Real World Evidence in Cancer Care: A Payer’s Perspective

CADTH SYMPOSIUM 2016

Scott Gavura, Director, Provincial Drug Reimbursement Programs
The speaker has no financial or other conflicts of interest to report.
We are spending hundreds of millions of dollars per year on cancer treatments with little investment to ensure that we’re getting the outcomes we think we’re buying.
The sustainability challenge

Drug costs for claims approved under the New Drug Funding Program.

NDFP increase if aligned with provincial budget forecast for health sector (from 2016 budget) 1.8% (14/15-18/19)

NDFP projected growth based on historical increases 12% (10/11-14/15)

Cost of Approved Submitted Claims

Forecast on NDFP Growth

Forecast on Health Care Growth
Balancing funding obligations and demands

**Financial obligations**

- Manage spending within budget
- Grow spending at sustainable rate
- Measure and ensure appropriateness of spending

**Treatment expectations**

- Address clinician expectations to fund “standard of care”
- Consider specific patient circumstances
- Deliver best possible population-level outcomes
- Maximize equity
Most trials are designed to meet regulatory demands, not to answer questions about their effectiveness in the real world.

Data on real-world benefits emerges sporadically.

Recognizing new data is unlikely to emerge, payers may be asked to accept lower quality evidence that’s less relevant.

Even when compelled by regulators, post-marketing commitments to Phase 4 research may remain unfulfilled for years after launch.*

What do payers want?

- Validate assumptions we made during our assessment
  - Compliance effects on efficacy (orals)
  - Regimen modifications (e.g., changing from 7/7 admin to 5/2/2)
  - Toxicity profile (long-term)
- Increase overall confidence in our reimbursement decisions
  - Resolve uncertainty remaining from decision-making process
- Infrastructure to adapt to funding uncertainty
  - e.g., rapidly evolving treatment pathways & lack of comparative effectiveness data
- The vision: a “learning” health system/reimbursement system
  - Ideally, link payment to outcomes realized vs. expected/anticipated
Why do we want it?

• Insufficient information often available to demonstrate a new treatment provides a meaningful clinical benefit.

• Rapid introduction of new therapies means study population may not be representative of target population (e.g., exposure to other therapies)

• Ideally, we’d like to link reimbursement to the actual delivery of benefit – not just expected benefit.

• If we can achieve the above, we can create a new framework for implementing new therapies, one that benefits patients, industry, and payers.
Programmatic Review Objectives:

• To identify and review the critical success factors of a sustainable drug reimbursement program with international, pan-Canadian and internal input.

• To reach agreement on a core set of recommendations for CCO and that may be relevant to other provincial reimbursement programs on strategic directions and improvements, in order to maximize the effectiveness of cancer drug use and support overall system sustainability in a patient-centred way.

• The Programmatic Review made seven recommendations to the MOHLTC and CCO’s Board of Directors, two of which referenced RWE.

• We are now developing our response to the Programmatic Review.
A consistent approach to gathering and analyzing real world evidence should be developed. This includes systematically capturing and incorporating patient-reported outcomes (e.g., quality of life, toxicity) into real world data collection (note, this recommendation is linked to recommendation #5).

*Accountabilities: CCO, MOHLTC, CAPCA*

Real world evidence (RWE) should be used to inform and monitor the effects of funding decisions (this includes validating assumptions, evaluating the benefits of funded therapies, revisiting funding decisions, informing future funding decisions).

*Accountabilities: CCO, MOHLTC, CAPCA*
What data could RWE encompass?

• Treatment data / Rx claims data
• Outcomes data
• Genomic data
• Socioeconomic data
• Patient-generated data (e.g., PRO’s)
CCO’s Evidence-Building Program (EBP)

Uncertainty

Expected Net Benefit

- Positive
- 0
- Negative

Do not fund
Consider appropriateness for EBP
Fund as full benefit


Cancer Care Ontario
Learnings from the Evidence-Building Program

- Outcome of interest may not be possible to measure with existing administrative data.
  - Specific data collection often required.
  - This can be cumbersome and labour-intensive.

- Difficult to find an endpoint for EBP “exit” that is objective, useful and (relatively) easy to measure.
  - Outcome of interest may require extended follow-up.

- There is significantly more payer work required than a regular product listing.
  - Collecting, maintaining and analyzing data requires an ongoing commitment.
What barriers to easy use of RWE exist?

- There’s a lack of consensus on the priorities and questions to answer.
- We need to integrate data from what may be disparate data sources, some of which may not be our own.
- Most data isn’t collected with RWE analysis in mind.
- There’s an incremental cost to collecting, cleaning maintaining and analyzing datasets developed expressly for RWE use.
- We lack a common framework (across multiple stakeholders, gov’t and non gov’t) that defines how data will be integrated and used.
What’s next for CCO with RWE?

- RWE questions are *research questions* that require rigorous methodology to produce meaningful answers.
  - Close links between academics, payers, and manufacturers required for acceptance of results
- CCO is interested in supporting RWE that addresses payer needs with the potential to inform or validate funding decisions.
- CCO is committed to expanding its efforts to use RWE to inform decision-making and its management of cancer funding programs.
  - We intend to collaborate with our cancer system partners (ministries, agencies, CPAC) in this work.
  - We welcome input on how this infrastructure could evolve.
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scott.gavura@cancercare.on.ca