

R064: National Core Study – Data and Connectivity: COVID-19 Vaccines Pharmacovigilance (DaC-VaP)

The aim of this study is to assess the safety, effectiveness and uptake of the currently licenced COVID-19 vaccines (Pfizer-BioNTech, Oxford-AstraZeneca and Moderna) in the UK. To do this, we will use anonymised individual level data routinely collected at primary, secondary, linked with mortality, laboratory and vaccination data across the UK. Unique national datasets will be developed and hosted within a Trusted Research Environment (TRE) in each UK nation with standardised individual-level analyses run across datasets. Pooled estimates across the UK national will also be provided. Specifically, our objectives are to: a) assess any vaccine related adverse events; b) assess vaccine effectiveness (VE) including household transmission; and c) measure variation in vaccine uptake.

The aim of this study is to assess the safety, effectiveness and uptake of the currently licenced COVID-19 vaccines (Pfizer-BioNTech, Oxford-AstraZeneca and Moderna) in Northern Ireland as part of a wider UK study. To do this, we will use anonymised individual level data routinely collected at primary, secondary, linked with mortality, laboratory and vaccination data across the UK. Unique national datasets will be developed and hosted within a HBS Safe Setting with standardised individual-level analyses run across datasets. Pooled estimates across the UK national will also be provided.

Our objectives are to:

Estimate the risk of vaccine associated adverse events within the same individual before (control period) and after vaccine administration (risk and post-risk periods)

Estimate the effectiveness of the vaccine between vaccinated vs unvaccinated patients for:

- i. Real-time polymerase chain reaction (RT-PCR) laboratory confirmed COVID-19 infection
- ii. Healthcare utilisation including a) GP consultations; b) Hospital admissions; c) Emergency Hospital admissions; and d) Intensive Care Unit (ICU) admissions (Note GP consultations will be applied for via GPIP)
- iii. Mortality
- iv. Duration of protection (how long does the protection lasts after 1st, 2nd doses for the corresponding vaccine type)
- v. Different vaccine doses and types (Pfizer-BioNTech vs Oxford-AstraZeneca vs Moderna)
- vi. Household transmission

Measure the uptake of COVID-19 vaccines by demographics, socioeconomic and clinical population characteristics