COVID Vaccine Effectiveness and Clinical Outcomes based on the electronic health record (EHR) Supervisors: Richard Hobbs, Simon de Lusignan, Clare Bankhead, Brian Nicholson

The novel coronavirus SARS-CoV-2, which emerged in December 2019 has caused severe illness and deaths in millions of people worldwide. Numerous vaccines are currently under development of which a few have now been authorised for population level administration in some countries. By the end of February 2021, the first doses of vaccines approved by the UK's Medicines and Healthcare products Regulatory Agency (MHRA) had been administered to over 20 million people across the UK and second dose to nearly 1 million. Timely measurement of the coverage, immune protection and adverse events of these newly introduced vaccines is essential.

We aim to assess the uptake rates, effectiveness, and safety of all currently approved COVID-19 vaccines in the UK using prospective cohort study designs to assess vaccine uptake and effectiveness against severe clinical outcomes and deaths. Based upon the Oxford-RCGP RSC network hosted within the ORCHID digital platform, we will use a test-negative case-control study design to assess vaccine effectiveness against laboratory confirmed SARS-CoV-2 infection.

Self-controlled case series and retrospective cohort study designs will be carried out to assess vaccine safety against mild-to-moderate and severe adverse events, respectively. Individual level pseudonymised data from primary care, secondary care, laboratory test and death records will be linked, accessed, and analysed in secure research environments in England. Univariate and multivariate logistic regression models will be carried out to estimate vaccine uptake levels in relation to various population characteristics. Estimates on vaccine effectiveness against laboratory confirmed SARS-CoV-2 infection will be generated using a logistic generalised additive regression model. Time-dependent Cox models will be used to estimate the vaccine effectiveness against clinical outcomes and deaths. The safety of the vaccines will be assessed using logistic regression models with an offset for the length of the risk period. Where possible, data will be meta-analysed across the UK nations.

Other EHR research: Many other pharmaco-vigilance studies are possible within ORCHID and other standard epidemiological associational studies. There are therefore a range of supervisors available dependent on study selected. For example, as well as vaccine outcomes, the group are exploring the consequences of COVID on non-infection related major clinical outcomes, such as cardiovascular disease, cancer, and mental health.

Other University of Oxford Wellcome DRF studies

The department of primary care at Oxford has an unrivalled investment and range of research infrastructure to support EMC researchers from an accredited CTU, to hosting 3 of the 4 major UK PC databases (each having particular benefits), to a strong multi-disciplinary environment of world class academics from clinical primary care, public health, epidemiology, statistics, health economics, social sciences, all available in-house. We also have excellent support teams for students, access to renowned masters-level modular training programmes, and superb physical space and access to the greatest provision of library and museum resources in Europe in the world's top university and historic city. Other projects are possible in CVD, diabetes, cancer, infection, behaviour change, disease diagnosis, risk prediction, digital health, and social sciences.