring system in China; 3) regulatory issues related to drug safety in China; and 4) similarities and differences between drug safety surveillance in China and surveillance in the United States and Europe.

Results: The SFDA oversees an extensive network of drug safety "watchdogs," including the China National Center for ADR Monitoring and 32 regional centers throughout China. China's system has faced a number of recent challenges. It has had to respond quickly to the withdrawal of various high-profile drugs like Vioxx (rofecoxib) and Baycol (cerivastatin) from other markets. Together with China's Ministry of Health, the SFDA has faced several unique drug safety events. Three of these events, involving the injectable form of the heartleaf houttuynia herb (Yu Xing Cao), Armillarisin A injections, and clindamycin glucose infusion (Xinfu), are discussed. The rapid development of drug safety surveillance in China is manifested in extensive organizational structure, development of large databases, and laws and regulations supporting drug safety. The two major laws are the China Drug Administration Law issued in February 2001 and the Regulation for the Administration of ADR Reporting and Monitoring issued in March 2004. The study also discusses and compares recent developments in drug safety surveillance in the United States and the European Union. These developments will most likely have implications for the Chinese system in the near future.

Conclusions: While postmarketing surveillance guidelines are not yet available in China, we fully expect their eventual issuance after adaptation to the particular culture and clinical practices in China.

Keywords: adverse drug reaction, China, drug safety, surveillance.

Value in Health Regional Issues

ASIA • LATIN AMERICA • CENTRAL & EASTERN EUROPE, WESTERN ASIA, AND AFRICA

***Value in Health Regional Issues (ViHRI)*:**
How to become a quality peer-reviewer?

Presented by the ViHRI Asia Editorial Board

Peer-Review

- Peer review is at the heart of the scientific method.
- Peer-review journal is a high-standard journal.
- Basically someone's research must survive the scrutiny of experts before it is presented to the larger scientific community;
- Peer-review is by no means a perfect system, it is still the best system of scientific quality control;
- Peer-review is such a central part of the scientific process:
  - Reviewers can identify questionable scientific findings, and
  - Authors can provide objections to the rigor of review.

Reviewers (also called Referees)

- Reviewers (or Referees) are experts in a particular topic area or study field.
- They have the relevant research experience and knowledge to evaluate:
  - Study methods,
  - Result accuracy,
  - Appropriate interpretations, and
  - Reasonable limitations/discussions.

Role of Reviewers

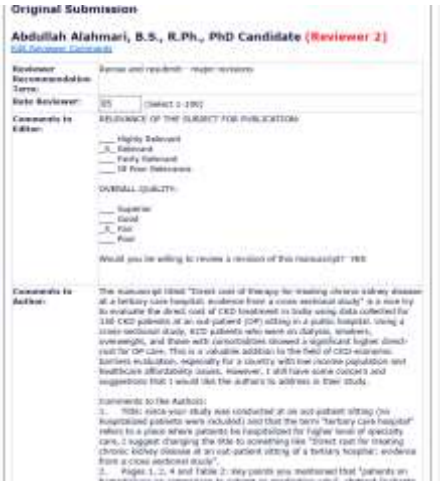
- For authors, reviewers should provide useful comments:
  - General impressions about the manuscript (both strong points and week points)
  - Specific problems, such as:
    - inappropriate research design,
    - inadequate data analysis,
    - limited sample size,
    - inappropriate outcome/dependent variables,
    - fail to control confounding variables,
    - wrong interpretation,
    - major limitation,
    - misspelling, or table-design, or figure-design, etc.
- For Editors, reviewers should alert the editor to any of above problems, and make recommendations as to whether a paper should be accepted, returned to the authors for revisions, or rejected.
- Referees are *not* expected to replicate results or (necessarily) to be able to identify deliberate fraud.

Editor's page for VIHRI

Quality Review

- Quality review increases the quality of manuscripts, and quality manuscript increases the quality of journal;
- Speedy review accelerates the editorial process and speed-up the publication;
  - Speed-up editorial process will satisfy authors.
- Our Editors usually score (0-100) the quality of reviewer for each manuscript review.
  - Higher quality review will be helpful and encouraged.

Example of Reviewer's Comments



Original Submission

Abdullah Alahmari, B.S., R.Ph., PhD Candidate (Reviewer 2)

Edit Reviewer Comments

Reviewer Recommendation Term: Revise and resubmit - major revisions

Date Reviewer: 05 (Select 1-100)

Comments to Editor:

RELEVANCE OF THE SUBJECT FOR PUBLICATION

___ Highly Relevant
_X_ Relevant
___ Fairly Relevant
___ Of Poor Relevance

OVERALL QUALITY:

___ Superior
___ Good
_X_ Fair
___ Poor

Would you be willing to review a revision of this manuscript? YES

Comments to Author:

The manuscript titled "Direct cost of therapy for treating chronic kidney disease at a tertiary care hospital: evidence from a cross sectional study" is a nice try to evaluate the direct cost of CKD treatment in India using data collected for 100 CKD patients at an out-patient (OP) setting in a public hospital. Using a cross-sectional study, ESD patients who were on dialysis, smokers, overweight, and those with comorbidities showed a significant higher direct-cost for OP care. This is a valuable addition to the field of CKD economic barriers evaluation, especially for a country with low income population and healthcare affordability issues. However, I still have some concern and suggestions that I would like the authors to address in their study.

Comments to the Authors:

1. Title: since your study was conducted at an out-patient setting (no hospitalized patients were included) and that the term "tertiary care hospital" refers to a place where patients be hospitalized for higher level of specialty care, I suggest changing the title to something like "Direct cost for treating chronic kidney disease at an out-patient setting of a tertiary hospital: evidence from a cross sectional study".

2. Pages 1, 2, 4 and Table 2: key points you mentioned that 'patients on

Different Review Comments for Different Kind of Manuscripts

- Experimental original research
  - design appropriate? Control employed? Ethical standard? Better way for research question?...
- Non-experimental original research
  - Design appropriate? Comparison? Confounding factors? Any major limitation?....
- Systematic review & review
- Methodological article
- Policy perspectives
- Brief report

Becoming a peer-reviewer for VIHRI

- Be a member of ISPOR (Asian-Consortium);
- Publish at least one manuscript in VIH/VIHRI;
- Publish one paper in Elsevier relevant journals;
- Accept our invitation for peer-reviewer and enter your interested areas by categories;
- Co-Editors can enroll a specific reviewer via system;
- Etc…