



Experimental Evidence to Inform Drug Funding Policy

- **March 29, 2010**
- **Ken Bassett UBC**



Overview

- Provincial drug funding policy
- Evaluative framework
- Examples
 - Drug Classes (statins, tryptans)
 - TZDs
 - Donepezil
 - Coxibs



Overview

Assumptions


- Levels of evidence known
- Context is everything



Provincial Drug Funding Policy


Overview

- Federal government licenses
 - Regulated
- Provincial governments pay
 - Unregulated



Provincial Drug Funding Policy Overview (cont.)

- A committee considers
 - Benefit/harm evidence
 - Price



Provincial Drug Funding Policy Overview (cont.)

- Rationing

- Seldom reversible
 - Yes, stays yes

- Seldom controllable
 - Partial yes, difficult to limit



Provincial Drug Funding Policy

Rules of Evidence/How to say 'No'

1. Manufacturers bear the burden of proof of benefit versus harm
 - Default position:
inadequate evidence of net benefit = Do Not List



Provincial Drug Funding Policy

Rules of Evidence/How to say 'No' (cont.)

2. Provincial Drug Plans determine:

- Strength of evidence
 - *necessary conditions*
 - *quality and quantity*



Provincial Drug Funding Policy

Rules of Evidence/How to say 'No' (cont.)

3. Provincial Drug Plans determine:

- Magnitude of effect
 - *sufficient conditions*
 - Clinical significance of outcome measures



Provincial Drug Funding Policy

Examples

- Type 1
 - First of Class
 - establishes evaluative framework

- Type 2
 - Addition to Class



Provincial Drug Funding Policy

Example 1.

- First of Class

- < 10%

- Evaluative framework

- Focus on pharmacology; is it a new Class?

- Manufacturer must justify net benefit versus placebo

- Key issue: clinical outcome measures



Provincial Drug Funding Policy

Example 1. First in Class

■ Donepezil

- Licensed by Health Canada, 1999
- Submitted to BC Drug Plan for Alzheimer's patients in 2000



Provincial Drug Funding Policy

Example 1. First in Class (Donepezil)

- Evaluative Framework

- RCTs versus placebo

- Outcome measures needed:

- delay entry into nursing homes

- delay mental or functional deterioration



Provincial Drug Funding Policy

Example 1. First in Class (Donepezil)

- Evidence

- No clinically significant benefit
- Significant increase in serious harm

- BC Policy: **Do Not List**



Provincial Drug Funding Policy

Example 1. First in Class (TZDs)

- Rosi- and Pio-glitazone
- Evaluative framework
 - RCTs versus placebo
 - Outcome measures:
 - accepted glycemic surrogates
- BC Policy: **eventually Listed**



Provincial Drug Funding Policy

Example 2. Addition to Class

- Most common (90%)
- Evaluative framework
 - No price premium
 - Price premium



Provincial Drug Funding Policy

Example 2. Addition to Class

- No price premium
 - Evaluative framework
 - Accept RCTs versus placebo
 - Include observational data on harm



Provincial Drug Funding Policy

Example 2. Addition to Class

- No price premium
- Many drugs and classes
 - Triptans
 - Statins
 - Anti-psychotics
 - Anti-depressants



Provincial Drug Funding Policy

Example 2. Addition to Class

- No price premium
- RCT and non-RCT evidence
 - Triptans
 - Eletriptan - ECG
 - Statins
 - Cirivastatin -rhabdomyolysis



Provincial Drug Funding Policy

Example 2. Addition to Class

- Price premium
 - Rofecoxib and Celecoxib
 - Licensed in Canada, 1999-2000
 - 10 NSAIDs already funded

- Marketed as
 - Equal efficacy
 - Less harm (justification for higher price)



Provincial Drug Funding Policy

Example 2. Addition to Class

- Price premium
 - Rofecoxib and Celecoxib
 - Evaluative framework
 - “me-too” NSAIDs
 - RCT, active comparator
 - Serious morbidity outcomes



Provincial Drug Funding Policy

Example 2. Addition to Class

- Evidence

- Rofecoxib and Celecoxib

- Small serious GI benefit (rofecoxib)
 - increased overall serious harm

- **Policy: Do Not List**



Provincial Drug Funding Policy

Example 2. Addition to Class

- Ongoing policy process
 - Rofecoxib and Celecoxib
 - Evaluative framework
 - Unchanged – RCT evidence
 - **Policy: List, 3rd Line**
 - **political reasons**



Provincial Drug Funding Policy

Example 3. Addition to Class

- Final Chapter
 - Rofecoxib
 - Evaluative framework
 - Unchanged
 - Full RCT reporting
 - Increased overall harm (MI > GI benefit)
 - **Withdrawn from market**
 - Also lawsuits USA



Summary

- **Provincial drug funding policy:**
 - **Sets necessary and sufficient conditions for funding**
 - **Needs sufficient evidence of net benefit to fund**
 - **Needs RCTs to say ‘no’**
 - **Utilizes mainly RCT evidence**
 - **Observational data for additions to Class**