New Innovations in Combining Clinical Data and Real-World Evidence to Understand the Long-Term Impact of Therapies:

*The Future Is Here*
Global Trends

Innovations in the data environment

Innovative methods to gain insights

Applying insights in practice and policy

Discussion
Disclosures

I am an employee of QuintilesIMS and conduct paid research studies on behalf of multiple government and commercial entities in Canada and globally.

The views and opinions expressed are my own and do not necessarily reflect those of QuintilesIMS, CADTH or the panelists.
A common lexicon

Real-World Data (RWD)

• Patient-level data not collected in conventional randomized controlled trials
• Examples: electronic medical records, claims data, mortality data, consumer data, registries, data collected in observational studies, chart reviews

Real-World Insights (RWI)

• Insights generated from RWD using appropriate scientific and/or generated commercial analytics

Real-World Evidence (RWE)

• Insights generated from RWD using appropriate scientific and/or generated commercial analytics with the intention to support a claim or belief to produce evidence for multiple stakeholders

See www.rwedictionary.com for more definitions
But really, what’s real world data???
Monitoring and diagnosis technologies are expanding exponentially
New forms of treatment cross traditional boundaries
More connected than ever
Data is growing exponentially, with the vast majority unstructured

Data Growth
Driven by Unstructured Data

125 Exabytes
79.2% Unstructured Data
37.4 Exabytes
20.8% Structured Data

2005
2013
Emerging growth of RWI can be seen by both existing and new players evolving in the field.
Who are the actual global consumers of this new evidence model?

<table>
<thead>
<tr>
<th>Life-science</th>
<th>Government</th>
<th>AMCs</th>
<th>Health IT</th>
<th>Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lilly</td>
<td>MHRA</td>
<td>RSM</td>
<td>3M</td>
<td>ASCO CANCER-LINQ</td>
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<tr>
<td>janssen</td>
<td>FDA</td>
<td>ERASMUS</td>
<td>GE Healthcare</td>
<td>inmar</td>
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<tr>
<td>AMGEN</td>
<td>NIH</td>
<td>National Institutes of Health</td>
<td>LabCorp</td>
<td>Kaiser Permanente</td>
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<td>muniPharma</td>
<td>University of Nottingham</td>
<td>3M</td>
<td>Sutter Health</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>Public Health England</td>
<td>University of Birmingham</td>
<td>3M</td>
<td>WASHINTON STATE HEALTH CARE AUTHORITY</td>
</tr>
</tbody>
</table>

- Trusted by the leading organizations
- Globally relevant and world-class
- Applicable to any use of RWD
- In combination with leading data or services capabilities
Quintiles + IMS Health = Disrupting the evidence generation lifecycle

Studies using secondary (RWE) data

Studies using just primary (clinical) data ("site-based")

Bridging Clinical with Real World Evidence

Smarter evidence design & execution:
• Enriched Study (aka Hybrid Study, Enhanced Study)
• Evidence Platforms & Technologies (aka Evidence Hub)
• Low Intervention Clinical Trial (aka Minimally Interventional Trial)
• Predictive Analytics
• One-Armed Study with External Comparator
• Pragmatic Randomized Trial
FDA asking for leadership from biopharma community

Transforming Evidence Generation to Support Health and Health Care Decisions


Making better choices about health and health care requires the best possible evidence. Unfortunately, many of the decisions made today in our health care system are not supported by high-quality evidence derived from randomized, controlled trials or well-designed observational studies. But as rich, diverse sources of digital data become widely available for research and as analytical tools continue to grow in power and sophistication, the research and health care communities now have the opportunity to quickly and efficiently generate the scientific evidence needed to support improved decision making about health and health care.

and will entail substantial changes to the culture of clinical research, interactions between providers and patients, and the ways in which health systems, clinicians, and patients work together with the clinical research community to create a new environment for generating and using evidence in practice. In this article, we propose a set of core principles for data collaboration and system organizational design that we believe will further enable research efforts by both the private sector and government agencies (see box). Although these principles represent high-level articulations of concepts that are not new, their distillation will help to focus collaboration across

Real world evidence applications are endless

Athletic trainers enter data into a customized EMR allowing studies of injury occurrence & management

“The data today does show an increase in concussions, and the NFL is committed to understanding the reasons… Several possibilities include increased screening, increased detection, increased self-reporting and potentially an absolute increase in the number of injuries.” –Nancy Dreyer

The NBA has quietly been gathering mountains of injury data since the 2012-13 season, according to sources with direct knowledge. In 2014-15, the league started working with Quintiles, a Durham, N.C.-based health-care company that focuses on data analytics and has recently worked directly with the NFL’s medical committees. Quintiles’ mission: break the data down.
Main messages

1. We have more data in more places, which coupled with new technology, is opportunity for generation of innovative and powerful insights.

2. Evolving landscape of evidence generation is demanding new approaches to analysis, delivery and consumption of these insights.

3. **The future is now:** Stakeholders need to adapt to this changing environment to make best use of this revolution.
Innovations in the data environment

Innovative methods to gain insights

Applying insights in practice and policy

Discussion
Improving access to “Real World” data for clinical research
Disclosure

I have no actual or potential conflict of interest in relation to this topic or presentation.
Nobody knew that health care could be so complicated

President Donald J. Trump, 2017
Combining clinical data with ‘Real World’ data

Linkage of historical RCTs
- WOSCOPS statin trial – 20 year follow-up

Explanatory trials evaluating secondary outcomes / adverse events
- Readmission rates
- Health care resource utilization
- GP follow-up

Pragmatic trials that may be completely or partially dependent on administrative data
- Randomization of practitioners /hospitals to use a product / technology
Value of linkage for RCTs

Administrative data covers almost entire population

Outcome evaluation – short and long term
- Death, hospitalization, ER visits 5yr, 10yr, 15yr,…
- Safety
- Surveillance of adverse outcomes (e.g., poly-pharm)
- Identification of rare/unexpected adverse outcomes

Minimize costs for evaluating secondary benefits
- Readmission rates
- Health care resource utilization
- GP follow-up

Bias / Quality evaluation
- Evaluation of loss-to-follow-up
- Evaluation of potential biases (e.g., Health seeking behaviour)
- Comorbidity
- Compliance (drug studies)
Challenges to linking to ‘Real-World’ data

Data sourcing / access
- Multiple data sources often required to observe patient trajectory
  - May be from multiple institutions, multiple formats
  - Data sharing agreements

Quality of data
- Administrative data not collected for scientific study
- Most rich data in challenging formats – EMR open text fields
- GP follow-up

Use of data
- Linkages may be complex – especially probabilistic
- Data preparation / analysis may be complex – collaboration/SME

Perception of data
- Reviews challenging algorithms
Addressing the challenges: Access

Starting 2014 Strategy for Patient Oriented Research (SPOR)

• Supporting provincial data platforms
  • Leveraging existing infrastructure
    • Addresses concerns about standardization, complexity, data sharing (in some cases)

ICES Data and Analytic Services (DAS)

• Established March 2014
  • Provides access to data and / or analytic reports to non-ICES entities
  • Augments external ‘third party’ data with Ontario Administrative data
  • Supports SPOR research networks
  • Supports SPOR researchers
    • All Canadian university-based researchers

• Performs analysis and reporting for private sector research
ICES CORE Data Repository: Coded and Linkable

Provider/Facilities
- Physicians
- Hospitals
- Complex care
- Long-term care homes
- Home care

Real-time Health Service Encounters
- Health Outcomes for Better Information Care (nursing home)
- Implantable Cardiac Defibrillators

Health Service Encounters
- Emergency visits
- Ontario Drug Benefit claims
- Narcotics Monitoring System
- Home care
- Rehab
- Long-term care

People & Geography
- Physician claims
- Hospital discharge abstracts
- Demographics
- Deaths
- Census

Special Collections*
- People in Ontario eligible for health care since 1985
- Unique individual ICES Key Number (IKN) used for linking across all data sets
- Disease registries (ex. cancer, stroke, cardiac, perinatal)
- HIV clinics
- Immigration
- First Nation
- Métis
- Social Assistance
- Disabilities
- Early Development Instrument
- Deaths
- Census

Derived Chronic Conditions
- Using routine ICES data
- Diabetes
- Respiratory problems (ex. Asthma, chronic obstructive pulmonary disease)
- Cardiac problems (ex. heart attacks, hypertension)
- Schizophrenia
- Many others

Project Specific Research Data

Unique algorithm based on Ontario health card number

Linked data set
* Special governance
What external data can be linked?

Most external data may be brought in for data linkage:

- Patient level
  - Registry
  - Medical records
  - Survey
  - Clinical trial
- Provider level
  - Physician – need physician identifier
- Ecological
  - Institution
  - Region
- Health-related
- Non-health related

Data on devices, with only device identifiers cannot be linked

- Need patient identifier
# Making Real-World data available: ICES Data and Analytic Services

<table>
<thead>
<tr>
<th>Without linkage to imported external research data</th>
<th>With linkage to imported external research data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data access alone</td>
<td>Data access alone</td>
</tr>
<tr>
<td>Analytic reports</td>
<td>Analytic reports</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Without linkage</th>
<th>With linkage</th>
</tr>
</thead>
<tbody>
<tr>
<td>34 days</td>
<td>95 days</td>
</tr>
<tr>
<td>120 days</td>
<td>130 days</td>
</tr>
</tbody>
</table>

Median period of time from agreement of services to final deliverable
DAS Requests

- **2014/15**: 105 requests, 2 feasible, 6 declined, 97 on hold
- **2015/16**: 132 requests, 26 feasible, 26 declined, 106 on hold
- **2016/17 Q1**: 20 requests, 3 feasible, 17 declined, 53 on hold
- **2016/17 Q2**: 60 requests, 2 feasible, 5 declined, 53 on hold
- **2016/17 Q3**: 90 requests, 2 feasible, 8 declined, 80 on hold
- **2016/17 Q4**: 119 requests, 10 feasible, 2 declined, 107 on hold

Legend:
- Blue: Feasible
- Red: Declined
- Green: On hold
Primary goal: RCT comparison of realtime monitoring in hospital and remote monitoring at home vs standard care

Secondary goal: Supervised training of realtime feeds and long-term outcomes
Moving the ball forward

Continued focus on expanding access to novel data

- Renegotiation of Data Sharing Agreements
  - Permitting access to non-ICES researchers
  - Demonstrated value for new and existing data partners
- Non-health data
- Electronic Medical Records
  - De-identification to allow appropriate access

Validation of administrative data for RCTs

- Collaboration between ICES and PHRI
- Linking prior RCTs to evaluate outcome assessment via administrative data

Increasing ease of access and improving tools

- Linking provincial data hubs
- Developing safe spaces for data collaboration
On the horizon: De-identified EMR / EHR data (De-identification through natural language processing)

- **Some structured data**
  - Sex

- **Some semi-structured data**
  - Weight (lbs vs kg)
  - Smoking status (definitions)

- **Large unstructured components:**
  - Identifying diseases and symptoms

*Privacy-preserved* access for researchers

John Doe was a patient with advanced Crohn’s disease. He was on a maintenance dose of medications for his regional enteritis. This time, he presented with pain, swelling, and inflammation of the lower back. He was admitted for treatment of sacro-iliac joint arthritis, a complication of the enteritis. John’s disease worsened over the course of his stay.

ICD10: K50 Crohn’s
On the horizon: Pan-Canadian Real World Health Data Network

Aims

Provide researchers, policy-makers, and decision-makers with services, tools, and resources to enable coordinated use of multi-jurisdictional health data

Strengthen Canada’s capacity to undertake and use actionable research and comparative analysis on a multi-jurisdictional basis

Build connections among patients, the public, policy/decision-makers, and researchers across Canada

Reduce barriers to the exchange of information and evidence that can improve outcomes are reduced
On the horizon: Data Safe Haven

- Creating “safe” spaces for collaboration
Thank You
Leveraging Innovative Data Sources To Deliver Real World Impact

Marie-Claude Laliberté, Ph.D.
Manager, Market Access & HEOR
AbbVie Canada

CADTH Symposium
April 25, 2017
Disclosure

- I have the following relevant financial relationship to disclose:
  - Employed by AbbVie Corporation
RWE generation in Canada: Are we innovating?

- Traditional study designs are still widely used (ex: cohort studies, case-control studies)

- Starting to see few more innovative data analysis
  - Combination/linking of data sources
  - Novel methodologies (ex: marginal structural models, spatial analysis)

- There is still room for integrating more innovative methodologies to gain insights from RWE
Innovative partnership: The COMPANION study

Research question: What is the impact of AbbVie Care services on patients’ treatment journey and health care costs?

HUMIRA® patient in AbbVie Care PSP

AbbVie Care PSP services

Improved adherence and persistence to HUMIRA®

Reduced health care costs

Improved clinical outcomes & work productivity

PSP: Patient support program
Linking a PSP database with pharmacy transactions: The COMPANION study

**Objective**
To evaluate the impact of the services provided by the HUMIRA® AbbVie Care PSP on the adherence, persistence and clinical outcomes of patients within the program.

**Methodology**
- Pharmacy-level longitudinal data (LRx database from QuintilesIMS) was linked to the AbbVie Care PSP dataset.
- Patients were matched using an externally validated algorithm based on a combination of variables.

LifeLink Longitudinal Insights (LRx)

n = 10,857 patients

PSP: Patient support program
Abbvie Care services positively impact persistence and adherence to HUMIRA – Results from the COMPANION study

In 1-year persistent patients who then received ongoing care coach calls, **16% more patients were on therapy** at 3 years

Persistence over 36 months

- **With ongoing CCCs (n=1,452)**
  - 78%
- **Without ongoing CCCs (n=1,414)**
  - 67%

**16% difference**

On average, patients receiving ongoing care coach calls were **12% more adherent to HUMIRA** over 3 years

Mean adherence (MPR) over 36 months

- **With ongoing CCCs (n=1,511)**
  - 75%
- **Without ongoing CCCs (n=3,119)**
  - 67%

**12% difference**

Non-persistent vs. persistent:
Hazard ratio (HR): 0.35, p<0.0001

Adherent (MPR ≥ 80%) vs. non-adherent (MPR<80%):
Odds ratio (OR): 2.25, p<0.0001

1 36-month persistence includes only patients who persisted to at least 1 year; adherence includes all patients in the 36-month sample

Source: Bessette L, et al. Presented at the 2017 CRA annual meeting, Ottawa, February 8-11, 2017
Abbvie Care services positively impact remission rates in IBD
Results from the COMPANION study

In IBD patients receiving ongoing care coach calls, **12% more patients achieved remission** (according to HBI score) after 6-18 months

HBI remission over 6-18 months

<table>
<thead>
<tr>
<th></th>
<th>With ongoing CCCs (n=880)</th>
<th>Without ongoing CCCs (n=523)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients in remission (%)</td>
<td>74%</td>
<td>66%</td>
</tr>
</tbody>
</table>

In remission (HBI < 5) vs. not in remission (HBI ≥ 5):
Hazard ratio (HR): 1.12, CI: 1.04-1.21, p=0.003

HBI, Harvey-Bradshaw index; IBD, inflammatory bowel diseases
The future of generating RWE – The future is here

• Need to use available datasets and new methodologies to have more holistic view of RWE

• Innovative partnerships can help overcoming data limitations

• Will allow the generation of rich RWE to support decision-making
Thank You
Bringing Insights on Real World Evidence into Practice and Policy

CADTH Symposium
April 25, 2017
Disclosures

I have the following relevant financial relationships to disclose:

- Grant/research support from the Ontario Ministry of Health and Long-Term Care
Integrating RWE into Drug Policy and Clinical Practice

Beliefs → Behaviours → Results
Integrating RWE into Drug Policy and Clinical Practice

Beliefs
- Competing Interests
- Societal Factors
- Financial Factors
- Evidence
- Equity
- Other Factors

Behaviours

Results
Opportunities in Ontario’s Data Rich Environment
Informing and Evaluating Policy

**Blood Glucose Test Strips**

**Opioid Dose and Related Death**

**Trial: Antipsychotic use in LTC**

- Interventional Time Series Analysis
- Nested Case-Control
- Repeated Measures Analysis
Example: Blood Glucose Test Strips in Ontario

Gomes, Juurlink, Shah et al. 2009. CMAJ; 182(1)50
Gomes, Juurlink, Shah et al. 2009. ICES Investigative Report

Ontario Policy (August 2013)

- Insulin users: maximum of 3000 strips annually
- Hypoglycemia-inducing OHAs: maximum of 400 strips annually
- All others: maximum of 200 strips annually

• Following the policy’s introduction, the OPDP requested an evaluation of the policy’s impact on:

  Utilization/Costs

  Patient Outcomes

  Model: Interventional Autoregressive Integrated Moving Average (ARIMA) models

  Hypoglycemia
  Hyperglycemia
  HbA1c
  Physician Visits
BGTS Utilization and Costs in Ontario

[Graph showing BGTS utilization and costs from 2010 to 2015]

One Year Cost Savings:
- Overall: $31.6 Million
- Age <65: $7.7 Million
- Age 65+: $23.9 Million

http://odprn.ca/research/core-themes/self-monitoring-of-blood-glucose/
Rates of Emergency Department Visits for Hypoglycemia and Hyperglycemia

Ontario’s Quantity Limit Policy

$p = 0.37$

$p = 0.67$

$p = 0.12$

$p = 0.24$

Mean HbA1c Values Overall and Among High User Cohort

*Among individuals with a record in laboratory database

Ontario’s Quantity Limit Policy

$p>0.05$

Collaborated with colleagues in BC and CIHI to evaluate potential cost-savings in other provinces:

<table>
<thead>
<tr>
<th>Province</th>
<th>Actual spending</th>
<th>Potential Cost Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alberta</td>
<td>$7.2M</td>
<td>$25K</td>
</tr>
<tr>
<td>Manitoba</td>
<td>$7.0M</td>
<td>$1.1M</td>
</tr>
<tr>
<td>Newfoundland</td>
<td>$6.5M</td>
<td>$1.3M</td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>$7.0M</td>
<td>0.9M</td>
</tr>
<tr>
<td>Prince Edward Island</td>
<td>$1.0M</td>
<td>$22K</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>$9.4M</td>
<td>$1.3M</td>
</tr>
<tr>
<td>Ontario</td>
<td>$107.1M</td>
<td>$21.1M</td>
</tr>
<tr>
<td>Quebec*</td>
<td>$103.9M</td>
<td>$20.0M</td>
</tr>
<tr>
<td>British Columbia</td>
<td>$23.6M</td>
<td>$4.5M</td>
</tr>
<tr>
<td>OVERALL</td>
<td>$272.6M</td>
<td>$50.2M</td>
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</tbody>
</table>

*Source: INESSS. Avis sur les mesures relatives au remboursement des bandelettes. Québec.
Example: Opioid Prescribing and Safety

- Use of opioids in CNCP subject to considerable debate
- **North America:** Marked increase in prevalence of:
  - Opioid use
  - High dose dispensing
  - Overdose deaths

Drug overdose death rates in the US have more than tripled since 1990.¹


Prevalence of high-dose (300 mg/MED) opioid use (%)
Studying Opioid-Related Deaths in Canada

- Deaths often under-reported:
  - Reliance on hospital records/ICD codes for toxicity or vital statistics/coroner’s determinations that can be vague

- Coroner’s records have a wealth of information → generally not electronic

Chart Abstraction and Linkage at ICES
• Nested case-control study

• **Population:**
  – Aged 15 to 64
  – Eligible for public drug coverage in Ontario
  – Not prescribed opioids for cancer pain or palliative care

• **Cases:** Died of Opioid-related drug overdose *(Coroner’s Data)*

• **Controls:** Also prescribed opioids, matched on:
  – Age (within 3 years)
  – Sex
  – Index Year
  – Charlson Comorbidity Score
  – Disease Risk Index (within 0.2 std dev)

• **Exposure:** Opioid dose category
2 to 3-fold increased odds of dying from an opioid overdose if individuals prescribed daily dose of opioids >50 mg MEQ.
Emerging Policy and Guideline Changes

- **New CDC Guidelines**: prescribers should carefully consider risk-benefit profile when treating patients with doses exceeding 50mg MEQ and avoid exceeding 90mg MEQ.

- **Revised 2017 Canadian Guidelines**: maximum 50mg MEQ at initiation, rising to maximum of 90mg MEQ.
Appropriate prescribing in nursing homes demonstration project (Dr. Noah Ivers)

- **Design**: Two-arm, pragmatic, cluster-randomized trial

- **Intervention**: Academic detailing on appropriate antipsychotic prescribing

- Blinded outcome analysis of administrative data

- Repeated measures analysis at baseline, 3, 6 months following intervention
# Outcome Ascertainment

## Primary outcome

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antipsychotic dispensing</td>
<td>Number of days with antipsychotic prescriptions in the last week (count, range 0 – 7)</td>
<td>RAI</td>
</tr>
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</table>

## Secondary prescribing outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antipsychotic prescribing</td>
<td>Any antipsychotic Rx during the past month (dichotomous)</td>
<td>ODB</td>
</tr>
<tr>
<td>Mean Antipsychotic dose</td>
<td>Dose equivalent of antipsychotic dispensed in the past month (continuous)</td>
<td>ODB</td>
</tr>
<tr>
<td>Benzodiazepine (or z-drug)</td>
<td>Any Rx during the past month (dichotomous)</td>
<td>ODB</td>
</tr>
<tr>
<td>Prescribing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-depressant prescribing</td>
<td>Any Rx during the past month (dichotomous)</td>
<td>ODB</td>
</tr>
<tr>
<td>Acetaminophen prescribing</td>
<td>Any Rx during the past month (dichotomous)</td>
<td>ODB</td>
</tr>
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## Secondary clinical outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty in performing activities</td>
<td>ADL long form scale (continuous variable, range 0-28)</td>
<td>RAI (ADL long cc)</td>
</tr>
<tr>
<td>Aggressive behaviour scale</td>
<td>Extent of aggressive behaviour (continuous variable, range 0-12)</td>
<td>RAI (ABS cc)</td>
</tr>
<tr>
<td>Pain</td>
<td>Pain scale (continuous variable, range 0-3)</td>
<td>RAI (PAIN cc)</td>
</tr>
<tr>
<td>Depression</td>
<td>Depression rating scale (continuous variable, range 0-14)</td>
<td>RAI (DRS cc)</td>
</tr>
<tr>
<td>Falls</td>
<td>Number of falls in the past month (count)</td>
<td>RAI (J4: a)</td>
</tr>
</tbody>
</table>

## Secondary health care utilization outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>ER visits</td>
<td>Number of ER visits during the previous 6 months (count)</td>
<td>CIHI/NACRS</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>Number of hospital visits visit during the previous 6 months (count)</td>
<td>CIHI</td>
</tr>
</tbody>
</table>
Primary Outcome:
Daily AP Use in past week

<table>
<thead>
<tr>
<th></th>
<th>Odds Ratio, 95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline to 6 months</td>
<td>1.0 (0.9 to 1.2)</td>
<td>0.9</td>
</tr>
<tr>
<td>Baseline to 3 months</td>
<td>1.0 (0.9 to 1.1)</td>
<td>0.8</td>
</tr>
</tbody>
</table>

Secondary Outcomes
- No changes in acute care utilization or complementary prescribing
- No changes observed in mean dose amongst those getting the antipsychotics
Combining RWE and clinical data to drive policy

**Opportunities**

- Evaluate **short-** and **long-term** implications with limited additional resources
- Identification of potential **unintended consequences** and investigation of **emerging concerns**
- Identifying new **collaborative** and **creative opportunities**

**Challenges**

- Integration of some **patient-oriented outcomes** (i.e. QoL) difficult
- Delays in **data availability**
- Varying degrees of **access** to administrative data (historically)
THANK YOU!

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