CAPT Conference Workshop

Defining "Decision-Grade" RWE and its Role in the Canadian Context: A Design Sprint

Lightning Talk: CADTH

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Objectives

1. Describe CADTH's strategic objectives re: uses of RWE, with emphasis on:
    a) life-cycle approach to HTA
    b) collaboration with partners
2. Share early thinking regarding potential reassessment framework
3. Describe desired state for the use of RWE from CADTH's perspective
4. Outline goals for today

2018–2021 Strategic Plan

Transforming How We Manage Health Technologies

CADTH Evidence Driven.

Strategic Goals and Objectives

Close the Gap Between Evidence, Policy, and Practice

1. Provide customized implementation support.
2. Strengthen engagement with patients, clinicians, and other stakeholders.
3. Enhance analytics and performance measurement.

Adopt a Life-Cycle Approach to Health Technology Assessment

4. Align drug and medical device review processes with federal, provincial, and territorial priorities throughout all phases of the technology life cycle.
5. Implement programs for reassessment and disinvestment.
6. Advance initiatives across the health technology life cycle that will improve access, appropriate use, and affordability.

Anticipate Health System and Technology Trends, and Develop Agile Management Strategies

7. Advance initiatives that anticipate, influence, and manage technological advancement and health system evolution.
8. Focus on health technologies that have the most potential to meet patient and health system needs.
9. Align CADTH efforts and investments with federal, provincial, and territorial priorities for health improvement.

https://cadth.ca/sites/default/files/corporate/planning_documents/CADTH_2018_2021_Strategic_Plan_Overview.pdf

2018-19 Business Plan

Priority Initiative 2: Establish processes to enable informed decision-making throughout the technology life cycle

CADTH will move beyond traditional assessments of new drugs and technologies at their point of adoption to inform decisions at all phases of the technology life cycle from pre-market to adoption to actual use in real-world settings, through to disinvestment and decommissioning. To support the effective management of the entry, ongoing use, and exit of technologies from the system, CADTH will:

- collaborate with Health Canada, the Patented Medicine Prices Review Board, the pan-Canadian Pharmaceutical Alliance, and the Canadian Association of Provincial Cancer Agencies on the alignment of processes that will increase the accessibility, affordability, and appropriate use of drugs and medical devices
- work actively alongside jurisdictions to support them in developing a framework for health equipment procurement as well as evidence-based options that contribute to more coordinated and consistent management of drugs, diagnostics, and medical devices in Canada
- engage with key stakeholders to explore development of a pan-Canadian framework for the collection of real-world data on technology use and outcomes (to enable reassessments informed by relevant, context-specific data)
- develop a framework for the reassessment of drugs and devices already in use in the health system (to facilitate price negotiation, update practice guidelines, and promote disinvestment in technologies that provide low value to Canadians)

https://www.cadth.ca/sites/default/files/corporate/planning_documents/2018%202019%20Business%20Plan%20FINAL.pdf

Current State

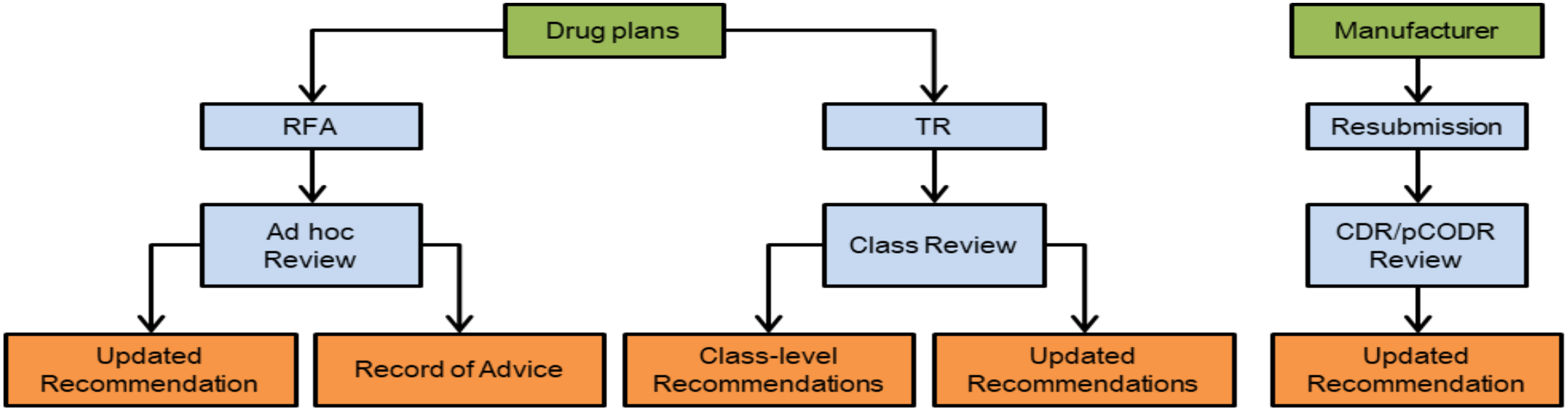
- RWE already in use!
  - Different data sources inform different questions
    - Quantitative & Qualitative
      - RCTs
      - RWE
      - Patient input
      - Qualitative evidence synthesis
- Pan-Canadian Oncology Drug Review's Expert Committee (pERC) has issued conditional coverage recommendations
- Approach isn't as transparent or as consistent as it should be
- System nodes not "joined up"

CADTH Reassessment Framework

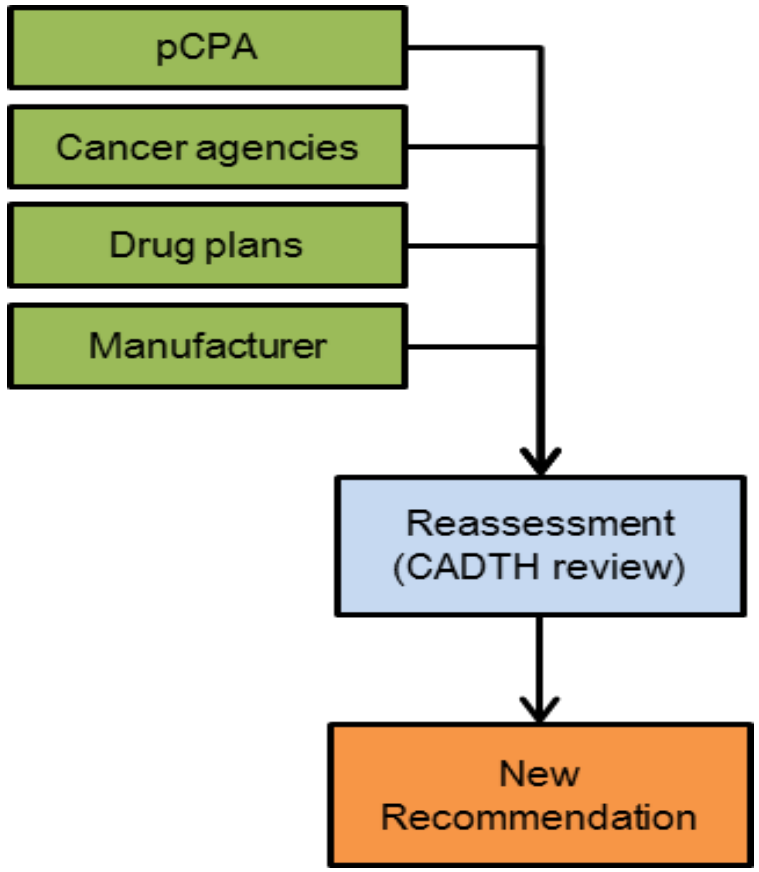
- A key goal of CADTH's Strategic Plan is to adopt a life-cycle approach to HTA
  - Integral to life-cycle approach is re-assessment
- CADTH is proposing a ***Reassessment Framework***

Approach to the Framework

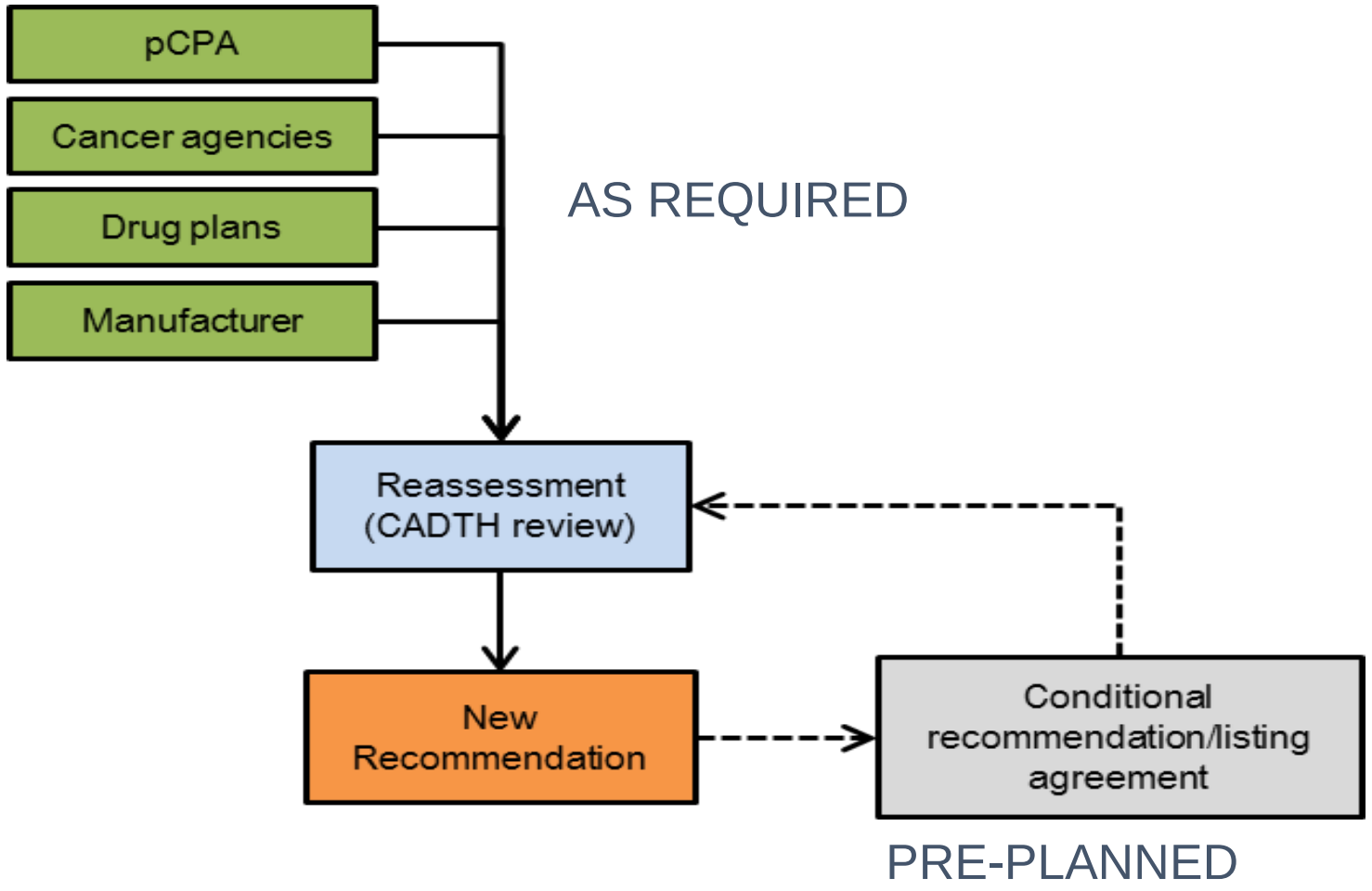
Based on existing well-established drug review pathways



CADTH Reassessment Framework



CADTH Reassessment Framework



Pre-planned Reassessments

- Currently no pan-Canadian process that ‘requires’ a listed drug to be reassessed at a future date (pre-planned)

- To address this gap, the need for a reassessment could be implemented as a conditional reimbursement agreement that includes RWE collection

- A pre-planned reassessment of RWE would subsequently occur as a mandatory condition of the reimbursement agreement

Challenges

CADTH cannot include reimbursement recommendations conditional upon reassessment within a Reassessment Framework until major implementation challenges are addressed.

Challenges to be addressed:

- Lack of leverage to force compliance with reassessment (compel RWE collection)
- Existing processes not designed to provide detailed guidance on RWE studies and data needed
- Unclear who is responsible for funding RWE collection and analysis

Desired State

- RWE is used appropriately across the life-cycle of a product
  - Scientific advice/early dialogues - jointly with the regulator and other HTA bodies – advise on pre-market and post-market data needs
  - Does not replace RCTs
    - Novel approaches to RCTs (e.g., registry RCT) can bring best of both approaches, efficiently
  - Any evidence – whether RCT or RWE – will be appraised in line with global best practices, and aligned with practices of partners
  - Reassesssments undertaken when appropriate (i.e., not every product needs to be reassessed)
- RWE for (re)assessments available when needed and of sufficient quality
  - Make better use of existing data repositories & networks
    - CADTH is not a data holder, not a data collector
  - Data needs are stipulated *a priori* and are aligned across all decision nodes
  - Closed loop – evidence ecosystem

Planned Approach

2018-19 Talking: Exploration, Consultation & Development of Plan (and more consultation)

Today's workshop is an essential element – thank you!

- What already exists to better enable the use of RWE in life-cycle HTA?
- What can be done in the short-, medium- and long-term?
- What (else) needs to be done to enable an efficient evidence ecosystem
- How do we manage the risks associated with the use of RWE to inform decision-making?
- What do you need from CADTH vis-a-vis RWE?

2019-20 Doing: Implementation – phased approach

- Guidance to provide transparency & consistency in approach
- Continued efforts to optimize alignment across health system nodes (e.g., NOC/c with RWE requirement could align with conditional coverage recommendation)
- Work with data partners to optimize data availability
- CQI in support of a learning health system