**Large-scale modeling of patients with thyroid conditions**

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**Disclosures:** Mr. DeFalco and Dr. Hardin are employees of Janssen Research & Development, Ms. Burcul is an employee of Novartis.

1. **Background**

There are an estimated 200 million people worldwide who suffer from some form of thyroid disease according to the Thyroid Foundation of Canada (1). Women are 5-8 times more likely to develop it than men. 5-10 % of pregnancies end up with postpartum thyroiditis. Over 12 % of the US population has some type of a thyroid condition (2). As a result, synthetic thyroid hormone is the top prescribed medication in USA with more than 20 million prescriptions per month (3). Patients who suffer from the symptoms of the disease often spend years un- or misdiagnosed. Depending on the type of the condition symptoms include, among others, anxiety, weight gain or loss, depression and brain fog. Patients can suffer from symptoms of the disease even though their thyroid stimulating hormone (TSH) values are within the reference ranges. Currently, the treatment for any type of a thyroid condition includes the process of testing different drug combinations and doses for a period of time until the optimal one is found.

To conclude, patients with a thyroid dysfunction would benefit from looking into treatment variations occurring due to the heterogeneous and drug and dose-sensitive nature of their disease.

1. **Objectives**

We aim to:

**1. Characterize the non-cancerous thyroid disorder population**

(demographic and comorbidities)and examine strata within the non-cancerous thyroid disorder population specifically hyper and hypothyroidism, Hashimoto’s thyroiditis, and Graves’ disease.

Within these thyroid disorder subpopulations we will specifically look into:

1. women who were pregnant at some time point during the observation period,

2. the occurrence of the infertility diagnosis anytime during the observation period, including before or after the thyroid diagnosis.

The populations will be defined to align with the Clinical Practice Guidelines (4).

**2. Identify and characterize the sources of variation within treatment pathways**

This will be achieved by:

1. enumerating the numbers of patients treated within each therapeutic category: (i) levothyroxine therapy, (ii) non–levothyroxine based thyroid hormone therapies (e.g. Cytomel), and (iii) use of thyroid hormone analogs (e.g. Armour Thyroid)

2. enumerating the numbers of patients at initial diagnosis using branded vs generic medications.

NOTE: In 2004 the FDA approved use of generic versions of synthetic thyroid hormone (5), therefore in order to take this event into account the following analysis will be performed:

1. proportion of branded vs generic medication used over time,

2. branded and generic drug switching frequency (average number of switches over time)

1. **Data sources**

The analyses will be performed across a network of observational healthcare databases. All databases have been transformed into the OMOP Common Data Model, version 5. The complete specification for OMOP Common Data Model, version 5 is available at: <https://github.com/OHDSI/CommonDataModel>.

1. **Study Design**
   1. **Overview**

This study will be a retrospective, observational study. By ‘retrospective’ we mean the study will use data already collected at the start of the study. By ‘observational’ we mean no intervention will take place in the course of this study.

* 1. **Population**

We define the index date as the start of the first treatment for thyroid condition.

Inclusion criteria are defined as follows:

1. recorded condition of thyroid condition,
2. at least 365 days of observation time prior to the index date,
3. at least x years of observation time after the index date,

Number of years of observation time (x) as well as the observation time prior to the index date will be determined after looking at the distribution of observation times available in the first two test datasets.

1. no diagnosis of the outcome of interest preceding the index date.
2. **Protection of human subjects**

The study is using only de-identified data. Confidentiality of patient records will be maintained at all times. All study reports will contain aggregate data only and will not identify individual patients or physicians.

1. **Plans for disseminating and communicating study results**

The study results will be posted on the OHDSI website after completion of the study. At least one paper describing the study and its results will be written and submitted for publication to a peer-reviewed scientific journal.

1. **References**

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