Fundamentals of Cost-Effectiveness Analysis in Medicine

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Why worry about the costs of Medical Care?

• National budget crisis:
  – US Health care expenditures rose 5.4% in 2009\(^1\);
  – Health care expenditures in 2009 exceeded $2.5 trillion, or more than $8,050 for every American man, woman, and child, according to the Centers for Medicare and Medicaid Services;
  – Total health care spending in the US now amounts to more that 17.3% of the GDP\(^1\), and is projected to reach 20% within 7 years.\(^2\)

• \(^1\) Los Angeles Times, Feb 4, 2010.
• \(^2\) Catlin et al, Health Affairs, 2008;27:14-29.
U.S. Health Care Expenditures as a % of GDP

- 1960: 5%
- 1970: 6%
- 1980: 8%
- 1990: 12%
- 2000: 14%
- 2007: 17%
- 2010 (p): 19%
- 2018 (p): 20%
International Comparison of Spending on Health, 1980–2006

Total expenditures on health as percent of GDP

Average spending on health per capita ($US PPP)

Data: OECD Health Data 2008 (June 2008).

From: a report compiled by The Commonwealth Fund
An Imperative to Control the Costs of Healthcare

• “Increasing costs erode our system of employer-sponsored insurance, swell the ranks of the uninsured, reduce workers' wages, crowd out spending on other social priorities, and strain federal and state budgets for Medicare and Medicaid.”¹

Why worry about the costs of Medical Care?

• Crisis in Access to Health Care:
  – At some point during each year, more than 80 million Americans are without health insurance. ¹, ²

From:
¹ Henry J. Kaiser Family Foundation: The Uninsured – A Primer; 12/2010
² Cover the Uninsured Web Site.
http://covertheuninsured.org/content/overview; accessed 3/24/2011.
Table 1.1a. Number of persons without health insurance coverage at the time of interview, by age group: United States, 1997–2011

<table>
<thead>
<tr>
<th>Year</th>
<th>Number in millions: All ages</th>
<th>Number in millions: Under 65 years</th>
<th>Number in millions: 18–64 years</th>
<th>Number in millions: Under 18 years</th>
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<td>40.7</td>
<td>30.8</td>
<td>9.9</td>
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<td>1998</td>
<td>39.3</td>
<td>39.0</td>
<td>30.0</td>
<td>9.1</td>
</tr>
<tr>
<td>1999</td>
<td>38.7</td>
<td>38.3</td>
<td>29.8</td>
<td>8.5</td>
</tr>
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<td>41.3</td>
<td>40.8</td>
<td>32.0</td>
<td>8.9</td>
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<td>2001</td>
<td>40.2</td>
<td>39.8</td>
<td>31.9</td>
<td>7.9</td>
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<td>2002</td>
<td>41.5</td>
<td>41.1</td>
<td>33.5</td>
<td>7.6</td>
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<td>2003</td>
<td>43.6</td>
<td>43.2</td>
<td>35.9</td>
<td>7.3</td>
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<td>2004 (Method 1)</td>
<td>42.5</td>
<td>42.0</td>
<td>35.0</td>
<td>7.0</td>
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<tr>
<td>2004 (Method 2)</td>
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<td>41.7</td>
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<td>41.0</td>
<td>34.4</td>
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<td>2006</td>
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<td>46.3</td>
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<tr>
<td>2010</td>
<td>48.6</td>
<td>48.2</td>
<td>42.5</td>
<td>5.8</td>
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<tr>
<td>2011</td>
<td>46.3</td>
<td>45.9</td>
<td>40.7</td>
<td>5.2</td>
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</table>
Figure 1.1. Percentage of persons of all ages without health insurance coverage at the time of interview: United States, 1997–2011

For 2011, the percentage uninsured at the time of interview was 15.1% (95% confidence interval = 14.66%–15.64%), which was lower than the 2010 estimate of 16.0%.

The percentage uninsured at the time of interview was lowest in 1999 and 2005 (14.2%) and highest in 2010 (16.0%).
Limited resources and unlimited wants

- Medicaid "is a target" for cuts because in most states it represents the second-largest portion of their budget.
  - On average, Medicaid accounts for 17% of state budgets.¹

- The current economic outlook has been challenging to say the least.

¹ Medical News Today, States Make Cuts To Medicaid, Other Health Coverage Programs To Address Budget Gaps; 30 Oct 2008.
Practice Pattern Variations raise a red flag (suggest unnecessary spending)

• Wide variation in practice –
  – 1.4- to 26-fold variation in Medicare procedure utilization (Chassin)
    • 26-fold for hemorrhoidectomy;
    • 11-fold for hip arthroplasty;
    • 17-fold for ERCP;
    • 4-fold for carotid endarterectomy;
  • Significant levels of inappropriate care.
Conflicting roles for the physician:\(^1\)

- Traditional role has been that of patient advocate whose goal is to do the utmost for each individual patient under their care;
- We are also members of "Society" with an interest in improving the overall health of the population;

\(^1\)Eddy DM. The individual vs society: is there a conflict? JAMA. 1991;265:1446-1450.
Payment Reform

Over the past decade the debate about health care reform has revolved about discussions of costs and benefit packages, and on how to manage "competition."

However, "very little attention has been paid to how quality of care will be assured and improved, to how the health of the public will be protected in the headlong rush to control costs." ¹

Payment Reform

• More recently approaches such as “pay-for-performance” have come into vogue –
  – “as a tactic for realigning payment with value.”¹

  – Although

    • “Payers' experiences during this period, as well as several major studies, clarified the limitations of this approach — characterized by some as putting lipstick on a pig.”¹

Alternate Principles for Allocating Resources:

• Maximize Health Outcomes at Any Cost - (the old system)
• Minimize Cost at Any Outcome – (what may become the new system)
• Redistribute Resources - from services with some benefit to services with greater benefit relative to cost \(^1\) - (cost-effectiveness and cost-utility analysis)
  
Three Dimensions of Clinical Economics¹

- Type of Analysis
- Point of View or Perspective
- Types of Costs & Benefits considered

Three Dimensions of Clinical Economics\textsuperscript{1}

• Type of Analysis –
  – Cost Identification or Cost Analysis
  – Cost-Benefit Analysis
  – Cost-Effectiveness or Cost-Utility Analysis

Three Dimensions of Clinical Economics

• Point of View or Perspective
  – Society
  – Patient
  – Payer
  – Provider or Hospital
Three Dimensions of Clinical Economics

• Types of Costs and Benefits
  – Direct Medical Costs
  – Direct Non-medical Costs
  – Indirect Costs of Morbidity & Mortality
  – Intangible Costs
Type of Analysis:

• Cost-identification - measures the costs incurred by a disease or treatment
  – Identifies the optimal strategy by implicitly assuming that the health outcomes are the same so the "cheapest" strategy is the best.
  – Measures the economic burden of a disease or treatment.
  – Provides no measure of the health outcomes.
Type of Analysis cont:

• Cost-benefit - single attribute.
  – All costs and benefits are expressed in the same unit of measurement (dollars).
  – Monetary value of human life
    • Human capital method (i.e., the value of the future stream of lifetime earnings);
    • Willingness to pay technique (i.e., monetary valuation placed by patient on avoidance of adverse event).
  – Provides a measure of the absolute dollar benefit (or loss) of a program.
  – Pick programs with the largest benefit.
Type of Analysis cont:

• Cost-effectiveness or Cost-Utility Analysis – (has multiple attributes).
  – Outcomes are reported in a single unit of measurement (e.g., years of life saved, or quality-adjusted life years).
  – All costs are expressed in another unit (e.g., dollars).
  – Tradeoffs are expressed as ratios at the margin (e.g., additional cost per additional life years gained).
  – Permits comparison between alternative uses of resources.
  – Fund those programs beneath a threshold for willingness to pay (e.g., $50,000/QALY).
Costs versus Charges:

- Costs - price paid for resources consumed in providing a service.
- Charges - price requested for reimbursement for providing a service (set by the marketplace, may have little relationship to actual cost of service).
Cost components:

• Direct costs –
  – Medical - expenditures for medical products and services (eg., hospitalization, drugs, physician fees).
  • Fixed costs - \textit{(would not be reduced in the short term by a change in the number of services provided, eg., cost of running an operating room)}.
  • Variable costs - \textit{(vary with the volume of services)}.
  – Non-medical - expenditures for non-medical products and services \textit{(in many analyses direct costs for non-medical expenses are not included, eg., transportation and lodging for family members)}. 
Cost components:

• Indirect costs
  – those that occur due to loss of life or livelihood (assign monetary value to morbidity or mortality through human capital approach or willingness to pay approach).
Cost components:

• Induced costs (and savings)
  – Tests added or averted.
  – Treatments added or averted.
  – Complications added or averted.
  – Costs of prolonged survival (other diseases).
Considering the Effect of Time (Discounting):

• In any consideration of costs (or health outcomes), it is important to note when they are incurred.

• Future Monies are "Worth Less" than present monies.

• Future Benefits are "Worth Less" than present.

• "A bird in the hand is worth two in the bush."
Discounting (cont):

• Consider Being Paid $1000 Now or One Year From Now.

• Consider Paying a $1000 Bill Now or One Year From Now.

• Which would you prefer?
Reasons for Discounting:

• Reflect general values
• Inflation
• Productivity (Opportunity for investment or alternative use)
• Future uncertainties
Discounting:

• The present value can be expressed as:

\[ P = \frac{S}{(1+r)^N}, \]

• where \( S \) is the dollar amount (or incremental utility) spent (or accrued) at some time in the future, \( r \) is the discount rate, and \( N \) is the number of years in the future when that amount is to be spent.
Discounting:

• For instance, the present value of $10,000, spent 10 years from now at a discount rate of 5% is:

\[ \frac{10,000}{(1.05)^{10}} = 6,139.13. \]
Discounting:

• If one considers a medical strategy that has continuing annual costs (e.g., $1,000/year), their present value can be calculated by summing the time stream of annual, discounted costs as follows:

\[ \$1,000 + \frac{$1,000}{(1.05)^1} + \frac{$1,000}{(1.05)^2} + \frac{$1,000}{(1.05)^3} \ldots \]

This can be implemented quite simply in a Markov transition state model.

\[
NPV = \sum_{i=1}^{T} \frac{C_i}{(1+r)^i}
\]
Discounting:

• The discount rate is often keyed (but not necessarily equivalent) to the interest rate and is described as the "social rate of time preference."

• Contemporary analyses typically use discount rates of 3%, while older analyses used rates of 5%-6%. 
Discounting:

- If we discount on the cost side, must we also discount effectiveness?

- "Most analysts believe that intangible outcomes (eg., measures of clinical effectiveness) also should be discounted to the present to take into account the deferral of satisfaction from these benefits to the future." ¹

Clinical Example

• Cost-Effectiveness of Screening for Chronic Hepatitis C Infection in the United States
  – Calculation of the incremental or marginal C/E ratio

• Eckman MH, Gordon SC, Talal A, Schiff ER, Sherman KE. Hepatology; 56:4s,261a, 2012.
Natural History of Chronic Hepatitis C Viral Infection -
(46 year old male at time of diagnosis
21 year duration of infection)
• Time horizon
  – Lifelong.

• Outcome metrics

• Discount Rate
  – 3%/year for both costs and effectiveness.

• Direct Antiviral Agents
  – most recent trial results and costs for boceprevir and telaprevir.
Table 2. Results of Base-Case Analysis †

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Cost ($)</th>
<th>Effectiveness (QALYs)</th>
<th>Marginal Cost ($)</th>
<th>Marginal Effectiveness (QALYs)</th>
<th>Marginal Cost-Effectiveness ($/QALY)</th>
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</thead>
<tbody>
<tr>
<td>Discount (3% per year)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do Not Screen</td>
<td>952.67</td>
<td>20.6839</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screen for HCV and Treat per Guidelines</td>
<td>1,111.50</td>
<td>20.6873</td>
<td>158.8228</td>
<td>0.0034</td>
<td>47,276</td>
</tr>
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</table>

† Boceprevir as DAA.
‡ Telaprevir as DAA - $44,000/QALY.
Probabilistic Sensitivity Analyses
Cost-Effectiveness Acceptability Curve

- mCER < $100K/QALY in > 99% of simulations
- mCER < $50K/QALY in > 76% of simulations
Deterministic Sensitivity Analyses
Another Clinical Example

- Cost Utility of Adjuvant High-Dose Interferon Alpha Therapy in Stage III Cutaneous Melanoma in Quebec.

• The purpose of this study was to estimate the cost-utility of adjuvant high-dose interferon in high-risk melanoma patients in Quebec compared to a watchful waiting strategy.
Background

• Melanoma occurs in roughly 11/100,000 individuals in the northern hemisphere.
• The annual cost impact of melanoma has been estimated for the United States at $563 million.
• Usual therapy consists of surgical resection of the tumor.
• Adjuvant treatments include radiotherapy, chemotherapy, and immunotherapy. But the overall results of these adjuvant treatments have been generally poor.
• More recently the use of high-dose interferon-alpha-2b has been showed to increase overall survival and disease-free survival in two benchmark trials:
  – Eastern Cooperative Oncology Group (ECOG) trial E1684
    • 287 patients with stage IIB and IIIA, B given high-dose interferon (HDI) over 1 year and followed over 7 years;
  – ECOG trial E1690
    • Combined low-dose interferon (LDI) and HDI group in similar stages II and III.
Survival from E1684 and model extrapolation.
Figure 1 State transition Markov model structure. IFN, interferon; HD, high dose.
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Interferon treatment cost (first year)</td>
<td>CAN$36,125</td>
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<tr>
<td>Yearly follow-up routine cost</td>
<td>CAN$277</td>
</tr>
<tr>
<td>Cost of recurrence and terminal care</td>
<td>CAN$12,340</td>
</tr>
<tr>
<td>Annual post-trial death rate year 8 to 9</td>
<td>0.054</td>
</tr>
<tr>
<td>Annual post-trial death rate year 10 to 35</td>
<td>0.025</td>
</tr>
<tr>
<td>Utility interferon treatment</td>
<td>0.52</td>
</tr>
<tr>
<td>Utility metastatic recurrence</td>
<td>0.23</td>
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<tr>
<td>Utility disease-free</td>
<td>1</td>
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<tr>
<td>Discount rate</td>
<td>3%</td>
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Table 2  Incremental cost-effectiveness of high-dose interferon therapy in stage II - III melanoma for 100 patients over 7 years (CAN$)

<table>
<thead>
<tr>
<th></th>
<th>C</th>
<th>E</th>
<th>Δ C</th>
<th>Δ E</th>
<th>ΔC/ΔE (ICER)</th>
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<tr>
<td>LY discounted</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>IFN</td>
<td>3,775,121</td>
<td>354 LY</td>
<td>2,809,609</td>
<td>61 LY</td>
<td>46,059</td>
</tr>
<tr>
<td>No IFN</td>
<td>965,512</td>
<td>293 LY</td>
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<td>QALY discounted</td>
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<td>262 QALY</td>
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<td>51 QALY</td>
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<td>965,512</td>
<td>211 QALY</td>
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C, cost; E, effectiveness; ICER, incremental cost-effectiveness ratio; IFN, interferon; LY, life-years; QALY, quality-adjusted life-years.
<table>
<thead>
<tr>
<th></th>
<th>C</th>
<th>E</th>
<th>Δ C</th>
<th>Δ E</th>
<th>ΔC/Δ E (ICER)</th>
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<td><strong>LY discounted</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IFN</td>
<td>3,982,606</td>
<td>698 LY</td>
<td>2,870,649</td>
<td>200 LY</td>
<td>14,353</td>
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<tr>
<td>No IFN</td>
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<td>498 LY</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>QALY discounted</strong></td>
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<td></td>
</tr>
<tr>
<td>IFN</td>
<td>3,982,606</td>
<td>640 QALY</td>
<td>2,870,649</td>
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<td>435 QALY</td>
<td>—</td>
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C, cost; E, effectiveness; ICER, incremental cost-effectiveness ratio; IFN, interferon; LY, life-years; QALY, quality-adjusted life-years.
Figure 3 Distribution of the incremental cost-effectiveness ratio per quality-adjusted life-year at 7 years with fixed discount rate of 3%.

Marginal C/E < $50,000/QALY ~60% of the time

Societal Threshold for “Willingness to Pay”
Marginal Cost-Effectiveness of Other "Expensive" Health Technologies

- Discounted quality-adjusted cost-effectiveness ratios of several "big ticket" items:

  - facility hemodialysis ($92,700 per additional year of life),
  - renal transplantation ($52,700 - $75,900 per additional year of life),
  - screening for and treating hypertension ($33,000 - $70,800 per additional year of life),
  - and the diagnostic evaluation of chest pain ($26,600 - $133,000 per additional year of life).
Issues & Pitfalls:

• First, it must be agreed that resources are truly limited.
• Second, "if resources are limited and trade-offs based on cost-effectiveness considerations are to be made, these trade-offs will only have professional legitimacy if it is clear that resources saved from denying services of low cost-effectiveness will be reinvested in services with greater cost-effectiveness, rather than siphoned off for ineffective care or for higher profits."
• Finally, ethical tensions must be resolved between maximizing health outcomes for a group or population versus the individual patient.

• ¹Eddy DM. The individual vs society: is there a conflict? JAMA. 1991;265:1446-1450.
"Physicians must broaden their perspective to balance the needs of individual patients directly under their care with the overall needs of the population served by the health care system, whether the system is an HMO or the nation's health care system as a whole."

"Professional ethics will have to incorporate social accountability for resource use and population health, as well as clinical responsibility for the care of individual patients." ¹

Evaluating an Economic Analysis:

1. What is the problem being examined?
2. Whose perspective does the analysis take?
   • 3. What type of economic analysis?
     a. Cost-identification
     b. Cost-benefit
     c. Cost-effectiveness
   • 4. What is the time-frame of the analysis (longitudinal or cross-sectional)
   • 5. What alternatives are examined?
   • 6. What is the source of the data? How valid is it?
   • 7. Are the cost and benefit specified completely?
   • 8. Are cost and benefit adjusted for time (discounting)?
   • 9. Are uncertainties and biases identified? Are their potential effect on results examined (sensitivity analysis)?
Additional Resources

• Texts
  – Health Economics CD-ROM: available in medical library
• Review articles
• Users’ guides
• Ethical issues
• **Miscellaneous**


Data

Cost-Utility Ratios 2002-2003 (PDF) includes all published ratios, standardized to 2002 US$ and sorted by disease area.


Data Collection Forms:

- Phase III
  - Methods
  - Disease Classification
  - Ratio
  - Weight
  - Abstract Screening

Other Tables:

- "Panel-Worthy" Table of Cost-Utility Ratios 1976-1997 (PDF) includes published ratios from analyses that conformed to certain recommendations of the US Public Health Service Panel on Cost Effectiveness in Health and Medicine
  - Adoption of a societal perspective
  - Community or patient preference weights
  - Use of net costs
  - Appropriate incremental comparisons
Cost-utility analyses published in 2002 and 2003, with ratios converted to 2002 US dollars

The data are taken from the published literature and inclusion in this table does not imply an endorsement of the quality or validity of the information. More detail about the objectives and scope of this project can be found in the "Overview" page of this web site and in papers listed in the "Publication" page.

<table>
<thead>
<tr>
<th>Article ID</th>
<th>Year of Publ</th>
<th>Intervention VERSUS Comparator IN Target Population</th>
<th>Quality Score of Analysis (1–7)*</th>
<th>$/QALY in 2002 US$</th>
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</thead>
<tbody>
<tr>
<td>2002-01-00747</td>
<td>2002</td>
<td>IFN-alfa therapy of 5 MU 3x weekly for 24 weeks VERSUS Usual supportive care with no IFN-alfa therapy IN Chronic hepatitis B patients in Taiwan with hepatitis B early antigen (HBeAg), no liver cirrhosis, and a serum alanine aminotransferase (ALT) concentration greater than twice the upper limit of normal - age 35</td>
<td>4.5</td>
<td>$15,000</td>
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<td>2002-01-00817</td>
<td>2002</td>
<td>Interferon-alpha (IFN) in a dose of 5 million units (MU) daily for 16 weeks VERSUS No treatment IN Patients with chronic hepatitis B infection (HBsAg positive and elevated serum aminotransferase activity for at least 6 months, evidence of active viral replication, and a histological diagnosis of chronic hepatitis but no cirrhosis) - age 30</td>
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<td>2002</td>
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<td>5.5</td>
<td>$21,000</td>
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<tr>
<td>2002-01-00858</td>
<td>2002</td>
<td>Interferon alfa and ribavirin (24 wks) VERSUS No treatment IN HIV/HCV coinfected patients with CD4 cell counts of 350 cells/microL &amp; moderate chronic HCV, Genotype I - age 35</td>
<td>5.5</td>
<td>$18,000</td>
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<td>5.5</td>
<td>$12,000</td>
</tr>
<tr>
<td>2002-01-00858</td>
<td>2002</td>
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<td>5.5</td>
<td>Dominated</td>
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<td>5.5</td>
<td>$42,000</td>
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<td>5.5</td>
<td>$3,000</td>
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<td>2002-01-00858</td>
<td>2002</td>
<td>Interferon alfa (48 wks) VERSUS Interferon alfa and ribavirin (24 wks) IN HIV/HCV coinfected patients with CD4 cell counts of 350 cells/microL &amp; moderate chronic HCV, Genotype I - age 35</td>
<td>5.5</td>
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