Real-world evidence
What role can it play in real-world decision-making?

Summary report of the IHE Roundtable
December 12, 2016

INSTITUTE OF
HEALTH ECONOMICS
ALBERTA CANADA

INSTITUTE OF HEALTH ECONOMICS

The Institute of Health Economics (IHE) is an independent, not-for-profit organization that performs research in health economics, synthesizes evidence in health technology assessment to assist policy making, and serves as a neutral broker to convene stakeholders from the public and private sectors to collaborate and solve key challenges in the health system.

IHE BOARD OF DIRECTORS

Chair

Dr. Lorne Tyrrell – Professor & Director, Li Ka Shing Institute of Virology, University of Alberta

Government and Public Authorities

Mr. Justin Riemer – Assistant Deputy Minister, Alberta Health

Mr. Jason Krips – Deputy Minister, Economic Development and Trade

Alberta Innovates

Dr. Kathryn Todd – VP Research, Innovation & Analytics, Alberta Health Services

Academia

Dr. Walter Dixon – Associate VP Research, University of Alberta

Dr. Jon Meddings – Dean of Medicine, University of Calgary

Dr. Richard Fedorak – Dean of Medicine & Dentistry, University of Alberta

Dr. Ed McCauley – VP Research, University of Calgary

Dr. Neal Davies – Dean of Pharmacy & Pharmaceutical Sciences, University of Alberta

Dr. Braden Manns – Svare Chair in Health Economics and Professor, Departments of Medicine and Community Health Sciences, University of Calgary

Dr. Constance Smith – Chair, Department of Economics, University of Alberta

Industry

Mr. Robert Godin –Director, Market Access Strategy & External Relations, AstraZeneca

Ms. Jennifer Chan – VP, Policy & Communications, Merck Canada

IHE

Mr. Doug Gilpin – Chair, Audit & Finance Committee

Dr. Egon Jonsson – Executive Director & CEO, Institute of Health Economics

Ms. Allison Hagen – Director of Finance, Operations & Administration, Institute of Health Economics

ELI LILLY CANADA INC.

Eli Lilly Canada Inc. is part of a global, publicly traded life sciences company, Eli Lilly and Company, committed to making medicines that help people live longer, healthier, more active lives. With headquarters in Toronto, Ontario, the pharmaceutical division of Eli Lilly Canada Inc. employs nearly 400 people across the country.

Real-world evidence

What role can it play in real-world decision-making?

Summary report of the IHE Roundtable

December 12, 2016

The IHE Real-World Evidence Roundtable was supported by Eli Lilly Canada Inc.

The views expressed herein do not necessarily represent the official policy of Eli Lilly.

Acknowledgements

The Institute of Health Economics is grateful to participants of the IHE Real-World Evidence Roundtable (listed in Appendix A), and those consulted leading to the production of the report.

The views expressed in this report are of the Institute of Health Economics.

Corresponding Author

Please direct any inquiries about this report to Don Husereau, dhusereau@ihe.ca.

Funding

The IHE Real-World Evidence Roundtable was supported by Eli Lilly Canada Inc. The views expressed herein do not necessarily represent the official policy of Eli Lilly.

Declared Competing Interest of Authors

Competing interest is considered to be financial interest or non-financial interest, either direct or indirect, that would affect the research contained in this report or create a situation in which a person's judgement could be unduly influenced by a secondary interest, such as personal advancement.

The authors of this publication claim no competing interest.

Suggested Citation (ICMJE or Vancouver Style)

Husereau D. *Real-world evidence: What role can it play in real-world decision-making? Summary report of the IHE Roundtable*. Edmonton (AB): Institute of Health Economics; 2017.

Web Address

This publication is available for free download from the IHE website at http://www.ihe.ca.

Executive Summary

On December 12th, 2016, the Institute of Health Economics (IHE) held a roundtable discussion regarding the role of real-world evidence (RWE) in decision-making in Canada, with a focus on RWE generated for pricing and reimbursement.

The meeting brought together 11 representatives of key stakeholders: experts in evidence assessment, payers, and those generating RWE including academia and industry. The purpose of the meeting was to discuss preferences and perceptions of the use of RWE for pricing and reimbursement of new medicines in Canada and what more may be needed to ensure its optimal use. This roundtable served as a forum to identify key points of discussion and highlights gaps and opportunities for further discussion in the future with a broader group of stakeholders. The proposed actions and next steps in this document **are not a consensus recommendation by roundtable participants**, but should be considered an accurate reflection of the discussion.

The following themes emerged from the discussion:

- **There is a desire to use more RWE** that would complement existing evidence provided by randomized clinical trials, provided it is useful for decision-making and decision-makers can be confident in its findings.
- Before more use of RWE can occur, **a clearer definition is required**.
- The usefulness of RWE also **depends on the context of the decision**.
- **There may be a lack of confidence in the results of studies intended to provide RWE**, due to poor study designs and differences in how data are captured and analyzed.

Given the above, some potential next steps were identified by the roundtable participants:

- The need for **standards**: A feasible next step is to further discuss the need for clear definition and standards with key stakeholders, including those conducting studies of RWE and those who will use them to inform policy (that is, end-users), with a view to developing pan-Canadian standards for RWE.
- The need for **linkage**: A feasible next step is to explore mechanisms to facilitate more interaction between health system researchers, industry, patients, and policymakers that results in RWE and processes that are relevant to everyone and can be publicly communicated.

This roundtable highlighted the desire for robust information from RWE to support payer decisions. It appears that, in Canada, the uptake of RWE has been limited by both a lack of standards and vehicles that connect industry and publicly-funded researchers to decision-makers. Future work should focus on these barriers.

Abbreviations

All abbreviations that have been used in this report are listed here unless the abbreviation is well known, has been used only once, or has been used only in tables or appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

CADTH	Canadian Agency for Drugs and Technology in Health
CDR	Common Drug Review
HTA	health assessment technology
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
pCODR	pan-Canadian Oncology Drug Review
RCT	randomized controlled trial
RWE	real-world evidence

Table of Contents

1. Background

On December 12th, 2016, the Institute of Health Economics (IHE) held a roundtable discussion regarding the role of real-world evidence (RWE) in decision-making in Canada, with a focus on RWE generated for pricing and reimbursement.

The meeting brought together 11 representatives of key stakeholders: experts in evidence assessment, payers, and those generating RWE including academia and industry (for a complete list of attendees, see Appendix A). The purpose of the meeting was to discuss preferences and perceptions of the use of RWE for pricing and reimbursement of new medicines in Canada and what more may be needed to ensure its optimal use. This roundtable served as a forum to identify key points of discussion and highlights gaps and opportunities for further discussion in the future with a broader group of stakeholders. The proposed actions and next steps in this document **are not a consensus recommendation by roundtable participants**, but should be considered an accurate reflection of the discussion.

1.1. Overview and definitions of *real-world evidence*

Real-world evidence is a term that is becoming increasingly used. Other terms closely associated and sometimes used interchangeably are *real-world data*, *observational data*, and *real-world effectiveness*. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) defines real-world data as "data used for decision making that are not collected in conventional randomized controlled trials (RCTs)."[1] The distinction between *evidence* ("organization of the information to inform a conclusion or judgment") and *data* ("factual information" and "one component of the research plan') are noted within the ISPOR Task Force report.[2]

More recently, a survey of European health assessment technology (HTA) bodies revealed varying definitions of the term *real-world data*, with 38 definitions identified falling into four categories:[3] 1) non-RCT data; 2) non-interventional/controlled data; 3) non-experimental data; and 4) other (see Figure 1). While these definitions are based primarily on research design and data sources, the ISPOR Task Force report also identified definitions based on type of outcome.[4]

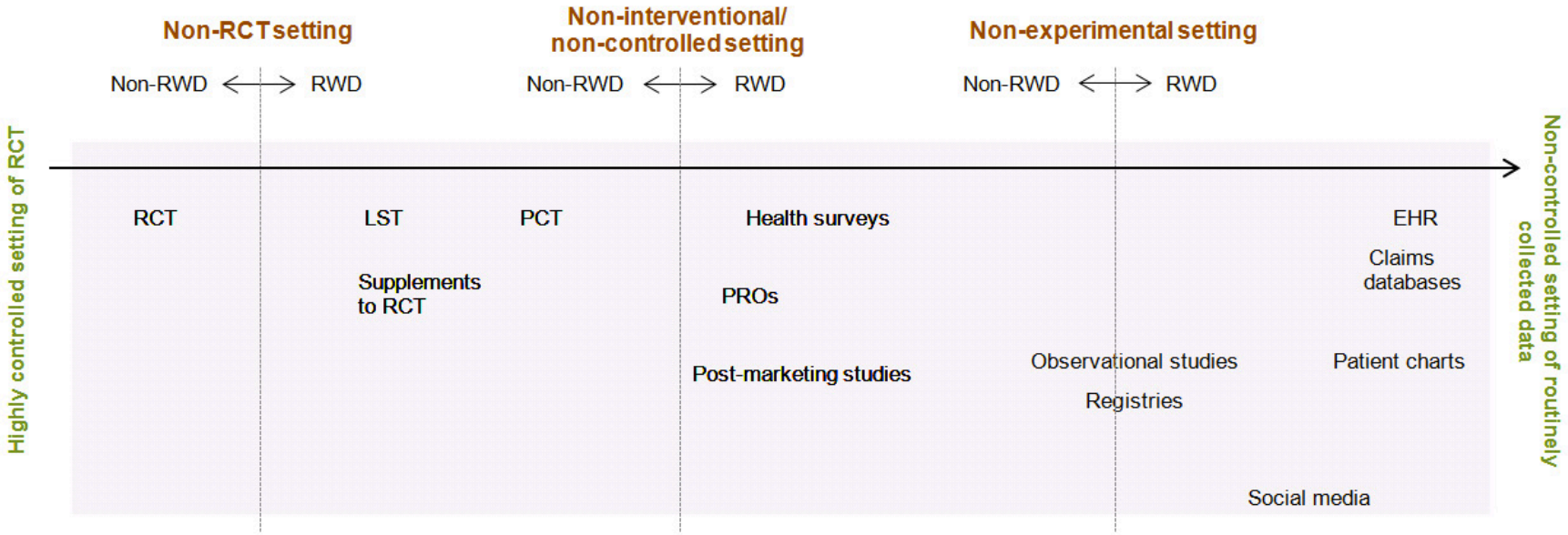
[1] Garrison LP, et al. Using real-world data for coverage and payment decisions: The ISPOR Real-World Data Task Force report. *Value in Health* 2007;10(5):326-335. doi:10.1111/j.1524-4733.2007.00186.x.

[2] Ibid.

[3] Makady A, et al. What is real-world data? A review of definitions based on literature & stakeholder interviews. *Value in Health* 2016;19(7):A502. doi:10.1016/j.jval.2016.09.900.

[4] Garrison et al., 2007.

FIGURE 1: Categorical definitions and sources of *real-world data*



Adapted from: Makady A, et al. *What is real-world data? A review of definitions based on literature & stakeholder interviews*. Presentation at ISPOR 19th Annual European Congress; October 2016; Vienna, Austria. Available from: *https://www.ispor.org/ScientificPresentationsDatabase/Presentation/68774?pdfid=47062*.

EHR: electronic health record; LST: large sample trial; PCT: pragmatic clinical trial; RCT: randomized controlled trial; RWD: real-world data

1.2. Why discuss real-world evidence?

In a 2014 roundtable on RWE supported by the IHE, discussion highlighted the fact that Canada has an abundance of RWE sources but "that accessing the data and linking it can be a challenge."[5] In this previous roundtable, discussing appropriate use of routinely collected data, participants felt that both patients and health professionals should be better engaged so as to foster a collective understanding of the potential economic value of improved access to data while addressing privacy issues.

At the 2014 roundtable, the discussion also identified a need to improve research capacity in the area of RWE, and acknowledged the increasing value and importance of RWE to the public, patients, payers, HTA bodies, researchers, and industry (see Box 1).

BOX 1: The increasing importance of real-world evidence

- *To public payers and evidence assessment agencies*: Payers must balance the need to provide improved health outcomes and access to new technologies with budgetary considerations. Clinical trials developed for regulatory purposes may be insufficient to resolve payer uncertainty.
- *To researchers*: Techniques and tools to analyze data for RWE have become increasingly widespread and accessible to researchers. Researchers are now able to answer an increasing number of important health services and policy questions without the considerable expense, length of time, and complication of conducting high-cost experimental studies.
- *To industry*: Industry views RWE as an additional opportunity to demonstrate the value of medicines, for both the patient and the health system. It may also provide new opportunities for industry to work with payers to advance novel approaches to pricing and reimbursement.
- *To regulators*: Regulators have become increasingly interested in the life cycle approach to technology management, including the better use of RWE for monitoring the safety and effectiveness of new technologies to as a means to improve patient outcomes.
- *To patients*: Ultimately, patients may benefit from better RWE, as access to new medicines and other healthcare interventions could be improved through reducing payer uncertainty around decisions to adopt. Increased certainty also avoids wasting scarce healthcare resources, which represent opportunities for other patients.

Adapted from: Nason and Husereau, 2014

Despite more frequent discussion on this topic, the use of real-world data for payer decision-making is far from a new concept. As far back as 1997 with the 2nd edition of the *Guidelines for economic evaluation of pharmaceuticals*, there is mention of the need for "prospective data reflecting the 'real-life' experience of the drug" and "performance of a drug in the real world" when creating estimates of effectiveness.[6] This distinction is also made in the most current edition of the guidelines, where

[5] Nason E, Husereau D. *Roundtable on real world evidence system readiness – Are we ready to use routinely collected data to improve health system performance? Summary report – September 2014*. Edmonton (AB): Institute of Health Economics; 2014.

[6] Canadian Coordinating Office for Health Technology Assessment (CCOHTA). *Guidelines for economic evaluation of pharmaceuticals: Canada*. 2nd ed. Ottawa (ON): Canadian Coordinating Office for Health Technology Assessment; 1997.

analysts are cautioned that results from RCTs (that is, efficacy results) may require adjustment to estimate real-world performance (that is, effectiveness).[7]

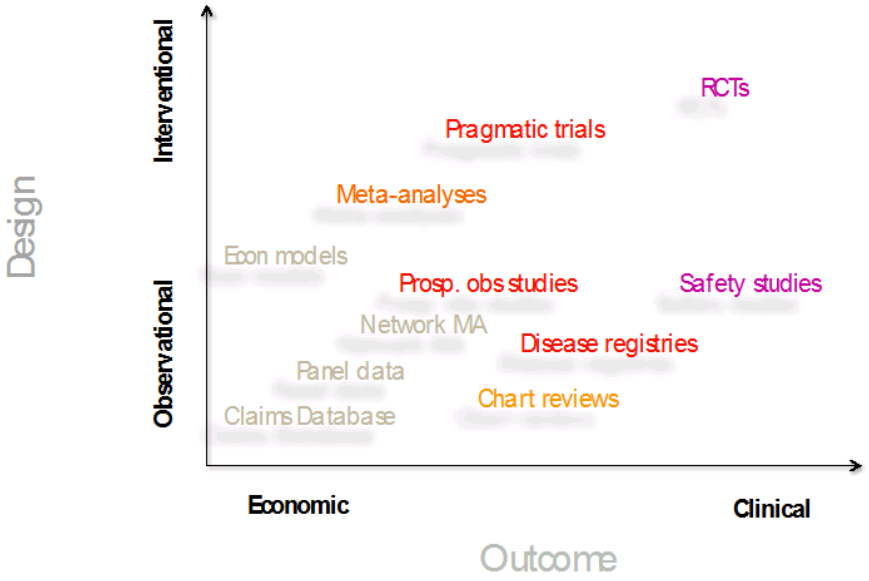
What has changed is the increasing amount of available data, and the potential for use of real-world data in product-listing agreements between producers of innovation and payers. In some jurisdictions, these outcome-based performance risk-sharing agreements or conditional reimbursement schemes have become more commonplace. However, they can be challenging to implement depending on the environment, as they require a high degree of coordination between researchers, health system service providers, administrators, and industry.

1.3. Policies and preferences for real-world evidence in Canada for new medicines

The starting point for the evaluation of new drugs or drugs with new indications in Canada is through submissions to the Canadian Agency for Drugs and Technology in Health (CADTH). Information about efficacy/effectiveness, safety, and economic and population impact, as well as pricing and distribution information is required in applications. A review of potential benefits and harms to patients, patient values, as well as economic and budget impact are then presented to expert committees who deliberate and create recommendations on whether to reimburse, reimburse with conditions, or not reimburse. These recommendations and the information used to inform them are then used to facilitate negotiation between public insurance providers and innovators regarding conditions to provide reimbursed access to patients. Submission packages and information presented to expert review committees require various types of analyses using different data sources and analytic methods, which often depend on what information is required (see Figure 2).

[7] Canadian Agency for Drugs and Technologies in Health (CADTH). *Guidelines for the economic evaluation of health technologies: Canada*. 4th ed. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health (CADTH); 2017. Available from: *https://www.cadth.ca/guidelines-economic-evaluation-health-technologies-canada-4th-edition*.

FIGURE 2: Types of outcomes, and supporting study designs



The CADTH Common Drug Review (CDR) and pan-Canadian Oncology Drug Review (pCODR) submission requirements do not make evidence from RCTs mandatory. Instead, applicants are asked to submit results from "pivotal" regulatory studies that in most cases are RCTs. Both bodies additionally ask studies to be described using CONSORT guidance (which was developed for RCTs),[8] and ask that any new clinical information for re-submission be submitted in the form of a RCT. It should be noted that some pivotal studies have been single arm phase 2 studies, which are basically highly controlled observational studies.

For existing and new information on safety/harm, non-randomized data is allowable from CDR/pCODR applicants. Specifically for re-submissions, CDR/pCODR guidance states that "case-control or cohort studies will be accepted if randomized controlled trials are unavailable."[9]

Economic evaluations require many more pieces of information than clinical evaluations, including information about natural disease progression (for model-based evaluations), societal preferences for health states (for cost-utility studies), adherence and switching rates, and resource use and costs. Current CDR/pCODR guidance does not put restrictions on where these data come from. However, the CADTH economic evaluation guidelines that inform this guidance do emphasize the need for approximating real-world effectiveness and costs in the analysis, including guidance for its use in creating model parameters and the external validation of extrapolated data (see Box 2). Also in the latest edition, no restrictions are placed on disease prevalence and incidence (epidemiological) information, and it is implied that robust Canadian data would lead to more accurate estimates.

[8] For more information, see the CONSORT website at: *http://www.consort-statement.org/*.

[9] See *https://www.cadth.ca/sites/default/files/pcodr/pCODR's%20Drug%20Review%20Process/pcodr-submission-guidelines.pdf* and *https://www.cadth.ca/media/cdr/process/CDR_Submission_Guidelines.pdf*.

Information on patient values used in a reimbursement dossier will often be based on global or national surveys conducted by patient organizations. Those submitting patient information are only asked to provide data sources and the manner in which they were achieved.

BOX 2: CADTH economic evaluation guidelines – Preferences for real-world evidence

"Potential sources for informing parameter estimates for effectiveness (e.g., clinical effects, detection, harms) could include RCTs, observational studies, administrative databases, non-comparative studies, or expert input."

"A determination of the appropriateness of the approach used to translate the surrogate outcome to the final outcome will ultimately require the availability of suitable real-world data sources in order to verify the results."

Resource Measurement: "Administrative databases represent a potentially valuable source of information for informing estimates of resource use. These databases provide real-world information on resource use specific to jurisdictions."

Source: CADTH, 2017

1.4. Current use of real-world evidence internationally

Few HTA bodies explicitly state through submission guidance that real-world data is preferred for evaluation. A recently conducted review of economic evaluation guidelines noted that many guidelines state RWE will be considered.[10] In some cases, preferences for RWE is made explicit for certain pieces of evidence, and in other cases, the guidelines are unclear (see Table 1).

TABLE 1: Use of real-world evidence in international economic evaluation guidelines

Country	Year of publication	Assessing clinical effectiveness and potential risks	Inclusion as parameters in pharmacoeconomic models	External validation of models
Americas				
Brazil	2009	▮	?	?
Canada*	2006	●	●	●
Colombia	2014	?	?	?
Europe				
Baltic (Latvia, Lithuania, Estonia)	2002	?	?	?
Belgium	2015	●	●	?
Denmark	2008	▮	▮	?
England and Wales	2013	▮	▮	?
Finland	2015	▮	▮	?
France	2012	▮	▮	▮

[10] Wang S, et al. Inclusion of real-world evidence in submission packages to health technology assessment bodies: What do current guidelines indicate? *Value in Health* 2016;19(3):A287. doi:10.1016/j.jval.2016.03.763.

Country	Year of publication	Assessing clinical effectiveness and potential risks	Inclusion as parameters in pharmacoeconomic models	External validation of models
Germany	2015	▮	▮	?
Ireland	2014	▮	▮	?
Norway	2012	▮	?	●
Poland	2009	●	●	▮
Portugal**	1998	▮	●	?
Scotland	2014	?	▮	?
Sweden	2003	?	?	?
Netherlands	2006	?	▮	?
Oceania				
Australia	2015	▮	▮	▮
New Zealand	2015	▮	▮	▮

Adapted from: Wang et al., 2016

●: RWE is recommended; ▮: RWE will be considered; ?: Position on RWE is unclear

*Updated guideline to come out in fall/winter 2016

**In June 2015, the National System of Health Technology Assessment was established in Portugal, and it is currently reviewing and updating the guideline

Note: Among the major European markets, only Spain and Italy lacked guidelines that are officially recognized or required by their HTA agencies; recommendations published by experts in the field are available

A survey of six key European HTA agencies (Sweden – TLV, United Kingdom – NICE, Germany – IQWIG, France – HAS, Italy – AIFA, and Netherlands – ZIN) further indicated where and how the importance of RWE is perceived by HTA bodies (see Table 2).[11] Respondents indicated that RWE may lend itself to three contexts in decision-making, namely: 1) initial reimbursement discussions; 2) pharmacoeconomic analysis; and 3) conditional reimbursement schemes.

TABLE 2: High-level summary of uses of real-world data by HTA bodies in Europe

Initial reimbursement discussions	Pharmacoeconomic analysis	Conditional reimbursement schemes
Real-world data welcome (not directly requested)	Real-world data directly requested	Only 3 agencies implement conditional reimbursement schemes
Preferably not for treatment effects	Preferably not for treatment effects	Real-world data requested highly case-specific
Can inform epidemiological data	Essential for resource use, cost, and epidemiological data	Agencies help identify evidence gaps and study protocols for real-world data collection

Adapted from: Makady et al., 2017

[11] Makady A, et al. Policies for use of real-world data in health technology assessment (HTA): A comparative study of six HTA agencies. *Value in Health* 2017;20(4):520-532. doi:10.1016/j.jval.2016.12.003.

1.5. Where might real-world evidence be more useful?

Although RCTs have evolved to answer questions of individual risk-benefit posed by regulators, they often create real evidence gaps for payers, who additionally have questions about population effects in the real world, including long-term safety, how dosing and compliance translate to effectiveness, use in broader populations with less monitoring, what the need is, and how new medicines perform versus currently available alternatives.

Non-randomized studies using real-world data provide an opportunity to answer questions payers may have including the following:

- Burden of illness – what is the real healthcare need in the patient population? Other populations?
- What is the real expected outcome/course of progression?
- What are patient experiences with illness? With current treatments?
- What health states and associated preferences are seen in the real world?
- What is being used in real-life practice, drugs, and doses for comparison?
- What endpoints are measured in real life, and how do they link with surrogate endpoints?
- What is the risk-benefit in less controlled populations?
- What utilization is expected? What does appropriate utilization look like?
- What is the clinical effectiveness and resource use in real-life patients?
- What is the clinical effectiveness and resource use of previously unevaluated comparators?
- How is the medicine used in complex chronic conditions, with multiple therapeutic options and switches over time?
- How is the medicine use/effect changed when part of a larger complex intervention?

2. Objectives of the IHE Roundtable

The focus of the roundtable discussion was to capture preferences and perceptions of the use of RWE for new medicine decisions in Canada. The use of RWE post-marketing or for conditional reimbursement was outside of the scope of the discussion. The following questions were addressed during the discussion:

- What is the state of system readiness in the Canadian health system and current approaches to RWE in drug reimbursement decisions in Canada and internationally?
- Is guidance for the use of RWE in pricing and reimbursement decisions desirable and feasible?
- What approaches or next steps might be taken to developing and implementing guidance or other tools to promote the consistent use of RWE?

3. Questions for the IHE Roundtable

The following questions were posed to the roundtable participants:

- How can RWE be incorporated into the current model of Canadian pricing and reimbursement process?
- Is better guidance for the use of RWE in pricing and reimbursement decisions desirable and feasible?
- How should RWE be utilized by HTA bodies when reviewing drugs?
- If payers/HTA bodies see value in the use of RWE, at what moment in a product's life cycle should this evidence be prepared?
- Where is RWE and accompanying guidance most needed? Least needed?
- How important is it to have RWE based on Canadian patients? In case of data gaps, can evidence collected in other countries be used?
- What are the biggest barriers for Canadian payers/HTA bodies to using RWE?
- What next steps are needed to best use RWE?
    - Changes to access to data?
    - Changes to governance of available RWD?
    - Standards for data analysis and use?
    - Guidance for payers on appropriate use?
    - Generation of a RWE framework or guidance document? If yes, who should develop this guidance?
    - Payers and producers engaging in a pilot utilizing RWE?
    - What is the role for industry in terms of RWE generation?

4. Themes from the IHE Roundtable

The following themes emerged from the discussion:

- **There is a desire to use more RWE** that would complement existing evidence provided by RCTs, provided it is useful for decision-making and decision-makers can be confident in its findings.
    - Participants noted that even well-conducted and reported observational studies can often lead to more questions than answers – research designs such as pragmatic clinical trials are perceived as more useful, but may require significant resources and capacity to carry out.
    - Evidence generated through a trusted source and using well-known and understood standards for data capture and analysis is important to decision-makers and those supporting them.
    - RWE generated in the pre-market space was felt by the group to be very useful, while there was also acknowledgement that RWE generated post-market is valuable.

- Before more use of RWE can occur, **a clearer definition is required**.
    - Participants stressed that a clear definition of *real-world evidence* is needed to facilitate future discussion and uptake. Participants felt that payers could not demand RWE if its definition and methods to generate it are ill defined.
- The usefulness of RWE also **depends on the context of the decision**.
    - Participants observed that RWE may be more useful when there is a lack of trial data, such as in studies of patients with rare conditions, or when important data, such as health-related quality of life or long-term outcomes affected by disease progression, are not captured in clinical trials.
    - Participants stated RWE may also be useful in cases where populations have been excluded from RCTs, such as the very young or very old, or those with comorbidity, poor health performance status measures, or poor renal function. Having clinical trial comparators that are not locally relevant also creates a need.
- **There may be a lack of confidence in the results of studies intended to provide RWE**, due to poor study designs and differences in how data are captured and analyzed.
    - Rigorous approaches to data capture and analysis was identified as a necessary factor to increase the confidence of findings and increase the use of RWE by decision-makers. This highlights the need for pan-Canadian standards or guidance for those using patient registries and electronic medical and health records as a data source for RWE.
    - Developing data standards may be facilitated through partnerships between health systems and the research community, including private-sector-led research. It also requires the involvement of regulators and clinicians.
    - Participants noted that improved data standards including standardized electronic health record information would not only improve the use of RWE for policymaking, but also facilitate its use in patient care.
    - Even if procedures for RWE are developed that create confidence, there must still be a process to identify policy- and patient-relevant questions.

5. Potential Next Steps

Given the above, some potential next steps were identified by the roundtable participants:

- The need for **standards**:
    - Participants stressed that a clear definition of *real-world evidence* is needed for the Canadian environment, as well as standard approaches to data capture and analysis that meet the needs of researchers, commercial innovators, and payers.
        - *A feasible next step is to further discuss the need for clear definition and standards with key stakeholders, including those conducting studies of RWE and those who will use them to inform policy (that is, end-users), with a view to developing pan-Canadian standards for RWE.*

- Activities identified may include:
  - The IHE, through partnership with established networks such as the Canadian Network for Observational Drug Effect Studies (CNODES), Drug Safety and Effectiveness Network (DSEN), the Institute for Clinical Evaluative Sciences (ICES), and others could be a leader in this initiative.
  - Leadership could also come from other pan-Canadian groups that link research to payers, including Health Canada, CADTH, the Canadian Institute for Health Information (CIHI), the Canadian Foundation for Healthcare Improvement (CFHI), Drug Safety and Effectiveness Network (DSEN), the Canadian Network for Observing Observational Drug Effects (CNODES), or the Canadian Institutes for Health Research (CIHR).
  - A review of cases and best practices in this area would be needed to support these discussions.
  - Sharing of unpublished or less-widely known learnings from the use of RWE by Canadian policymakers and health payers would also be helpful for these discussions.

- The need for **linkage**:
  - Participants observed that better mechanisms for linkage between key stakeholders in producing RWE are required.
    - *A feasible next step is to explore mechanisms to facilitate more interaction between health system researchers, industry, patients, and policymakers that results in RWE and processes that are relevant to everyone and can be publicly communicated.*
  - Activities identified may include:
    - Identifying what funding mechanisms may better facilitate thoughtful interaction between key stakeholders in developing RWE studies or platforms.
    - Engaging in pilot projects between healthcare system payers and industry, where methods and outcomes are public and well-communicated to others.
    - Conducting multi-stakeholder meetings as well as broader separate surveys of patients, experts, payers, and industry regarding what additional guidance is needed and what is viewed as a priority.

6. Conclusion

The IHE Roundtable highlighted the desire for robust information from RWE to support payer decisions. It appears that, in Canada, the uptake of RWE has been limited by both a lack of standards and vehicles that connect industry and publicly-funded researchers to decision-makers. Future work should focus on these barriers.

Appendix A: IHE Roundtable Participants

Payers

- Angie Wong, Ministry of Health and Long-term care, Toronto, Ontario
- Chad Mitchell, Alberta Health, Edmonton, Alberta

Healthcare providers/HTA committee members

- Silvia Alessia-Severini, University of Manitoba, Winnipeg, Manitoba
- Anil Joy, Cross Cancer Institute, Edmonton, Alberta
- James Silvius, Alberta Health Services, Calgary, Alberta
- Danica Wasney, CancerCare Manitoba, Winnipeg, Manitoba

Real-world evidence experts

- **Academia**
    - Muhammad Mamdani, St. Michael's Hospital, Toronto, Ontario
- **Industry**
    - Tarry Ahuja, Eli Lilly Canada Inc.
    - Enkeleida Nikai-Fitzgerald, Eli Lilly Inc.

Institute of Health Economics

- Don Husereau (moderator), Ottawa, Ontario
- Dan Palfrey, Kelowna, British Columbia

This report provides a summary of the IHE Real-World Evidence Roundtable, which took place on December 12, 2016. The intent of the roundtable was to capture initial thinking regarding preferences and perceptions of the use of real-world evidence for pricing and reimbursement of new medicines in Canada and what more may be needed.

INSTITUTE OF HEALTH ECONOMICS
ALBERTA CANADA

Institute of Health Economics
1200 – 10405 Jasper Avenue
Edmonton AB Canada T5J 3N4
Tel. 780.448.4881 Fax. 780.448.0018
info@ihe.ca

www.ihe.ca

ISBN 978-1-926929-81-1 (online)