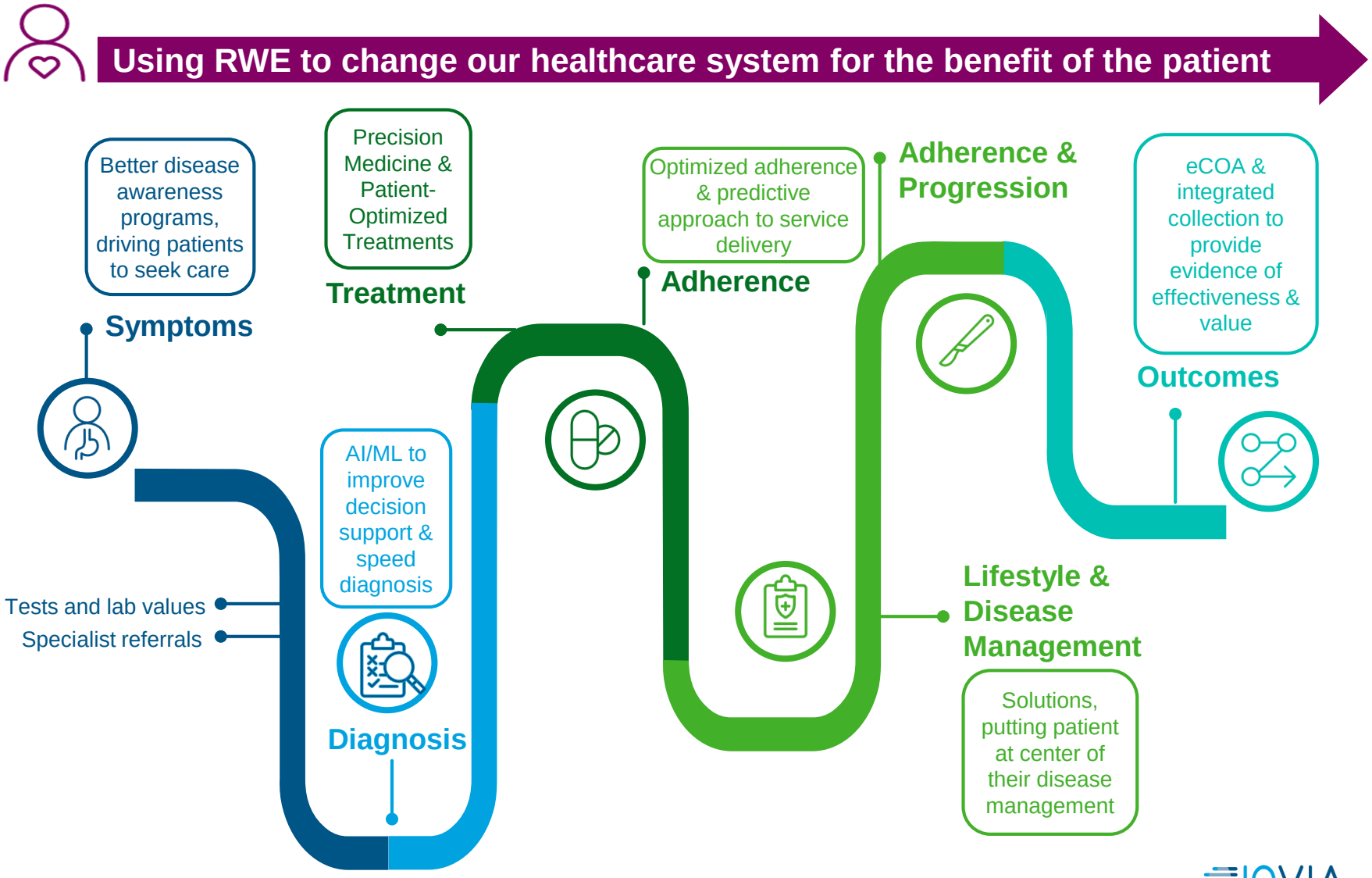
CAPT 2020 Conference

Panel Discussion - Modern methods of generating RWE to demonstrate value

Moderator: Brad Millson,
Sr. Principal, Real World Solutions, IQVIA

Tuesday October 27th, 2020

A vision for the patient journey enhanced through evidence



Our Panel for Today

1. **François Péloquin,**
   Sr. Manager, Market Access, Pfizer
2. **Farah Husein,**
   Director Evidence Generation, Takeda
3. **Charles Victor**,
   Sr. Director, Strategic Partnerships and Digital Services, IC/ES
4. **Nicole Yada,**
   Manager HDRN Partnerships, IC/ES
5. **Laurie Lambert,**
   The New Lead, Real-World Evidence, CADTH

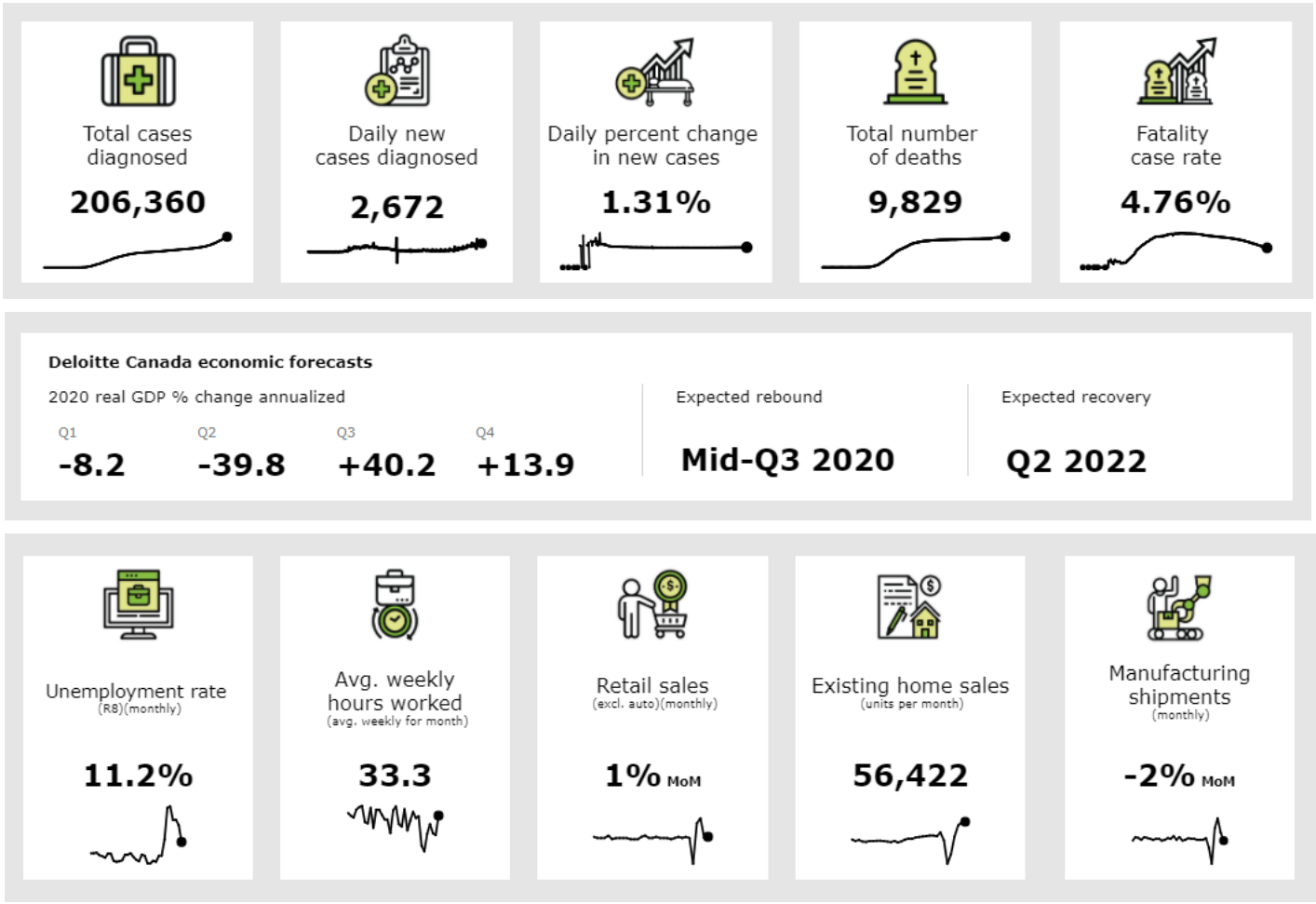
Modern methods of generating Real World Evidence to demonstrate value

More than ever, we must shift from utilization to value

Francois Peloquin

27OCT2020

COVID-19 significantly impacted the Canadian economy



https://www2.deloitte.com/ca/en/pages/about-deloitte/articles/covid-dashboard.html (Accessed 23OCT2020)

We each remain accountable to our stakeholders

Manufacturers

Maintain access to products

Timely and practical access to data

Partners that value innovation

Market that allows for profit & growth

Institutions / Drug Plans

Simple and tailored solutions to specific needs

KPI's and ROI from investment in innovation

Transparency & accountability

Financial deals with trusted partners

.

Patients

Involvement in decision making

Improved outcomes

Avoidable and shorter admissions

Access to HCPs & medicines

Society / Taxpayer

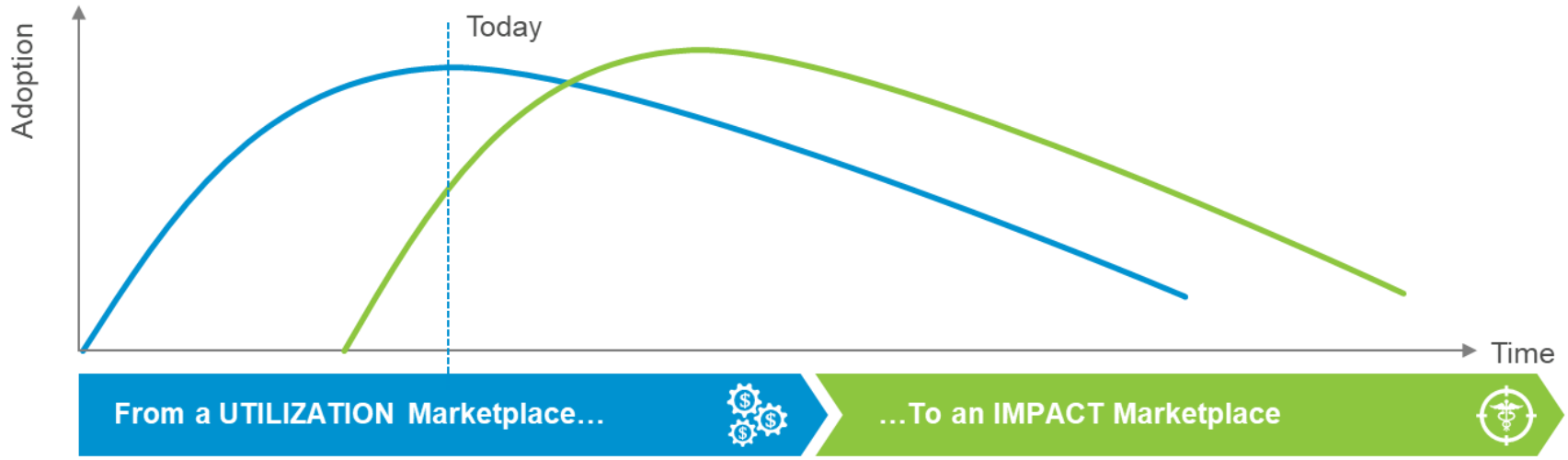
Better use of public funds

Increased productivity

Economic growth

Reduced healthcare costs

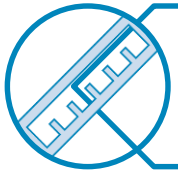
More than ever, we must shift from utilization to value



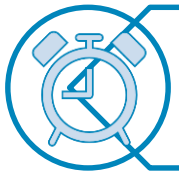
	From a UTILIZATION Marketplace…	…To an IMPACT Marketplace
Patients	• Limited access to health data • On-demand use of technology • Focus on disease treatment	
Society / Systems	• Contracting based on volume • Pricing per pill	• Outcomes based contracting • Transition to value based pricing model • Benefit focused • Targeted populations

A set of key principles should guide value-based healthcare

Value should be **patient centric**



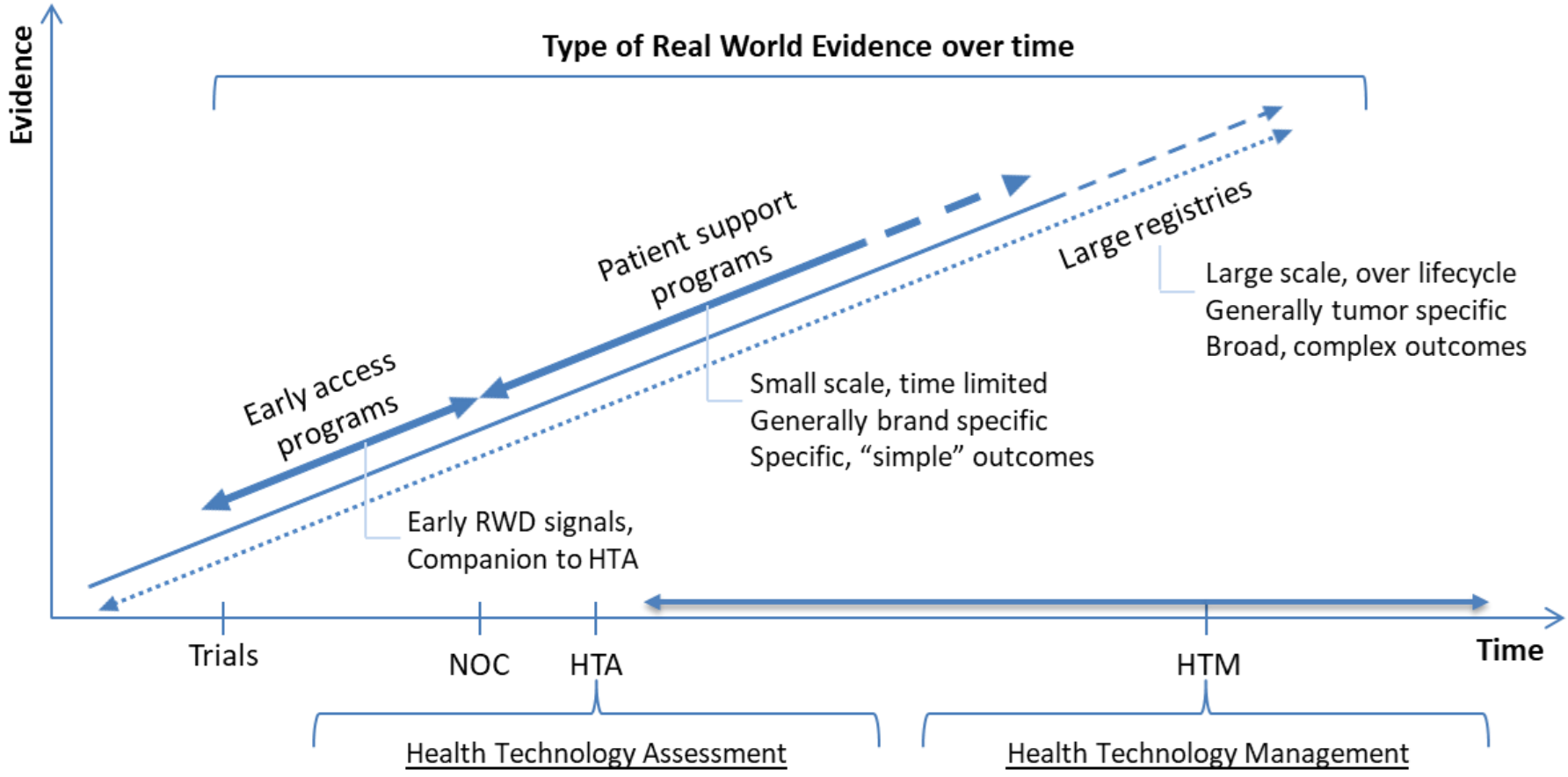
Value measurement should be **fit-for-purpose, and evidence based**



Value is **dynamic and changes over time**

Value assessment must be **objective, transparent, simple, and efficient**

Research questions and RWE evolve in parallel to lifecycle



Better Health, Brighter Future

Modern methods of generating Real-World Evidence to demonstrate value

Farah Husein, Director Evidence Generation, Takeda Canada

Research Questions addressed by RWE

Is the appropriate patient population being treated?	• Epidemiologic data • Patient journey, treatment pathway
Are patients using the treatment as expected?	• Drug utilization data
Are patients achieving the expected outcome(s) of interest?	• Clinical outcomes data, including PROs, safety and tolerability
Is the impact on patients, the health system as anticipated?	• Burden of Illness, Treatment Satisfaction data • Health Resource Utilization (HRU), cost data • Cost-effectiveness data • Budget Impact

Different types of RWE projects meet different Stakeholder needs at different Phases of the Lifecycle

EARLY PRE-LAUNCH THROUGH TO LAUNCH (L_{-36+} to L_0)	POST-LAUNCH (L_0 to $L_{+18\text{-}24m}$)
Consider: ❑ **Epi:** Prevalence, incidence ❑ **Patient Journey, Treatment Pathway** ❑ **Burden of Illness (BOI); Health Resource Utilization (HRU), cost data** *(current treatment pathway)* ❑ **SLRs** e.g.: Needed inputs to CE model (*Utility values, etc*), or to inform study planning ❑ **CE model -** Adaptation of core global model	**Consider:** ❑ **Drug Utilization data** ❑ **Clinical Outcomes data** (long-term safety, effectiveness - incl PROs - *QoL, Patient preference/Treatment Satisfaction*, etc,) ❑ **BOI; HRU, cost data** *(treatment pathway including new entrant)* ❑ **BIM**

Réseau de recherche sur les données de santé du Canada
Health Data Research Network Canada

Modern methods of generating Real World Evidence to demonstrate value

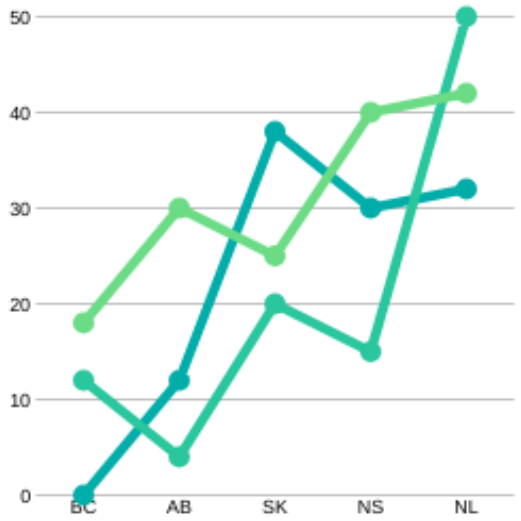
Charles Victor, Senior Director, Strategic Partnerships and Digital Services at ICES

Nicole Yada, Manager, HDRN Canada Partnerships

October 27, 2020

The biggest challenge for health data research in Canada

Data centres across Canada often collect slightly different data and have different processes for researchers who want to access health data:



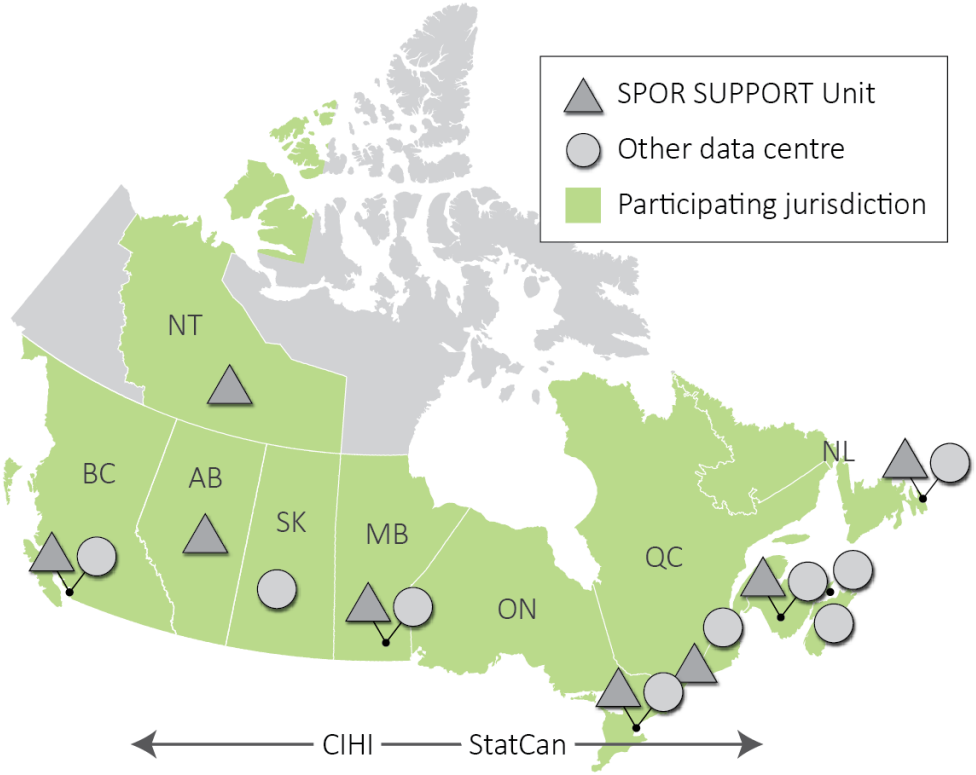
- Almost all health data research studies are based on data from a single province or territory; hard to make “apples to apples” comparisons
- Different jurisdictions = different legislation = different processes = ↑ time, $$
- Different rules for private-sector access

About HDRN Canada

Health Data Research Network Canada (HDRN Canada) is made up of provincial, territorial and pan-Canadian organizations that hold and manage data.

Our Vision

A distributed network that facilitates and accelerates multi-jurisdictional research



Our Principles and Commitments

- Distributed network with distributed funding
- Respect for local context and policy environment
- Leverage and share wherever possible
- Openness to ideas, input and opportunities

By working together, we can:

- Share expertise
- Identify opportunities for collaboration
- Foster innovation

Key data holdings at HDRN Canada Organizations

Last updated June 2020

	BC	AB	SK	MB	ON	QC	NB	NS	NL	CIHI	STC
COVID-19 TEST RESULTS DATA											
HEALTH ADMINISTRATIVE DATA											
Acute care hospitalizations											
Ambulatory clinic visits											
ED visits											
Physician claims											
Prescribed medications											
Home care							plan		plan		
Continuing care											
OTHER HEALTH DATA											
Vital statistics											
Primary care EMR											
Cancer registry											
PREMs and PROMs											
Genomics						plan			plan		
Lab and imaging						plan		plan			
SOCIAL DATA											
Education											
Immigration											
Workers compensation											
Early childhood development					plan						
	BC	**AB**	**SK**	**MB**	**ON**	**QC**	**NB**	**NS**	**NL**	**CIHI**	**STC**

LEGEND AND NOTES:

= Population-wide coverage

= Less than population-wide coverage

plan = Linkage and integration planned not yet implemented

USE OF REAL-WORLD EVIDENCE TO HELP OPTIMIZE USE OF CARDIOVASCULAR DEVICES

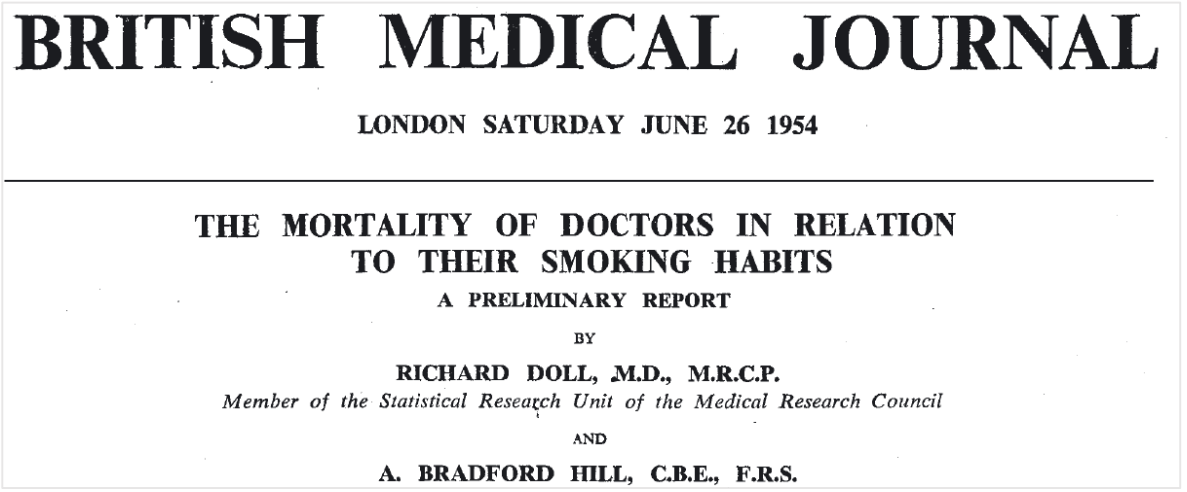
LAURIE LAMBERT

THE NEW LEAD, REAL-WORLD EVIDENCE

CADTH

The view that RWE has value is not new! And is shared by statistical experts!

"The truth of the matter has always been advanced by all types of information."



BRITISH MEDICAL JOURNAL

LONDON SATURDAY JUNE 26 1954

THE MORTALITY OF DOCTORS IN RELATION TO THEIR SMOKING HABITS

A PRELIMINARY REPORT

BY

RICHARD DOLL, M.D., M.R.C.P.

Member of the Statistical Research Unit of the Medical Research Council

AND

A. BRADFORD HILL, C.B.E., F.R.S.

Proof in Medicine: The Role of Real World Evidence

Joel Greenhouse, PhD
Professor of Statistics

CORNFIELD J. A method of estimating comparative rates from clinical data; applications to cancer of the lung, breast, and cervix. J Natl Cancer Inst. 1951

Ways that RWE can help to optimize the value of new innovative technologies

Table 1. Goals of the Registry

- Facilitate the refinement of patient selection to maximize outcomes with current and new device options.
- Identify predictors of good outcomes as well as risk factors for adverse events after device implantation.
- Develop consensus "best practice" guideline to improve clinical management by reducing short- and long-term complications of mechanical circulatory support device therapy.
- Utilize Registry information to guide improvements in technology, particularly as next generation devices evolve.
- Guide clinical testing and approval of new devices.

INTERMACS Database for Durable Devices for Circulatory Support: First Annual Report

in 2008!

James K. Kirklin, MD,[a] David C. Naftel, PhD,[a] Lynne Warner Stevenson, MD,[b] Robert L. Kormos, MD,[c] Francis D. Pagani, MD,[d] Marissa A. Miller, DVM, MPH,[e] Karen Ulisney, MSN, CRNP,[e] and James B. Young, MD[f]

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RWD can be good quality data

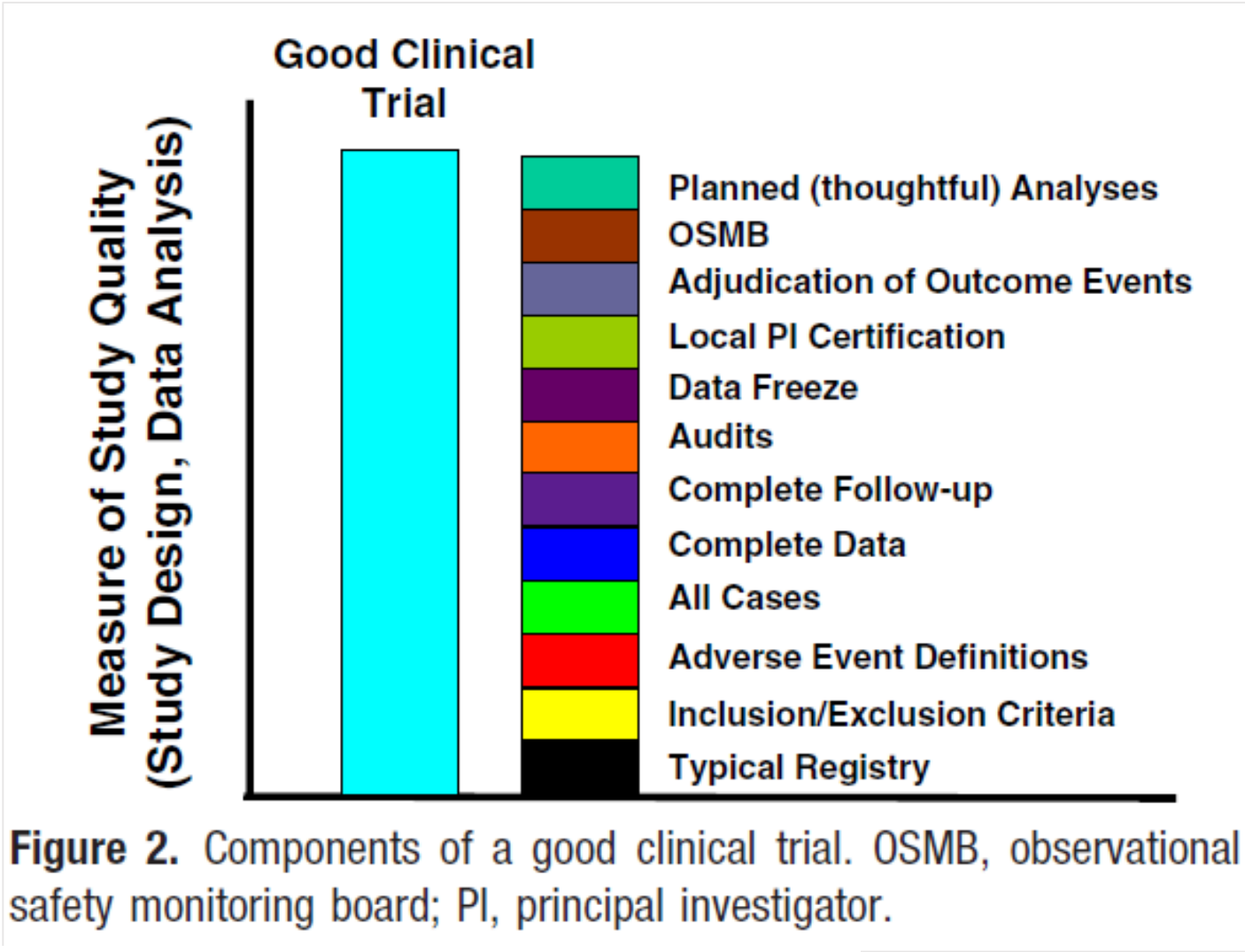

Figure 2. Components of a good clinical trial. OSMB, observational safety monitoring board; PI, principal investigator.

INTERMACS Database for Durable Devices for Circulatory Support: First Annual Report

James K. Kirklin, MD,[a] David C. Naftel, PhD,[a] Lynne Warner Stevenson, MD,[b] Robert L. Kormos, MD,[c] Francis D. Pagani, MD,[d] Marissa A. Miller, DVM, MPH,[e] Karen Ulisney, MSN, CRNP,[e] and James B. Young, MD[f]

CADTH

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http://dx.doi.org/10.1016/j.jacc.2013.03.060

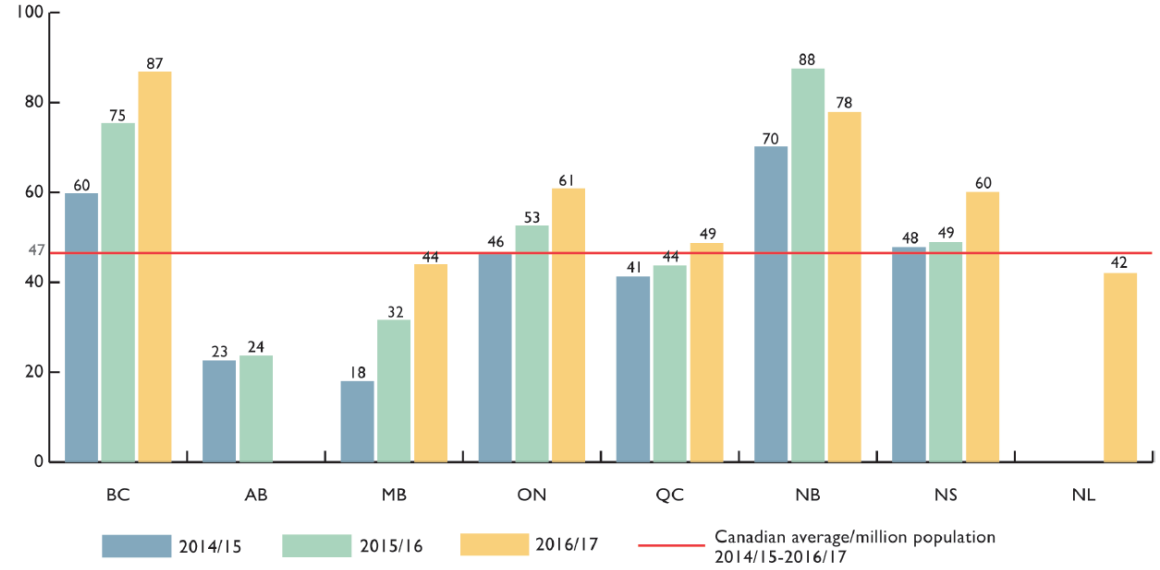
NEWS FROM THE ACC

The STS-ACC Transcatheter Valve Therapy National Registry

A New Partnership and Infrastructure for the Introduction and Surveillance of Medical Devices and Therapies

Decision Memo for Transcatheter Mitral Valve Repair (TMVR) (CAG-00438N)

5. The heart team and hospital are participating in a prospective, national, audited registry

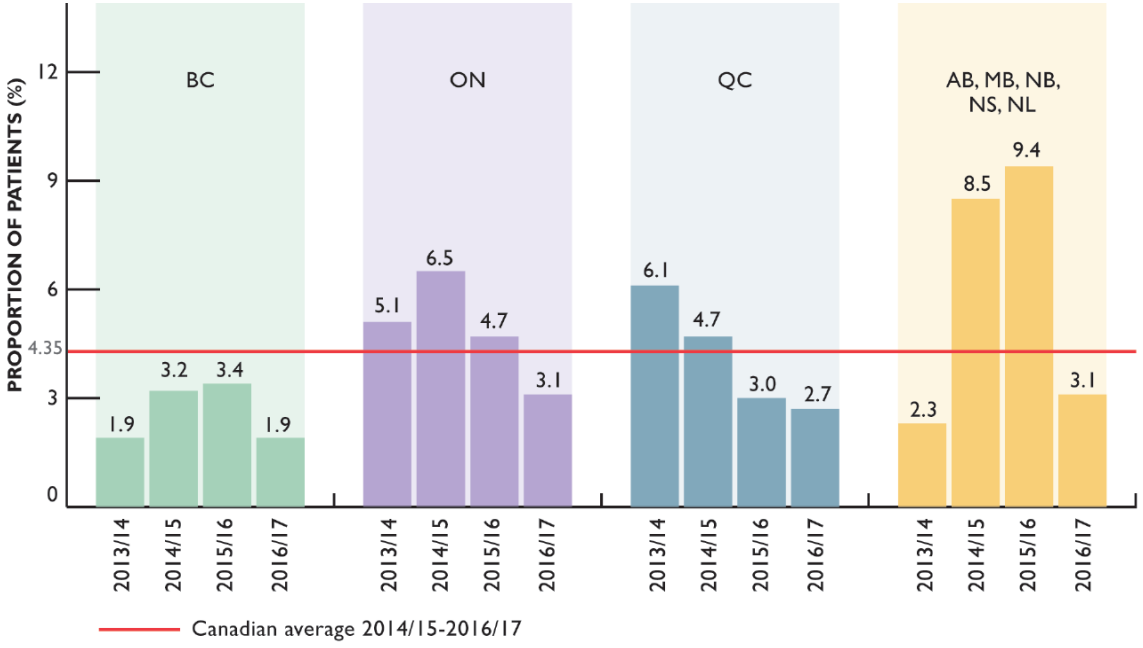


For TAVI, there is variation across Canada in respect to both patient access and 30-day mortality.

CANADIAN CARDIOVASCULAR SOCIETY

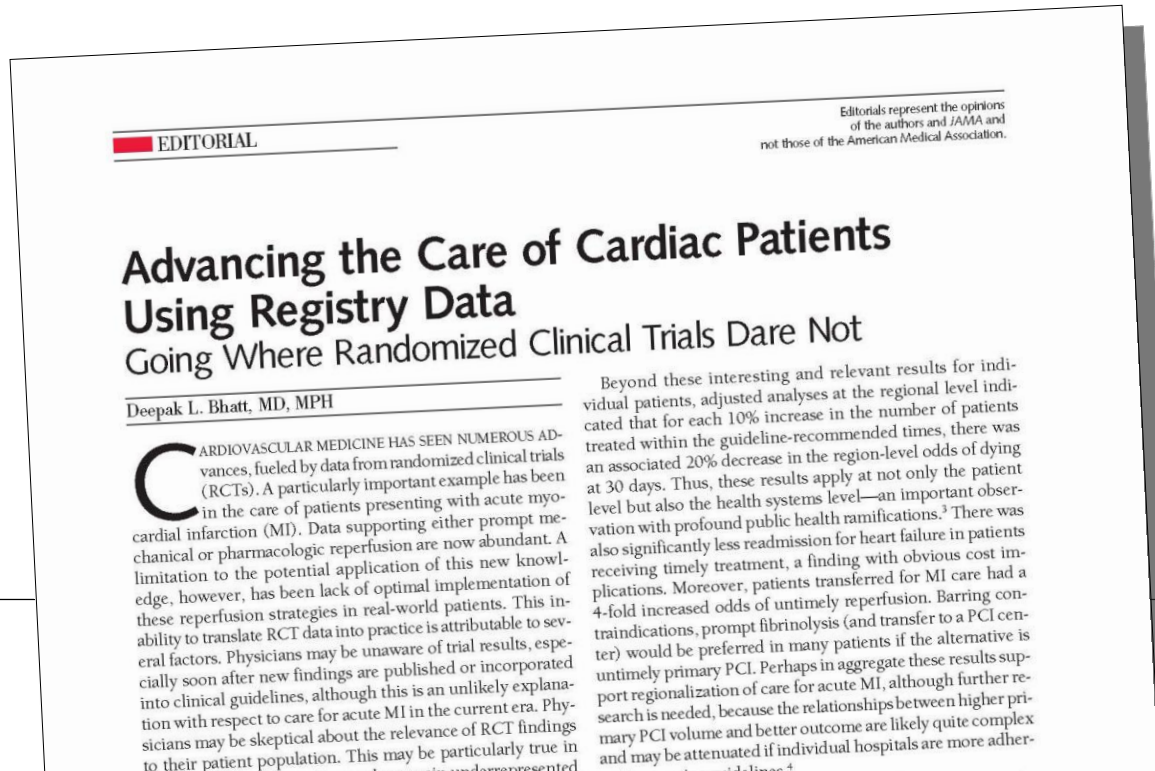
NATIONAL QUALITY REPORT: TRANSCATHETER AORTIC VALVE IMPLANTATION

OCTOBER 2019



CADTH

CADTH Evidence Driven.



EDITORIAL

Editorials represent the opinions of the authors and *JAMA* and not those of the American Medical Association.

Advancing the Care of Cardiac Patients Using Registry Data

Going Where Randomized Clinical Trials Dare Not

Deepak L. Bhatt, MD, MPH

CARDIOVASCULAR MEDICINE HAS SEEN NUMEROUS ADvances, fueled by data from randomized clinical trials (RCTs). A particularly important example has been in the care of patients presenting with acute myocardial infarction (MI). Data supporting either prompt mechanical or pharmacologic reperfusion are now abundant. A limitation to the potential application of this new knowledge, however, has been lack of optimal implementation of these reperfusion strategies in real-world patients. This inability to translate RCT data into practice is attributable to several factors. Physicians may be unaware of trial results, especially soon after new findings are published or incorporated into clinical guidelines, although this is an unlikely explanation with respect to care for acute MI in the current era. Physicians may be skeptical about the relevance of RCT findings to their patient population. This may be particularly true in

Beyond these interesting and relevant results for individual patients, adjusted analyses at the regional level indicated that for each 10% increase in the number of patients treated within the guideline-recommended times, there was an associated 20% decrease in the region-level odds of dying at 30 days. Thus, these results apply at not only the patient level but also the health systems level—an important observation with profound public health ramifications.[3] There was also significantly less readmission for heart failure in patients receiving timely treatment, a finding with obvious cost implications. Moreover, patients transferred for MI care had a 4-fold increased odds of untimely reperfusion. Barring contraindications, prompt fibrinolysis (and transfer to a PCI center) would be preferred in many patients if the alternative is untimely primary PCI. Perhaps in aggregate these results support regionalization of care for acute MI, although further research is needed, because the relationships between higher primary PCI volume and better outcome are likely quite complex and may be attenuated if individual hospitals are more adher-

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CADTH Evidence Driven.

ACMTS Preuves à l'appui.