Should different drugs have different thresholds?
A CED Perspective

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"There are no replacements for a George Orwell, just as there are no replacements for a Bernard Shaw or a Mark Twain . . . . In his literary criticism and political essays he pricked, provoked and badgered lazy minds, delighted those who enjoyed watching an original intelligence at work."

— TIME

"...A PARABLE THAT MAY RANK AS ONE OF THE GREAT POLITICAL SATIRES OF OUR ANXIOUS TIMES."

Christopher Morley

ILLUSTRATED BY JOY BATCHelor and JOHN HALAS
All animals are equal, but some animals are more equal than others.
CED Evaluative Framework

- Traditional benchmarks
  - Efficacy/Effectiveness
  - Safety
  - Pharmacoeconomic analysis (PEA)
    - ICER thresholds
    - Before speaking about differential thresholds, let’s consider the usefulness of PEA in HTA
Pharmacoeconomic Analyses

- For most drugs, the PE analyses tend to be poorly done with occasional exceptions.
- PE analyses for all drugs remain particularly problematic:
  - Non-conservative
  - Inconsistent outcome probabilities
  - Invalid assumptions
  - Poor sensitivity analyses
Problems Encountered in Assessing Pharmacoeconomic Data

- Limited clinical data
  - Surrogate or interim outcomes not predictive of clinical benefits
  - Incremental benefits not based on clinical evidence
  - Chronic diseases studied for short duration
- Relevant comparators not included
  - Mix of common, least-expensive and recommended
- Lack of consistency with clinical data
  - Dose, duration, outcomes
Problems Encountered in Assessing Pharmacoeconomic Data

- Included costs not comprehensive
  - Adverse effects, monitoring
- Assumptions not validated
- Analysis not conservative
  - Repeatedly biased, assumptions not clear
- Non-Canadian costs, practices, and outcomes
- Sensitivity analyses restricted to a narrow range of values
Oncology Drugs

- Does the CED treat oncology drugs differently from non-oncology drugs?
  - Do we spend less on oncology drugs?
  - Approval rates?
  - Different criteria for efficacy, safety, or cost-effectiveness?
Top-10 Therapeutic Classes By Drug Cost

Cardiovascular Drugs: $951M
Central Nervous System Drugs: $496M
Gastrointestinal Drugs: $293M
Antineoplastic Agents*: $221M
Autonomic Agents: $192M
Hormones & Substitutes: $146M
Anti-Infective Agents: $125M
Blood Formation & Coagulation: $57M
Eye, Ear, Nose & Throat Prep.: $55M
Skin & Mucous Membrane Prep.: $31M

Total Drug Cost: $2.9B

ODB Annual Report 2005-06
Top Therapeutic Classes for High-Cost Claimants (>$5,000)

ODB Annual Report 2004-05
CED: Product Approvals 2006

- Non-Oncology:
  - Total Approved: 50
  - Approved: 43
  - Not Approved: 7
  - Approval Rate: 12%

- Oncology:
  - Total Approved: 23
  - Approved: 23
  - Not Approved: 8
  - Approval Rate: 25%
Are there evaluative differences?

- Non-oncology drugs
  - Implicit threshold
    - $50,000/QALY
  - Quality of evidence
    - More surrogate outcomes
    - Placebo-controlled vs. active therapy
  - Marketing guidelines

- Oncology drugs
  - Implicit threshold
    - $100,000/QALY
  - Quality of evidence
    - Myriad clinical outcomes
      - Life-year gained, DFS, OS etc.
    - Comparator is often outdated therapy
  - Objective guidelines
Evolution of CED Evaluative Framework

- Overall Clinical Benefit
- Value for Money
- Consistency with Societal and Ethical Values
  - Citizens’ Council
- Feasibility of Adoption into Health System

Ref: International Journal of Technology Assessment in Health Care, 25:2 (2009), 141–150
Evolution of Pharmacoeconomic Evaluation

- **Established framework**
  - Traditional threshold
    - Typical common diseases e.g. HTN

- **Modified framework**
  - Higher threshold?
    - “Special” common diseases e.g. Cancer
  - Subcommittee

- **New framework**
  - No threshold
    - Rare disease e.g. Genetic disorders
Personal Observations: Oncologists

- In general, seem more fervent in their advocacy for their patients.
- More interested in looking at difficult-to-measure criteria for reimbursement decisions, e.g. ethics, “limited options” for patients and their physicians, etc.
But beware...

All Pigs Are Equal

But Some Are More Equal Than Others.