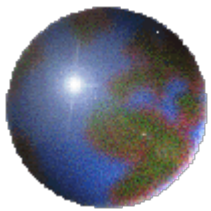

QALY's
The Canadian Experience

Applied Pharmacoeconomics & Outcomes Research Forum

University of California, San Diego

May 14, 2007

Proposed Focus

- Overview of Canadian drug approval and reimbursement system
- Overview of the questions
- Deeper focus on use of QALYs in Formulary decisions
- Thoughts for the future of QALYs

My background

- Completed BscPharm, PharmD, MBA
- Clinical & Pharmacoeconomic Research responsibilities for 7 years in industry
- Ontario Ministry of Health - ODB
  - North America's 2nd largest payer for drugs
  - Associate Director for 5 years
  - Senior Advisor to Ministry's external expert committee-DQTC
- Most recently GR – Janssen Ortho
  - National Director, Provincial Healthcare Relations
  - Currently: Director, Federal Affairs & Health Policy


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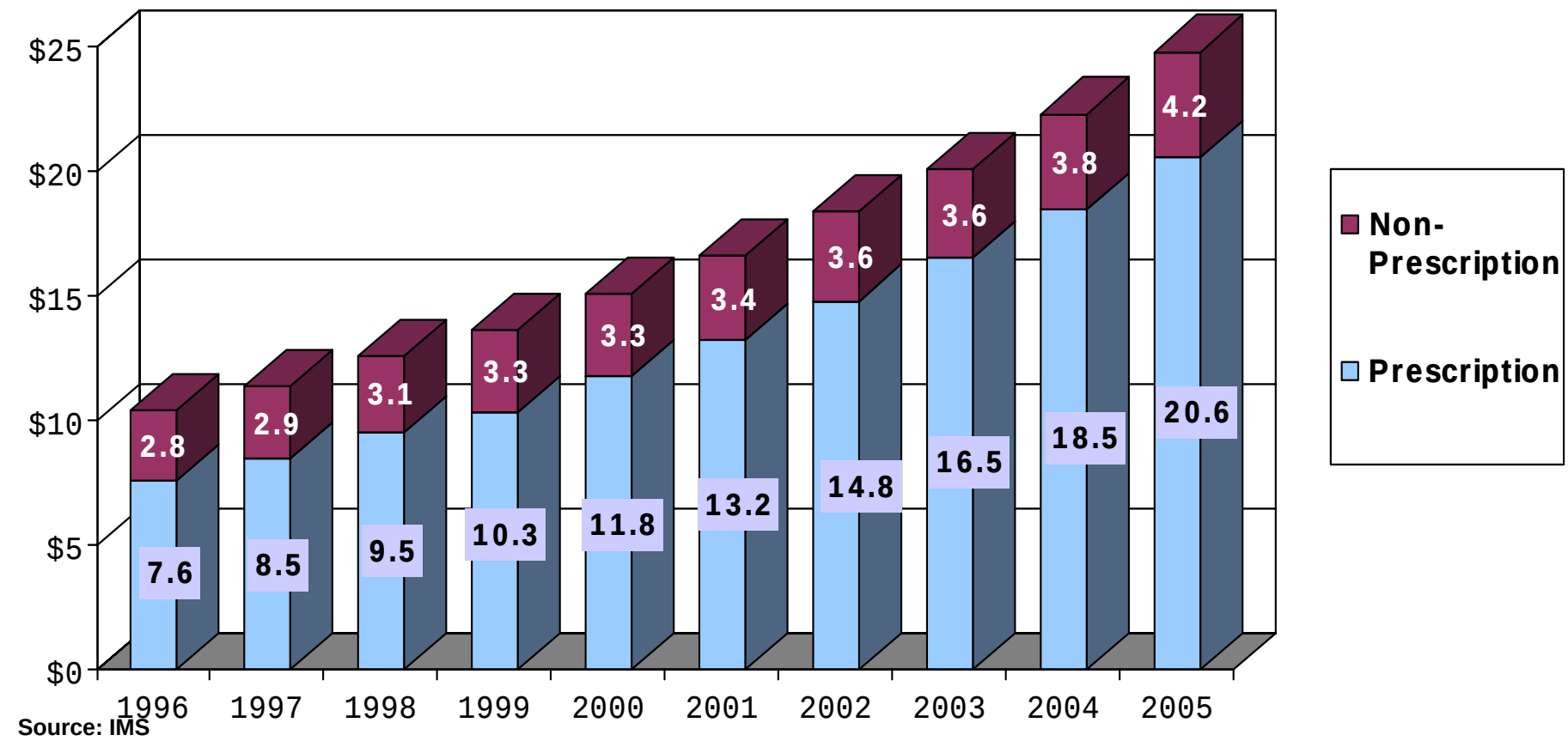
Drug Expenditures, 1996-2005

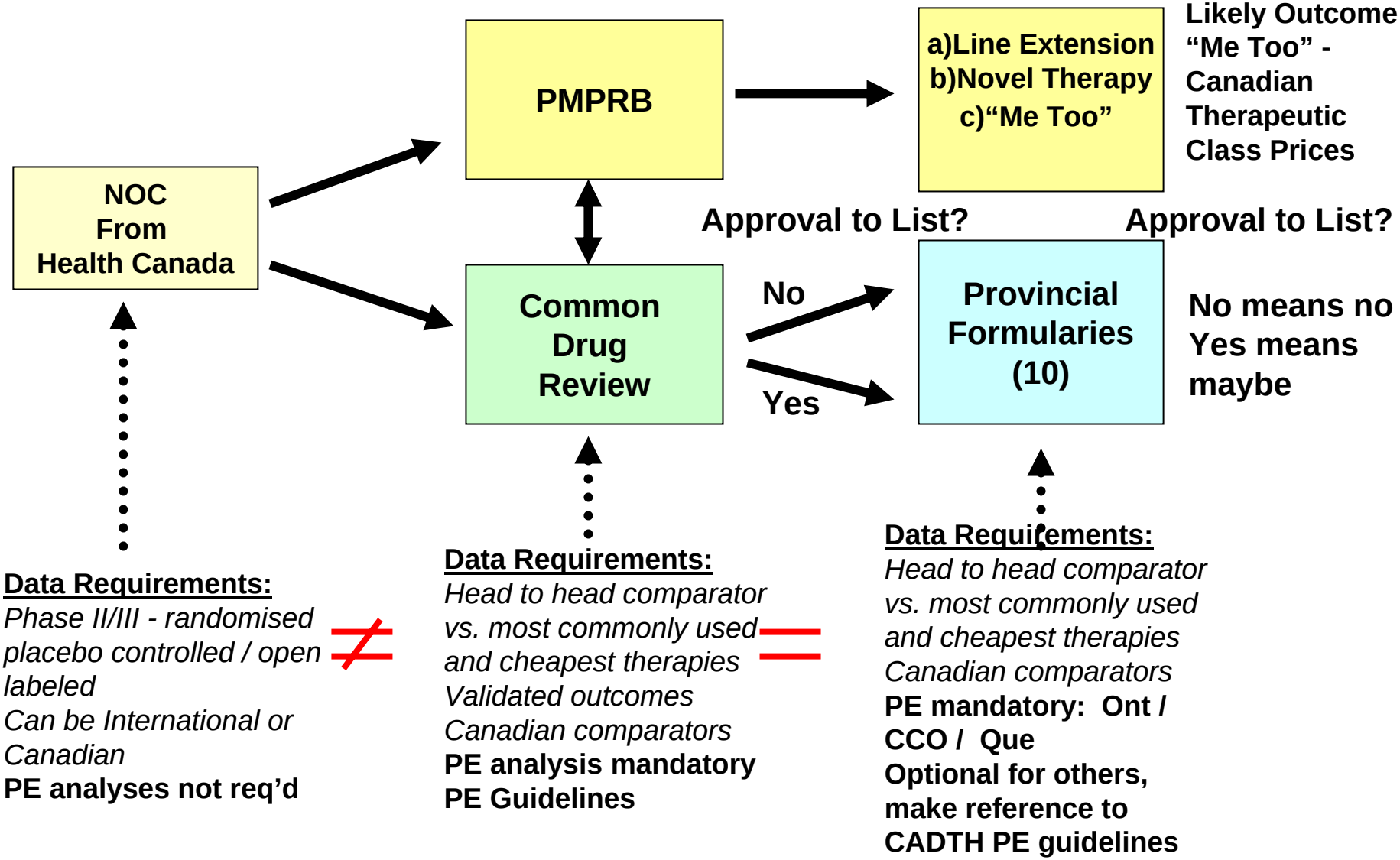


Source: IMS

Ontario's Drug Program

- **Largest payer for drugs in Canada, 2nd largest in North America**
- **Drug Expenditures:**
  - $3.9 Billion (2005/06) representing 10% of Health expenditures (9% growth over previous year)
  - 2.2 million beneficiaries
- **Breakdown of Ontario payers:**
  - ODB – 43%
  - TPP – 35%
  - Out of Pocket – 20%
  - Federal – 2%

Pricing and Access Process Map



CADTH – Who are they?

- *Founded in 1989, by the Canadian federal, provincial, and territorial (F/P/T) Deputy Ministers of Health -*

  " We need a more coordinated approach across the country to ensure that all Canadians are benefiting from the advances being made in health technology " (Perrin Beatty, Minister of National Health and Welfare, 1989)

- *Private, not-for-profit organization*
- *Funded by Health Canada, the provinces and territories*
- *Head office in Ottawa; second office in Edmonton; liaison presence in provinces*

Evolution of CADTH

- *1989: CCOHTA launched*
- *1993: Drug assessments added*
- *2000: HTA expanded*
- *2002: Common Drug Review launched*
- *2003: Increased federal funding*
- *2004: COMPUS launched*
- *2006: CADTH launched*

CADTH's Vision and Mission

- *CADTH's vision is to facilitate the appropriate and effective utilization of health technologies within health care systems across Canada*

- *"Our mission is to provide timely, relevant, and rigorously derived evidence-based information to decision makers and support for decision-making processes"*

  - Health technologies include drugs, vaccines, devices, equipment, materials, medical and surgical procedures, and systems

Who are their customers?

- *Government policy makers*
- *Drug plan managers*
- *Regional health authorities*
- *Hospitals*
- *Health professionals*

CADTH's Three Core Programs

- *HTA*

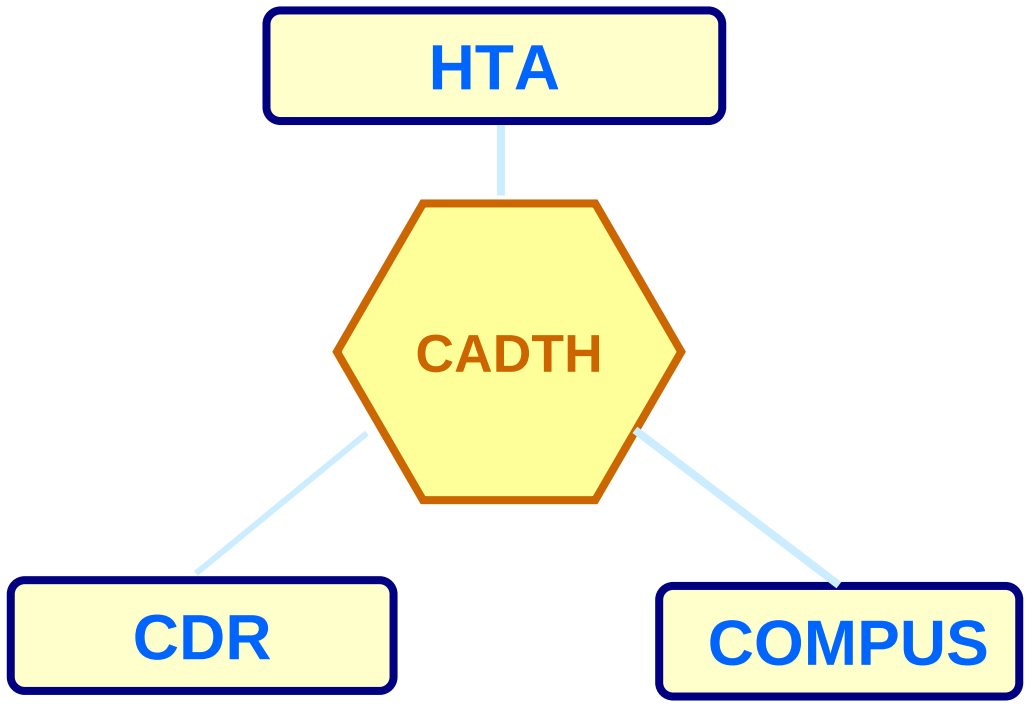
Health Technology Assessment

- *CDR*

Common Drug Review

- *COMPUS*

Canadian Optimal Medication Prescribing and Utilization Service



Common Drug Review – CDR

- *Single process for:*
  - conducting objective, rigorous reviews of the clinical and economic evidence for new drugs in the assessment of cost effectiveness, and
  - providing formulary listing recommendations to the publicly funded drug plans in Canada (except Quebec)
- *CDR listing recommendations are made by the Canadian Expert Drug Advisory Committee (CEDAC)*
- *Final listing decisions made by individual drug plans*
- *No province has yet dismantled their own expert review process*

CADTH's HTA Program

- *CADTH's HTA program:*
  - performs in-house and externally commissions HTA studies
  - provides recommendations and advice
  - used by jurisdictions to support decisions
  - government is not given any preview of reports
- *Scope includes:*
  - drugs, vaccines, blood products
  - devices and equipment
  - medical and surgical procedures
  - health care systems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Who was interviewed?

CDR

- Mike Tierney - Vice President, CDR - CADTH
- Dr Braden Mans - Chair, CEDAC
- Dr Andreas Laupacis - Former Chair, CEDAC

HTA

- Don Husereau - Director, HTA – CADTH

Provinces

- Bob Nakagawa - Assistant Deputy Ministry, British Columbia
- Judith Glennie - Former ODB Associate Director

Oncology

- Debbie Milliken - Director, Cancer Care Ontario

#1 Why are QALYs being used in Canada?

- Academic experts developed interest and actively researched and published on QALYs since 1970's
  - David Feeny, George Torrance, Bernie O'Brien, Amir Gafni
- Clinicians involved in reimbursement decisions translated the academic concepts and made QALYs more accessible for reimbursement decision making
  - Alan Detzky, Andreas Laupacis, Peter Tugwell
  - 1992 Can Med Assoc J

Why are QALYs being used in Canada?…con't

- Large single payers, increasing cost pressures
- Pharmacoeconomic (PE) Guidelines issued provincially & nationally; incorporated QALYs
  - Early 90's – ODB, later CCHOTA
  - Most recently - CDR
  - Outside of Ontario, provincial drug programs make reference made to CADTH PE Guidelines for guidance
- Preference for utility analyses in Guidelines:
  - 'consistent with desire to permit broad comparisons CUA are preferred'
  - 'QALYs considered the gold standard'
  - 'Brings together experience of benefits, side effects and QOL into one measure and can compare across different drugs/diseases'

#2 What types of decisions used for?

- *Program budget allocation?* ***No***
  - 'Not possible, too many assumptions, too broad, no validity of estimates'
  - 'Largely an academic exercise for rationing resources'
  - A few examples of Canadian evaluations:
    - Renal transplantation vs dialysis
    - Hip and knee joint replacement
- *Formulary placement?* ***Yes***
  - Provincial drug plans primarily
  - Hospitals
    - Very limited use, depends on whether expertise exists eg London Sciences Center
    - Budget impact of greater concern

What types of decisions used for?…cont

- *Funding decisions for medical services & devices?* ***Inconsistently***
  - Quality of evidence for non drug areas generally poor
- *Patient level decision making?* ***No***
  - Too technical and not well understood by practicing physicians
  - Concerns that not sufficiently sensitive to use at bed side
  - Possible use in an environment where physicians have responsibility for ‘fund holding’, concerns however that cost/QALY ‘not real’, most likely focus on budget impact

#3 Is using QALYs working?

- Effectiveness of QALYs in enhancing decision making has not been evaluated
- Perceptions vary significantly across the country about their effectiveness

#4 Are there specific diseases where QALYs are more or less appropriate?

- Generally, QALYs considered more relevant for chronic diseases rather than acute or short term impairment
  - eg. Nausea associated with chemotherapy
- QOL, ADLs should be significantly affected
  - Useful in - pain, oncology, ADHD
  - Not useful for - hypertension, elevated cholesterol

#4 Are there specific diseases where QALYs more or less appropriate?…con't

- Threshold for acceptable cost/QALY currently not different for different diseases
- There is a debate however for the need for disease specific thresholds
  - Drugs for rare diseases
  - Oncology drugs

#5 How aware is the public of the use of QALYs in decision making?

- Very limited awareness amongst public
  - Some patient groups aware of their use and question the $50 K/QALY threshold
  - CDR to begin issuing ‘lay versions’ of CEDAC recommendations, these will refer to cost/QALY
  - CDR to develop backgrounder on QALYs
- Limited to no awareness amongst prescribing community


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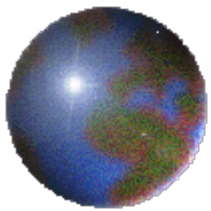

The Canadian Experience with QALYs

Bringing it all together

The CDN Experience with QALYs

- QALYs actively explored by academia since 1970's
- Use in decision making introduced by clinicians schooled in economics in the early 1990's
- Of major interest:
  - Allow for comparisons across drugs/diseases
  - Promised simplicity in decision making – making the complex simple
  - Useful indicator of cost effectiveness – with a useful social judgement on quality of health gains
  - Provides publicly defensible basis for difficult reimbursement decisions

The CDN Experience with QALYs

- There is however, a widespread uncertainty about QALYs ...
  - Lack of confidence in the measures
    - Some view that QALYs have been well validated (NICE – Rawlins et al BMJ 2004), others have observed ongoing debates within the academic community over the validity and accuracy of the various measures, and have become more uncertain about the measures themselves
  - Concerns about the many assumptions made in modeling
  - Too abstract for some decision makers
    - Opaque and understandable to only a few individuals

The CDN Experience with QALYs

- Other concerns:
  - Despite concerns about accuracy & validity, QALYs rarely verified retrospectively
    - Eprex for treatment of anaemia in patients on dialysis
      - 1990 evaluation by York Center for HE, cost/QALY was 103,145 UK pounds
      - 2000 re-evaluation, cost/QALY now 17,067 pounds
  - In Canada, QALYs used at time of launch by CDR, could deny access to new advances, which when examined in the context of real world experience may become much more cost effective
  - A recent panel of oncology reimbursement decision-makers failed to agree about value of economic evidence, although required, not systematically considered
    - Rocchi et al CADTH Policy Forum, 2007

Bringing it all together…..

- Drug Program Managers, early in a mandate of managing significant cost pressures, strive to make decisions in a framework of rigor, consistency, fairness and which are publicly defensible
  - ODB early 90's, CDR 2003, CCO 2005
  - QALYs has been a useful single measure of 'value for money'
- Established programs, appear more comfortable in operating in a challenging multifactorial decision making process
- Early adopters of QALYs appear to be moving away from the promise and simplicity of QALYs
- Some provinces have found a limited role for QALYs in decision making, and employ a multifactorial approach

The future of QALYs in Canada

- For the short term
  - QALYs will be requested and preferred by some decision makers
  - Actual use in decision making will continue to vary
  - Although no clear ‘thresholds’ for cost/QALYs, informal thresholds do influence decisions, although this too varies
- For the medium term
  - A more active and public debate on the usefulness of QALYs is looming
  - Public discourse on the concerns with QALYs may lead to a reevaluation by national and provincial bodies, of the perceived value of QALYs