Cost-Benefit and Cost-Effectiveness Analysis  
HCMG 901/301

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Ben Franklin and CE/CB Analysis (Sort Of)

• With a little shoe horning:
  – “An Ounce of Prevention is worth a Pound of Cure.”
    • Maximize (+ ounces – pounds) (CB)
  – “There are no gains without pains.”
    • How much of a gain does it take to offset an option’s pains? (CE)

Economic Evaluation in Health Care

• General idea: enumerate pros and cons of interventions
  – What to include
  – How to value/combine
• Cost benefit: convert all pros and cons to a common unit
  – Usually dollars, but could express “cost” as lost QALYs or some other outcome
• Cost effectiveness: convert some of the cons to dollars
  – Measure some of the pros in non-monetary terms
Intellectual Heritage

- Welfare economics
  - Run an economy to maximize the sum of consumers’ and producers’ surplus. Enshrines CB
- Defense Dept. analysis
  - Maximize bang for the buck. Invented CE
- Public health
  - Population health is of value to the king
  - Extreme version: animal husbandry, treat hoor and mouth disease

What is Commonly Meant by “Cost-Effective”?

- “Here are four creative, cost-effective strategies that will boost customer retention….Help them grow….Focus on your product….Be transparent….Engage customers in your brand.”
- “Super RTL is looking to implement a new ‘lean and cost-effective’ structure as it slashes about 15 per cent of its 130-person workforce.”
- “Conyac Offers Fast And Cost-Effective Social Translation Services…replace[s] traditional translation agencies with a quicker and cheaper alternative….”
- “Cost-Effective Moves the Miami Heat Can Make in Free Agency”
- “Using ETFs To Build A Cost-Effective Portfolio”

Steps in Economic Evaluation
Steps in Economic Evaluation

Step 1: Quantify costs of care
Step 2: Quantify outcomes
Step 3: Assess whether and by how much average costs and outcomes differ among treatment groups
Step 4: Compare magnitude of difference in costs and outcomes and evaluate “value for costs”
  – e.g. by reporting a cost-effectiveness ratio, net monetary benefit, or probability that ratio is acceptable
  – Potential hypothesis: Cost per quality-adjusted life year saved significantly less than $75,000
Step 5: Perform sensitivity analysis

Cost-Benefit / Cost-Effectiveness Study Designs

Study Designs

• Clinical trials
  – Economic evaluation in clinical trials widespread
  – Little to no selection bias, but potential issues of generalizability
• Observational studies
  – Often more generalizable, but problems with selection bias
• Decision models
  – Often used to address pressing questions for which direct data are not available
  – Shares strengths and weaknesses of source data
  – Added uncertainties related to combining data from multiple sources and projection beyond the data
Decision Analysis Approaches

- Most frequently used healthcare decision analytic approaches
  - Decision trees
  - Markov models
- Less frequently used approaches
  - Discrete event simulation
  - Dynamic transmission models
  - Partitioned survival models
  - Compartment models

Decision Trees

- "Models" that use a tree-like structure to organize thoughts and data about problems (e.g., treatment decisions) and their consequences
- Characterized by decisions, chances, and outcomes
- Results based on probabilities and "rewards" for outcomes
- Time usually not directly modeled in decision trees

Markov Models

- Repetitive decision trees used for modeling conditions that have events that may occur repeatedly over time or for modeling predictable events that occur over time (e.g., screening for disease at fixed intervals)
  - e.g., Cycling among heart failure classes or screening for colorectal cancer
- Use of Markov models simplifies presentation of tree structure
- Markov models explicitly account for timing of events
Cost-Effectiveness Methods Overview

Overview
- Types of analyses
- Types of outcomes
- Perspective

Types of Analysis
- Types of analysis
  - Cost identification
  - Cost-effectiveness
  - Cost Utility
  - Cost-benefit
  - Net monetary benefit
  - Value of information
  - Comparative effectiveness
- Generally distinguished by:
  - Outcomes included: e.g., costs only vs costs and effects
  - How outcomes are quantified: e.g., as money alone or as health and money
Cost-Identification / Cost-minimization

- Estimates difference in costs between therapies, but not difference in other outcomes
- Commonly conducted when no difference observed in effectiveness
  
  "As no statistical significant difference among the mean QALYs gained with the different [hormonal therapies] was detected (p = 0.12), CUA was replaced by a cost minimization analysis."


Appropriate Only When Therapies are Identical

Dish Network TV Spot, "Apples", 2015

Is failure to detect a difference same as a demonstration of equivalence?
Problems With Cost Identification

• Old version
  – If two therapies’ effects are identical, adopt cheaper of two
    • Effect maximization corollary: If two therapies’ costs identical, adopt more effective of two
• New version
  – Generally can’t conclude two therapies are identical
  – At most we fail to reject the null hypothesis
  – Cost-identification unlikely to be appropriate

Cost-Effectiveness Analysis

• Estimates costs and outcomes of intervention
• Costs and outcomes measured in different units
• Costs usually measured in money terms; outcomes in some other units

Costs₁ - Costs₂
Effects₁ - Effects₂

Cost-Effectiveness A Relative Measure

• Cost-effectiveness is a relative measure; no program is “cost-effective” in abstract
  – Results meaningful in comparison with:
    • A predetermined standard
      – e.g., $50,000 per quality-adjusted year of life saved
    • Other accepted and rejected interventions (e.g., a league table)
    • Utility curves
What Effectiveness Measure?

- Can calculate a ratio for any outcome
- e.g., Cost per toe nail fungus day averted
- To be informative, must know willingness to pay

<table>
<thead>
<tr>
<th>Rx</th>
<th>Cost</th>
<th>Incr Cost</th>
<th>TNFD</th>
<th>ITNFD</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciclopirox</td>
<td>953.6</td>
<td>--</td>
<td>563</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Itraconazole</td>
<td>1232.1</td>
<td>278.5</td>
<td>612</td>
<td>49</td>
<td>5.68</td>
</tr>
<tr>
<td>Fluconazole</td>
<td>1303.4</td>
<td>71.3</td>
<td>620</td>
<td>8</td>
<td>8.81</td>
</tr>
</tbody>
</table>

What Is Maximum WTP?

- No general agreement on WTP
- US Gov’t
  - EPA: $9.1 M / life (~222K / undiscounted YOLS)
  - FDA: $7.9 M / life (~176K / undiscounted YOLS)
  - DOT: $6 M / life (~133K / undiscounted YOLS)
- Australia: $AU 42K - 76K /YOLS
- Italy: €60,000/QALY
- Netherlands: €80,000/QALY
- Sweden: SEK 500,000 (€54,000) / QALY
- UK: £20 - 30K / QALY
- WHO report: 3 times GDP per DALY

Cost-Utility Analysis

- Costs and outcomes measured in different units AND outcomes expressed in units of utility (e.g., QALYs)
- Referred to either as a fourth type of analysis or as a subset of cost-effectiveness analysis
Dominance and Choice

- Old version: Calculate cost-effectiveness ratios only when one therapy cost more and is more effective
  - Other outcomes indicated either dominance (e.g., cost less and does more) or a toss-up (e.g., equal cost and effect)
- New version: Omit calculation of cost-effectiveness ratios only when one therapy costs significantly less and is significantly more effective (i.e., significantly dominates the alternative)
  - e.g., when one therapy is significantly more effective but its cost-savings are not significant, the resulting CI for the CER may indicate we can’t be confident that the value of the two therapies differs

Net Monetary (Health) Benefit

- Composite measure (part cost-effectiveness, part cost benefit analysis), usually expressed in dollar terms, derived by rearranging cost-effectiveness decision rule:
  \[ W^* > \frac{\Delta C}{\Delta Q} \]
  where \( W^* \) = maximum willingness to pay (e.g., 50,000 per QALY)
- Net monetary benefit (NMB), expressed on cost scale, more commonly reported than net health benefit (NHB), expressed on health outcome scale
  \[ \text{NMB} = (W \times \Delta Q) - \Delta C \]
- Particularly important for statistical evaluation of cost-effectiveness analysis
  - e.g., sample size; direct statistical testing by use of patient-level data; etc.

Cost-Benefit Analysis

- Estimates differences in costs and benefits in same units
  - Usually money, but any common unit possible
- As with cost-effectiveness, requires a set of alternatives
- Net benefits (preferred)
  \[ \text{Benefit} - \text{Cost} \]
- Alternative: Benefit-cost ratio (potentially problematic)
Benefit/Cost Ratio

- Different options for classification of costs and outcomes pose problem for Ratio
  - Classifying outcome as positive benefit (numerator) or negative cost (denominator) doesn’t affect whether ratio is >1 (good value) or <1 (bad value)
  - But does affect magnitude of resulting ratio

Potential Problem with B/C Ratio

<table>
<thead>
<tr>
<th>Rx</th>
<th>Medical Cost Now (Net)</th>
<th>Medical Cost Saved Later</th>
<th>Wages Saved Now</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>10</td>
<td>31</td>
<td>6</td>
</tr>
<tr>
<td>B</td>
<td>10</td>
<td>50</td>
<td>0</td>
</tr>
</tbody>
</table>

- Ratios vary depending on how we classify saved wages
  - As benefit: A \(\frac{31+6}{10} = 3.7\); B \(\frac{50}{10} = 5\)
  - As cost offset: A \(\frac{31}{(10-6)} = 7.75\); B \(\frac{50}{10} = 5\)
- Net benefit unaffected by how we treat wage savings
  - A: \((31+6) - 10 = 27\); B: \(50 - 10 = 40\)
  - B: \(31 - (10-6) = 27\); B: \(50 - 10 = 40\)

"Varieties" of CBA

- Cost offset (or "cost-cost") analysis: More costs saved elsewhere than cost of the intervention. (Benefit zero or positive) (alcoholism treatment)
- Present value analysis: cost today saves more cost tomorrow in present value terms. (Benefit zero or positive) (polio vaccine)
- Full cost benefit analysis: net present value of cost is positive, positive benefits are obtained. (Medical preventive care)
CBA VS NMB

- Principal difference between CBA and NMB is in how willingness to pay is estimated
  - When estimated at the individual level, and ideally, when principles of welfare economics are employed, use of WTP yields CBA
  - When calculated as a decision maker's rule of thumb (e.g., 50,000 or 100,000), use of W yields NMB, a simple transformation of CEA

Value of Information

- Divides NMB distribution into fraction that represents good value for one therapy vs fraction that represents good value for alternative

Expected Value of Perfect Information

- Calculate fraction of distribution that is negative vs positive
  - 75.48% vs 24.52%, respectively
- Calculate conditional expected values of negative and positive NMBs
  - -477.48 vs 246.21
- Calculate unconditional expected values
  - -360.38 (0.7548*-477.48) vs 60.38 (.2452*246.21)
- Per-person EVPI = minimum of the absolute values
  - min(abs(-360.38), 60.38) = 60.38
Comparative Effectiveness Analysis

• Calls for direct comparison of active therapies (i.e., diuretics vs ACE inhibitors essential hypertension), not comparison with placebo, status quo, or do nothing
• Current Federal flavor seems divorced from economic considerations
• Given proponents claim it will reduce costs, may inevitably lead to such considerations (or fail in achieving goal)

Review

• Investigators compared 2 treatments, “LessCost” and “MoreCure”
• Found that “LessCost” was less expensive and recommended its adoption by physicians
  – 1000 vs 1200

  • What type of economic analysis are investigators carrying out?
  • Do you agree with their conclusion?

Example 2

• Investigators compared 2 treatments, “LessCost” and “MoreCure.” Observed the following:

<table>
<thead>
<tr>
<th></th>
<th>MoreCure</th>
<th>LessCost</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>1200</td>
<td>1000</td>
<td>200</td>
</tr>
<tr>
<td>Benefit</td>
<td>3000</td>
<td>1500</td>
<td>1500</td>
</tr>
</tbody>
</table>

  • Authors concluded that MoreCure is net beneficial.
  • What type of economic analysis are investigators carrying out?
  • Do you agree with their conclusion?
Example 3

• Investigators compared 2 treatments, "LessCost" and "MoreCure." Observed that MoreCure cost 200 more than LessCost and provided 0.03 additional QALYs

• Authors recommended that MoreCure was good value for cost

• What type of economic analysis are investigators carrying out?
• Do you agree with their conclusion?

Types of Outcomes

Varieties of Costs: Old Version

• Direct
  – Medical
  – Non-medical (e.g., purchased transportation)

• Indirect
  – Time cost
  – Psychic (or "intangible") cost

• External

• Types of costs included in an analysis depend on:
  – What is affected by illness and its treatment
  – What is of interest to decision makers
    • e.g., a number of countries' decision makers have indicated they are not interested in time costs
Varieties of Benefits: Old Version

- Direct
  - Medical, including cost offsets
  - Non-medical
- Indirect
  - Value of health (output)
- Intangible
  - WTP less value of output

Current Taxonomy (Drummond)?

<table>
<thead>
<tr>
<th>Costs</th>
<th>Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1 Health care costs</td>
<td>S1 Health care savings</td>
</tr>
<tr>
<td>C2 Patient/family costs</td>
<td>S2 Savings in patient/family costs</td>
</tr>
<tr>
<td>C3 Costs in other sectors</td>
<td>S3 Savings in other sectors</td>
</tr>
</tbody>
</table>

and

- Health state improvement
- Utility (U)
- WTP (W)

Varieties of Effectiveness Measures

- Can calculate a ratio for any outcome
  - Cost per toe nail fungus day averted
- In many jurisdictions, quality-adjusted life year (QALY) is recommended outcome of cost-effectiveness analysis
QALYS

- Economic outcome that combines preferences for both length of survival and quality into a single measure
- Help us decide how much to pay for therapies that:
  - Save fully functional lives/life years  
    VS
  - Save less than fully functional lives/life years  
    • e.g., heart failure drug that extends survival, but extra time spent in NYHA class III  
    VS
  - Don’t save lives/life years but improve function  
    • e.g., heart failure patients spend most of their remaining years in class I instead of class III

QALY Scores

- QALY or preference scores generally range between 0 (death) and 1 (perfect health)  
  • E.g., health state with a preference score of 0.8 indicates that year in that state is worth 0.8 of year with perfect health  
  • There can be states worse than death with preference scores less than 0

Prescored Health State Classification Instruments

- Dominant approach for QALY measurement uses prescored health state classification instruments (indirect utility assessment)  
- Participants' report their functional status across a variety of domains  
- Preference scores derived from scoring rules that usually have been developed from samples from general public
Study Perspective

- Economic studies should adopt 1 or more “perspectives”
  - Societal
  - Payer (often insurer)
  - Provider
  - Patient
- Perspective helps identify services that should be included in analysis and how services should be cost out
  - e.g., patient out-of-pocket expenses may be excluded from insurer perspective
  - Not all payments may represent costs from societal perspective

Decision Rules
Decision Rules with CB and CE

- Variable Budget
  - CB: Do all projects for which (B-C)>0 or B/C>1
  - CE: Ratios themselves can’t answer “spend vs do nothing” decision; instead must identify a willingness to pay (W) for the outcome
    - Do if C/Q < W OR WQ – C > 0
    - W used in CE typically differs from the W used in CBA
      - Former typically unrelated to measures of consumer surplus

Variable Budget: Maximize Value If ICER<W

- 122 Rx candidates
- Angioplasty and CABG cost 2400 and 3050 and yield 0.1 and 0.125 QALY gains, respectively
- Budget sufficient to treat everyone with either procedure
- W=50K

<table>
<thead>
<tr>
<th>Group</th>
<th># treated</th>
<th>Cost</th>
<th>QALYS</th>
<th>MB</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angioplasty</td>
<td>122</td>
<td>292.8k</td>
<td>12.2</td>
<td>317.2k</td>
<td>--</td>
</tr>
<tr>
<td>CABG</td>
<td>122</td>
<td>372.1k</td>
<td>15.25</td>
<td>390.4k</td>
<td>26k</td>
</tr>
</tbody>
</table>

- When budget sufficient to treat everyone, if ICER<W, use more expensive / more effective therapy (CABG)

Decision Rules with CB and CE (2)

- Fixed Budget
  - CB: Order projects by “budget-based” B/C ratio, do projects until budget is used up OR do projects which maximize (B-C)
  - CE: Order into a “league table,” specify project size, and do projects in order of B/C until budget is used up
    - Indivisibilities can cause problems for simple “buy down the list” decision making
CEA League Table

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive behavioral therapy in teens at risk for depression</td>
<td>$11,000</td>
</tr>
<tr>
<td>Warfarin therapy (vs Aspirin) in patients with chronic atrial fibrillation, age 70</td>
<td>$18,000</td>
</tr>
<tr>
<td>Breast conserving surgery plus radiation in women with ductal carcinoma in situ, age 55</td>
<td>$42,000</td>
</tr>
<tr>
<td>Parmipexole in subjects with early Parkinson's disease</td>
<td>$50,000</td>
</tr>
<tr>
<td>Voluntary 5-yearly HIV-screening, assumed benefit to patient and reduced transmission to partners</td>
<td>$75,000</td>
</tr>
<tr>
<td>Toddler single dose meningococcal vaccination (vs no vaccination)</td>
<td>$120,000</td>
</tr>
<tr>
<td>Radiation in men diagnosed for first time with prostate cancer, age 75</td>
<td>$220,000</td>
</tr>
</tbody>
</table>

CEA Registry, https://research.tufts-nemc.org/cear

If Budget Fixed, Recommendation Can Change

- In CEA lecture (2 weeks), will STRONGLY recommend AGAINST making decisions based on comparison of \( \frac{C_0}{Q_0} \) versus \( \frac{C_1}{Q_1} \) ratios
  - Should instead calculate single incremental ratio \( \frac{(C_1-C_0)}{(Q_1-Q_0)} \)
- But relative magnitude of \( \frac{C_0}{Q_0} \) and \( \frac{C_1}{Q_1} \) ratios determines whether Rx recommendation is same or differs in variable and fixed budget cases
- When budget is fixed, if \( \frac{C_0}{Q_0} < \frac{C_1}{Q_1} \) use \( \frac{C_0}{Q_0} \); if \( \frac{C_0}{Q_0} > \frac{C_1}{Q_1} \) use \( \frac{C_1}{Q_1} \)
- In current example: 24000 (2400/0.1) < 24,400 (3050/0.125)
  - For fixed budget, should expect reversal of recommendations

Suppose Budget Fixed at 292.8k

- 122 Rx candidates
- Angioplasty and CABG cost 2400 and 3050 and yield 0.1 and 0.125 QALY gains, respectively
- Given 292.8k budget, can provide angioplasty to all 122 candidates, but CABG to only 96
- \( W=50k \)

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<tr>
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<th>MB</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angioplasty</td>
<td>122</td>
<td>$292.8k</td>
<td>12.2</td>
<td>$317.2k</td>
<td>D+</td>
</tr>
<tr>
<td>CABG</td>
<td>96</td>
<td>$292.8k</td>
<td>12.0</td>
<td>$307.2k</td>
<td>D-</td>
</tr>
</tbody>
</table>
But Need Not Be a Reversal

- If, all else equal, $C_0/Q_0 = C_1/Q_1$, will be indifferent between angioplasty and CABG
- E.g., suppose $C_0 = 2440$ ($C_0/Q_0 = 24,400$)

<table>
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<td>307.2k</td>
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<tr>
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<td>292.8k</td>
<td>12.0</td>
<td>307.2k</td>
<td>0</td>
</tr>
</tbody>
</table>

- Finally, if -- all else equal -- $C_0 > 2440$, CABG will be preferred in both variable and fixed budget cases

Who is Listening?

Not U.S. Congress

"The Patient-Centered Outcomes Research Institute . . . shall not develop or employ a dollars per quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII"

The Patient Protection and Affordable Care Act
Some Use Exists in US

- Common Belief: CE/CB data not used in US
  - Medicare Advantage Value-Based Insurance Design Model demonstration
  - NIH expert guideline panels and Environmental Protection Agency can and do use
  - Aspinall et al.: Veterans Health Administration “has emphasized use of cost-effectiveness data, especially for newer, costly drugs.”

But Not All Agencies

- Advisory Committee on Immunization Practices (ACIP) and US Preventive Services Taskforce (USPSTF) prohibited
- Technically, Medicare and Medicaid also prohibited from consideration of costs and cost-effectiveness in recommendations and policies (but use informally)
  - Chambers et al.: Lack of an estimate of cost-effectiveness associated with a decreased likelihood of Medicare coverage

Medicare’s Coverage Policy

- So far, inclusion of economic considerations limited to:
  - If new technology is worse, don’t cover no matter what the cost
  - If new technology is no better and costs more, don’t cover
  - If new technology is possibly better but possibly not, don’t cover unless it costs less
  - If new technology is definitely better, always cover
Azactam/Aztreonam

• Squibb Azactam Aztreonam 1988 promotional pamphlet (citing Eisenberg et al. study)

- Avoids the $183 additional cost (when amortized over all patients) of aminoglycoside-associated nephrotoxicity*

  *Cost may vary depending upon physician, hospital, and region. Please consult full prescribing information before initiating therapy.

FDA

• Division of Drug Marketing, Advertising and Communications (DDMAC) regulates pharmaceutical labeling and advertising

• Of 291 DDMAC warning letters sent to pharmaceutical companies between January 2002 and December 2011, 35 (12%) cited a health economic violation
  - Implied claim of cost savings due to work productivity or functioning (n=20)
  - Economic claims containing unsubstantiated comparative claims of effectiveness, safety, or interchangeability (n=7)


Others

• AMCP Guidance for Submission of Clinical and Economic Evaluation Data to Support Formulary Listing in U.S. Health Plans and Pharmacy Benefits Management Organizations

• Cost effectiveness analysis (never cost benefit) used in other countries (UK, Canada, Australia, etc.) to suggest/determine what will be paid for under a (nearly) free single insurance plan. The plan either pays in full or pays nothing
Who is Listening Internationally

• PE Recommendations/Guidelines (Partial list)
  • Australia  Italy
  • Austria  Mexico
  • Brazil  Netherlands
  • Baltic countries  Norway
  • Belgium  Poland
  • Brazil  Russia
  • China  South Korea
  • Denmark  Spain
  • Egypt  Sweden
  • Finland  Taiwan
  • France  Thailand
  • Hungary  U.K.

CB Analysis and the (Ideal) Competitive Market

• The purpose of CB analysis is to reproduce the results that would have occurred if a competitive market existed
  – i.e., Competitive markets are CB/CE calculators
  – When competitive markets exist, formal CB easy to do, but not needed
• Formal CB analysis most needed when markets do not and will not exist or will not function “well”:
  – Public goods/externalities
  – Distortions
  – Imperfect and costly information
  – Any other examples of “market failure”
• CB analysis least feasible when most needed, when markets do not exist at all!

CE Analysis and the (Ideal) Competitive Market

• [Given patent protection and demand that exceeds supply at $p_{max}$,] profit maximizing firms facing regulators who use CE rule to determine adoption may set price by use of following rule:

\[ p_{max} = \frac{\Delta Q W^* + C_0 - \Delta OC}{D_1} \]

• where $p_{max}$ = maximum price for (new) Rx 1; $W^*$ = regulators’ maximum WTP; $\Delta Q$ = the difference in effectiveness; $\Delta OC$ = the difference in other costs and $C_0$ = cost of Rx0
• If cost-offsets exist ($\Delta OC < 0$), price captures offsets for firm
Five Approaches We Could Follow in the Course

- Technical/nerd issues (Yes)
- “How do they usually do it?” (To some extent)
- What do decision-makers really want to know (Medicare, managed care and drug companies)? (Try to)
- What makes “real” economists happy? (Yes)
- What should decision makers be doing (Try to)