Access to Innovative Medicines and Value: The Fine Balance

Tuesday, October 18, 2016
MaRS Discovery District, Toronto

This session was generously sponsored by Amgen Canada Inc.
Meet the Panel

Moderator:
- Angela Rocchi (Athena Research)

Speakers:
- Sherry O’Quinn (PDCI Market Access Inc.)
- Glenn Monteith (Innovative Medicines Canada)
- Andrew Loblaw (Sunnybrook Health Sciences Centre)
- Rocco Rossi (Prostate Cancer Canada)
Session Overview

Given the increasing demands for access to innovative medicines and increasing cost-pressures on a limited budget, payers are looking for more guidance on public listing (and thus patient access) based on cost. This session will explore how certain Canadian stakeholders determine value of innovative medicines while remaining objective during the HTA process and leaving the issue of affordability to the provincial payers.
Access to Innovative Medicines and Value

The Fine Balance
Introductions
Discussion Question

Given the increasing demands for access to innovative medicines and increasing cost-pressures on a limited budget, how do Canadian stakeholders determine the “value” of innovative medicines?
Public Payer Perspective
Innovation and Cost: the fine balance
(Ex) Public Drug Plan Payer Perspective

October 18, 2016
Sherry O’Quinn
Understanding the challenges of public drug plans

• Budgets are set for them
• Forecasts far exceed budgets they will receive from the government
• Significant stakeholder pressure to fund most drugs
  – Manufacturers
  – Patients
  – Patient groups
  – Clinicians
  – Media
  – Political
• Increasing volume of workload: new launches, negotiations, re-evaluation
• Resources: time & people

Their dilemma: how to manage their current budgets within their constrained system now? Focus is on strategies that can be implemented quickly
Value varies by stakeholder and their lens: Public Payer

Value is not placed on the fact that a drug is an “innovation” or is new.

Value to payers consists of many factors, most notably:

• Provides **significant** improvement in clinically meaningful outcomes for patients (morbidity, mortality, QOL, safety)
• **Demonstrates** value to the health care system overall
• Replaces existing therapies (cost-offsets) versus additive

A “cost-effective” drug typically results in budget impact to the drug plan. In a world of fixed budgets, there comes a breaking point...a cost effective and clinically relevant drug can be unaffordable.

Payers now also placing greater emphasis on the following question: Is the drug affordable?

Stakeholders have different value assessments based on the same evidence
Canadian environment & approach appears to be shifting

2006: Bill 102 – Reforms in Ontario

• With a major focus on improving patient access to drugs, ensuring better value for money, rewarding innovations and strengthening transparency and accountability

• Approach: Value-based pricing and decision making

Now: Environment and approach appear to be shifting

• Major media attention globally on pharmaceutical pricing

• Sustainability and Affordability is now at the centre in every public forum

• “Approaching a crossroad: can’t expect to be able to afford everything.”

• Approach: Best possible deals for the public plans = affordability-driven

Genuine apprehension that current approach no longer works given the shifting fiscal environment
Move to Affordability, Sustainability, “Fair Price” Lens?

World Health Organization:

- An ‘affordable and fair price’ is one that can reasonably be funded by patients and health budgets and simultaneously sustains research and development, production and distribution within a country.
- Countries should make their pricing policies, processes and decisions transparent.

BMJ Article\(^1\) 2016 asks the question: Can we find a “just” price for drugs?

- Although a thriving drug industry may be an economic and financial benefit to governments, the triumphs of pharmaceutical innovation are hollow victories if they cripple health systems and generate massive inequities.

\(^1\)Ghinea N, Lipworth W, Kerridge I. Propaganda or the cost of innovation? Challenging the high price of new drugs. BMJ 2016; 352
What could the future hold?

• Drug plan managers have been discussing how to manage their challenges in public forums:
  – Disinvestment
  – Saying “no” to more drugs
  – Therapeutic re-negotiations
  – Prioritization

• None of these approaches are ideal for any party, including government
• Without some assistance from other stakeholders, governments will likely make decisions to manage their budgets through these types of policy and decision mechanisms

Drug Plan “Solutions” will be imposed unless other alternatives are presented
Industry Perspective
The Value of Innovation:
Value vs. Cost

Presented by Glenn Monteith
Vice President, Innovation & Health Sustainability

October 2016
• Increasing entry of new innovations (drugs, but also technologies e.g.: diagnostics, etc.)

• Increasing focus on managing fiscal resources

• Value for the investments made are increasingly important

• Value for whom?
Value Concepts

<table>
<thead>
<tr>
<th>Value in health - what is goal of patient care?</th>
<th>Achieve best health outcomes or health gain for the patient</th>
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</thead>
<tbody>
<tr>
<td>How to achieve the goal?</td>
<td>Timely access and delivery of the best standard of care, <em>the first time around</em></td>
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<tr>
<td>Decision makers’ perspective matters</td>
<td>Narrow Drug plan/ Cancer agency perspective? <em>or</em> Patient’s perspective? <em>or</em> Health System perspective? <em>or</em> Societal/Holistic perspective?</td>
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# Challenges for different decision-makers

<table>
<thead>
<tr>
<th>Decision-maker</th>
<th>Decision Role</th>
<th>Challenges</th>
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</thead>
<tbody>
<tr>
<td>Regulator (Health Canada)</td>
<td>Market authorization based on safety, efficacy and quality (Proof of concept)</td>
<td>Increasing complexity of science and need to modernize and be more efficient</td>
</tr>
<tr>
<td>PMPRB</td>
<td>Determine Non-excessive price</td>
<td>Pressure by the payers and consumers to demonstrate its relevance</td>
</tr>
<tr>
<td>HTA</td>
<td>Comparative effectiveness assessment Value for money assessment</td>
<td>Young discipline, evolving but rooted in quantitative evidence based assessments Need for evidence and value based decision making processes- better engagement with patients and clinicians</td>
</tr>
<tr>
<td>Payers</td>
<td>Reimbursement or funding decisions, provide equitable and timely access to their beneficiaries</td>
<td>Budget allocation and management strategies not fit for purpose, price and cost driven decision making processes instead of value based decisions, lack of appropriate data infrastructure or capacity to enable pay for performance strategies</td>
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<tr>
<td>Patients</td>
<td>Participation in clinical studies, informed decision making for their treatment</td>
<td>Patient input being sought by many in the process but the influence of their input on decision making processes not clear</td>
</tr>
<tr>
<td>HCPs</td>
<td>Prescribe and deliver the care in best interest of the patient</td>
<td>Optimal involvement in clinical trials to gain experience with novel medicines, rapidly changing treatment protocols, not part of the final decision making process</td>
</tr>
<tr>
<td>Innovative bio-pharma Industry</td>
<td>Innovate, develop, manufacture and supply medicines that improve upon the current standard of care, or provide choice</td>
<td>High attrition rate in the discovery and development phase, increasing cost of innovation and drug development Increasing barriers to adoption of innovation Increasing timelines to listing decisions due to multiple sequential process steps</td>
</tr>
</tbody>
</table>
## Who can help the decision-makers in determination of value?

<table>
<thead>
<tr>
<th>Who</th>
<th>What information would help in determination of value</th>
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<tbody>
<tr>
<td>Patients</td>
<td>Lived experience with disease and patient values</td>
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<tr>
<td></td>
<td>Active participation through the continuum of care</td>
</tr>
<tr>
<td>Health care providers</td>
<td>Help define the current standard of care, unmet clinical need, experience with the new drugs and interventions, place in therapy</td>
</tr>
<tr>
<td>Industry ( Developers, Manufacturers and Suppliers)</td>
<td>Human drug development data (positive as well as negative data)</td>
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<tr>
<td></td>
<td>On-market data (real world) development</td>
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<td>Patient support programs and their value</td>
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<td>Investments to foster innovation in the country (new innovation support models)</td>
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<tr>
<td></td>
<td>Global price dynamics and willingness to negotiate under pre-agreed and predictable frameworks</td>
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<tr>
<td>Health Canada</td>
<td>Proof of concept (clinical efficacy, safety and quality of data assessment)</td>
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<tr>
<td></td>
<td>Clear description of the indication and clinical use, and precautions required</td>
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<td>Guidance on real world evidence development in the Canadian context</td>
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<tr>
<td>PMPRB</td>
<td>Set non-excessive price in consumer interest</td>
</tr>
<tr>
<td>Data systems</td>
<td>Real World/ On-market data</td>
</tr>
<tr>
<td></td>
<td>Measuring health outcomes (effectiveness and safety) in the real world</td>
</tr>
<tr>
<td></td>
<td>Facilitate outcomes based value discussion</td>
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<tr>
<td>HTA experts</td>
<td>Comparative effectiveness and value for money assessment</td>
</tr>
<tr>
<td></td>
<td>Willingness to pay thresholds</td>
</tr>
<tr>
<td>Public and politicians</td>
<td>What balance do we want to achieve as a nation and what is our aspiration?</td>
</tr>
</tbody>
</table>
Are we prepared for the future of oncology therapeutics?
Evolution of pharmacotherapies in Oncology

*Multidisciplinary progress made to change cancer from a death sentence to chronic treatment in many cases*

**Progress from extensive harms towards an improved benefit-risk profile**

<table>
<thead>
<tr>
<th>1950s to 1980s</th>
<th>1990s – beginning of targeted therapies</th>
<th>21st century – targeted to personalised</th>
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</thead>
<tbody>
<tr>
<td>Primarily cytotoxic drugs e.g. methotrexate, platinums, taxanes etc.</td>
<td>bcr-abl target (CML)</td>
<td>B-raf target, mek, mTOR, vegfr, pdgfr targets (melanomas, kidney cancer, multiple cancer types)</td>
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<tr>
<td></td>
<td>her-2 neu target (breast cancer)</td>
<td>Immuno-Oncology</td>
</tr>
<tr>
<td></td>
<td>vegfr target (colorectal cancer)</td>
<td>dozens of new targets under investigation</td>
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<td></td>
<td></td>
<td>Rapid evolution towards developing personalised approaches</td>
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</table>
## Oncology specific challenges and opportunities

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market entry based on surrogate outcomes (e.g. progression free survival, disease free survival)</td>
<td>Early access of innovative therapies for patients</td>
</tr>
<tr>
<td></td>
<td>On-market data development to capture longer term health outcomes and enable pay for performance schemes</td>
</tr>
<tr>
<td>Disruption of existing treatment protocols as a result of introduction of new drug (s)</td>
<td>Work closely with the clinical experts to identify the best place in therapy</td>
</tr>
<tr>
<td>Focus on price/cost of treatment Challenge in measuring value of innovation</td>
<td>Create better data systems to enable Pay for performance or Outcomes based negotiation frameworks</td>
</tr>
<tr>
<td>Companion diagnostics</td>
<td>Integrated access decision frameworks to ensure timely and accurate diagnosis Optimal patient selection</td>
</tr>
<tr>
<td>Cost of not adopting innovation</td>
<td>E.g. Oral treatments (health system perspective), better productivity for patients and caregivers</td>
</tr>
</tbody>
</table>
Bringing research to life.

innovativemedicines.ca

@innovativemedicines
Clinician Perspective
Prostate Cancer Treatment
A Health Policy Incubator?
Prostate Cancer

• Most common (non-cutaneous) in North American men
  – 1 in 8 will be diagnosed during their lifetime
  – 24,000 men will be diagnosed in Canada in 2015
  – 4,100 will die of prostate cancer
  – Highly curable (therefore long-term quality of life critical!)
Why is this Important?

42,000 men
Prostate Cancer: Largest Increase in Cost

37% increase!
Public Healthcare Not Sustainable

2015 Healthcare Budget $50.8M

2014 Healthcare Proportion 41%

* Source: Ontario Ministry of Finance
Vancouver to Miami
The Litmus Test of Public Healthcare

- Last Resort
- Do More of This
- Stop Doing This
- Figure out best trade-off methodology

Patient Outcomes
- Worse
- Better

Net Management Costs
- More
- Less
PROTECT Study

N=1643
mFU 10y

Hamdy F et al., NEJM 2016; Donovan JL et al., NEJM 2016
**Surgery**
- 2-3 day hospital stay
- 8-12 week recovery
- 60% success rate
- >50% erectile problems
- 5% diaper rate
- $7080
  - $11873

**External Radiation**
- Up to 39 daily visits
- No recovery required
- 70% success rate
- 25% erectile problems
- 0% diaper rate
- $2985 - $5254
  - $3055 - $5324

**Brachytherapy**
- 2 hour hospital stay
- 1 day recovery
- 95% success rate
- 25% erectile problems
- 0% diaper rate
- $4202 – 4540
  - $4272 - $4610
## Comparative RT Costs

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<tr>
<th>Treatment</th>
<th>1 phase</th>
<th>2 phase</th>
<th>2 phase long</th>
</tr>
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<td>HDR</td>
<td>$1,919</td>
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<td></td>
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<tr>
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## Comparative Prostate Costs

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The Litmus Test of Public Healthcare

Patient Outcomes
- Worse
- Better

Net Management Costs
- Less
- More

Stop Doing This
- RALRP

Last Resort
- EBRT
- ORP

Do More of This
- SABR
- HDRB

Figure out best trade-off methodology
Innovation Definition

Phase 1/2 study published; Health Canada NOA

Innovative Rx

Experimental Rx

Standard Rx

Publicly reimbursed; Guideline approved
Value Perspective

Transparent
Adaptive
Value-based
Decision

[Diagram showing cost vs. QALYs with decision points for rejecting or funding treatment]

Cost

Reject treatment

Fund treatment

QALYs
Patient Perspective
Presentation for
CAPT Conference 2016
October 17 – 18, 2016

Session 7. Innovation and Cost: the fine balance

Rocco Rossi
President & CEO, Prostate Cancer Canada
@roccorossiTO
rocco@prostatecancer.ca
Promoting Equal Access & Incorporation of New Medicines in the Health Care System

• The Patient Perspective

• Health Systems: Disparities
  - PSA test coverage
  - Receptiveness to Innovative Medicines
    - Drug Approval and Coverage

• Closing Remarks
Patients’ Perspective & Value of Patient Input

• Patients and PCC are concerned with:
  – Having treatments equally available across the country
  – How the health care system is positioned to incorporate new medicines

• Disease affects entire family, not just the patients.
  – Patients, families and caregivers are **ALL** bearing costs

• Inclusion of patients’ and caregivers’ concerns, opinions, and experiences in decision-making process is crucial as they are the ones most directly affected by any decisions and/or recommendations
  – Ex. Patient input in pCODR process
Health systems: Disparities

- As treatments and advancements near clinical readiness, differences between health systems across Canada will mean differences in access to care.

  - **Example:** PSA testing is **NOT** covered in BC and ON.

  PSA tests are covered for men in eight out of ten provinces. Patients want equal and fair access to PSA testing in ON and BC.

- In BC, early diagnosis of 580 men who died of prostate cancer could have resulted in up to $10M in savings (2014).
Receptiveness to Innovative Medicines

• Lack of receptiveness and flexibility towards new innovations within health system’s drug review process is the limiting step

• As a result, approval and coverage of treatments varies throughout provinces (as with many other drugs), thus denying patients the positive results that research is yielding

• Need health systems and processes that allow for integration of different drugs that deviate from what is deemed currently in place
Discovery to Finished Product

• As PCC research gets closer to clinical readiness, a parallel push needs to occur to get health systems on the same page to make sure that:
  – Research findings are put into practice as soon as possible, **NOT** hold up progress and **NOT** be the limiting step
  – Health care is made available equally to men
• Flexibility and synchrony amongst provincial health systems are key
Thank you!

Rocco Rossi
President & CEO, Prostate Cancer Canada
@roccorossiTO
rocco@prostatecancer.ca
Panel Questions
Question #1

“Current relationships appear more strained than ever. How can we collaborate in this environment? for example, to evolve risk-sharing, or on other solutions?”
Question #2

“To make room for the ‘new’, we may need to delist significant therapies. How do we make the decision to stop funding A in order to allocate funds to B, and how do we manage that challenge?”
Question #3

“Innovation is not equally distributed across disease. What can we do to assure equitable and sustainable funding across diverse diseases?

What is our responsibility to achieve equity between provinces?”
Question #4

“The oncology world has greater control of prescriber behaviour through institution-mandated treatment guidelines.

Is this a sustainability answer? Can we extrapolate this to the non-oncology world?”
Question #5

“Are there any learnings from other countries that we can examine?”
Audience Questions
Summary
Thank You