STUDY PROTOCOL

Study Protocol: Prospective, observational, cohort study of COVID-19 in General Practice (North Dublin COVID-19 Cohort ['ANTICIPATE'] Study) [version 1; peer review: awaiting peer review]

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Abstract

Background: It is accepted that COVID-19 will have considerable long-term consequences, especially on people’s mental and physical health and wellbeing. Although the impacts on local communities have been immense, there remains little data on long term outcomes among patients with COVID-19 who were managed in general practice and primary care. This study seeks to address this knowledge gap by examining how the COVID-19 pandemic has impacted the medium and long-term health and wellbeing of patients attending general practice, especially their mental health and wellbeing.

Methods: The study will be conducted at 12 general practices in the catchment area of the Mater Misericordiae University Hospital, i.e. the North Dublin area, an area which has experienced an especially high COVID-19 incidence. Practices will be recruited from the professional networks of the research team. A member of the general practice team will be asked to identify patients of the practice who attended the practice after 16/3/20 with a confirmed or presumptive diagnosis of COVID-19 infection. Potential participants will be provided with information on the study by the clinical team. Data will be collected on those patients who consent to participate by means of an interviewer-
administered questionnaire and review of clinical records. Data will be collected on health (especially mental health) and wellbeing, quality of life, health behaviours, health service utilisation, and wider impacts of COVID-19 at recruitment and at two follow up time points (6, 12 months).

**Deliverables:** The project involves collaboration with Ireland's Health Service Executive, Ireland East Hospital Group, and the Mater Misericordiae University Hospital, Dublin. The study is funded by the Health Research Board. Findings will inform health policies that attenuate the adverse impacts of COVID-19 on population mental health and health generally.

**Keywords**
COVID-19, Coronavirus, cohort study, follow up study, general practice, primary care

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**Introduction**

COVID-19 was declared a global pandemic on 11th March 2020. As of the 14th August 2020, there were over 20 million reported cases of COVID-19 worldwide, and more than 750,000 people are believed to have died with confirmed infection. In Ireland, the total number of confirmed cases is currently 26,929 with 1,774 related deaths. The current median age of people in Ireland infected with COVID-19 is 47, 56.5% of those infected are female, and as is the case globally, infected persons most at risk of suffering severe illness and/or death have been elderly persons and individuals with underlying health conditions. While the pandemic has impacted considerably on healthcare throughout Ireland, this has been especially so in the North Dublin area.

The effects of COVID-19 and the COVID-19 pandemic more generally are many and diverse. Patients with COVID-19 infection present with a range of symptoms including fever, cough, shortness of breath, and fatigue. Severe cases of COVID-19 infection have caused considerable damage to various internal bodily structures and functions, resulting in the onset of multiple issues including acute respiratory stress disorder (ARDS), acute heart, liver, and kidney injury, and septic shock. Moreover, it is likely that many discharged COVID-19 patients will have experienced health problems due to intensive care treatment. Prolonged stays in intensive care have been linked to a range of physical and psychological problems including decreased muscle strength, impaired mobility, and cognitive impairment. It is also likely that because of COVID-19 related fears, grievances, and traumas, patients, their families, and the general population will need care for various mental health problems including anxiety, depression, and post-traumatic stress.

The medium and long-term effects of the COVID-19 pandemic on health are still unclear. To address the needs of patients experiencing long-term health complications, appropriate long-term care plans are necessary. This study aims to examine the medium and long-term health effects of the COVID-19 pandemic in North Dublin. Using a sample of patients attending general practices in the area, the study will observe the pandemic’s effects on general health, mental health, quality of life, substance use behaviour, health service utilisation, and patients’ communities. The study can inform health policies that seek to attenuate the adverse impacts of the COVID pandemic on population health in Ireland and internationally.

**Protocol**

This study will be conducted in line with recommendations outlined by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist for cohort studies. The STROBE checklist is a widely used and trusted framework for ensuring high scientific standards in the conducting of studies of this nature.

**Setting**

The study will be conducted at 12 general practices in North Dublin and will involve the eight-week time period from 16/3/20, the Monday of the first week when national guidelines recommended that patients with possible symptoms of COVID-19 infection contact their GP and when GPs could refer patients for testing if specific criteria were met. Practices will be recruited from the professional networks of the research team and recruitment will purposefully seek to ensure the sample is representative of practices in the area in terms of practice size.

**Participants**

Upon agreeing to participate in the study, practices will be asked to review their practice records for the eight-week time period from 8/3/20 to identify patients with a presumptive diagnosis (i.e. experiencing symptoms consistent with COVID-19 infection) or confirmed cases of COVID-19. In the first instance, they will be asked to provide brief practice reports outlining information on the total number / demographic characteristics of those who attended during this time. Practices will be asked to assign a diagnostic code indicating those patients who were either ‘a presumptive diagnosis’ or a ‘confirmed case’ of COVID-19, using relevant diagnostic codes from the International Classification of Disease. All adult (aged 18 years or more) patients who contacted practices during the eight-week time period starting 16/03/2020 who were diagnosed as either a confirmed or presumptive diagnosis of COVID-19 and who have the capacity to provide informed consent will be eligible for the study.

**Sample size and power calculations**

It is estimated that the prevalence of mental health disorders among patients attending general practice in Europe pre-COVID-19 is 29%. Based on this estimate of mental health disorders among patients attending general practice, we estimate that a sample size of 360 will detect a 29% prevalence of mental health disorders, with a margin of error of +/-5% at a 95% confidence level. Allowing for attrition during recruitment, to reach a target of 360 patients, we will over-sample. Thus, we expect to achieve a sample of 40 patients per practice (total N=480).

**Procedures**

Participating general practices will provide researchers with brief practice reports. These reports will contain anonymous aggregated data pertaining to a sample of patients attending the practice since 16/03/2020 with either a presumptive or confirmed case of COVID-19 infection. After at least one month of their initial attendance at the practice, a member of the practice team will contact those patients who meet the eligibility criteria by text message, to ask if they would like to participate in the study’s follow-up procedures. Consenting patients will be contacted by a member of the research team, who will then outline study information and what their participation will involve. At recruitment and at two subsequent time points (6, 12 months) data will be collected using an interviewer administered questionnaire, and by reviewing each patient’s clinical record (see Figure 1).

**Measures**

**Anonymous aggregated data:** The anonymous aggregated (i.e. ‘brief practice report’) data will provide details of patients’ demographic profile(s). The data will help us determine what
factors are associated with COVID-19 related health issues. The reports will contain various types of information including practice location, the number of patients contacting the practice with COVID-19 infection and/or concerns, patient age, gender, General Medical Services (GMS) status, and physical/mental health history. To establish long-term trends, the reports will be collected at recruitment, and at two follow-up time points. Further, to ensure instrument validity, the reports will be prepared using existing tools within practice management systems, one of which has previously reported on the prevalence of mental health disorders among patients attending general practice\textsuperscript{18,20}.

**Interviewer-administered questionnaires:** Patient questionnaire responses, including a chart review instrument\textsuperscript{18}, will help us understand whether patients have been experiencing health problems because of the COVID-19 pandemic. Specifically, they will query patients on their age, gender, medical history, general health, mental health, COVID-19 experiences, recent health service experiences, quality of life, substance use behaviour, and their perception of how the COVID-19 pandemic has impacted their community. The questionnaire comprises multiple measures, some of which have been validated and have been frequently used in clinical practice and research settings (i.e. the SF12 Quality of Life Scale\textsuperscript{21}; the PRIME-MD instrument

\textbf{Figure 1. Study flow chart.}
for assessing mental health; the ‘Impact of Event Scale-Revised’ (IES-R) post-traumatic distress measure; and the AUDIT-C scale for measuring alcohol use. Our questionnaire also contains two measures that are study specific. These instruments relate to patients’ experiences of the COVID-19 pandemic, their healthcare experiences during the pandemic, and the pandemic’s impact on their community. As these measures are specific to particular contexts and have been developed in response to an unprecedented public health emergency (i.e. the pandemic), they have not been previously validated. Should a health issue be identified during the interview, appropriate follow up with the person’s general practitioner will be arranged.

Review of clinical records: Using a study specific instrument, data will be collected on demographic characteristics, the presence of any long-term medical conditions, any recent medical conditions, medicines prescribed.

Data analysis
This study aims to provide an overview of how the COVID-19 pandemic has impacted the physical health, mental health, and wellbeing of patients attending general practices in the North Dublin area. The COVID-19 pandemic has been an unprecedented public health emergency, and so it is not clear how the pandemic will have affected this population. Exploratory statistical analyses will therefore be used to ascertain macro-level practice and patient trends, and to identify unanticipated or noteworthy differences and/or relationships between study variables (e.g. differences between follow-up points and genders in terms of study outcomes, association between health outcomes and COVID-19 diagnostic status). These analyses will likely include a combination of descriptive and inferential statistical methods including frequency, correlation, regression, and between group analysis methods. Statistical tests will be run using IBM SPSS statistical software version 26.

Ethical considerations
With regards to informed consent, potential participants will be approached by a member of the clinical team and will be provided with information on the study. Potential participants will be contacted initially via text message and if interested, they will be provided with a study information sheet and consent form by post. Those who wish to participate in the study will be asked to indicate their informed consent to participate by signing and returning this consent form via prepaid post to the research team. Thus, the researchers will only have access to participants’ contact details when participants themselves agree to provide them via their GPs. We will ensure that this agreement is recorded in written form. Lastly, no individual will be identifiable during dissemination. Only grouped results will be published, and we will ensure that details which may render a study participant identifiable are amended in any publications / presentations that arise. All participants (practices and patients) can withdraw their participation at any time up until the point where their data has been anonymised. At this point it will not be possible to identify and delete their information.

With respect to confidentiality, anonymised, aggregated practice reports will be collected from participating practices. Furthermore, when collecting data on study participants, an alphanumeric code will be assigned to individual participants (i.e., pseudonymised data). Data will be stored on a password protected server computer hard drive at the UCD School of Medicine Education & Research Centre (i.e. the Catherine McAuley Centre). Further, all hard copy data will be stored in a secure cabinet in a locked room at the same location. All data will be destroyed by the principal investigator after a retention period of three years after study completion. This is to allow dissemination of findings and secondary data analysis by the members of the research team named on this application.

With regards to data protection, no third party (i.e. persons external to named investigators) will have access to study participants’ information. All electronic data will be stored as pseudonymised data on a secure, password protected server computer hard drive at the UCD School of Medicine Education & Research Centre (i.e. the Catherine McAuley Centre). Further, all hard copy data will be stored in a secure cabinet in a locked room at the same location. All data will be destroyed by the principal investigator after a retention period of three years after study completion. This is to allow dissemination of findings and secondary data analysis by the members of the research team named on this application.

The study has been approved by the UCD Life Sciences Human Research Ethics Committee (reference: LS-20-27-Broughan-Cullen; original approval granted 27/04/20; amendment and extension granted 17/07/20 until 30/06/21).

Dissemination
The project will involve collaboration with the Irish Health Service (HSE) Clinical Programmes, Ireland East Hospital Group, and the Mater Misericordiae University Hospital Dublin. The study is funded by the Health Research Board (HRB). The study will inform health service policies to attenuate the adverse impacts of the COVID-19 pandemic on population health. Outputs such as technical reports for stakeholders will be delivered accordingly. Study reports will also be submitted for publication in scientific journals, and study datasets, as well
as related material (e.g., study instruments, recruitment forms) will be made publicly available on the Zenodo open-access repository website.

**Study status**
We are currently recruiting general practices to participate in the study. Once recruited, practices will initiate the collection of service level data, and recruitment of patients on our behalf. The first stage of data collection is expected to occur in October 2020.

**Data availability**
Underlying data
No underlying data are associated with this article.

Extended data

This project contains the following extended data within the file ‘ANTICIPATE. GP ARM. Study Instruments, Information Leaflets, and Consent Forms.docx’:
- Study instrument to be used collecting data from clinical records (chart) review
- Study instrument to be used collecting anonymised aggregated data from practices
- Study instrument to be used in patient interviews on recent healthcare experiences
- Patient information leaflet
- General Practitioner information leaflet
- Patient consent form
- General Practitioner patient consent form

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

**References**