Routinely Collected Data (RCD) and ‘Adaptive’ Drug Reimbursement Arrangements

Craig Earle, MD MSc FRCPC
Disclosures

• none
## Public drug funding pathway

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Agency/Body</th>
<th>Output</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Safety, Efficacy, Quality</td>
<td>Health Canada</td>
<td>Market authorization</td>
</tr>
<tr>
<td>2. List price</td>
<td>Patented Medicines Pricing Review Board (PMPRB)</td>
<td>Maximum price</td>
</tr>
<tr>
<td>3. Value (Health Technology Assessment)</td>
<td>Canadian Agency for Drugs &amp; Technologies in Health (CADTH)</td>
<td>Reimbursement recommendation to provinces</td>
</tr>
<tr>
<td></td>
<td>• CDB / pCODR</td>
<td></td>
</tr>
<tr>
<td>4. Value &amp; Affordability</td>
<td>Provincial drug plans / Private insurers</td>
<td>Reimbursement decision</td>
</tr>
<tr>
<td>5. Reimbursed price</td>
<td>Pan-Canadian Pharmaceutical Alliance (pCPA)</td>
<td>Best reimbursement price</td>
</tr>
</tbody>
</table>
What the provinces need to know:

• What does the drug really cost?

• Will it blow the budget? (drug and non-drug costs)

• Is it effective in real world patients?
WHAT DOES THE DRUG REALLY COST? Almost no one knows.
Conditional listing Schemes

**Health outcome-based**
- Pay for results: e.g., free drug initiation
- Coverage with Evidence Development
- Finance disease management programs, education, etc.
- Providing additional trial data as it becomes available

**Non-outcome-based**
- Volume discount
- Utilization reviews → cap or discount if:
  - budget impact
  - per-patient cost
  - per-patient volume (mfr supplies beyond a certain # of doses) is exceeded

All of these are less common since the advent of the PCPA (↑ complexity)
WILL IT BLOW THE BUDGET?
Budget Impact Assessment

- Patient numbers
- Likely uptake
- How long will they be on treatment?
- What is the cost of providing the drug? (including ancillary costs: provider resources, CVAD, genomic testing, ER/hospital utilization...)
- Are there offsets? (e.g., reduced chair time, downstream changes to treatment algorithm...)
  - Ideally the payer can see beyond the drug budget, but not always
- What’s the patent situation?

ISPOR Guidelines: Value in Health 17(2014) 5-14
IS IT EFFECTIVE IN REAL WORLD PATIENTS?
Limited by:
• Patient selection
• Intervention fidelity
• Outcome ascertainment, ambiguity, f/u time

BUT, in many cases one could infer some things:
• Major toxicities/complications
• Duration on treatment as a proxy for PFS
• The assumptions underlying the BIA
So, what if we...
...made all our Product Listing Agreements ‘Conditional’?

i.e., ‘Adaptive’ reimbursement decisions

• Commit at 1-3 years to analyze RCD to see if the assumptions of costs and effectiveness were borne out

• If they weren’t, reserve the option to:
  – renegotiate price
  – eligibility criteria
  – conditional listing scheme
  – de-list
Other points

• If uncertainty exists about some aspect of drug use, (optimal duration of treatment, order of therapies), randomized evaluation could be a condition of listing.

• Primary data collection is expensive and in most cases not worth it. Use existing data.

• The manufacturer has much to lose: RCD data could affect prices in larger markets
  – Pre-specify thresholds and consequences
  – Sometimes data may suggest price increases
Requirements

• Good data, sample size
  – Ideally pan-Canadian (eventually)

• Transparent, rigorous analyses
  – Make same data available to manufacturer?
    ⇒ Come to an ‘agreement of facts’ (definition of success, interpretation of data)

• Resources for evaluation

• Education/communication/socialization
  – Public/patients/providers that de-listing may happen

• Facilitate private pay/insurance for de-funded drugs
And once we start doing this...

Evaluate the evaluations:

• Assess the ‘value of information’ collected
• What types of risk/cost-sharing agreements work, and what doesn’t, in specific situations:
  – e.g., expensive drug vs. high-volume indication vs. uncertainty around benefit or cost assumptions
  – Simplicity of the agreement and data collection
• etc...
Questions to consider

• Do we want to try to do this?
  – Do we think it will significantly impact sustainability?

• Do we have the capacity?
  – What investments are needed?

• What should the scope be?
  – All cancer drugs; only new ones; focus on patients not matching RCT enrollment criteria; other treatments and procedures too ...