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

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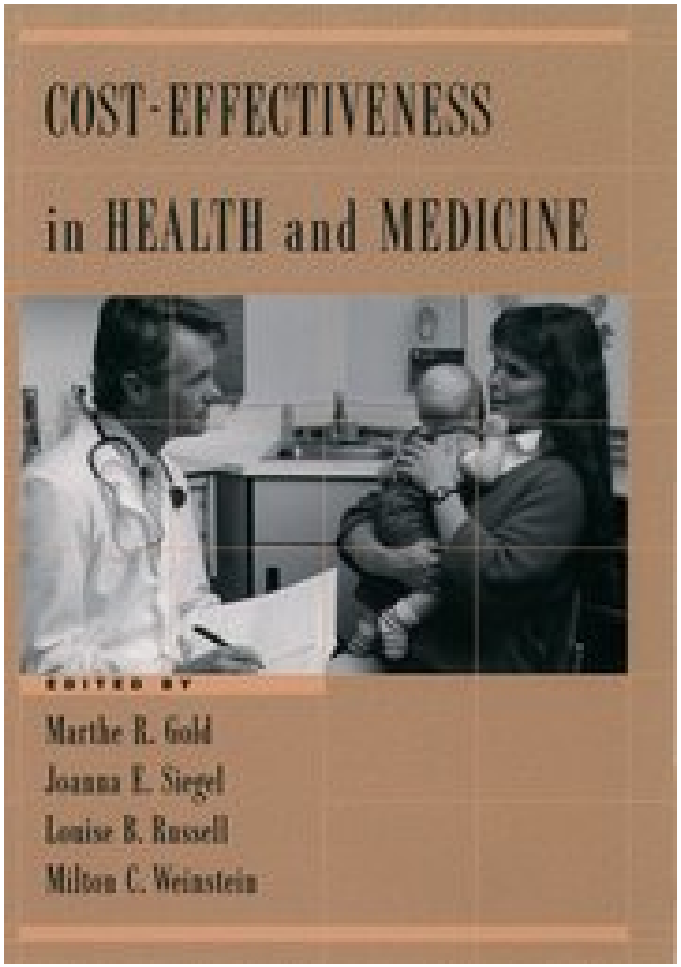
in Health and Medicine

#2ndPanelCEA

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

Original Panel

CO-CHAIRS: Louise Russell Milt Weinstein	
Norman Daniels	Bryan R. Luce
Dennis G. Fryback	Jeanne S. Mandelblatt
Alan M. Garber	Willard G. Manning, Jr.
David C. Hadorn	Donald L. Patrick
Mark S. Kamlet	Louise B. Russell
Joseph Lipscomb	George W. Torrance
	Milton C. Weinstein
Editors: Marthe Gold, Joanna Siegel, Louise Russell, Milt Weinstein	

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

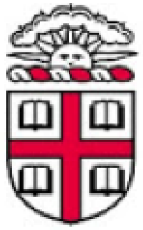
CO-CHAIRS: **Peter Neumann (Tufts Medical Center)** **Gillian Sanders Schmidler (Duke)**	
Anirban Basu (U Washington)	Doug Owens (VA/Stanford)
Dan Brock (Harvard)	Lisa Prosser (U Michigan)
David Feeny (McMaster)	Josh Salomon (Harvard)
Murray Krahn (U Toronto)	Mark Sculpher (U York)
Karen Kuntz (U Minnesota)	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)	

University of Minnesota
Driven to Discover℠

University of Washington

Stanford Medicine
Dept. of Medicine

University of York



Brown School of Public Health

Harvard T.H. Chan School of Public Health

Duke University School of Medicine

McMaster University

Tufts Medical Center

UC San Diego School of Medicine

University of Toronto

The State University of New Jersey RUTGERS

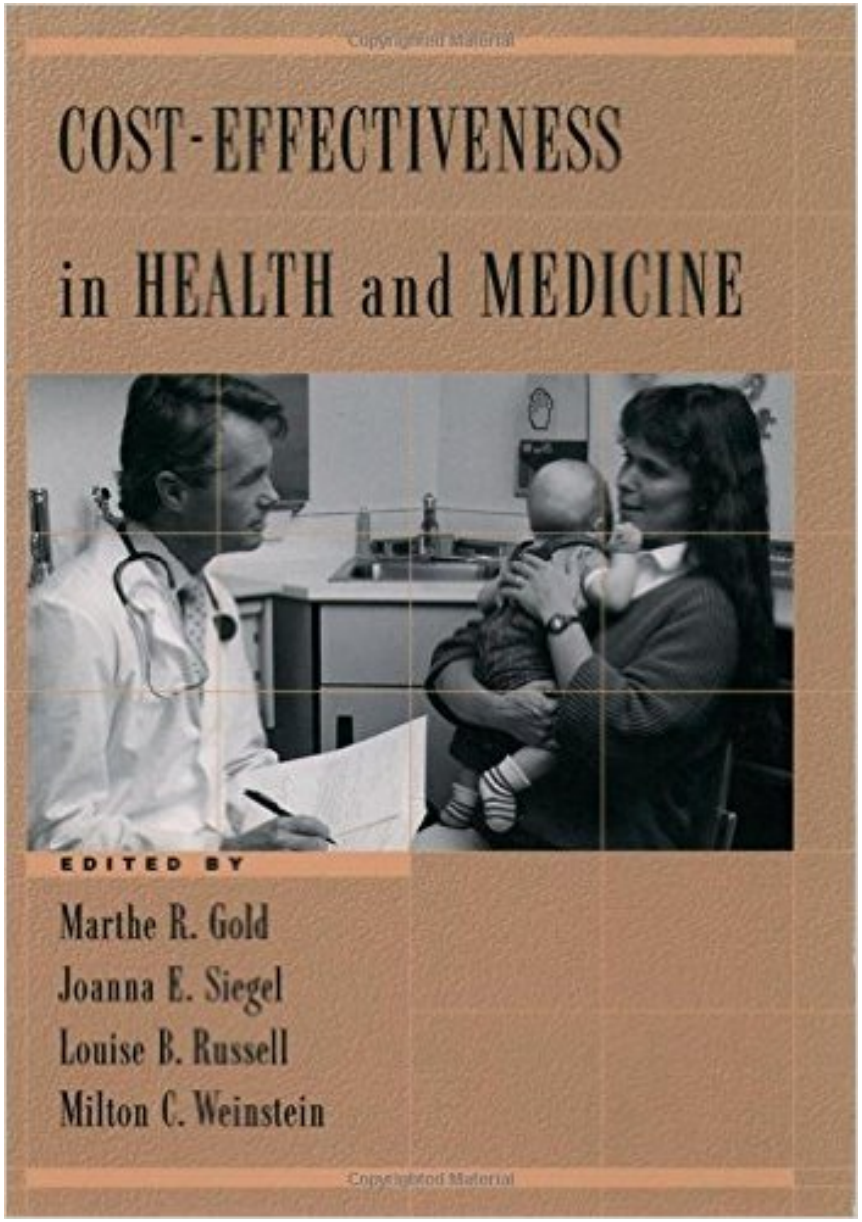
Harvard Medical School

University of Michigan

The University of Chicago Pritzker School of Medicine

Overview of Key Recommendations

Moderator: Peter Neumann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Funding for 2nd Panel

2nd Panel's Objectives

- Review the state of the field
- Provide recommendations to improve the quality and comparability of CEAs

Intended Audiences

- Policy makers
- Payers
- Researchers
- Clinicians
- Patients
- Others

The 2nd Panel's Process

Planning for an update

1st T/C

Bethesda

Seattle

Boston

JAMA
The Journal of the American Medical Association

2011 2012 2013 2014 2015 2016 2017

2nd Panel selected

Baltimore

Miami

Chapter reviews

Key considerations

- How closely to adhere to the original Panel?
- Theory vs. pragmatism
- How prescriptive?
- Analyst burden
- US vs. international

External review

- Chapters reviewed by external experts
- Chapters posted for public comment, Fall 2015
- Also…Rebecca Gray, Technical Editor (extraordinaire!)

JAMA®

The Journal of the American Medical Association

JAMA | Special Communication

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

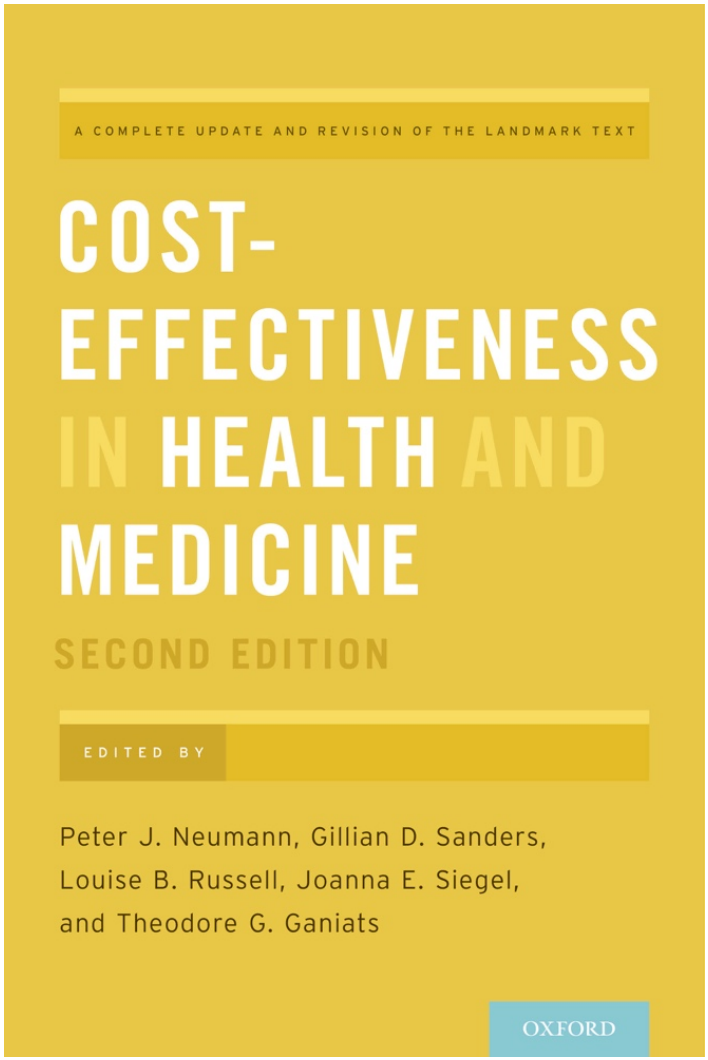

Table of Contents

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Today's Agenda

9:00 AM	**Overview and key recommendations**
10:30 AM	*Break*
10:50 AM	**Components of the Cost-Effectiveness Ratio**
11:40 AM	**DISCUSSION PANEL: The Second Panel's Recommendations**
12:30 PM	*Lunch*
1:30 PM	**Designing, Conducting, and Interpreting CEAs**
2:20 PM	**DISCUSSION PANEL: CEA and Policy Considerations**
3:10 PM	*Break*
3:30 PM	**DISCUSSION PANEL: Looking Ahead-the Next 20 Years**
4:30 PM	*Adjourn*

Overview and Key Recommendations

Foundations and Controversy
David Meltzer, MD, PhD, University of Chicago
Mark Sculpher, PhD, University of York
Key Recommendations: Reference Case and Impact Inventory
Gillian Sanders, PhD, Duke University
Louise Russell, PhD, Rutgers University
Lisa Prosser, PhD, University of Michigan

Foundations and Controversies

David Meltzer, MD, PhD

Recommendations of the
Second Panel on Cost-Effectiveness
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Role of Theory vs. Practical Decision Making

- CEA widely agreed to be a tool for maximizing desired outcomes from decisions subject to constraints
  - Decisions may be medical, public health or non-health spending or research
- Conventions (e.g., QALYs), variations (e.g., QoL) and controversies (e.g. distributional) about outcomes to measure
- Great diversity in which costs to consider, often tied to variation in perspective of a practical nature
- Theory (e.g., economic, psychological, ethical) can often inform these choices
  - Examples: net health benefits, future costs, value of information analysis

Need to align analysis with purpose vs. Comparability

- Need to align analysis with purpose suggests flexibility to assess costs benefits as relevant to decision-maker or decision-makers
  - Recommendation for Impact Table
- One key purpose is comparability across analyses
  - Comparability as opposed to alignment with purpose is motivation for reference case
  - Societal and Health Care Sector as commonly valued perspectives

Practitioner burden, publication challenges, and accessibility of findings

- Multiple references case and impact inventory create:
  - Added practitioner burden
  - Challenges in publication
  - Accessibility of findings
- Two reference cases and impact inventory were hard to agree upon because of these concerns

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

Foundations and Controversies

Mark Sculpher, PhD

Professor of Health Economics
Centre for Health Economics
University of York, UK

The role of the loan European

- Use of CEA in Europe (even UK) often over-stated
- But NICE provides something of an experiment
  - CEA central feature
  - Drives decisions across number of programmes
  - Health care and public health
  - NICE methods guide has sought to reflect the science
- CEA has had wins and defeats at NICE

Methods developments since 1st Panel

- Evidence synthesis
  - Network meta-analysis
  - Meta-regression
- Decision-analytic modelling
  - Cohort vs. individual-level simulation
  - Infectious disease modelling
- Uncertainty analysis
  - Probabilistic modelling and value of information
  - Reflected in policy decisions

Perspectives

- NICE perspectives vary by programme
  - Technology appraisal vs. public health
- Conceptual and practical issue: is there one 'societal perspective'?
  - Which costs and benefits?
  - How are these valued, weighed and aggregated?
  - Example of non-health outcomes
  - No single 'social welfare function'
  - Who defines the 'social welfare function'?
- Key contributions of 2nd Panel
  - Impact Inventory
  - Providing more than one perspective

Cost-effectiveness thresholds

- Appropriate cost-effectiveness ‘threshold’ key issue for NICE
- Conceptually clear: should represent opportunity costs
- Empirically unclear: NICE ‘thresholds’ have no empirical basis
- Debate in USA conflates two different questions:
  - How to allocate system’s current financial resources
  - How to determine appropriate level of resource
- Health opportunity cost important for both questions
- ‘Demand side’ concepts (willingness to pay) still supported
- Contributions of 2nd US Panel
  - Outline different views on ‘thresholds’
  - Key issue for policy implementation of CEA

The Reference Case and Impact Inventory

Gillian Sanders, PhD

Recommendations of the
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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 ICER
- NMB and NHB may also be reported
- Range of CE 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

The Impact Inventory

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
		Health Care Sector	Societal	
Formal Health Care Sector				
Health	Health outcomes (effects)			
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- **Types of impact**

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- **Formal healthcare sector**

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- Formal healthcare sector
- **Informal healthcare sector**

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- **Non-healthcare sectors**

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For each type of impact (specific effect or cost), a checkbox indicates whether it is included in the reference case analysis from a particular perspective.

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Legal or Criminal Justice	Number of crimes related to intervention			
	Cost of crimes related to intervention			
Education	Impact of intervention on educational achievement of population			
Housing	Cost of intervention on home improvemen (eg, removing lead paint)			
Environment	Production of toxic waste pollution by intervention			
Other (specify)	Other impacts	NA	☐	

For each type of impact (specific effect or cost), a checkbox indicates whether it is included in the reference case analysis from a particular perspective.

Type of Impact (list category within each sector with unit of measure if relevant)[a]	Included in This Reference Case Analysis From...Perspective?	
	Health Care Sector	Societal
Health outcomes (effects)		
Longevity effects	☑	☑
Health-related quality-of-life effects	☑	☑
Other health effects (eg, adverse events and secondary transmissions of infections)	☑	☑

The Impact Inventory

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
		Health Care Sector	Societal	
Formal Health Care Sector				
Health	Health outcomes (effects)			
	Longevity effects	☐	☐	
	Health-related quality-of-life effects	☐	☐	
	Other health effects (eg, adverse events and secondary transmissions of infections)	☐	☐	
	Medical costs			
	Paid for by third-party payers	☐	☐	
	Paid for by patients out-of-pocket	☐	☐	
	Future related medical costs (payers and patients)	☐	☐	
	Future unrelated medical costs (payers and patients)			
Informal Health Care Sector				
Health	Patient-time costs			
	Unpaid caregiver-time costs			
	Transportation costs			
Non–Health Care Sectors (with examples of possible items)				
Productivity	Labor market earnings lost			
	Cost of unpaid lost productivity due to illn			
	Cost of uncompensated household produc			
Consumption	Future consumption unrelated to health			
Social Services	Cost of social services as part of interventi			
Legal or Criminal Justice	Number of crimes related to intervention			
	Cost of crimes related to intervention			
Education	Impact of intervention on educational achievement of population			
Housing	Cost of intervention on home improvemen (eg, removing lead paint)			
Environment	Production of toxic waste pollution by intervention	NA	☐	
Other (specify)	Other impacts	NA	☐	

For each type of impact (specific effect or cost), a checkbox indicates whether it is included in the reference case analysis from a particular perspective.

Type of Impact (list category within each sector with unit of measure if relevant)[a]	Included in This Reference Case Analysis From...Perspective?	
	Health Care Sector	Societal
Patient-time costs	NA	☑
Unpaid caregiver-time costs	NA	☑
Transportation costs	NA	☑

The Impact Inventory

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
		Health Care Sector	Societal	
Formal Health Care Sector				
Health	Health outcomes (effects)			
	Longevity effects	☐	☐	
	Health-related quality-of-life effects	☐	☐	
	Other health effects (eg, adverse events and secondary transmissions of infections)	☐	☐	
	Medical costs			
	Paid for by third-party payers	☐	☐	
	Paid for by patients out-of-pocket	☐	☐	
	Future related medical costs (payers and patients)			
	Future unrelated medical costs (payers and patients)			
Informal Health Care Sector				
Health	Patient-time costs			
	Unpaid caregiver-time costs			
	Transportation costs			
Non–Health Care Sectors (with examples of possible items)				
Productivity	Labor market earnings lost			
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Consumption	Future consumption unrelated to health			
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Legal or Criminal Justice	Number of crimes related to intervention			
	Cost of crimes related to intervention			
Education	Impact of intervention on educational achievement of population			
Housing	Cost of intervention on home improvemen (eg, removing lead paint)			
Environment	Production of toxic waste pollution by intervention			
Other (specify)	Other impacts			

For each type of impact (specific effect or cost), a checkbox indicates whether it is included in the reference case analysis from a particular perspective.

Type of Impact (list category within each sector with unit of measure if relevant)[a]	Included in This Reference Case Analysis From...Perspective?	
	Health Care Sector	Societal
Labor market earnings lost	NA	☑
Cost of unpaid lost productivity due to illness	NA	☑
Cost of uncompensated household production[b]	NA	☐
Future consumption unrelated to health	NA	☐
Cost of social services as part of intervention	NA	☑
Number of crimes related to intervention	NA	☐
Cost of crimes related to intervention	NA	☐

Louise Russell, PhD

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

Purpose and Use of the Impact Inventory

- Main purpose: to ensure that all consequences, including those outside the formal healthcare sector, are considered routinely and comprehensively.

- Provides a framework for organizing, thinking about, and presenting various types of consequences.

Recommendation 3B

Quantifying and Valuing Non-health Components in the Impact Inventory

Analysts should attempt to quantify and value nonhealth consequences in the Impact Inventory unless those consequences are likely to have a negligible effect on the result of the analysis.

Recommendation 3C

Summary and Disaggregated Measures

- It would be helpful to inform decision makers through the quantification and valuation of all health and nonhealth effects of interventions, and to summarize those effects in a single quantitative measure, such as an incremental cost-effectiveness ratio, net monetary benefit, or net health benefit.

- However, there are no widely agreed on methods for quantifying and valuing some of these broader effects in cost-effectiveness analyses.

Recommendation 3C, continued

Summary and Disaggregated Measures

- Analysts should present the items listed in the impact inventory in the form of disaggregated consequences across different sectors.
- It is also recommended that analysts use 1 or more summary measures, such as an incremental cost effectiveness ratio, net monetary benefit, or net health benefit, that include some or all of the items listed in the impact inventory.
- Analysts should clearly identify which items are included and how they are measured and valued, and provide a rationale for their methodological decisions.

JAMA letter

- A general framework describing the mechanisms of action of interventions, and their links to the items in the impact inventory, would increase the comparability and the effect of cost-effectiveness analyses. Development of such a framework, which corresponds to the structure of the impact inventory and suits most analyses, is an important future research need.

- In the meantime, the Panel’s recommendation 3C advises analysts to present both summary and disaggregated measures of costs and health outcomes but stops short of recommending a single summary measure.

Reporting CEAs

Lisa Prosser, PhD

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

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
- Data sources
- Outcome Measures
- Results of base-case analysis
- Results of uncertainty analysis
- Limitations
- Conclusions

Elements to include in Standard Abstract Format

- Objective
- Methods
  - ✓Intervention
  - ✓Target Population
  - ✓Perspectives
  - ✓Time horizon
  - ✓Discount rate
  - ✓Costing year
  - ✓Study Design
  - ✓Data sources
  - ✓Outcome Measures
- Results
  - ✓Results of base-case analysis
  - ✓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
- ❑ 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

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

Disclosures

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

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

Role of Impact Inventory

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
		Health Care Sector	Societal	
Formal Health Care Sector				
	Health outcomes (effects)			
Health				
	and patients)			
Informal Health Care Sector				
Health	Patient-time costs	NA	☐	
	Unpaid caregiver-time costs	NA	☐	
	Transportation costs	NA	☐	
Non-Health Care Sectors (with examples of possible items)				
Productivity	Labor market earnings lost	NA	☐	
	Cost of unpaid lost productivity due to illness	NA	☐	
	Cost of uncompensated household production[b]	NA	☐	
Consumption	Future consumption unrelated to health	NA	☐	
Social Services	Cost of social services as part of intervention	NA	☐	
Legal or Criminal Justice	Number of crimes related to intervention	NA	☐	
	Cost of crimes related to intervention	NA	☐	
Education	Impact of intervention on educational achievement of population	NA	☐	
Housing	Cost of intervention on home improvements (eg, removing lead paint)	NA	☐	
Environment	Production of toxic waste pollution by intervention	NA	☐	
Other (specify)	Other impacts	NA	☐	

IMPACT INVENTORY

Journal Submission/ Peer Review

Table A1. Quadrivalent Vaccine - Vaccine Efficacy Parameter Estimates

	Proposed Estimates		Source
HPV Infection Type	3 doses	Relative efficacy of 2 doses	
	(85% – 100%)	(50% – 100%)	
31/33/45/52/58	22% (0% -53%)	0% (0% -100%)	(8-10)

Technical Appendix

Highlighted Recommendations

2. For peer review, journal article plus **technical appendix, including impact inventory**

3. Use of a **structured abstract** for the journal article.

7. Reporting of **intermediate health outcomes, disaggregated results,** and **measure of robustness** as part of recommended set of results.

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