Recommendations of the Second Panel on Cost-Effectiveness in Health and Medicine

Gillian Sanders Schmidler PhD
Professor of Medicine
Duke University

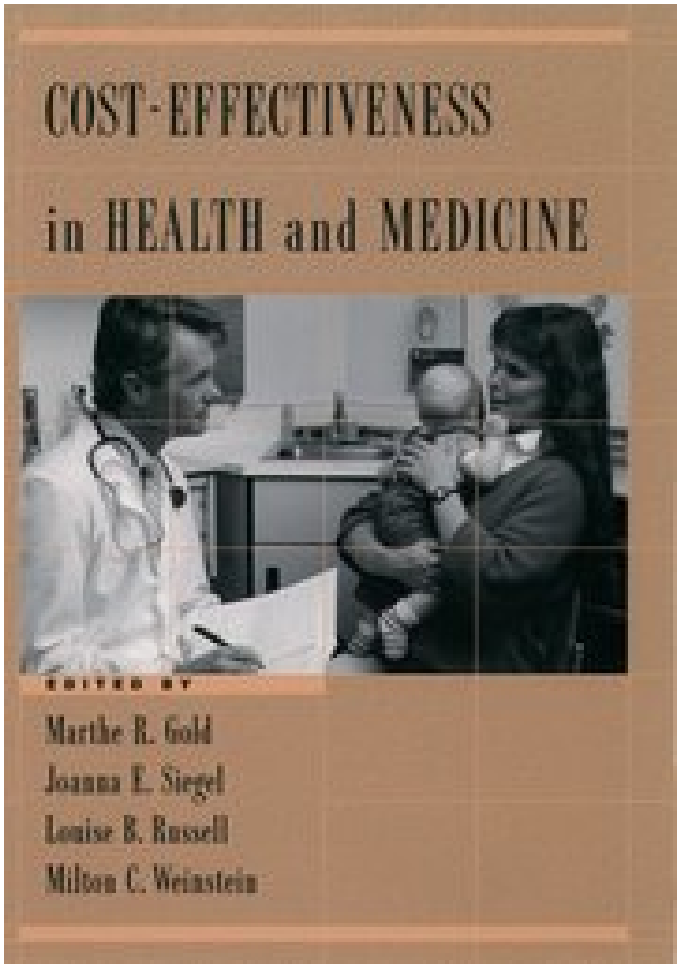
Poll Question #1

- What is your primary role in VA?
  - Student, trainee, or fellow
  - Clinician
  - Researcher
  - Administrator, manager or policy-maker
  - Other

Poll Question #2

- What best describes your familiarity with cost effectiveness analyses (CEA)?
  - I have performed my own CEA and am a CEA expert
  - I have performed my own CEA but am not an expert
  - I am a consumer of CEA, but have not performed CEA
  - I am unfamiliar with CEAs

Original Panel



- "The Gold Book" — 1996
- Recommendation for reference case
- Emphasis on cost/QALYs
- Became standard reference for CEA, cited more than 8,000 times

Selected events since Original Panel

1996	US Panel publishes “Gold Book”
1998	WHO CHOICE project
1999	NICE established in UK
2004	IQWiG founded in Germany
2006	IOM report calls for CEA use, including $/QALY, for regulations analyses
2008	ACIP establishes CEA guidelines for CDC
2010	ACA prohibits PCORI from using cost/QALY threshold
2012	2nd Panel formed
2014	Gates Reference Case for Economic Evaluation

2nd Panel

CO-CHAIRS: **Peter Neumann (Tufts Medical Center)** **Gillian Sanders Schmidler (Duke)**	
Anirban Basu (U Washington)	Doug Owens (VA/Stanford)
Dan Brock (Harvard)	Lisa Prosser (U Michigan)
David Feeny (McMaster)	Josh Salomon (Harvard)
Murray Krahn (U Toronto)	Mark Sculpher (U York)
Karen Kuntz (U Minnesota)	Tom Trikalinos (Brown)
David Meltzer (U Chicago)	
LEADERSHIP GROUP: Peter Neumann, Gillian Sanders, Ted Ganiats (UC San Diego), Joanna Siegel (AHRQ/PCORI), Louise Russell (Rutgers)	

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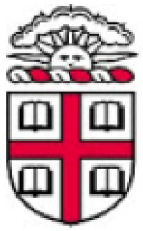

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University

UC San Diego
SCHOOL OF MEDICINE

Tufts Medical Center

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

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MEDICAL SCHOOL

THE UNIVERSITY OF
CHICAGO
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OF MEDICINE

Funding for 2nd Panel

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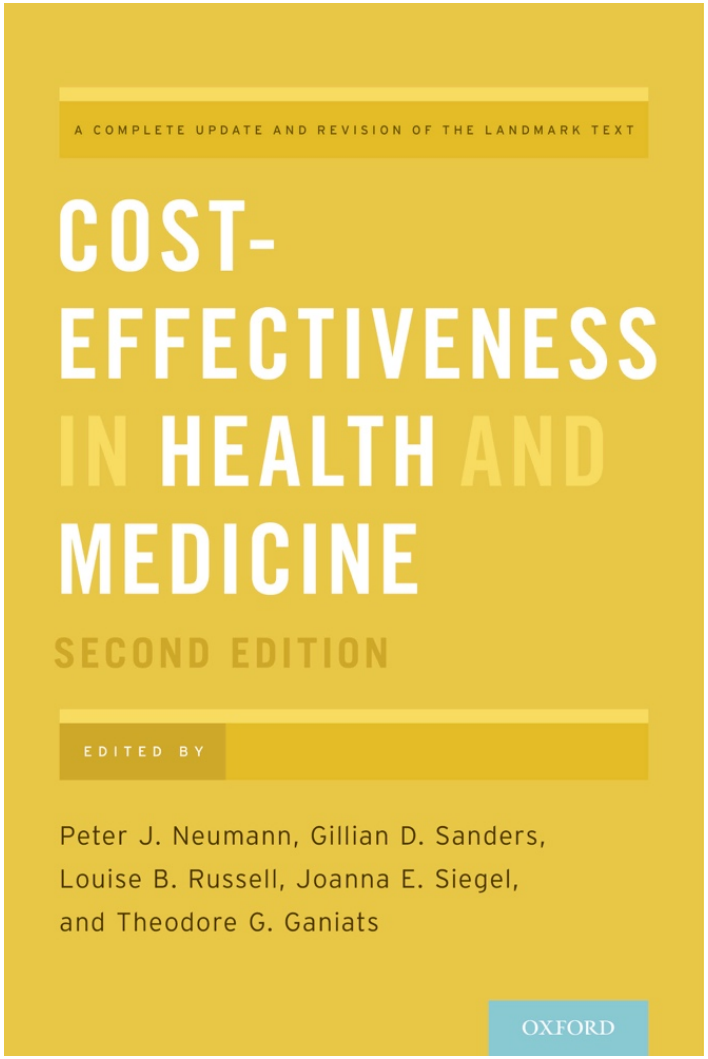
Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses

Second Panel on Cost-Effectiveness in Health and Medicine

Gillian D. Sanders, PhD; Peter J. Neumann, ScD; Anirban Basu, PhD; Dan W. Brock, PhD; David Feeny, PhD; Murray Krahn, MD, MSc; Karen M. Kuntz, ScD; David O. Meltzer, MD, PhD; Douglas K. Owens, MD, MS; Lisa A. Prosser, PhD; Joshua A. Salomon, PhD; Mark J. Sculpher, PhD; Thomas A. Trikalinos, MD; Louise B. Russell, PhD; Joanna E. Siegel, ScD; Theodore G. Ganiats, MD

September 13, 2016



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The Reference Case and Impact Inventory

Recommendations of the
Second Panel on Cost-Effectiveness
in Health and Medicine

Poll Question #3

- What perspective do you feel is **most important** when evaluating the cost effectiveness of available strategies?
  - Patient perspective
  - Healthcare perspective
  - Societal perspective

Original Panel's Recommendations

- Reference Case
- Societal Perspective
- Consider all parties affected
- Address specific decision contexts as needed

Experiences since the Original Panel

- Many CEAs, most not using the societal perspective
- Even when stating using societal perspective – important elements often omitted
- Decision makers using CEA – often have taken more focused perspective

Perspective: Second Panel's Considerations

- Appeal of societal perspective
- Potential to disregard revealed preferences of decision makers
- Is there a single "societal perspective"?
- Need to promote quality and comparability

Recommendation – Reference Cases:

- All studies represent a reference case analysis based on a **health sector perspective** and a reference case based on a **societal perspective**
- Measure health effects in QALYs
- Intended to enhance consistency and comparability

Recommendation: Health Sector Perspective

- Results should be summarized in incremental cost effectiveness ratio (ICER)
- Net monetary benefit (NMB) and net health benefit (NHB) may also be reported
- Range of cost effectiveness thresholds should be considered

Recommendation: Impact Inventory

- Include impact inventory table which lists the **health and non health impacts** of an intervention
- Main purpose is to ensure that **all consequences**, including those outside the formal healthcare sector, are considered regularly and comprehensively
- Provides a **framework** for organizing, thinking about, and presenting various types of consequences

Sector	Type of Impact (list category within each sector with unit of measure if relevant)[a]	Included in This Reference Case Analysis From...Perspective?		Notes on Sources of Evidence
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Formal Health Care Sector				
Health	Health outcomes (effects)			
	Longevity effects	☐	☐	
	Health-related quality-of-life effects	☐	☐	
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Designing a CEA

Designing a Cost-Effectiveness Analysis

- All aspects of the interventions that may affect their cost or effectiveness should be defined for the analysis.
  - Target population
  - The specific technologies
  - Type of personnel delivering the intervention
  - Site of delivery
  - Whether the service is “bundled” with other services, the frequency of the intervention, and its timing

- The scope of a study should be defined broadly enough to encompass the full range of groups of people affected by the intervention and all important consequences

Designing a Cost-Effectiveness Analysis

- Reference Case analyses should consider the full range of available and feasible options, including existing practice (the status quo) and a do- nothing option, as appropriate

- The time horizon adopted in a CEA should be long enough to capture all differences between options in relevant costs and effects

Valuing Costs

Valuing Costs: 2nd Panel Reference Cases

- A **societal reference** case
  - medical costs (current and future, related and unrelated) borne by third-party payers and paid for out-of-pocket by patients,
  - time costs of patients in seeking and receiving care,
  - time costs of informal (unpaid) caregivers,
  - transportation costs,
  - effects on future productivity and consumption, and
  - other costs and effects outside the healthcare sector.

Time Costs

- Time costs for patients and caregivers - real changes to the use of resources by the patients and society
- Time spent while seeking health care is usually thought to come from one’s leisure time
- Time spent by caregivers in providing care to patients considered to be a productive activity

Productivity

- Productivity costs reflect the lost production value due to a patient's health status.
  - Measure productivity costs/benefits explicitly and **NOT** subsume them in QALY measurements
  - **Deviates from First panel recommendations**

- Three types of productive time
  - (a) time spent in formal labor markets;
  - (b) time spent in informal labor markets; and
  - (c) time spent in household production.

- Productive time valued using the marginal pre-tax wage rate plus fringe benefits

Cost Component	Reference Case Perspective	
	Health Care	Societal
Formal Health Care Sector[a]		
Costs paid by third-party payers	Yes	Yes
Costs paid out-of-pocket by patients	Yes	Yes
Informal Health Care Sector		
Patient-time costs	No	Yes
Unpaid caregiver-time costs	No	Yes
Transportation costs	No	Yes
Non-Health Care Sectors		
Productivity	No	Yes
Consumption	No	Yes
Social services	No	Yes
Legal or criminal justice	No	Yes
Education	No	Yes
Housing	No	Yes
Environment	No	Yes
Other (eg, friction costs)	No	Yes

[a] Includes current and future costs related and unrelated to the condition under consideration.

Valuing Health Outcomes

Recommendations of the
Second Panel on Cost-Effectiveness
in Health and Medicine

Valuing Health Outcomes

- Conceptualization of Health-Related Quality of Life retained from the Original Panel
- Health consequences should be aggregated into a single measure using QALYs
- Use community preferences
- For the Reference Case recommend the use of generic preference-based measures
- We did **not** recommend the use of one particular measure

Methodological Challenges

- States worse than dead
- Special populations: children; some types of mental health problems; some types of cognitive impairment
- Capturing spillover effects on family members/caregiver(s)

Areas of Ongoing Controversy

- How to value non-health effects of policy
  - Value non-health outcomes (e.g., educational attainment, crime)
  - Value effects on budgets of non-health parts of government
- How to value effects on others
  - Within the family (esp. via utility effects and altruism)
  - Distributional effects

Modeling, Uncertainty, and Evidence Synthesis

Recommendations of the
Second Panel on Cost-Effectiveness
in Health and Medicine

Importance of Modeling as Framework

- Original Panel devoted little attention to modeling
- Analysts often face situations for which modeling can be informative
- Many country-specific guidelines for conducting CEAs for health technology appraisals include recommendations for developing decision models

Key Modeling Recommendations

- Initial conceptualization of model should be independent of data identification phase
- Full documentation and justification of structural assumptions should be provided
- Analyst should specify starting population whether they are analyzing a cohort or population
- Validation of model should occur throughout the conduct of a CEA
- Uncertainty analysis should be performed

Importance of Interpreting, Adjusting, Synthesizing Evidence for CEAs

- Identify the important model parameters – these should be informed by an evidence synthesis
- Provide a description and critique of evidence base
- The evidence synthesis should model variability of data, allow for between-study heterogeneity, be explicit about how bias is handled and how estimates were adjusted for transferability

Reporting CEAs

Reporting: Updated Recommendations

- Purpose
  - Transparency
  - Completeness
  - Comparability
- Key Updates
  - Structured abstract
  - Impact inventory
  - Intermediate outcomes
  - Disaggregated results

Structured Abstract Format

- Objective
- Intervention
- Target Population
- Perspectives
- Time horizon
- Discount rate
- Costing year
- Study Design
  (trial-based or model- based analysis; model type; size and characteristics of the simulated population)
- Data sources
- Outcome Measures
  (e.g., ICER in $/QALY, $/LY, or $/clinical endpoint; total costs; total QALYs)
- Results of base-case analysis
  (primary outcome measure(s); intermediate outcomes; disaggregated result)
- Results of uncertainty analysis
- Limitations
- Conclusions

Reporting Checklist

Introduction

- ❑ Background of the problem

Study Design and Scope

- ❑ Objectives
- ❑ Audience
- ❑ Type of Analysis
- ❑ Target population(s)
- ❑ Description of interventions & comparators
- ❑ Boundaries of the analysis (scope)
- ❑ Time horizon
- ❑ Analytic perspectives
- ❑ Whether this analysis meets the requirements of the reference case
- ❑ Analysis plan

Methods & Data

- ❑ Trial-based analysis or model based (plus additional descriptors)
- ❑ Key outcomes
- ❑ Complete information on data sources
- ❑ Methods for obtaining estimates of effectiveness /evidence synthesis
- ❑ Methods for estimating costs & preference weights
- ❑ Critique of data quality
- ❑ Costing year
- ❑ Method used to adjust costs io
- ❑ Type of currency
- ❑ Source and methods for obtaining expert judgment
- ❑ Discount rate(s)

Reporting Checklist, cont

Impact Inventory

- ❑ Full accounting of consequences within and outside of the health sector

Disclosures

- ❑ Statement of any potential conflicts of interest relating to funding source, collaborations, or outside interests

Results

- ❑ Results of model validation
- ❑ Reference case results: total costs & effectiveness, incremental costs & effectiveness, ICERs, measure(s) of uncertainty
- ❑ Disaggregated results for important categories of costs and/or outcomes
- ❑ Sensitivity analysis, other estimates of uncertainty
- ❑ Graphical representation of cost-effectiveness results & uncertainty analysis
- ❑ Aggregate cost and effectiveness information
- ❑ Secondary analyses

Discussion

- ❑ Summary of reference case results
- ❑ Summary of sensitivity of results to assumptions and uncertainties in the analysis
- ❑ Discussion of the study results in the context of related CEAs
- ❑ Discussion of ethical implications
- ❑ Distributive implications of an intervention
- ❑ Limitations of the study
- ❑ Relevance of study results to specific policy questions or decisions

Reporting: Summary

- Continued emphasis on transparency: enough detail should be provided to allow for replication
  - Structured abstract
  - Reporting checklist
  - Impact inventory
  - Intermediate outcomes & disaggregated results
  - Technical appendix
- New guidance on conflict of interest
- Going forward: sharing models/data, new formats for presenting results, communicating results in an era of emerging technologies

Ethical Issues in CEA

Ethical Issues in Constructing CEA

- Whose preferences should be used in evaluating health states? Should we value more the experience (ex post) a condition vs ex ante the societal experience?
- Does age matter? Is a QALY a QALY wherever it goes within a life?
- What costs and benefits should count in CEA?

Ethical Issues in the Use of CEA

- Should priority be give to the sickest or worst off? (the priority problem)
- When should large benefits to a small number of people outweigh small benefits to a large number of people? (the aggregation problem)
- When should best outcomes outweigh fair changes at some benefit? (the fair chances/best outcomes problem)
- Does CEA discriminate against people with disabilities?
- Why not use equity weights in CEA?
- Can we justify using cost/QALY thresholds?

DISCUSSION

Further questions? email gillian.sanders@duke.edu