Characterizing adults hospitalized with influenza in 2009-2010 and 2014-2019, and COVID-19 in 2019-2020: protocol for an OHDSI network study

# Introduction

## Background

Since December 31st 2019, when the first case was reported to WHO, infections by SARS-CoV-2 have spread worldwide. Our current understanding of the disease clinical outcomes is limited to case series. The baseline characteristics of 138 patients with 2019 Novel Coronavirus hospitalized in Wuhan due to pneumonia, for example, have been reported.[1] In another study, a series of 21 cases admitted to an ICU in Washington state reported clinical and demographic characteristics at hospital admission.[2]

As more routinely-collected data emerges on individuals with COVID-19 emerges, a federated network study could provide a fuller picture of the individuals hospitalised with COVID-19. Moreover, the use of such data to inform comparisons with hospitalisations from previous viral outbreaks, like regular seasonal and avian flu epidemics, could also help us to better understand the profiles of individuals hospitalised with COVID-19. Data assets mapped to the Observational Medical Outcomes Partnership (OMOP) common data model (CDM)[3] provide a unique opportunity to make a difference in the current crisis, allowing for robust analyses to be performed in a timely across a network of sites.

## Objective

We aim to characterize individuals hospitalised with COVID-19 after December 1st 2019, individuals hospitalised with influenza between September 1st 2014 and 1st April 2019, and individuals hospitalised with influenza between September 1st 2009 and 1st April 2010. For each of these cohorts we will describe their characteristics at time of hospital admission.

# Methods

## Study design

The study will be an observational cohort study based on routinely-collected health care data which has been mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM). Cohorts of individuals hospitalised with COVID-19 or influenza will be identified, and the characteristics of these individuals at their index date will be described.

## Study participants

Study participants in the hospitalised with *COVID-19 cohort* will:

* have a hospitalisation (index event) after December 1st 2019,
* with a record of COVID-19 in the 3 weeks prior and up to end of hospitalisation,
* be aged 18 years or greater at time of the index visit,
* have no COVID-19 associated hospitalisation in the six months prior to the index event

Study participants in the *2014-2019 hospitalised with* *influenza cohort* will:

* have a hospitalisation (index event) between September 1st 2014 and 1st April 2019,
* with a record of influenza in the 3 weeks prior and up to end of hospitalisation,
* be aged 18 years or greater at time of the index visit,
* have no influenza associated hospitalisation in the six months prior to the index event

Study participants in the *2009-2010 hospitalised with* *influenza cohort* will:

* have a hospitalisation (index event) between September 1st 2009 and 1st April 2010,
* with a record of influenza in the 3 weeks prior and up to end of hospitalisation,
* be aged 18 years or greater at time of the index visit,
* have no influenza associated hospitalisation in the six months prior to the index event

These cohorts will all be identified without any requirement for prior observation time, and also with the added restriction of having a minimum of 365 days of prior observation time available.

## Exposures of interest

Narrow and broad were defined for both COVID-19 and influenza to maximize sensitivity and specificity, respectively. The narrow definition of COVID-19 was the presence of a diagnosis code indicating the presence or suspicion of COVID-19 or a positive test result for the disease. Similarly, the narrow definition of influenza also required either a specific diagnosis code or positive test result. For both, broad definitions also allowed for a fever along with one of dyspnea (shortness of breath), malaise and/or fatigue, myalgia, cough, or pneumonia. A time window covering 21 days prior to the day of admission up to the end date of the hospitalization was used to identify both COVID-19 and influenza, allowing for diagnoses and test results shortly prior to and during the hospitalization to be included.

## Characterising cohorts of time of hospital admission

Individuals’ age and sex will be extracted. Individuals’ prior medical conditions observed over the year prior to their index date will be summarized. Medications will be summarized over three time periods: 1) over the year before index date, 2) over the 30 days before index date, and 3) being taken at time of hospitalization.

Continuous variables will be summarized using median and interquartile ranges, while binary covariates will be described in terms of the proportion of the cohort having the covariate. Standardized mean differences (SMD) will be calculated when comparing characteristics of study cohorts, with plots showing comparing the mean values of characteristics for each of the characteristics (with the colour indicating the absolute value of the standardized difference of the mean).

# References

1 Wang D, Hu B, Hu C, *et al.* Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China. *JAMA* 2020;**323**:1061–9. doi:10.1001/jama.2020.1585

2 Arentz M, Yim E, Klaff L, *et al.* Characteristics and Outcomes of 21 Critically Ill Patients With COVID-19 in Washington State. *JAMA* Published Online First: 19 March 2020. doi:10.1001/jama.2020.4326

3 Voss EA, Makadia R, Matcho A, *et al.* Feasibility and utility of applications of the common data model to multiple, disparate observational health databases. *J Am Med Inf Assoc* 2015;**22**:553–64. doi:10.1093/jamia/ocu023