

Allergy Immunotherapy Products: Pharmacoepidemiology Unit

FINAL COMPREHENSIVE RESEARCH PLAN

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Study Team: Tara Gomes, Diana Martins, Sandra Knowles, Mina Tadrous, David Juurlink, Mike Paterson, Samantha Singh, Muhammad Mamdani

Objectives

1. To examine national and provincial trends in use of allergen immunotherapy across Canada
2. To perform cross provincial comparisons of the trends in allergen immunotherapy utilization in public drug programs (if data available)
3. To describe characteristics of individuals prescribed publicly-funded allergen immunotherapy in Ontario among a subset of publicly funded users
4. To describe the details of submissions for public drug funding for allergen immunotherapy serums in Ontario

Objective 1: National and Provincial Trends in Allergen Immunotherapy Utilization

Study Design: Cross-sectional analysis with quarterly time intervals

Study Period: National and provincial trends (IMS Compuscript): October 2009 to March 2015

Population: All provinces

Data Sources: IMS Compuscript: aggregated data for all prescriptions dispensed at retail pharmacies across Canada

Inclusion Criteria: All privately and publicly-funded allergen immunotherapy prescriptions dispensed in Canada:

- Sublingual (SLIT):
 - Oralair
 - Grastek
 - Ragwitek
- Subcutaneous (SCIT):
 - Pollinex-R

Outcomes (measured quarterly):

- Number and rate of prescriptions dispensed
- Total cost of prescriptions

Stratifications:

- Province
- Payer (Public, Private, Cash, NIHB)
- Allergen Immunotherapy (Oralair, Grastek, Ragwitek, Pollinex-R)

Limitations:

- The IMS data is only available at the prescription and unit level. Therefore, national and provincial trends in prescribing cannot determine the number of *users* of these products.
- IMS does not capture information on the individualized, serum SCIT, and therefore we restricted the SCIT analyses to Pollinex-R only.

Objective 2: Cross Provincial Comparisons of the Trends in Allergen Immunotherapy Utilization in Public Drug Programs

This analysis will only be performed if we have complete data available to make provincial comparisons. We are currently investigating data availability issues in each province.

Study Design: Cross-sectional analysis with quarterly time intervals

Study Period: January 2000 to December 2014

Data Sources:

- National Prescription Drug Utilization Information System Database (NPDUIS): aggregated data for all publicly funded prescriptions dispensed in Alberta, Saskatchewan, Manitoba, New Brunswick, Nova Scotia, PEI and BC
- Ontario Drug Benefit Database (ODB): individual level data for all publicly funded prescriptions dispensed in Ontario.

Inclusion Criteria: All publicly-funded allergen prescriptions dispensed in Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, PEI and BC

Outcomes (measured quarterly):

- Number and rate of users

Outcomes (measured in 2014 only):

- Number and rate of users
- Number of prescriptions dispensed
- Total costs of allergen immunotherapy
- Average cost of allergen immunotherapy per user

Stratifications:

- Province
- In 2014 only:
 - Age groups (<18, 18-64, 65+)
 - Allergen Product:
 - SLIT:
 - Oralair (Pollen, oral)
 - SCIT:
 - Venom
 - Pollen (injectable, excluding Pollinex-R)
 - Pollinex-R
 - Non-pollen
 - Pollen/non-pollen
 - Undetermined pollen/non-pollen

Limitations:

- Publicly-funded, patient-level prescription data is only available as of 2002 for Nova Scotia, 2005 for PEI, 2006 for BC and 2009 for Newfoundland and Labrador. We are therefore unable to determine allergen immunotherapy use prior to that date in these provinces.
- There is no patient-level data available for publicly paid prescriptions in Quebec or the

Territories. Therefore, we will be unable to make comparisons between Ontario rates and rates of use in these provinces.

- Details on components of SCIT therapy vary by province. Therefore, we are only able to determine the elements of SCIT in some jurisdictions.

Objective 3:

Characteristics of Individuals Prescribed Publicly-Funded SCIT Allergen Immunotherapy in Ontario

Study Design: Cross-sectional analysis

Study period: April 2012 to March 2014

Data Sources:

- Ontario Drug Benefit Database (ODB)
- Canadian Institute for Health Information-Discharge Abstract Database (CIHI-DAD)
- Canadian Institute for Health Information- National Ambulatory Care Reporting System (CIHI-NACRS)
- Ontario Health Insurance Plan Claims Database (OHIP)
- ICES Physician Database (IPDB)

Inclusion Criteria: All publicly-funded beneficiaries in Ontario who are prescribed SCIT allergen immunotherapy

Cohort Entry Date: Date of first prescription for allergen immunotherapy over the study period.

Index Drug: Defined as the allergen immunotherapy that was prescribed on cohort entry date

For the Established Cohort, Measure:

- Number of patients
- Age at cohort entry date (mean, SD, and by category (<18, 18-64, 65+))
- Proportion of patients who were male
- Proportion of patients residing in LTC at cohort entry
- Proportion of urban residents at cohort entry
- Socioeconomic status (measured using income quintiles at cohort entry)
- Prescriber of initial prescription:
 - Specialist
 - Allergist/Immunologist (“Clinical Immunology” or “Pediatric Clinical Immunology”)
 - General Practitioner
- Asthma (using validated database)
- Number of physician office visits within the last 1 year (median, IQR)
- Inpatient hospitalization or ER visit for anaphylaxis in the past 1 year
- Measures of Comorbidity
 - Charlson comorbidity score (based on last 3 years of hospitalization data)
 - Number of medications used in past 1 year
- Past medication use (120 days):
 - Intranasal corticosteroids
 - Leukotriene Receptor Antagonists (LTRAs)
 - Inhaled corticosteroids (ICS)
 - ICS+LABA combination products

- Omalizumab (Xolair)

Stratification:

- Drug:
 - SCIT
 - Pollinex-R
 - All others

Limitations:

- Some medications (i.e., oral antihistamines) are available over the counter, and therefore we may not capture all use of concomitant medications
- We are unable to look at patient characteristics of SLIT in this analysis because these products were not made available in Ontario until mid-2014, and we only have complete data up to March 2014.
- Characteristics of allergen immunotherapy users will be presented among a subset of all publicly funded allergen immunotherapy users due to incomplete data available at ICES.

Objective 4:**Details of Submissions for Public Drug Funding for Allergen Immunotherapy Serums in Ontario**

Study Design: Cross Sectional Study

Study Period: 2014

Data Sources: Sample of 50-100 Allergen Program application forms

Key Variables of Interest:

- Age
- Number of allergens in serum
- Type of allergens: environmental (pollen, non-pollen) or venom
- Cost (drug cost and total claimed)