Access to Cancer Drugs
Trends & International Comparisons

W. Neil Palmer
President & Principal Consultant
Neil.Palmer@pdc.ca

September 30 2010
Ottawa
Agenda

• Persective & Overview

• Pharmaceutical Pricing, Reimbursement, HTA

• How Canada Compares

• Equity

• Outlook
Cancer Drugs...

Perspective Matters...

• Individual patients and their families
• Patient advocacy groups, disease groups/associations
• Healthcare providers
• Industry: diagnostics, pharmaceutical, related industries
• Funding: public, private drug plans, cancer care agencies
• Health technology assessment (HTA) agencies
• Price regulators
• Policy makers
• Media
Overview
Canada – Quick Facts

- Population: 33 million
- Federation of 10 provinces and 3 Territories
  - 4 largest provinces account for ~ 90% of population
    - (Ontario, Quebec, British Columbia, Alberta)
- Health care system is government funded
  - Universal, comprehensive, accessible, portable, publicly administered
  - Federal government funds health care and established general policies – provinces/territories responsible for administration & delivery of health care
  - “Comprehensive” coverage includes all physician and hospital costs but not cost of prescription drugs outside hospital
  - Provinces have established drug plans primarily for seniors (age > 65) and the poor
Origins of health care systems

Otto Eduard Leopold von Bismarck 1815 - 1898

William Henry Beveridge 1879 - 1963
Comparison of Health Care Systems

• Europe
  – Comprehensive, universal health care primarily government coordinated and/or funded, some private insurance involvement
    • Beveridge – National Health Service (NHS) systems
    • Bismarck – Social Security Health Care systems
  – Prescription drug programs are an important part of the universal health care systems

• Japan
  – Universal health care coverage with all citizens covered by some form of public health insurance
  – Most medical services (including prescription drugs) provided on a fee for service basis
  – Government sets the fees
  – Patients pay a co-payment of 10% - 30% depending on eligibility criteria

• United States
  – Health care coverage is provided through government (Medicare, Medicaid) and private insurers
  – Medicare provides coverage to seniors, Medicaid provides coverage to the poor
  – Private insurance covers working population (where/if available)
  – With 2010 health care reform, 37 million previously uninsured Americans now have health care insurance including drug benefits
Who pays for prescription drugs in Canada?

- **Public (government funded) schemes**
  - Federal / Provincial Drug Plans
    - Over 65 years of age, Social assistance, (welfare), High drug costs to Income
  - Hospital in-patients (covered by hospital “global” budget)
  - Cancer products – separate cancer agencies in Ontario and western provinces
  - Vaccines: public health programs
  - Blood products: blood agencies

- **Private insurers provide coverage to working populations**

- **Consumers / Out of Pocket**
  - No coverage / uninsured
    - Unemployed, self-employed, small employers
  - Non-reimbursed drugs (e.g., lifestyle drugs)
  - Deductibles / co-payments

Source: Canadian Institute for Health Information (CIHI), *Drug Expenditure in Canada, 1985 – 2008* (Published 2009)
Economic case for universal pharmacare

Recommendation

• Universal Pharmacare

• 1st Dollar Coverage

• “New Zealand” model would save billions
CADTH and Common Drug Review (CDR)

- The CDR reviews new drugs and provides formulary listing recommendations to all publicly-funded drug benefit plans in Canada except Quebec.
- The CDR Directorate oversees clinical and P/E reviews but not budget impact (each drug plan reviews BI).
- Each plan independently advises manufacturer of its listing decision and coverage status of the drug.
  - Affordability / budget impact are the key factors for the drug plans.
- The Joint Oncology Drug Review (JODR) reviews and provides recommendations for cancer drugs.
  - To become pCODR in fall 2010.

CDR Decisions as of January 2010 (N = 149):
- List: 3%
- List as Similar: 13%
- List with Conditions: 33%
- Do not List: 51%

The majority of new drugs are refused by CDR. Those with a positive recommendation usually have restrictions – provincial plans generally follow CDR recommendations.
Comparison of CDR and SMC Recommendations  
(64 drugs reviewed by both CDR and SMC)

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>% Distribution of Recommendations (N=64)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Canada (CDR)</td>
</tr>
<tr>
<td>List</td>
<td>1.6%</td>
</tr>
<tr>
<td>List with Restrictions</td>
<td>51.6%</td>
</tr>
<tr>
<td>Do not List</td>
<td>46.9%</td>
</tr>
<tr>
<td>Total</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

- Scottish Medicine Consortium (SMC) is far more likely than the Canadian CDR to recommend new drugs be publicly funded.
- Analysis suggests that CDR is unconvinced that new products offer incremental value when older, less expensive alternatives are available.
- CDR tends to rely more on cost comparison to an established comparator rather than cost-utility analysis ($/QALY)
- These results are consistent with other studies that concluded that CDR is more restrictive than decisions made by other HTA agencies.

Source: Palmer, WN A Comparison of Recommendations by the CDR and the Scottish Medicines Consortium, PRA / February 2009
International variations in drug usage.

Professor Sir Mike Richards

Extent and causes of international variations in drug usage

A report for the Secretary of State for Health by Professor Sir Mike Richards CBE
July 2010
## Country rankings - cancer drug utilization

Cancer drugs launched within the last five years (Richards 2010)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>France</td>
</tr>
<tr>
<td>2</td>
<td>Austria</td>
</tr>
<tr>
<td>3</td>
<td>USA</td>
</tr>
<tr>
<td>4</td>
<td>Germany</td>
</tr>
<tr>
<td>5</td>
<td>Spain</td>
</tr>
<tr>
<td>6</td>
<td>Switzerland</td>
</tr>
<tr>
<td>7</td>
<td>Denmark</td>
</tr>
<tr>
<td>8</td>
<td>Sweden</td>
</tr>
<tr>
<td>9</td>
<td>Italy</td>
</tr>
<tr>
<td>10</td>
<td>Norway</td>
</tr>
<tr>
<td>11</td>
<td>Australia</td>
</tr>
<tr>
<td><strong>12</strong></td>
<td><strong>UK</strong></td>
</tr>
<tr>
<td>13</td>
<td>Canada</td>
</tr>
<tr>
<td>14</td>
<td>New Zealand</td>
</tr>
</tbody>
</table>
Country rankings – cancer drug utilization
By launch timeframe (Richards 2010)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Within Last 5 years</th>
<th>6-10 years ago</th>
<th>More than 10 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>France</td>
<td>France</td>
<td>France</td>
</tr>
<tr>
<td>2</td>
<td>Austria</td>
<td>Denmark</td>
<td>Italy</td>
</tr>
<tr>
<td>3</td>
<td>USA</td>
<td>Switzerland</td>
<td>Spain</td>
</tr>
<tr>
<td>4</td>
<td>Germany</td>
<td>Austria</td>
<td>Germany</td>
</tr>
<tr>
<td>5</td>
<td>Spain</td>
<td>Spain</td>
<td>Switzerland</td>
</tr>
<tr>
<td>6</td>
<td>Switzerland</td>
<td>Italy</td>
<td>Austria</td>
</tr>
<tr>
<td>7</td>
<td>Denmark</td>
<td>Germany</td>
<td>Denmark</td>
</tr>
<tr>
<td>8</td>
<td>Sweden</td>
<td>USA</td>
<td>USA</td>
</tr>
<tr>
<td>9</td>
<td>Italy</td>
<td>UK</td>
<td>Sweden</td>
</tr>
<tr>
<td>10</td>
<td>Norway</td>
<td>Australia</td>
<td>UK</td>
</tr>
<tr>
<td>11</td>
<td>Australia</td>
<td>Sweden</td>
<td>Canada</td>
</tr>
<tr>
<td>12</td>
<td>UK</td>
<td>Canada</td>
<td>Norway</td>
</tr>
<tr>
<td>13</td>
<td>Canada</td>
<td>Norway</td>
<td>Australia</td>
</tr>
<tr>
<td>14</td>
<td>New Zealand</td>
<td>New Zealand</td>
<td>New Zealand</td>
</tr>
</tbody>
</table>
# Market Access Hurdles for New Drugs

<table>
<thead>
<tr>
<th>Market Access Hurdles</th>
<th>Canada (foreign)</th>
<th>Output</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. Efficacy</strong></td>
<td>Effectiveness, Cost Effectiveness</td>
<td>CDR/CADTH, (NICE, HAS)</td>
</tr>
<tr>
<td><strong>3. Quality</strong></td>
<td>Internal &amp; External Price Referencing</td>
<td>PMPRB (Pricing agencies)</td>
</tr>
<tr>
<td><strong>4. Value</strong></td>
<td>Budget Impact, Risk Sharing</td>
<td>Drug Plans (Health Ministries)</td>
</tr>
<tr>
<td><strong>5. Price</strong></td>
<td>Financing/funding</td>
<td>Provinces (PCTs, Regions)</td>
</tr>
<tr>
<td><strong>6. Affordability</strong></td>
<td></td>
<td>Reimbursement Decision</td>
</tr>
<tr>
<td><strong>7. Local / Regional</strong></td>
<td></td>
<td>Local Guidelines Funding decision</td>
</tr>
</tbody>
</table>
Health Technology Assessment
Health Economics

• The main purpose of an economic evaluation is to inform “value for money” judgments about a drug (or non-drug)

• A high quality economic evaluation must provide information that is useful, relevant, and timely.

• Economic evaluations should be:
  – based on rigorous analytical methods
  – balanced and impartial (credible)
  – transparent and accessible to the user.

• There are five types of economic evaluations - the selection of the appropriate type of evaluation depends on the research question, the condition of interest, and the availability of data on outcomes.

Source: CADTH: Guidelines for the economic evaluation of health technologies:
# Five types of economic evaluations

<table>
<thead>
<tr>
<th>Type of Evaluation</th>
<th>Description</th>
<th>Usefulness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost-utility analysis (CUA)</td>
<td>• outcomes are measured as health-related preferences, which are most often expressed as QALYs gained (i.e. a final outcome)</td>
<td>• when interventions have an impact on the HRQL, and on the length of life.</td>
</tr>
<tr>
<td>Cost effectiveness analysis (CEA)</td>
<td>• outcomes are measured in natural (health) units, such as life years gained, lives saved, or clinical event avoided or achieved.</td>
<td>• when a CUA is an inappropriate choice.</td>
</tr>
<tr>
<td>Cost minimization analysis (CMA)</td>
<td>• alternatives are considered to be equivalent in terms of outcomes - the lowest cost alternative is selected.</td>
<td>• comparing similar drugs with similar outcomes</td>
</tr>
<tr>
<td>Cost-benefit analysis (CBA)</td>
<td>• values costs and outcomes in monetary terms. Values are usually obtained through using a willingness-to-pay approach, such as contingent valuation or conjoint analysis</td>
<td>• use of a CBA in health care decision making has been limited</td>
</tr>
<tr>
<td>Cost-consequence analysis (CCA)</td>
<td>• Costs and outcomes of the alternatives are listed separately in a disaggregated format</td>
<td>• Useful for obtaining a picture of the impact of the intervention. Allows the user to assign weights, and to value and aggregate the components</td>
</tr>
</tbody>
</table>
Limitations of Health Economics

• The strength of HE model is limited by:
  – Underlying clinical data
    • Comparators (are they relevant to the HE decision)
    • Level of clinical evidence
    • Selection of outcomes
    • Time horizon
  – Availability of relevant data
    • Utilities, Quality of Life measurements
    • Resource utilization
    • Time horizon
  – Clinical trial efficacy vs.. real world effectiveness
  – Evolving clinical practice
## Evidence Hierarchy

<table>
<thead>
<tr>
<th>Level</th>
<th>Therapy/Prevention</th>
<th>Economic and decision analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Systematic Review (SR) (with homogeneity) of RCTs</td>
<td>SR (with homogeneity) of Level 1 economic studies</td>
</tr>
<tr>
<td>1b</td>
<td>Individual RCT (with narrow Confidence Interval)</td>
<td>Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses</td>
</tr>
<tr>
<td>1c</td>
<td>All or none</td>
<td>Absolute better-value or worse-value analyses</td>
</tr>
<tr>
<td>2a</td>
<td>SR (with homogeneity) of cohort studies</td>
<td>SR (with homogeneity) of Level &gt;2 economic studies</td>
</tr>
<tr>
<td>2b</td>
<td>Individual cohort study (including low quality RCT; e.g., &lt;80% follow-up)</td>
<td>Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence, or single studies; and including multi-way sensitivity analyses</td>
</tr>
<tr>
<td>2c</td>
<td>“Outcomes” Research; Ecological studies</td>
<td>Audit or outcomes research</td>
</tr>
<tr>
<td>3a</td>
<td>SR (with homogeneity) of case-control studies</td>
<td>SR (with homogeneity) of 3b and better studies</td>
</tr>
<tr>
<td>3b</td>
<td>Individual Case-Control Study</td>
<td>Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.</td>
</tr>
<tr>
<td>4</td>
<td>Case series (and poor quality cohort and case-control studies)</td>
<td>Analysis with no sensitivity analysis</td>
</tr>
<tr>
<td>5</td>
<td>Expert opinion without explicit critical appraisal, or based on or based on physiology, bench research or “first principles”</td>
<td>Expert opinion without explicit critical appraisal, economic theory or “first principles”</td>
</tr>
</tbody>
</table>

Source: PMPRB, Adapted from Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)
RCTs vs Observational studies

• “The notion that evidence can be reliably placed in hierarchies is illusory. Hierarchies place RCTs on an undeserved pedestal for, as I discuss later, although the technique has advantages it also has significant disadvantages. Observational studies too have defects but they also have merit. Decision makers need to assess and appraise all the available evidence irrespective as to whether it has been derived from RCTs or observational studies, and the strengths and weaknesses of each need to be understood if reasonable and reliable conclusions are to be drawn.”

Source: Professor Sir Michael Rawlins (Chairman of NICE), The Harveian Oration of 2008, On the evidence for decisions about the use of therapeutic interventions
There is no official incremental cost effectiveness ratio (ICER) threshold in Canada:
- Probability of rejection increases quickly above $50K/QALY
- Rejection almost certain above $70K/QALY

The threshold for oncology drugs and drugs for rare disease may be moving higher.

However, most CDR recommendations do not reference an ICER threshold.

Source: Adapted from Longson C (NICE), *The NICE Health Technology Appraisal Programme* (April 2008)
Is it cost-effective to rescue stranded sailors?

Abby Sunderland (16 years)
Rescue Cost: $300,000 +

Laura Dekker (14 years)
Rescue Cost: ? $$$
Life Jackets on Airplanes – Cost Effective?

Each life jacket costs ~ $50

*Miracle on the Hudson*
How many are wearing life jackets?
Equity
Canada: Access to 42 Cancer Drugs, 2007

- Province of residence determines access to drugs

### % Distribution of Drug Sales by Major Therapeutic Class for Canada and Comparator Countries, 2009

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Canada</th>
<th>France</th>
<th>Italy</th>
<th>Germany</th>
<th>Sweden</th>
<th>Switzerland</th>
<th>UK</th>
<th>U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Alimentary Tract and Metabolism</td>
<td>12.6</td>
<td>10.4</td>
<td>10.7</td>
<td>11.9</td>
<td>9.9</td>
<td>12.6</td>
<td>11.0</td>
<td>12.4</td>
</tr>
<tr>
<td>C: Cardiovascular System</td>
<td>21.6</td>
<td>15.0</td>
<td>16.8</td>
<td>11.6</td>
<td>9.0</td>
<td>14.3</td>
<td>12.5</td>
<td>11.9</td>
</tr>
<tr>
<td>L: Antineoplastic and Immunomodulating Agents</td>
<td>10.0</td>
<td>14.6</td>
<td>13.1</td>
<td>14.8</td>
<td>14.5</td>
<td>12.9</td>
<td>10.7</td>
<td>11.6</td>
</tr>
<tr>
<td>N: Nervous System</td>
<td>18.7</td>
<td>13.9</td>
<td>11.6</td>
<td>16.2</td>
<td>18.6</td>
<td>16.1</td>
<td>19.1</td>
<td>20.3</td>
</tr>
<tr>
<td>Other</td>
<td>37.1</td>
<td>46.1</td>
<td>47.8</td>
<td>45.5</td>
<td>48</td>
<td>44.1</td>
<td>46.7</td>
<td>43.8</td>
</tr>
</tbody>
</table>

*Source: PMPRB Annual Report 2009, citing IMS data:*
Some thoughts on “equity”

• Regional health care is a constitutional reality in Canada
• Common funding policies can lead to lowest common denominator mentality
• Regional disparity creates leadership opportunities for individual provinces
• Does increased funding for cancer drugs necessarily mean fewer funds for other drugs? Is that equitable?
• Do increases in other areas of healthcare spending (e.g. salaries for healthcare workers) mean less money for cancer drugs? Is that equitable?
• Differences (rather than “equity”) should stimulate discussion, research, analysis and action
• Equity is not the objective – Access is
OECD Report – inconvenient truths?

Recommendations

- Allow private insurance for core services and mixed public-private contracts for doctors

- Pharmaceuticals, home and therapeutic care should be integrated into the core public package.

- Revenues could be raised and excess demand curbed by implementing capped patient co-payments and deductibles.
Outlook - the way forward

• Cancer drugs (and other critical drugs, technologies) should be funded immediately upon approval by Health Canada
  – Risk sharing agreements should be negotiated by public drug plans with manufacturers to mitigate government’s financial exposure
  – Discussions with drug plans should begin as soon as Health Canada starts reviewing the drug
  – Post marketing research - partnership of government, industry, patient groups and academia to address data gaps, clinical uncertainty for the future

• Look to health care systems / cancer funding in other countries (e.g. France) for ideas to improve the Canadian system in general and improve access to cancer drugs in particular
Thank You
Neil Palmer leads a senior team of market access professionals with pricing & reimbursement engagements covering Canada, Europe, and the United States.

Since 1996, PDCI Market Access has been a leading Canadian P&R consultancy based in Ottawa. Between December 2006 to August 2009 the firm was a subsidiary of RTI Health Solutions where Neil served as vice president of global pricing and reimbursement and headed up the Canadian office. Previously, Neil was a senior official with the Canadian Patented Medicine Prices Review Board (PMPRB) in Ottawa. Prior to the PMPRB he worked with the Health Division of Statistics Canada and the Kellogg Centre for Advanced Studies in Primary Care in Montreal.

Neil has written extensively on global pharmaceutical pricing and reimbursement issues and is a frequent speaker at pharmaceutical congresses in Europe, the United States and Canada.