Introduction to Costs And Outcomes Research

Parts 1 and 2

Methods and Examples of Costs and Outcomes Evaluation For Decision-Making in Health Care Organizations

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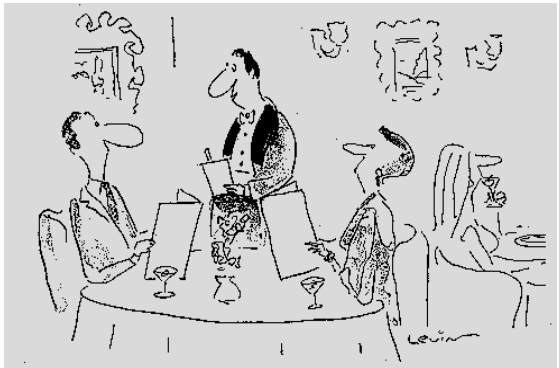
Outline of Presentation

- Principles and methods of economic evaluation in health care.
  - Definitions, standards and accepted practices.
- Decision-rules and practical approaches.
  - When is an intervention cost-effective?
- Example:
  - A CEA of coated central venous catheters

Economic Evaluation in Health Care

- **Definition**
  - Does a medical intervention (drug, device, program, surgery) when used to prevent or treat a condition improve health outcomes in patients enough to justify the additional dollars spent compared to the existing medical strategy?

Value for Money



Might I suggest the most expensive wine and the most expensive dinner?

The New Yorker 12/7/98

Economic Evaluation in Health Care

- Is not:
  - A method to show which interventions reduce costs.
  - A method that removes individual (patient) or group responsibility for making clinical and financial decisions about interventions. That is, decision-makers should not act solely on the information supplied by a cost-effectiveness study.
  - A tool that considers all decision-making factors, such as equity and justice, political realities, feasibility, budget impact and customer/provider perception.

Economic Evaluation Methods

Method	Cost	Health Benefit
Cost-of-illness (COI)	Dollars	NA
Cost-benefit (CBA)	Dollars	Dollars
Cost-effectiveness (CEA)	Dollars	Natural units
Cost-utility (CUA) survival	Dollars	Quality adjusted
Cost-minimization (CMA)	Dollars	Benefits are equivalent
Cost-consequence (CCA)	Dollars	All benefits listed in a balance sheet format.
Economic models	Simulation of costs and outcomes using data from trials and other sources.	

Benefit-Cost Analysis

- Principles/Framework
- The Procedure
- Benefit-Cost Criteria: The Fundamental Rule
- Applying the Fundamental Rule(s)
  - Accepting or rejecting a single project/program
  - Choosing one of a number of discrete and indivisible projects or programs
  - Accepting or rejecting a number of projects subject to a resource constraint

Principles/Framework

- Today: BCA is used to evaluate public expenditure decisions.
  - BCA requires systematic enumeration of ALL benefits and costs:
    - tangible and intangible,
    - whether readily quantifiable or difficult to measure,
    - that will accrue to ALL members of society if a project or program is adopted.

Definition

Health care evaluations can be thought of in more general cost and benefit terms where the allocation problems are identified in terms of a production relationship between resource inputs used and health outputs gained. (A. Williams, 1974)

Defining cost-benefit analysis

Definition

CBA compares the discounted future streams of incremental program benefits with incremental program costs. The difference between these two streams being the net social benefit <cost> of the program.

- A positive net social benefit indicates that a program is worthwhile
- An alternative is the ratio of benefits to costs; B/C > unity

Definition

CBA is a full economic evaluation because all program outputs must be measured and valued. The literature is replete with partial analyses - ones in which the value of health outcomes are not considered.

Definition

Early example of a published CBA.

Koplan et al, Pertussis vaccine: an analysis of benefits, risks and costs, NEJM, 1979

Costs => Vaccine price, tx of vaccine-related complications, tx of pertussis cases despite being vaccinated.

Benefits => Savings in medical care costs by preventing pertussis and its sequelae.

What about lives saved?

Principles/Framework

- BCA incorporates a description of the total monetary outcomes of various projects and a RULE for choosing among them in accordance with the decision-maker's preferences.
- Some view BCA as an *ex ante* method –
  - to evaluate a program before it is undertaken,
  - to decide in what form (and in what scale) it should be undertaken,
  - or whether it should be undertaken at all.

Principles/Framework

- Rationale for benefit-cost analysis is efficiency.
  - It aims to ensure that public resources are put to their most valuable use, including the very real possibility of leaving them in private hands. The "do nothing" or "do not spend" option.

Principles/Framework

- Benefit-cost analysis is most useful for evaluating well-defined projects.
  - For example, selecting from among alternative sites for a new public hospital or choosing among alternative pollution-control systems.
  - For less well-defined programs or policy options, such as Medicare reform, benefit-cost analysis is more useful as a paradigm where conceptualization of the costs and benefits of alternative approaches would be useful.

Principles/Framework

- Liabilities of BCA (and CEA):
  - Is vulnerable to misapplication through carelessness, naivete, or outright deception.
  - The technique is dangerous to the extent that it conveys an aura of precision and objectivity.
  - BCAs can be no more precise than the assumptions and valuations that they employ.
  - Analysts have powerful incentives to involve submerged assumptions, unfairly chosen valuations or alternatives, and purposeful misestimates in BCA.

Principles/Framework

BCA are somewhat less susceptible to manipulation than the more informal approaches to decision-making, for they are designed to highlight the ingredients that go into the choice.

BCA is a methodology with which we pursue efficiency and which has the effect of limiting the vagaries of the political process.

Stokey and Zeckhauser. A Primer for Policy Analysis. 1978. WW Norton and Company, New York

The Procedure

- Five steps:
  1. the projects or programs to be assessed are identified.
  2. ALL impacts, both favorable and unfavorable, present and future, on all society are determined.
  3. values are assigned (monetary) to these impacts. Favorable impacts as benefits and unfavorable impacts as costs.
  4. the net benefit (total benefit minus total costs) is calculated and the benefit:cost ratio is calculated.
  5. resources are allocated according to decision rules.

Assigning Monetary Values to Health Outcomes

- **Three general approaches to estimating the value of a statistical life.**
  - Human capital - health care is an investment in a persons human capital. The payback on this investment can be valued in terms of renewed or increased production.
  - Revealed preferences - Based on individuals preference for risky health situations in exchange for money.
  - Willingness-to-pay - A survey approach designed to elicit a market price from potential consumers of a program.

Compensation Test

- Kaldor-Hicks Criterion:
  - All programs with net social benefit > 0 are "worthwhile" to undertake. That is, society is compensated for its monetary investment in the program. Thus, for a single project evaluation if the net benefits are > 0 the program should be funded.
    - The result is independent of the real budget constraint.
    - It is possible that all evaluated projects produce a negative net benefit in which case the "do nothing" alternative would be preferred.

Applying the Compensation Test

- Accepting or Rejecting a Single Project:
  - Suppose a project under consideration is a new public hospital for the City of Seattle. The availability of resources is not an issue. The discounted cost of the building is estimated at $500 million, discounted benefits in the form of net savings over the years on reduced maintenance costs are worth $400 million and discounted net savings on energy costs are worth $150 million. The net benefit is:

    $400m +$150m - $500m = $50m

Applying the Compensation Test

- Accepting or Rejecting a Single Project:
  - The compensation test for BCA would argue in favor of funding the new hospital purely on efficiency grounds. There are no variables in the simple model concerning alternative uses for $500 million or whether society is "better off" from a justice/equity standpoint by investing in the new hospital.

Concerns with net benefit and application to multiple choices

Program	Societal Benefits	Societal Costs	Net Benefits	B:C Ratio
A	3.0	2.0	1.0	1.5:1
B	2.0	1.0	1.0	2:1
C	4.0	3.0	1.0	1.3:1
D (1/2 scale of C)	2.2	2.0	0.2	1.1:1

1. Programs produce the same net benefit at different levels of investment. Thus, there is no guidance to decision makers on how to allocate resources among the equivalent choices.
2. Programs with zero net benefit may be worthwhile to undertake.
3. Reduced scale projects do not give the same net benefit and BC ratio as full scale project.

Concerns with net benefit and application to multiple choices

Program	Societal Benefits	Societal Costs	Net Benefits	B:C Ratio
A	3.0	2.0	1.0	1.5:1
B	2.0	1.0	1.0	2:1
C	4.0	3.0	1.0	1.3:1
D (1/2 scale of C)	2.2	2.0	0.2	1.1:1

Resource Allocation Decision Rule for Multiple Choice:

1. Rank options according to benefit:cost ratio.
2. Allocate funds from the budget to pay for programs until the funds are exhausted.
   - If budget was $5m then => B, A, D
3. Consider reduced scale investments as appropriate.

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Cost-Effectiveness Analysis

- Definition:
  - A formal method for comparing the cost and benefits of a medical intervention in order to determine whether it is of sufficient value to adopt or reimburse.
  - Costs [C] are measured in physical units and valued in monetary units.
  - Effectiveness [E] is measured in natural units - clinical outcome measure (symptom-free time), years of added life (quality-adjusted years of life), averted events (fractures avoided)
- Model:
  - $[\{C_{int1} + C_{care1} + C_{se1} + C_{am1}\} - \{C_{int2} + C_{care2} + C_{se2} + C_{am2}\}] / [E_1 - E_2]$

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The Incremental Cost-effectiveness Ratio

Incremental Cost-Effectiveness Ratio (ICER) $= \frac{\Delta C}{\Delta E} = \frac{C_T - C_C}{E_T - E_C}$

The ICER relates the difference in total costs (C) of two interventions to the difference in health benefit (E).

Def. Does a medical intervention (drug, device, program, surgery) when used to prevent or treat a condition improve health outcomes in patients enough to justify the additional dollars spent compared to existing medical strategy?

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Simple Misconceptions

- Expensive interventions are not cost-effective.
- Inexpensive interventions are cost-effective.

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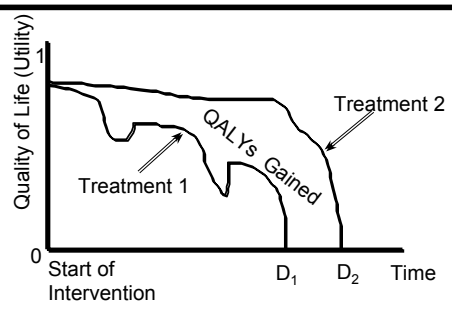
The quality-adjusted survival endpoint in cost-effectiveness analysis.



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The Incremental CEA Ratio

- Definition:
  - A measure of the expected incremental cost of using a new technology in relation to the expected gain in outcome. "Value"
- Issues with the CEA ratio.
  - CI of the ratio. Interdependency of costs and benefits leads to bias in covariance estimation.
  - Double-counting. The US panel recommends that the denominator be free from cost measures. Ratios of the nature "cost per event-avoided" should be avoided because of double counting.
  - Comparability. Cost/QALY is not always feasible or relevant. If CEA studies are to be used for resource allocation, then there is a need for a standardized measure.

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Methods and Issues

- Evidence of effectiveness
  - Efficacy implies that clinical strategies can achieve their stated goal of improving clinical outcomes when used in optimal circumstances.
  - Effectiveness implies that the clinical strategy "works" when used in general clinical practice among a wide range of patients.

Methods and Issues

- Issues in determining effectiveness of clinical strategies.
  - Which measures to select?
    - Intermediate or final outcome measures. How to link intermediate with final outcome measure? Can you model effectiveness from efficacy data?
  - Which studies to select?
    - What if conflicting evidence? Do you use evidence-based approaches?
    - Single trial, pooled weighted average, or formal meta-analysis
  - When in the life cycle of the technology do you evaluate effectiveness?
    - It is always too early in the life cycle until it is too late.

Methods and Issues

- Evidence of effectiveness
  - Requires demonstration that a new technology does more good than harm compared with the existing technology when applied to a target group of patients when delivered by a defined group of providers.
  - High quality evidence will result in a quantitative estimate of the relative effectiveness of the new technology that is both valid (unbiased) and reliable (precise and reproducible).

Methods and Issues

- Evidence of effectiveness
  - Alternative study designs for determining effectiveness:
    - RCTs - High internal validity, low generalizability
      - Large pragmatic trials to improve generalizability
    - Observational - Low internal validity, moderate to high generalizability, nonrandom selection bias
      - Case series for surgical interventions
    - Meta-analysis - Internal validity, low-high generalizability

Methods and Issues

- Issues in determining effectiveness of clinical strategies.
  - Choice of alternative therapies?
    - Because CEA studies are comparative, clinical outcomes of a new technology must be compared to an alternative. Controlled trials frequently use an alternative therapy that may not be appropriate for CEA studies (e.g. placebo). How does the analyst incorporate the appropriate alternative?
      - From RCTs and MA.
      - Modeling studies based on literature estimates of different alternatives. However, limitations of the literature based estimates (e.g. study design, sample size and power, population characteristics, etc.) apply.
      - Historical cohort of alternatives.

Methods and Issues

- Issues in determining effectiveness of clinical strategies.
  - Time horizon and modeling issues?
    - Many effects of interventions are delayed and not observable in a clinical trial time frame.
      - Example:

        RCT over 5 years Pr of death is 0.1 in treatment and 0.2 in control, a 50% relative risk reduction. The therapy in this example improves life expectancy by delaying premature death.

        How do you determine lifetime effectiveness of the intervention?

Methods and Issues

- Issues in determining effectiveness of clinical strategies.
  - Clinical use of the technology?
    - Often a new technology is compared to an existing and well established technology. The new technology is frequently disadvantaged in clinical studies. For example, treatment failures of established therapies may constitute the sample for the clinical study.
    - How does one control or account for the learning curve in the clinical experience of the alternative strategies? This issue is rarely considered in economic analyses.

Methods and Issues

- Measuring resource use and costs for CEAs.
  - Duration of study period and calculation of cost.
    - Restricting cost analyses to a fixed time period after the intervention may introduce bias. Since a disproportionate amount of expenditures is made when a patient is near death, the treatment offering the shorter life expectancy will have higher costs, all other things equal. One solution is to lengthen the study duration.

Methods and Issues

- Measuring resource use and costs for CEAs.
  - International studies
    - Frequently, new medical technologies will be assessed using multicenter, multinational trials. Recent examples include the GUSTO trial and the 4S trial. What are the costing issues?
      - Subset data from the country of interest.
      - Pool all utilization data and use price estimates from one country.
      - Derive a weighted price by converting all expenditure estimates from each country using monetary conversion factors.
        - » What are the biases introduced by each of these methods?

Recommendations of the US PHS Panel on Cost Effectiveness in Health and Medicine

- The reference case (base case) should be based on the societal perspective even if another perspective is chosen.
- CEAs are an aid to decision-making and not a complete procedure for making decisions because they can not incorporate all the values relevant to the decisions.
- The use of any one method (CEA, CUA, CBA, CCA) does not preclude the use of any of the others.

Recommendations of the US PHS Panel on Cost Effectiveness in Health and Medicine

- All aspects of the interventions that may affect their cost or effectiveness should be defined for the analysis.
- The reference case should compare the intervention of interest to existing practice. If existing practice is not cost-effective, then the analyst should include other relevant options such as the best-available alternative, a viable low-cost alternative or a do-nothing strategy.

Recommendations of the US PHS Panel on Cost Effectiveness in Health and Medicine

- When varying levels of program intensity are relevant, alternative options should be included in the analysis.
- Boundaries of a study should be defined broadly enough to encompass the range of groups of people affected by the intervention and all types of costs and health consequences.
- The time horizon adopted in a CEA should be long enough to capture all relevant future effects of a health care intervention.

Recommendations of the US PHS Panel on Cost Effectiveness in Health and Medicine

- All decisions relative to costs and health outcomes to include should strike a balance between expense and difficulty on the one hand and potential importance to the study analysis on the other.
- The estimates of resource consumption, effects and preferences are those for the population or group that is actually affected by the intervention.
- QALYs are preferred and community preference weights are required for the reference case.

Recommendations of the US PHS Panel on Cost Effectiveness in Health and Medicine

- In the reference case analysis, health-related quality of life should be captured by an instrument that implicitly incorporates the effects of morbidity on productivity and leisure.
- Income effects related to changes in health status (disability) should be reflected in the denominator of the CEA. Time and income effects (productivity loss) unrelated to health status should be counted in the numerator.
- Data for CEAs should be derived from best available sources. Expert judgement should be used to fill in values where no data exist.

Recommendations of the US PHS Panel on Cost Effectiveness in Health and Medicine

- Evaluation of effectiveness should incorporate both benefits and harms.
- Resource use and costs should be included in the numerator only and should reflect an opportunity cost approach and not an accounting approach.
- At the analysts discretion, the reference case may either include or exclude health care costs for unrelated illness in added years of life.

Recommendations of the US PHS Panel on Cost Effectiveness in Health and Medicine

- In the reference case analysis, costs and benefits should be discounted at the same rate of 0, 3 and 5 percent. 3% is the reference case.

Applying CEA to resource allocation

Costs, effectiveness, and quality of life of treating patients with 2 alternatives

Treatment	Costs	Effect	Quality of Life	QALY
A	$20,000	4.5 years	0.80	3.6
B	$10,000	3.5 years	0.90	3.15

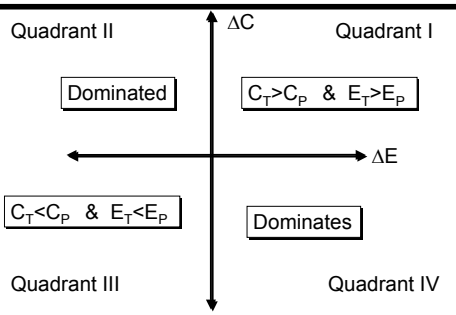
Applying CEA to resource allocation

What is the additional cost per incremental gain in health?

$$\frac{\$20,000 - \$10,000}{4.5 \text{ years} - 3.5 \text{ years}} = \$10,000 \text{ per life-year gained}$$

$$\frac{\$20,000 - \$10,000}{3.6 \text{ QALYs} - 3.15 \text{ QALYs}} = \$22,222 \text{ per QALY gained}$$

Interpretation of CEA results



Cost-effectiveness of commonly used interventions (per life-year gained) in 1997 dollars

ABMT for relapsed Hodgkins	$421,000
Liver transplantation	$237,000
Mammography (<50 yo)	$232,000
2-vessel CABG	$106,000
ACE for moderate HTN	$82,600
Mammography (>50 yo)	$20-50,000
HCTZ for moderate HTN	$23,500
Left main CABG	$17,400
Intervention A	$10,000
Smoking cessation (men)	$1,300

What is the budget constraint of the payer?

ABMT for relapsed Hodgkins	$421,000
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League Tables

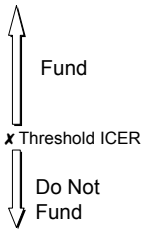
Intervention	Incremental CER
A	$25,000/QALY
B	$33,000/QALY
C	$35,000/QALY
D	$40,000/QALY
E	$60,000/QALY

Resource allocation decision rules for CEA

- Absolute Budget Constraint Rule:
  - Implement interventions, starting with the most cost-effective alternatives, until health care budget is exhausted.
    - The Oregon Medicaid experiment.
- Relative Budget Constraint Rule:
  - Implement all interventions that fall below a stated threshold (budget constraint) ICER.

Budget Constraint Application

Intervention	Incremental CER
A	$25,000/QALY
B	$33,000/QALY
C	$35,000/QALY
D	$40,000/QALY
E	$60,000/QALY



Limitations of league tables

- Methods and measurements:
  - All resources measured and valued.
  - Perspective and discount rate used.
  - Measurement of utility.
  - Relevant comparator.
  - The impact of uncertainty on point estimates of ICER.

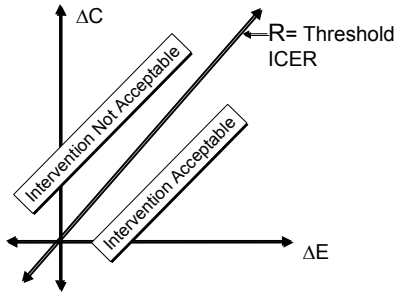
Limitations of the decision rules

- Implementation for decision making
  - Under the "relative" rule, a decision-maker could exhaust resources on cost-effective therapies. There is no absolute financial constraint.
  - Under the "absolute" rule, some interventions judged to be cost-effective would not be funded.
  - If an equal cost-effectiveness ratio (i.e., same cost/QALY) was achieved for two drugs in different therapeutic categories, a budget impact analysis would show a preference for the drug used to treat a disease with a lower prevalence, since this would lead to lower expenditures, all other things equal.

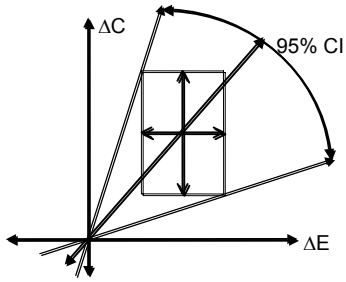
Point estimates and confidence limits: budget constraint of $50,000

Intervention	Incremental CER	95% CI	
A	$25,000/QALY	$23,000 - $27,000	✓
B	$33,000/QALY	$25,000 - $65,000	?
C	$35,000/QALY	$31,000 - $37,000	✓
D	$40,000/QALY	$30,000 - $50,000	✓
E	$60,000/QALY	$35,000 - $95,000	?

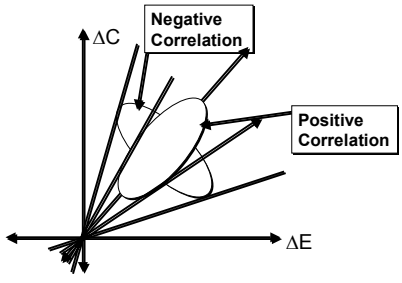
Budget constraint and CI estimation



Stochastic Methods: Box



Stochastic Methods: Confidence Ellipse



How would hospitals use CE information to make resource allocation decisions?

- Can hospitals and health systems apply CEA data to formulary decisions?
  - What is the decision-making model?
  - What is the level of sophistication of the evaluators?
  - Are hospitals ready to declare a budget constraint for technology consumption?

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Are Antiseptic-impregnated Central Venous Catheters Cost-effective?

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Catheter-related bloodstream infection (CR-BSI)

- 3 million central lines used per year in U.S.
- 3-7% of central lines lead to CR-BSI
- Approx. 150,000 cases per year in U.S.
- 10% to 25% attributable mortality rate
- Increased hospitalization and costs

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CR-BSI: prevention

- Aseptic insertion techniques
- Routine catheter replacement
- Antiseptic/Antibiotic catheters

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Are antiseptic catheters effective?

- Preliminary reports published in 1994
- Maki study (1997) indicated significant decrease in CR-BSI
- Several other studies reported non-significant decreases in CR-BSI

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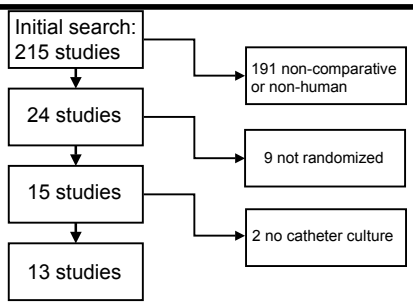
Search results



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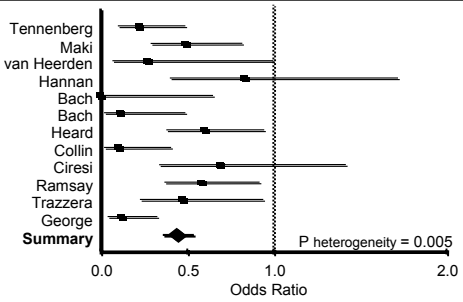
Studies Retrieved: I

Study	N	Population	Outcomes
Tennenberg ('97)	282	Hospital-wide	CC, CR-BSI
Maki ('97)	403	ICU	CC, CR-BSI
van Heerden ('96)	54	ICU	CC
Hannan ('96)	128	ICU	CC, CR-BSI
Bach ('94)	26	ICU	CC
Bach ('96)	233	Surgical	CC, CR-BSI
Heard ('98)	308	ICU	CC, CR-BSI

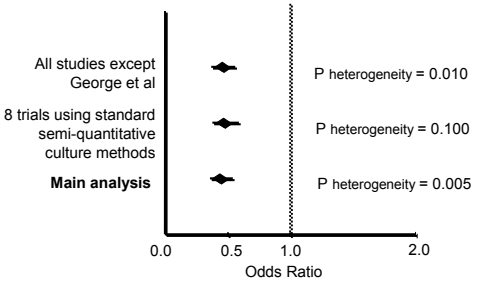
Studies Retrieved: II

Study	N	Population	Outcomes
Collin (in press)	237	ER/ICU	CC, CR-BSI
Ciresi ('96)	251	TPN	CC, CR-BSI
Pemberton ('96)	72	TPN	CR-BSI
Ramsay ('94)	388	Hospital-wide	CC, CR-BSI
Trazzera ('95)	222	ICU/BMT	CC, CR-BSI
George ('97)	79	Transplant	CC, CR-BSI

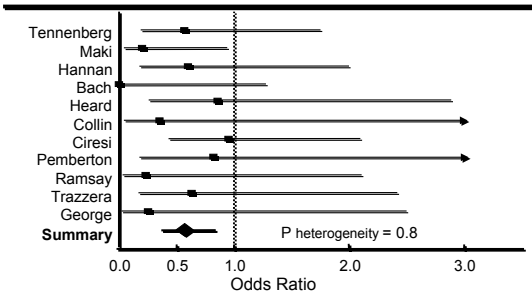
Results: catheter colonization



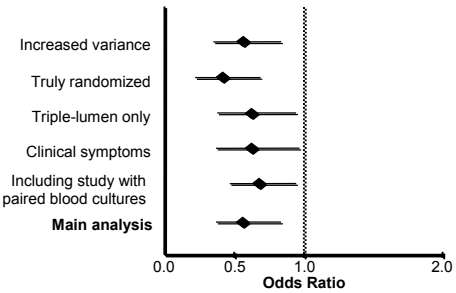
Catheter colonization: heterogeneity



Results: bloodstream infection (CR-BSI)



Sensitivity analyses: CR-BSI

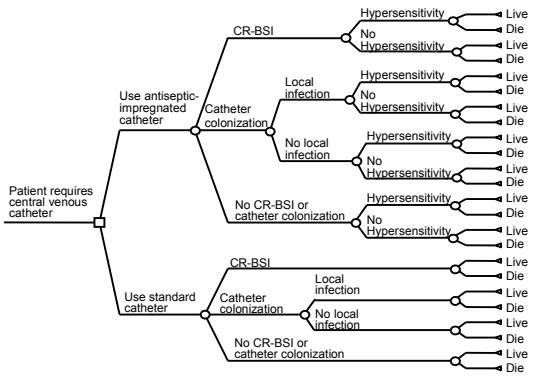


Are antiseptic catheters cost-effective?

- Additional cost of $20-$25
- Risk of hypersensitivity reaction
- Reduction in healthcare costs?
- Reduction in patient mortality?

Patient cohort

- Hospitalized patients at high-risk for CR-BSI (e.g. ICU, TPN patients)
- Catheters:
  - central lines
  - short-term
  - multi-lumen



Results: Base-case analysis

	Costs	CR-BSI	Death
Antiseptic Catheter	$383	3.0%	0.45%
Standard Catheter	$616	5.2%	0.78%
Difference	-$233	-2.2%	-0.33%

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Sensitivity analyses: ranges

Parameter	Base-case	Range
CR-BSI	5.2%	3.9-6.5%
RR for CR-BSI	0.58	0.40-0.85
Cost of CR-BSI	$11,466	$5,733-22,932
Cost of catheter	$25	$20-30
Mortality	15%	5-25%
Hypersensitivity	1:10,000	1:20,000-1:5,000

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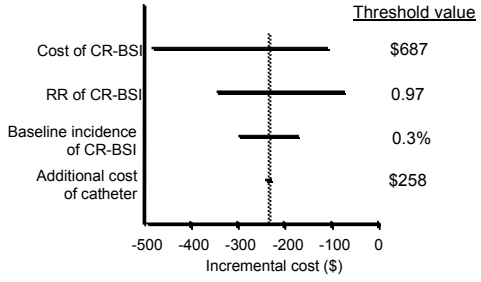
One-way sensitivity analyses: Costs



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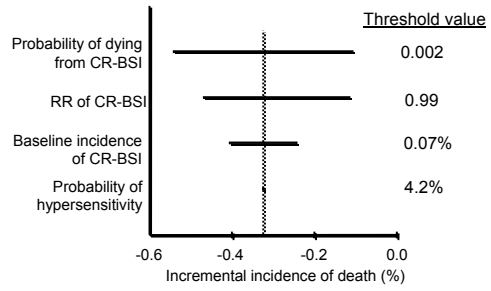
One-way sensitivity analyses: Deaths



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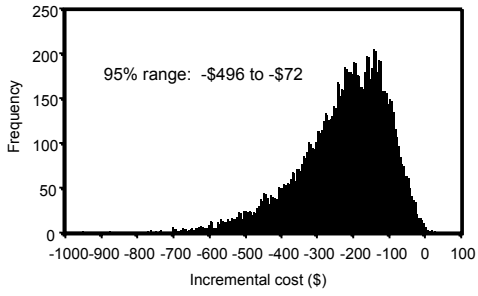
Incremental cost



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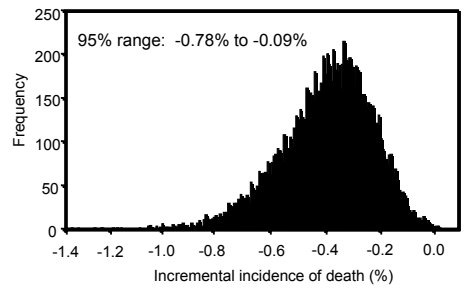
Incremental deaths



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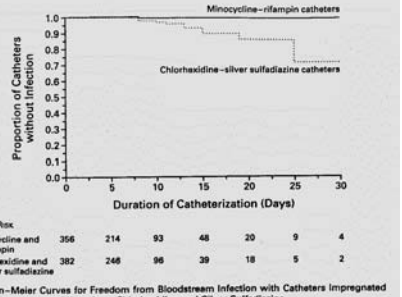
Worst-case scenario

Incremental		
Cost	CR-BSI	Death
-$4	-0.6%	-0.03%

Summary

- Antiseptic-impregnated catheters:
  - Reduce catheter colonization, CRBSI, and mortality (modeled).
  - Likely save money under a wide variety of assumptions.
- Decision-maker Message: For approximately every 300 catheters used, $70,000 will be saved, 7 cases of CR-BSI avoided, and 1 death prevented.



No. at Risk							
Minocycline and rifampin	356	214	93	48	20	9	4
Chlorhexidine and silver sulfadiazine	382	246	96	39	18	5	2

Figure 1. Kaplan–Meier Curves for Freedom from Bloodstream Infection with Catheters Impregnated with Either Minocycline and Rifampin or Chlorhexidine and Silver Sulfadiazine.

The numbers of catheters in each group that were at risk for causing infection at various times are shown below the figure. The risk of bloodstream infection was significantly lower for catheters impregnated with minocycline and rifampin than for those impregnated with chlorhexidine and silver sulfadiazine ($P=0.001$ by the log-rank test).

Conclusions

- Which method is most appropriate for decision-making?
  - There is no universal support for any one method, though most decision-makers prefer comparative methods.
  - The results and interpretation of these evaluations are subject to the limitations of the science.

Conclusions

- There is no evidence that health plans or government agencies worldwide make medical care payment decisions strictly on rules of economic efficiency.
  - The PBAC and other bodies subscribe to a multifactorial model of decision making. Economic appraisal plays a somewhat limited role.

"If economists could manage to get themselves thought of as humble, competent people on a level with dentists, that would be splendid."

John Maynard Keynes (1883–1946), British economist. *Essays in Persuasion,* ch. 5, "The Future," (1931).