Real-World Data Assessment Plan for a Heated Tobacco Product: A Proof of Concept

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Background

- The use of novel tobacco products, such as Philip Morris International's heated tobacco products (HTP) — currently marketed under the brand name *IQOS*®, is increasing around the world. Therefore, there is a need to understand the effects that these products will have on smokers who switch to them, both at the individual and population levels.
- Here, we explore if and how real world data (RWD) from sources such as electronic records, insurance claims, and hospital discharge data can be used to help build an understanding of these effects.
- Tobacco use is generally not captured in RWD. So, we need to explore data sources and identify ways to integrate tobacco use into RWD.
- Ecological studies have been used to assess the potential impact of smoking bans on smoking-related diseases at a population-level. Recently, this approach has been used to explore the impact that the introduction of HTPs in Japan has had on cigarette sales (Stoklosa 2019; Cummings 2020).

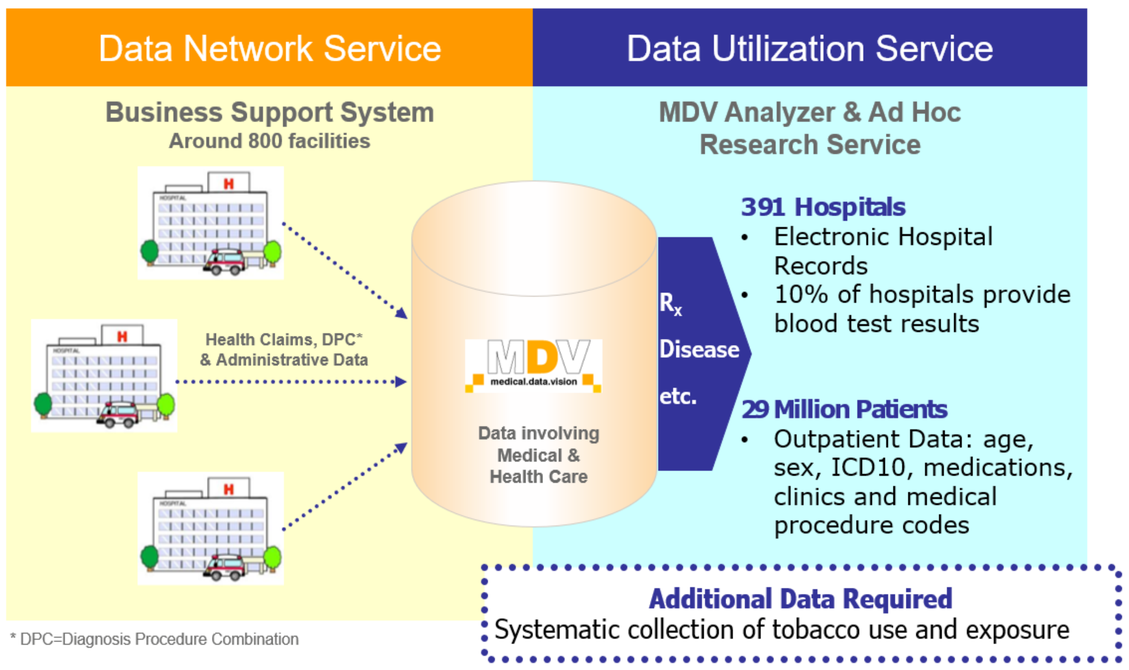
Rationale:

If HTP use impacts the progression of smoking-related diseases, we would expect that hospital admissions data would show a decline in smoking-related admissions following the launch of HTPs in Japan**.**

Methods

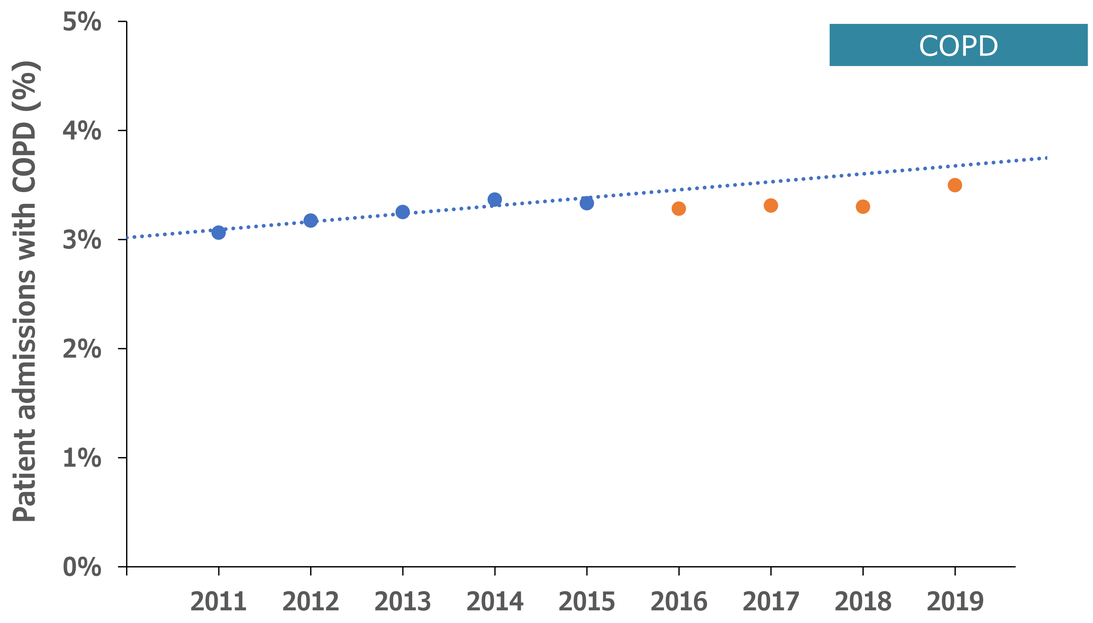
- **Database**: Medical Data Vision (MDV) database of hospital admissions.
- **Records of interest:** International Statistical Classification of Diseases and Related Health Problems codes version 10 (ICD-10) were used to identify hospital admissions associated with chronic obstructive pulmonary disease (COPD) and ischemic heart disease (IHD).
- **Time Period**: 2011 to 2019 (from 5 years before to 4 years after the introduction of HTPs in Japan). Hospitals were only included if their data covered the entire study period.
- **Endpoint**: Proportion of total annual hospital admissions associated with COPD or IHD.
- **Model**: A simple linear trend model using data from the 5 years prior to HTP introduction, and the line of best fit was extrapolated over the following 4 years after the HTPs entered the market.
- No formal test of change in slope was performed.

Study Data Source

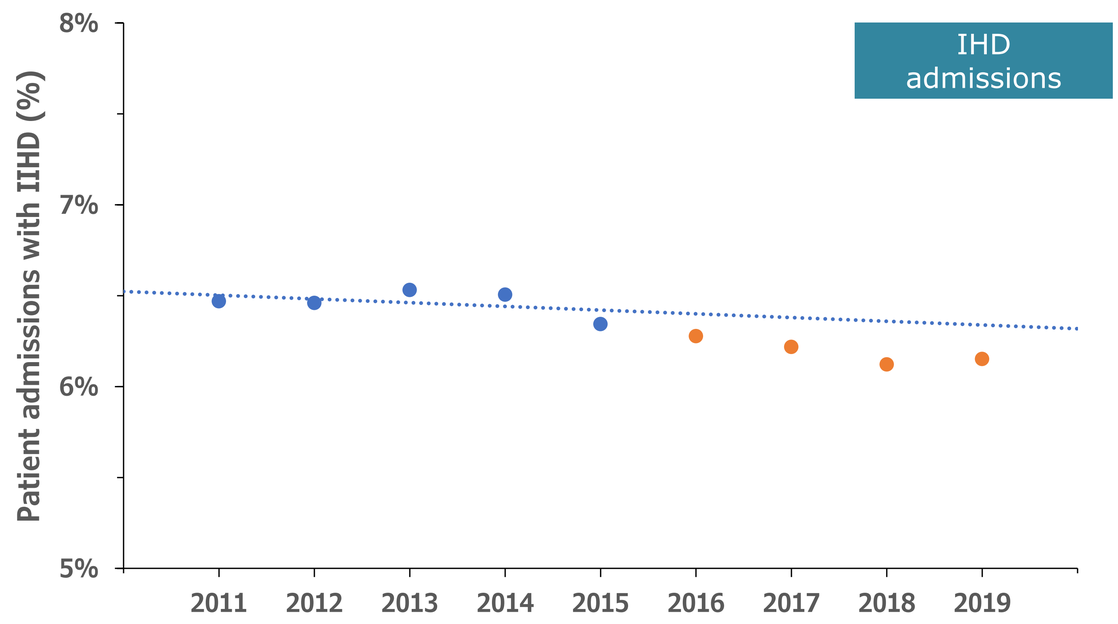


Results

Ecological studies are frequently the first step in identifying and assessing potential relationships and risk factors. As RWD are growing in importance, these types of studies have taken on an important role in medical research, where their findings can prompt further study.



- After a smoker quits smoking, the excess risks of COPD takes years (>13 years) to reduce by half. Therefore, we would not expect to see a reduction in admission within the first 4 years.
- Pre-HTP (2011–2015): The proportion of COPD hospital admissions were increasing slightly (<0.1% per year) on an annual basis.
- Post-HTP (2016–2019): The proportion of COPD hospital admissions continues to increase; however, the slope is slightly dampened (all points are below the trajectory).



- The reduction in excess risk of IHD starts to diminish quite quickly after smoking cessation, and a 50% reduction in excess risk of IHD from smoking is seen within 3–4 years.
- Pre-HTP (2011–2015): IHD admissions are decreasing on an annual basis.
- Post-HTP (2016–2019): We see a slight decrease in the number of IHD hospitalizations during this period.

Conclusions

The introduction of HTPs in Japan was temporally associated with a slight decline in the number of hospitalizations for COPD exacerbation and IHD, indicating that it could be interesting to further evaluate these data sources by incorporating other variables (including potential confounders) in the analysis.

Using RWD (ecological studies) is a viable and helpful way to assess and understand the potential impact novel tobacco products, such as HTPs, can have on the health of the population, with the well-known caveats.

The use of RWD for studies investigating association/causality will require that tobacco exposure is systematically collected in order to move beyond population/temporal associations and increase the robustness of the evidence.

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