The Ontario Biologics Research Initiative (OBRI): An Innovative Platform for Real-World Drug Surveillance and Evidence-Based Practice Indicators

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Aims:
- To determine the real-world effectiveness and safety of anti-rheumatic therapies for the treatment of RA
- To incorporate best practice strategies and post-marketing surveillance in usual care and
- To create, implement and evaluate a multi-faceted knowledge translation strategy, including the measurement of quality of care indicators.

**OBRI CLINICAL COHORT**

- This provincial surveillance research program builds on the examples and experiences of the best post-marketing surveillance initiatives worldwide and includes a clinical cohort of patients receiving anti-rheumatic treatments for RA, for a minimum of five years of follow-up, regardless of drug changes.

**OBRI ADMINISTRATIVE DATABASE COHORT**

- The OBRI has established a cohort of seniors with RA using administrative health claim databases at the Institute for Clinical Evaluative Sciences.

- Drug utilization analyses have been performed which have identified the province-wide suboptimal use of disease-modifying anti-rheumatic drugs (DMARDs), confirming the dramatic shortfalls in RA care that currently exist.

- New Biotherapies
  - 33% of patients (n=245) on new biologics (anti-TNFs)
  - 15% of patients (n=110) on anti-IL12/23
  - 10% of patients (n=71) on anti-RA (anti-IL6 and others)

- Linkage of Clinical Data with Administrative Data will Enable Evaluation of:
  - Real-world patterns of disease,
  - Outcomes of disease and/or treatments,
  - Quality of care: Patterns & variations in access to care,

- Ongoing Safety Analyses
  - Using Ontario physician billing & hospitalization data to determine rates of Serious Adverse Events (SAEs) and to assess predictors (demographics, comorbidities, markers of RA severity, drug exposures) of SAEs using a cohort of 85,458 seniors with RA.
  - Predictors of infection:
    - Rural residence, more co-morbidities, markers of disease severity, and previous infections.
    - Both previous and current drug use (biologics, DMARDs and NSAIDs/Coxibs) appear to confer risk as well.
    - Corticosteroids are an important independent risk factor noticeable trend for increasing risk at increasing doses.

- Health insurers, physicians, and patients need information on the safety of prescription drugs in routine care. Comprehensive epidemiological surveillance requires population-based, real-world data.

- As Canada moves towards a life-cycle management approach for drugs and a potential increase in post-marketing safety and comparative effectiveness studies, collaborative endeavors such as a Drug Safety and Effectiveness Network (DSEN) to access provincial administrative data, develop standardized methodologies and create other data resources are warranted.

- The OBRI is the result of international and national policy initiatives targeted to optimize access to quality care in RA, and moniter the role, effectiveness and safety of RA therapies in usual care, while considering system-level variables which may impact on patient and health system outcomes.

- This research program will serve as a model to demonstrate how successful partnerships can be used to create a sustainable infrastructure to provide evidence which will inform drug policy decision-making in Canada.