Patient Input for Pharmaceutical Reviews: An Embarrassment of Riches?

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CADTH

CADTH

is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence about the optimal use of drugs and medical devices.

Our Programs and Services

DRUG REIMBURSEMENT RECOMMENDATIONS

- CADTH Common Drug Review (CDR)
- CADTH pan-Canadian Oncology Drug Review (pCODR)

HEALTH TECHNOLOGY MANAGEMENT PROGRAM

- Rapid Response Service
- Health Technology Assessment Service
- Optimal Use Service
- Environmental Scanning
- Horizon Scanning

OTHER PROGRAMS AND SERVICES

- Scientific Advice

KNOWLEDGE MOBILIZATION AND LIAISON OFFICERS

- Located in jurisdictions across Canada
- Understand the needs and priorities of local decision-makers
- Provide advice and tools to help turn evidence into policy and practice

CADTH

Related Reviews

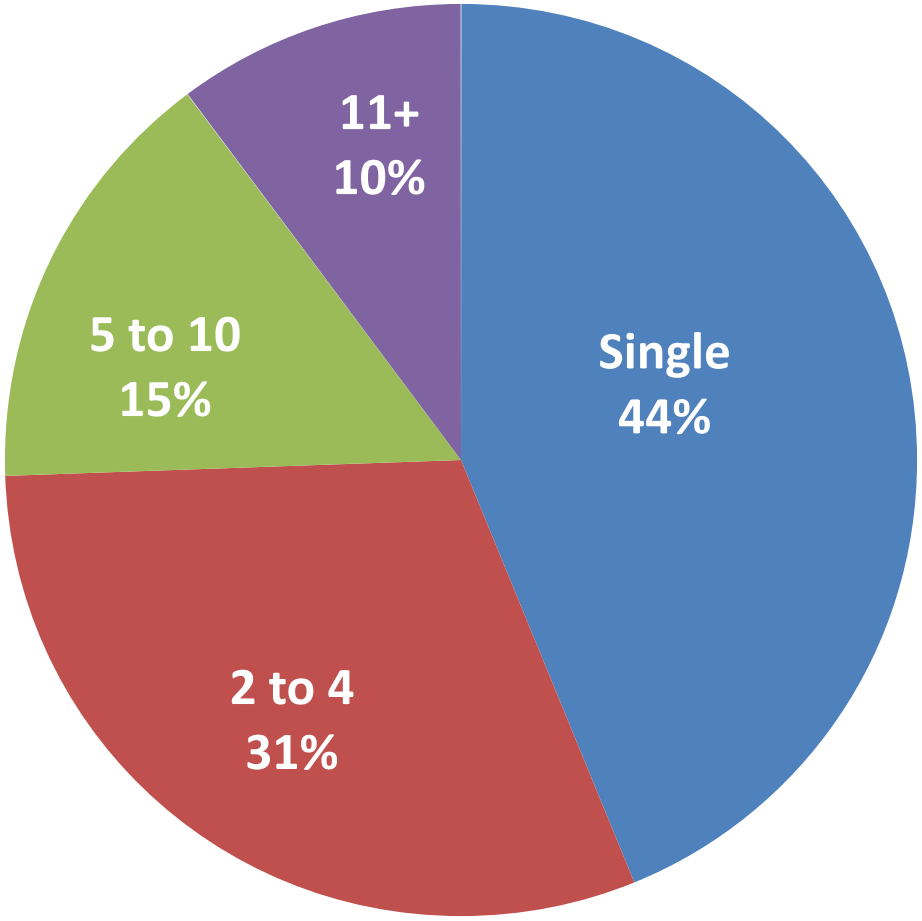
- Therapeutic Reviews
- Request for Reconsideration
- Requests for Advice
- Biosimilar Reviews
- Companion Diagnostics

Patients Tell Us About…

- Standardized questionnaire/template

- Impact of health condition (disease journey)
- Experience with current therapy
- Unmet need
  -Opinion on importance of various PROMs
- Impact on caregivers
- Expectations for new therapy
- Experience with new therapy

Patient Input to Pharmaceutical Reviews



June 2010 – June 2016

532 patient input submissions from **137** patient groups

Many groups answer multiple calls for patient input

CADTH

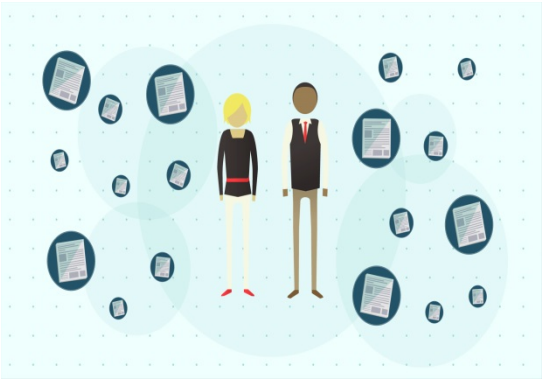
Pharmaceutical Reviews

CADTH Review Team

Patient input used to inform protocol & report

Expert Committees (CDEC, pERC)

Patient input presented, used in deliberations & reflected in recommendations



Public Drug Plans

Shared with plans and shared at www.cadth.ca

How does CADTH use patient input?

To identify gaps in existing data

Example: “None of the included studies reported results of incontinence or micturition during the night, achievement of continence, nocturia or pad counts. These outcomes were considered important by the consulted clinical experts and/or by the patient’s group who provide input to this review.”

Clinical Report: propiverine-hydrochloride

To clarify assumptions

Example: “Patient group input indicated that IV infusion was not considered to be a major issue for most patients, noting that IV administration is currently required for some currently available treatments (e.g., infliximab).”

Clinical Report: vedolizumab

To critique economic evaluations

Example: “patient groups noted that heart failure is a condition which restricts patients’ functional capacity and the activities of daily living, leads to frequent hospitalization, and is often associated with a range of comorbid conditions, including depression and anxiety. These aspects were accounted for in the manufacturer’s economic evaluation by the inclusion of utility weights reflective of disease severity and hospitalization. Both patient groups also indicated that the burden of this disease is often felt by caregivers. Information relating to the impact on caregivers was not provided by the manufacturer, and it was not considered in the economic analysis.”

Pharmacoeconomic Report: Ivabradine

First-hand experience with drug

Example: “The patient reported undetectable viral levels two months after initiating treatment and had a positive experience with the drug despite nausea and insomnia, which were managed by modifying diet and the time of day the medicine was taken. **Clinical Review: Tivicay**

Example: Canadian Drug Expert Committee “accepted that evidence provided by a review of the relationship between Phe levels and diet liberalization, in conjunction with patient input, suggested that diet liberalization is likely associated with an improvement in quality of life.”

Recommendation and Reasons: Kuvan

What Is Working Well

- Outcomes of interest to patients not included in trials
- Expert committee members believe patient input "brings issues to life"
- Information collected consistently and predictably
- Additional opportunities for patient input/perspective

Challenges

- Does template collect right information?
- Patient groups responsible for burden of rigor/relevance of research and may lack expertise/resources
- Simple ranking of relative importance of outcomes
- Uncertainty about how qualitative information should be used:

  -What to think when it disagrees with direction of clinical evidence?

Future Steps

- Reducing duplication/sharing across processes
  - Health Canada, PMPRB, PCPA
  - Pan-Canadian HTA partners
- Disease area submissions: diabetes, asthma, arthritis
- Patient Advisory Committee

CADTH Evidence Driven.

It’s a Balance!

Information needs

-Rigour and relevance

Timeliness

-Procedural constraints and customer

Resources

-Availability and added cost

Participation

-Democratic and capacity building

CADTH ASKED PATIENT GROUPS:

what are the important outcomes for drug assessment?

Based on patient input for 30 drugs reviewed by the CADTH Common Drug Review, with recommendations published between March 2013 and June 2014.

CADTH Evidence Driven.