Decentralization in pharmaceutical reimbursement decisions: Canada’s experience

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Outline

• Describe the Canadian approach to drug reimbursement decision-making

• Recent development of
  – The Canadian Common Drug Review
  – Canadian Joint Oncology Drug Review

• Discuss the pros and cons of centralized vs. decentralized decision making

• Discuss proposed methods for making better reimbursement decisions
My Perspective

• Drug Policy Advisor
  – Chair of CED
  – Member of CED-CCO Subcommittee
  – Member of hospital-based P&T committee

• Clinician
  – Academic, hospital-based internal medicine & infectious disease

• Researcher
  – Clinical pharmacoeconomics “guy”
The Pressures on Drug Reimbursement

- Public Affordability
- Industry Innovation
- Public Expectations
Health Expenditures in Canada


- Physicians and Other Professionals: 24.8%
- Hospitals/Other Institutions: 38.5%
- Other Expenditures: 14.9%
- Capital: 4.6%
- Rx Non-Patented: 3.2%
- Retail Distribution: 5%
- Rx Patented: 6.5%
- OTC: 1.5%
Trends in expenditures on pharmaceutical products from 1944 to 2004

- Year-2004 expenditure per capita, $
- 5-yr average growth rate, %

- Retail value of prescription-only drugs
- Wholesale value of pharmaceutical products
- 5-yr average growth rate

Morgan, S. CMAJ 2005;172:1323-1324
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Canadian Health Care Jurisdictions

• National/Federal
  – Health policy legislation governing the all aspects of the universality of access to health care for Canadians
  – Approval process for licensing and approving drugs for sale in Canada

• Provincial
  – Expenditures on health for hospital care, physicians, public health and drug costs
  – Approval process for drug reimbursement by public payment plans
Province of Ontario

- Most populous province in Canada
  - 12,541,400 (2005 estimate)
- Public spending on drugs approx. $3.4 billion dollars (2005-06 estimate)
Provincial Health Expenditures -
Total $35.7 Billion, Ontario 2004

- Public Health & Admin. 11% $4.0B
- Capital 6% $2.1B
- Physicians & Other Profes. 21% $7.4B
- Drugs 9% $3.4B *
- Other 7% $2.4B
- Hospitals & Other Institutions 46% $16.4B

Source: Forecast from the Canadian Institute for Health Information, 2005

* Includes ODB Programs ($3.2B) + Other Public Programs ($0.15B)
Ontario 2004 Drug Costs -
Total $7.4 Billion
Public, Private & Beneficiary Costs

- ODB Programs: $3.2B (43%)
- Private Insurers: $2.6B (35%)
- Patient Out-Of-Pocket: $1.5B (20%)
- Other Public: $0.15B (2%)

Source: Canadian Institute for Health Information (CIHI)
Note: Other Public Programs include NIHB, Veteran’s programs, and misc. Federal Programs (e.g. RCMP, etc.)
What is the Committee to Evaluate Drugs?

• The Ontario Ministry of Health and Long-term Care's expert advisory committee on drug therapy
  – Previously known as the DQTC
• Systematically evaluates new [and increasingly] older drugs in comparison to currently available therapies to treat the same disease
• Performs a comprehensive assessment, based on a thorough review of the scientific evidence available for a new drug compared to what we know about the drugs that we already fund
Committee to Evaluate Drugs

• Members appointed by Order-in-Council
• 16 members plus Chair
  – Medicine
  – Pharmacy
  – Pharmacology/
    Pharmacokinetics
  – Epidemiology
  – Health Economics
  – Two Patients as Persons

• Over 150 active reviewers
  – Specialists
  – Generalists
  – Economic reviewers
  – Identities not revealed

• May also participate in Individual Clinical Review process
Ontario Drug Review / Reimbursement Process

1. Manufacturer Submits
   - Health Canada Issues NOC & DIN
   - CDR & CEDAC Recommendation to drug plans

2. CED Reviews Drug for Reimbursement Recommendation

3. Decision made by Executive Officer on reimbursement
CED Recommendations

• Formulary
  – General Benefit listing
  – Conditional listing
  – Exceptional Access listing
    • Individual Clinical Review mechanism
    • Criteria for internal review
    • External review on a case-by-case basis
  – No reimbursement

• Special Drugs Program
DQTC(CED) Recommendations
Submissions for First Review, 1999-2004

Note: Reviews of oral solid dosage forms were streamlined starting in 2002 and no longer require DQTC review.
The Impact of the Ontario Formulary

- “In addition, …Ontario’s formulary, … has an impact on all other sales in the province as other formularies and prescribing physicians often follow its lead. While other payers and prescribing physicians may have the ability to gain access to newer drugs, once approved by Health Canada, many take their lead from the Ontario formulary.”

Atlantic Institute for Market Studies President Brian Lee Crowley
Provincial Drug Review Committees

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<thead>
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<th>BC</th>
<th>AB</th>
<th>SK</th>
<th>MB</th>
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Provincial Listings for Single-Source Products Launched Between June 1, 1999 and May 31, 2004

Source: Provincial Reimbursement Advisor – August 2004
Diversity in Provincial Drug Reimbursement

• By 2001, it was evident that provinces were making different decisions regarding funding for similar drugs

• Perceived inequities around drug funding between provinces spilled into the political arena engendering discussion about a single, national process

• The Common Drug Review (CDR) was born
What is the Canadian Common Drug Review?

• Started in September 2003
  – Modeled on the Ontario DQTC (now CED)

• A single process for:
  – Conducting objective, rigorous reviews of the clinical and economic evidence for new drugs, and
  – Providing formulary listing recommendations to the publicly funded drug plans in Canada (except Quebec)

• Formulary decisions are made by the drug plans
  – Based on CDR recommendation, and plan mandates, priorities, resources
Who Does What – CDR’s Role

**FEDERAL GOVERNMENT**

Health Canada-TPD
Approval of new drugs for sale in Canada

**CDR Program at CADTH**

Evidence-based review
Common listing recommendation (CEDAC)

**F/P/T DRUG PLANS**

Listing and coverage decision
What Does CDR Review?

- CDR was initially limited to new drugs
  - Excludes hospital-only drugs, most injectable oncology drugs
  - Includes any drug that would potentially be covered by the participating plans
- Submission to CDR = a submission to all participating plans
  - Typically made by the drug manufacturer
  - Drug plans may also initiate a CDR submission
CDR Process

Manufacturer Responsibility

Clinical reviewers & experts

Reviews by CDR

Economic reviewers

CADTH Responsibility

Reviews to CEDAC for recommendation

Recommendation to drug plans

Drug Plan Responsibility

Each drug plan makes its decision

Each drug plan makes its decision

Manufacturer Responsibility

Submission to CDR by manufacturer
CDR Timelines

• Total process takes 20-26 weeks from submission to CEDAC recommendation
  – 1 week to review submission
  – 9 weeks to prepare reviews
  – 3 weeks for manufacturer’s comments and CDR response
  – 3-8 weeks to schedule for CEDAC
  – 1 week to prepare recommendation
  – 2 weeks when recommendation is embargoed
  – 1 week to issue final recommendation
# CDR Activity to January 15, 2007

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<td>Number of submissions</td>
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<td>Number of priority reviews requested/granted</td>
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<td>Number of final recommendations issued</td>
<td>62</td>
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<tr>
<td>Number of recommendations to “list”</td>
<td>30</td>
</tr>
<tr>
<td>Number of recommendations to “not list”</td>
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Program Success to Date

• Incorporated 18 processes into one
• Have met targeted timeframes >90% of time
• ~90% agreement between CEDAC recommendations and drug plan decisions
• High quality systematic reviews of published and unpublished trials
• Publicly available reasons for recommendations
• Stakeholder consultations, including formal evaluation of CDR
• Ongoing process improvements
The “C” Word

…the scariest word in pharmaceutical reimbursement decision-making!
Affordability/Ability to Pay – Cancer Therapies

New Drug Funding Program (NDFP) - Expenditures

Reference: NDFP Microstrategy iPort May, 2006
Affordability/Ability to Pay – Cancer

Avg. Cost Per Treated Case

Reference: NDFP Microstrategy iPort April, 2007 (exception: premetrexed, bortezomib, Zevalin, Bexxar, bevacizumab, and alemtuzumab are estimated values, paclitaxel, pamidronate, irinotecan, vinorelbine – pre-generic pricing)
Why a Joint Oncology Drug Review Process?

• Cost
  – Oncology drug expenditures have risen 20-25% per year in recent years (roughly 2x the rate of other drugs)
  – Growing numbers of oral therapies for cancer

• Consistency
  – Differing drug approval mechanisms based on province
  – CDR process (2003) mandate did not include IV oncology drugs
  – Growing variations and inconsistency in coverage/criteria across jurisdictions despite review of a single body of clinical evidence
  – Patient concerns regarding inequitable access

• Pharmacoeconomics not considered in all jurisdictions
Joint Oncology Drug Review Chronology

Western Premiers commitment

May 2006

June 2006

July 2006

Sept 2006

Dec 2006

Jan/Feb 2007

Phase I - Implementation

Phase II

Consultation

Phase III

MOU

Business Case

March 2007

July 2007
JODR – CED/CCO Review Process

1. Existing drug with new indication
2. Evidence-based reports developed by CCO/DSG
3. Submission information and guidelines reviewed
4. CCO/CED Subcommittee recommendation to CED
5. Through government approval process, to formalize funding status

- Hospital-based IV medications
  - Available through NDFP
- Negative decision, no reimbursement
- Community-based PO, injectable medications
  - List on ODB formulary

NCE – New Chemical entity
CED – Committee to Evaluate drugs
DSG – Disease Site Group
JODR – CED/CCO Review Process
Link with CDR
Canadian Drug Reimbursement: Questions

• A decentralized system evolving into a more centralized one?
• Which is best?
• Has it adversely affected pharmaceutical investment nationally or regionally?
• Will provinces ever give spending decisions over to a centralized one?
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<th>Centralized</th>
<th>Decentralized</th>
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<td>• Access to all relevant information from central agency</td>
<td>• Fine-tune decisions based on unique population demographics or economics</td>
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<td>• Reduction in filing submissions and documentation</td>
<td>• Introduces a “check and balance” into system</td>
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<tr>
<td>• Ability to include pharmacoeconomic data into licensing decision</td>
<td>• Potential for diversity of investment to different regions</td>
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Centralized vs. Decentralized: The Cons

Centralized
• A negative decision allows for little chance to obtain reimbursement in all jurisdictions
• Only reviewed by a single group of reviewers, e.g. opportunity for bias in data review
• Inconsistent application of positive recommendations

Decentralized
• More expensive
• Duplicative
• Perceived asymmetry in recommendation decisions for reimbursement
• Impact of different decisions on access to drugs
• Potential for jurisdictions to undermine each other in negotiations to list
Pharmaceutical Investment in Canada

• Over the past 17 years in Canada, $11.8 billion has been invested in R&D
  – $2.1 billion has been spent in universities and hospitals
• Since 1988, spending in R&D has increased by 605%
• In 2004, spending in Canada amounted to $1.17 billion

Pharmaceutical Pricing in Canada

• The prices of patented medicines in Canada are approximately 9% below the international median (US, UK, France & Sweden)

• Canadian patients pay on average 30% more for generic medicines than the international median

Source:  
Provincial Listings for Single-Source Products
Launched Between June 1, 1999 and May 31, 2004

Source: Provincial Reimbursement Advisor – August 2004
Pharmaceutical Investment in Ontario 2006

- R&D investment has increased by 751% since 1988 to $537.2 million in 2003
- Pharmaceutical companies have $718.4 million invested in land, facilities and equipment in Ontario

Pharmaceutical Investment in Quebec 2005

• Quebec attracts more than 50% of all investments in pharmaceutical research in Canada
• More than $2 billion invested directly in the economy of Quebec
• $450 million invested in research and development
• Of this total, more than $30 million are allocated to universities and hospitals

The Canadian Drug Reimbursement System

Strengths
• Well established
• Objective
• Process driven
• Allows for some regional differences
• Rigorous use of pharmacoeconomics

Weaknesses
• Too diverse
• Potential for inequity
• Duplicative
• Lack of transparency
• Tied to provincial expenditures
How can we improve drug reimbursement decision-making?

• Real-world randomized trials
• Pharmacosurveillance
  – Post-marketing assessment of drug use, compliance and association of drug use with projected outcomes
  – Observational studies using administrative databases
• Primary data collection using drug registries

Source: Laupacis et al CMAJ 2003;169:1167-70
Fig 1: A proposed model for drug evaluation in Canada. CEIPs = Centres of Excellence in Pharmacosurveillance.
Conclusions

• Canada maintains a decentralized drug reimbursement system with decisions made at the provincial level

• Two national processes have been developed to address the perceived inequities in drug funding; the CDR and the JODR

• As to whether these processes can successfully resolve the regional disparities remains to be seen