

Evaluating Drugs Apples vs Oranges?

Face to Face: Drug Plan Management Forum
December 1, 2010

Suzanne Lepage, Private Health Plan Strategist



Evaluating Drugs

- Why do some formularies cover a certain drug while other formularies do not?
- Don't all formulary managers review the same scientific evidence to evaluate drugs?
- Why don't they arrive at the same coverage decision?



Evaluating Drugs

Challenges:

- How to compare similar drugs and establish their relative value?
- If a drug claims to be superior, how to determine if it is incrementally better than current therapies?
- How to assess if additional costs of the new drug are justifiable vis -a-vis the reported benefits?



Evaluating Drugs

Challenges:

- How to decide which drugs to cover?
- What criteria do you use to compare similar drugs and establish their relative value?
- What is value?



Evaluating Drugs


Efficacy	Effectiveness
Measures how the drug produces a predefined benefit under carefully controlled conditions	Measures the observed benefits and harms of drugs in real-world clinical settings and broader populations

Randomized controlled trials (RCT)	Comparative Effectiveness Research (CER)
<ul style="list-style-type: none">▪ “Gold standard” of scientific evidence - required for regulatory approval by Health Canada▪ Tests a drug against a placebo	<ul style="list-style-type: none">▪ How effective is the drug and how does it perform in the “real-world”?▪ Compares drug against its commonly used alternatives





Randomized controlled trials (RCT)


CANADA

CONSOLIDATION	CODIFICATION
Motor Vehicle Safety Regulations	Règlement sur la sécurité des véhicules automobiles
C.R.C., c. 1038	C.R.C., ch. 1038
Current to December 28, 2009	À jour au 28 décembre 2009
Published by the Minister of Justice at the following address: http://laws-lois.justice.gc.ca	Publié par le ministre de la Justice à l'adresse suivante : http://laws-lois.justice.gc.ca

Comparative Effectiveness Research (CER)

edmunds.com 

ANNUAL AUTO ISSUE **ANNUAL AUTO ISSUE**

TOP 10 PICKS OF THE YEAR **BEST NEW CARS UNDER \$20,000** **3 MAINTENANCE RIP-OFFS** **WHO MAKES THE BEST CARS?**

APRIL 2009 | CONSUMERREPORTS.COM

ConsumerReports
Exclusive Ratings Reliability Fuel Economy Performance Value

Best & Worst 2009 Cars


Top Value: 2009 Honda Fit Page 18

Phil Edmonston
LEMON-AID
2010
NEW CARS and TRUCKS

- Get the Best for Less
- Good and Bad Buys
- How to Get a Refund
- 2009-10 Reviews



1.5 MILLION COPIES SOLD IN CANADA

RCT Challenges

RCTs are conducted on "ideal" patient

- Doesn't represent the "average" or general patient population
- Only 18% of real world early rheumatoid arthritis patients would have met the criteria to be included in RCTs¹
- May not help when making decisions for an "average" patient

1- Early Rheumatoid Arthritis (ERA) Trials have almost no Generalizability to ERA patients: Results from a Large Multi-center Cohort V Bykerk, J Smuczek, G Boire, B Haraoui, C Hitchon, S Jamal, J Pope A&R Supplement 2008 Abstract 1609 ACR 2008



RCT Challenges

RCT can't tell which:

1. patients will benefit most from the treatment
2. drug is better at treating a particular condition
3. drug is most cost effective



Comparative Effectiveness Challenges

- No widespread agreement
- Determining the value depends on
 - the perspective of the evaluator
 - what is included in benefit and cost for the value equation

$$\text{Value} = \frac{\text{benefit}}{\text{cost}}$$



Comparative Effectiveness Challenges

- The least expensive alternative
 - not always the most economical
 - may not produce an optimal outcome for both the patient and the drug plan



**Can private formulary
managers look to government
drug plan decisions to guide
their formulary management?**



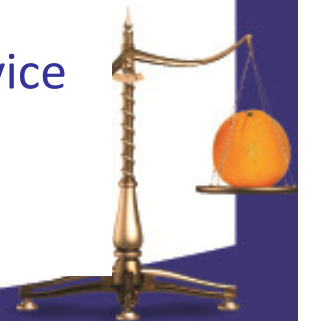
Government Reports

Canadian Agency for Drugs and Technologies in Health (CADTH)

- Independent, not-for-profit agency funded by Canadian federal, provincial, and territorial governments
- Provides information about the effectiveness of drugs and other health technologies to [Canada's federal, provincial and territorial health](#) care decision makers.

CADTH offers three main programs:

1. [Health Technology Assessment \(HTA\)](#) : assessing drugs and health technologies,
2. [Common Drug Review \(CDR\)](#) : conducting drug reviews and providing formulary listing recommendations,
3. [Canadian Optimal Medication Prescribing and Utilization Service \(COMPUS\)](#): identifying and promoting optimal drug therapy.



Government Reports

CADTH Therapeutic Review pilot

- Project was established to test the framework for conducting a review of a CDR submission(s) concurrently with a therapeutic review of the same drug class or category as the CDR submission
1. Biological response modifier agents for adults with rheumatoid arthritis
 2. Third-line therapy for patients with type 2 diabetes inadequately controlled with metformin and a sulfonylurea



Government Reports

CADTH's mandate is to provide support to

*"Canada's federal, provincial and territorial health care decision makers"*¹

Provincial Formulary

Designed for seniors or
low income residents

≠

Private Drug Plan

Intended to protect an active
working population

1 - Canadian Agency for Drugs and Technology in Health <http://www.cadth.ca/index.php/en/home>



Government Reports

“CADTH reports are tailored with a public payer end user in mind.

When asking the question, ‘Is this drug cost effective,’ they may consider the impact on hospitalizations and the healthcare system.

They are not looking at things like workplace productivity and absenteeism that might be of more interest to private payers.”

Dr. Neil MacKinnon, Professor, College of Pharmacy and Faculty of Medicine at Dalhousie University



Government Reports

Consider the following:

1. Who conducted the research? Who is the study's intended end user? Do they value the same thing you value?
2. What costs are included? Are these costs relevant to you?
3. What benefits are considered? Are these benefits for you?



WellPoint (US)

- Use clinical efficacy **and** clinical effectiveness real-world data to make formulary decisions.
- Goal is to improve clinical health outcomes, quality of life and productivity and reduce total cost of care.



WellPoint (US)

- “A more expensive medication can be less expensive overall if the member’s health is improved”
- Assessed outcomes for medications for chronic obstructive pulmonary disease (COPD)
- Drug with the highest price tag was actually the most cost effective for the plan to cover



WellPoint (US)

“At WellPoint we recognize that there are circumstances in which RCTs may not be sufficient alone for decision-making and that CER data may complement RCT data by providing data on outcomes achieved in a real-world setting.”

Jeff White, director, Drug Evaluation and Clinical Analytics.



Drugs are only a piece of the puzzle

- “Ideally plan sponsors should also consider other health benefits, disability and absenteeism to better understand their benefit plan usage and compare costs to outcomes.” (*IMS Brogan*)
- “Until a private plan sponsor is able to integrate this data, it will be difficult for them to measure the value of the outcomes or assess real-world effectiveness.” (*Cubic Health*)



Comparing relative costs

- Much more than the price tag
- Consider actual cost to treat a patient
- Standardize data to ensure comparable values
- Important to understand how drugs are used before evaluating them



Comparing relative costs

- One calendar year may not provide an accurate picture of relative drug costs
- Consider five-year period to annualize drug cost
- Important to benchmark your data vs industry norms
- Lower drug costs not always be a good thing - could be a sign of poor adherence



Best practices

Drug submissions and evaluations

- No best practice in Canada
- Very few new drug submissions are tailored to private plans



Best practices

WellPoint

- Transparent drug coverage evaluation process
- First health benefits company to publish
 - health technology assessment guidelines
 - standardized comparative effectiveness research guidelines
- Provides guidance to pharmaceutical companies



Best practices

Academy of Managed Care Pharmacy (AMCP)

- Format for Formulary Submissions (October 2000)
- Template for pharmaceutical manufacturers' submissions of drug products
- Standardized process of evaluation
- Based on sound scientific evidence

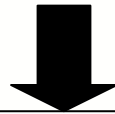


Evaluating Drugs

- Why do some formularies cover a certain drug while other formularies do not?
- Don't all formulary managers review the same scientific evidence to evaluate drugs?
- Why don't they arrive at the same coverage decision?



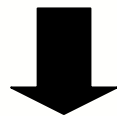
Formulary managers review the same scientific evidence



Considerations that can influence drug evaluation decisions:

- Cost
- Benefit
- Value
- Efficacy
- Effectiveness

- Perspective
- Expertise
- Evidence
- Data
- Tools



Evaluation can be significantly different



Questions and Discussion



Suzanne Lepage
(519)954-8873 (Business)
(519)635-5175 (Cell)
suzanne@suzannelepage.ca
www.suzannelepage.ca

