QALYs as a Factor in Decision Making for Pharmaceuticals in the U.S.

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Question 1

How can we best use our resources to improve public health?
Level of Economic Analysis

- Macro level--informs policy
- Micro level--informs clinical decisions
Example Macro Problem

- Oregon - late 1980s
- Medicaid costs were increasing 25% per year
- Medicaid coped with the problem by changing eligibility threshold
- Number of people covered reduced to 200,000 among 600,000 eligible
- Proposed rationing services rather than people
- Goal was to increase number covered
Macro Level Decision

- Fixed level of resources
- Potentially infinite demand
- Need to make effective/efficient use of resources
- Set priorities-make choices
Micro Level Decision

- I am 82 years old
- I feel good and my memory is fine
- My doctor says I have >85% stenosis of my carotid arteries
- She wants to operate ASAP
- She says I may die from the surgery
- She also thinks I may die of a stroke
- What should I do?
If widely different interventions are to be compared...

- The measure of health must be able to encompass not only differences in length of life but differences in the quality of that life, in symptoms and ability to function.
Overview

- Cost-utility analysis
  - Effectiveness measured as Quality Adjusted Life Years
- Societal Perspective
  - Related medical and nonmedical costs included
- Time Horizons
  - Primary: within trial
  - Secondary: projected 5- and 10-year outcomes
Medicare Expense Variations

Medicare reimbursements for all services

Total Medicare reimbursements per medicare enrollee. (1993)

Source: The Dartmouth Atlas of Health Care

- $4,340 to $5,966
- $3,702 to $4,020
- $2,729 to $3,336
- $4,020 to $4,340
- $3,336 to $3,702
- not populated
The Boston New Haven Difference Continues Through 2000
Days spent in intensive care during last six months of life among patients receiving most of their care in one of 77 “best” US hospitals (Wennberg, 2005)
Total Medicare Expenditures in 2003: Los Angeles vs San Diego Communities

Note: no overlap
Physician Visits LA vs SD
CHIS 2005

Doctor Visits

Mean Visits

County

LA

SD
Percent Medicare Recipients With No Physician Visits: CHIS 2005

% Zero Visits

Percent

County

LA

SD
Percent Medicare Recipients In Hospital Last 12 Months: CHIS 2005

[Bar chart showing percent Medicare recipients in hospital for LA and SD counties.]
Percent Medicare Recipients In Fair or Poor Health (by self report): CHIS 2005

- LA: 40%
- SD: 30%

County: LA, SD
Association between hospital beds per 1,000 (1996) and discharges per 1,000 (1995-96) among Medicare enrollees in 306 HRRs (Wennberg, 2005)
# Per capita resource inputs and health outcomes: Ratio high/low quintiles of spending among 306 HRRs

<table>
<thead>
<tr>
<th>Resource Inputs</th>
<th>Cohort Health Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Spending</td>
<td>Death</td>
</tr>
<tr>
<td>Hospital Beds (1000)</td>
<td>R.R.</td>
</tr>
<tr>
<td></td>
<td>95% CL</td>
</tr>
<tr>
<td>Physician Supply*</td>
<td>Hip Fracture</td>
</tr>
<tr>
<td>All Physicians</td>
<td>1.019</td>
</tr>
<tr>
<td>Medical Specialists</td>
<td>1.012</td>
</tr>
<tr>
<td>General Internists</td>
<td>1.052</td>
</tr>
<tr>
<td>Family Practice</td>
<td>Functional Status: No difference</td>
</tr>
<tr>
<td>Surgeons</td>
<td>Satisfaction: No difference</td>
</tr>
<tr>
<td></td>
<td>Access: Worse</td>
</tr>
</tbody>
</table>

*per 10,000
Adjusted relative risk for death during follow-up across quintiles of Medicare spending

- Circles represent adjusted relative risk for death among residents of hospital referral regions in the specified quintile of the End-of-Life Expenditure Index (EOL-EI) compared to the risk for death among residents of hospital referral regions in quintile 1 of the EOL-EI; bars represent 95% CIs. MCBS = Medicare Current Beneficiary Survey; MI = myocardial infarction; Q1 = quintile 1; Q2 = quintile 2; Q3 = quintile 3; Q4 = quintile 4; Q5 = quintile 5.
- Higher expenditure areas have more, rather then less mortality
Relationship between angiography and procedures

Association Between the Incidence of Angiography and the Rates for either CABG or PTCA (1992-3)

R² = 0.64
Where would you prefer to have your MI. USA or Canada?
Procedures US Vs Canada
Mortality US Vs Canada
Example Policy Problem

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Oregon Medicaid Experiment

- Initial proposal included prioritization by cost/utility of as an alternative to a more subjective approach
Ohio Prioritized List, February 1995 (Top)

- Medical or surgical treatment for moderate or severe head injury
- Medical therapy, insulin dependent diabetes mellitus
- Treatment of peritonitis
- Therapy (including dialysis) for acute glomerulonephritis
Oregon Prioritized List, February 1995 (Middle)

- Medical therapy for rheumatoid arthritis
- Medical/psychotherapy for anxiety disorder
- Surgical repair for cleft palate
- Medical therapy for rheumatic fever
Oregon Prioritized List, February 1995 (Bottom)

- Evaluation of conditions of the eye for which there is no effective treatment
- Evaluation of conditions of the heart for which there is no effective treatment
- In-vitro fertilization for tubal dysfunction
- Radial keratotomy for disorders of refraction
NETT Policy Impact

- May 22, 2003. NETT results published in NEJM
- August 10, 2003. CMS announces intent to cover LVRS for groups that benefited in trial
- November 7, 2003. CMS Announces coverages guidelines for LVRS
- January 1, 2004. Coverage begins
Effects of interventions in DPP (DPP Group 2003, Diabetes Care 26: 2518)

Table 2— Health utility scores and QALYs gained by treatment group and year

<table>
<thead>
<tr>
<th>Year</th>
<th>Utility scores</th>
<th>QALYs gained</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lifestyle</td>
<td>Metformin</td>
</tr>
<tr>
<td>1</td>
<td>0.703 ± 0.118</td>
<td>0.687 ± 0.119</td>
</tr>
<tr>
<td>2</td>
<td>0.695 ± 0.122</td>
<td>0.680 ± 0.123</td>
</tr>
<tr>
<td>3</td>
<td>0.692 ± 0.125</td>
<td>0.673 ± 0.117</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data are means ± SD.
Costs of interventions in DPP *(DPP Group 2003, Diabetes Care 26: 2518)*

<table>
<thead>
<tr>
<th></th>
<th>Lifestyle</th>
<th>Metformin</th>
<th>Placebo</th>
<th>Lifestyle vs. placebo</th>
<th>Metformin vs. placebo</th>
<th>Lifestyle vs. metformin</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Direct medical costs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case finding</td>
<td>139</td>
<td>139</td>
<td>139</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Intervention</td>
<td>2,780</td>
<td>2,542</td>
<td>79</td>
<td>2,701</td>
<td>2,463</td>
<td>238</td>
</tr>
<tr>
<td>Care outside DPP</td>
<td>4,579</td>
<td>4,739</td>
<td>5,011</td>
<td>-432</td>
<td>-272</td>
<td>-160</td>
</tr>
<tr>
<td>Total costs from health system perspective</td>
<td>7,498</td>
<td>7,420</td>
<td>5,229</td>
<td>2,269</td>
<td>2,191</td>
<td>78</td>
</tr>
<tr>
<td><strong>Direct nonmedical costs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17.137</td>
<td>15.683</td>
<td>15.692</td>
<td>1.445</td>
<td>-9</td>
<td>1.455</td>
<td></td>
</tr>
<tr>
<td>Indirect costs</td>
<td>2,430</td>
<td>2,834</td>
<td>2,604</td>
<td>-174</td>
<td>230</td>
<td>-404</td>
</tr>
<tr>
<td>Total costs from societal perspective</td>
<td>27.065</td>
<td>25.937</td>
<td>23.525</td>
<td>3.540</td>
<td>2.412</td>
<td>1.128</td>
</tr>
</tbody>
</table>
Cost/QALY in DPP (DPP Group 2003, Diabetes Care 26: 2518)

Cost/QALY of Lifestyle and Metformin in DPP: Health System Perspective

Intervention

- Placebo
- Nothing
What has held us back?

- Distractions
  - Disagreements on which measure is best
  - Disagreements on general philosophy of outcome measurement
    » Generic vs disease specific
    » Psychometric vs. utility based
    » Disciplinary differences – statistics, economics, medicine, psychology, anthropology…. 
We do agree on some of the core issues

- Most measures can be traced back to Sullivan (1966)
  - Sullivan rarely cited
- Content of items is remarkably similar
- Most measures combine measures of life length and life quality
- Most quality of life measures are hybrid health status/utility measures
  - Health states and health weights (Erickson)
Think of different approaches as brand names of products designed to measure the same underlying construct... health
Response Shift

- Preferences of patients and non-patients differ
- As a result, preferences weights have no meaning
- But, is this supported by evidence?
Comparison between ever and never in wheelchair or walker for 31 items:
Data from Oregon Health Services Commission

\[ r = 0.97 \]

Figure 5. Regression of QWB Scores for Respondents

\[ \text{QWB\,MEAN} = -0.0031 + 1.0021 \times \text{qwb\,tr}\,tmn \]

- N = 235
- \text{R}^2 = 0.5626
- \text{Adj. R}^2 = 0.5625
- \text{RMSE} = 0.0172
Preference and Utility Assessment

- Standard Gamble
- Time Trade-off
- Rating Scales
- Think scoring systems
Figure 1. Mean Utility by Measure

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean Score (0-1.0 Scale)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUI2</td>
<td>0.65</td>
</tr>
<tr>
<td>HUI3</td>
<td>0.40</td>
</tr>
<tr>
<td>EQ-5D</td>
<td>0.50</td>
</tr>
<tr>
<td>Fryback</td>
<td>0.60</td>
</tr>
<tr>
<td>Nichol</td>
<td>0.70</td>
</tr>
<tr>
<td>Brazier VAS</td>
<td>0.40</td>
</tr>
<tr>
<td>Brasier SG</td>
<td>0.85</td>
</tr>
</tbody>
</table>
All measures captured clinical change
EXHIBIT 2
Percentage Uninsured Among Workers And Per Capita Health Expenditure Divided by Median Income, 1979-2002

Per capita health expenditure divided by median income

Percent uninsured among workers

Percent uninsured

Per capita health expenditure divided by median income


NOTE: Percentage uninsured is scaled on the left axis and per capita health expenditure divided by median income is scaled on the right axis. Results from 1979-1999 have been adjusted to make them consistent with the insurance verification question that was added to the CPS in 2001. The series for workers is restricted to those not covered as a dependent or by a public program.
Utility-based measures are available to estimate the impact of pharmaceutical products.

Generic methods allow the comparison of investments in drugs with investments in other aspects of health care.

There are very few applications at present.

We look forward to the development of these methods for studies on pharmaceutical regulation.