British Heart Foundation Data Science Centre
Led by Health Data Research UK

BHF Data Science Centre: CVD-COVID-UK / COVID-IMPACT Project Proposal Form

Project reference:	CCU008
Project title:	Evaluating impact of COVID-19 pandemic on the prevalence and management of risk factors (working title: CVD risk factor study)
Proposal version:	2.1
Start date (best estimate):	01/05/2021
End date (best estimate)[1]:	30/04/2023
Named project lead and institution/organisation:	Naveed Sattar, University of Glasgow (Project Lead) Frederick Ho, University of Glasgow Julian Halcox, Swansea University Reecha Sofat, University of Liverpool Caroline Dale, University College London Jonathan Sterne, University of Bristol Munir Pirmohamed, University of Liverpool Marion Bennie, University of Strathclyde

Plain English summary
Approx. 200 words[2] overall to succinctly summarise the project in language suitable for a non-specialist lay public.[3] This summary should be written using the headings below for clarity, with approximately one paragraph for each heading.

Describe the **challenge** or problem your project will address:

Although cardiovascular disease (CVD), including heart attacks and strokes, is still the leading cause of death in the UK, the risk of CVD events and death can be reduced by identifying and treating major risk factors such as high blood pressure (BP), lipids (e.g. cholesterol), and fasting blood glucose (FBG) / haemoglobin A1c (HbA1c, marker for average blood glucose levels of last 3 months, widely used by doctors). Due to the COVID-19 pandemic, access to routine clinical care was dramatically disrupted during 2020. This led to changes in the patterns of attendance in primary care from March 2020 onwards, which in turn significantly altered patterns of drug prescribing and dispensing, including for cardiovascular drugs. Clinical observation has shown that an increasing number of people had risk factors, such as high body mass index (BMI) and BP, high cholesterol or triglyceride levels, and poor liver function markers, during the pandemic. The extent to which this occurred in the population and has had a lasting impact on some people's risk factor trajectories is still unknown.

How will your project be the **solution** to address/understand the challenge or problem?

Although these changes in practice are likely to have had an influence on the nature of testing, treatment and control of major risk factors for CVD, the extent and potential impact of these changes is unknown. We propose to use routine healthcare records to examine patterns of BMI measurement, BP, lipid, HbA1c and liver function (ALT, AST, GGT) testing in the general population and evidence for control of these risk factors (according to expert clinical guideline recommendations) in patients with CVD and at high risk of developing CVD.

[1] Current approvals extend for about three years from June 2020, although we envisage that we should be able to extend these for some projects looking at longer term outcomes, if needed.
[2] Word counts are only a guide and can be exceeded, if necessary.
[3] Your plain English summary will appear on the BHF Data Science Centre CVD-COVID-UK / COVID-IMPACT webpages. Please use the sort of language you might use to describe your project to a non-specialist friend, relative or journalist. Please avoid using technical jargon and aim to keep sentences short for ease and clarity of reading.

We will also examine whether differences in the quality of testing, diagnosis and control of risk factors are related to any particular patient characteristics (e.g. sex, area-based deprivation indices, ethnicity, common chronic conditions). Finally, we will compare the level of these risk factors during the pandemic with those in 2014-2019.

What is the potential **impact** from this work, e.g. how will it benefit patients/NHS, inform policy etc?

This work will be undertaken in close alignment with another approved CVD-COVID-UK project, examining changes in CVD drug prescribing during the same period. Considered together, these analyses will provide important insights into the potential impact of the COVID-19 pandemic on the detection and control of key changeable CVD risk factors in the UK population. Outputs from these analyses will be used to model the potential consequences for future CVD events in the UK and help to identify where efforts could potentially be focused most effectively to address emerging gaps in the provision of preventive care.

Background
Approx. 300 words[2] summarising why the question(s) you are addressing matter, and how your project fits within the broad scope of CVD-COVID-UK / COVID-IMPACT

Despite recent advances in the treatment of cardiovascular disease (CVD) and its risk factors (RFs) it remains the most common cause of death and a major morbidity burden in the UK. The numbers of patients with acute CVD events admitted to acute care settings fell during the first phase of the COVID-19 pandemic, which followed trends in other diseases as well as GP attendances. The direct and indirect impacts of COVID-19 on CVD outcomes at a population level are currently unclear. Whilst it is likely to take many years to understand the full impact of the pandemic on CVD outcomes, it remains important to examine data documenting the nature of clinical contacts and outcomes to evaluate changes in patterns and quality of care in patients with and at increased risk of CVD in order to identify emerging treatment gaps and potential opportunities to address these.

It is well recognised that identification and effective treatment of the major modifiable CVD risk factors, hypertension and dyslipidaemia, can reduce the burden of CVD events in those with and without established CVD. For example, high blood pressure accounts for half of all myocardial infarctions (MI) and strokes; statin treatment can reduce CVD events by over 20% per 1mmol/L achieved reduction in low density lipoprotein-cholesterol (LDL-C) levels in high-risk patients.

Detection and treatment of risk factors has until now been through the Quality and Outcomes Framework (QOF), CVD health checks, and opportunistic screening most commonly in primary care. A Health Foundation analysis (using Clinical Practice Research Datalink, CPRD https://www.health.org.uk/news-and-comment/charts-and-infographics/use-of-primary-care-during-the-covid-19-pandemic) demonstrated that primary care visits fell an average of 30% from March-June 2020 with many of the existing visits being replaced by electronic or telephone-consults. It is currently unknown to what extent measurement of BMI, BP, lipid levels, and liver function markers has been affected by these changes and also whether control of these risk factors (according to national guideline recommendations) has been affected in “at risk” patients. We have shown that primary care prescribing and dispensing has been significantly affected in the UK as part of the BHF HDR-UK Data Science Centre Collaboration.

We know from extensive clinical study data that identifying and effectively treating hypertension and lipid abnormalities can substantially improve cardiovascular outcomes in those with established clinical CVD and also those without clinical CVD but known to be at increased cardiovascular risk (e.g. those with hypertension, diabetes mellitus and hypercholesterolaemia). Furthermore, observational studies have shown that inadequate detection and treatment of these RFs is associated with a higher burden of CVD at the population level. It is therefore likely that changes in the effectiveness of detection and treatment of these RFs in those with and without established CVD arising as a consequence of the pandemic, will have an impact on CVD outcomes over the intermediate to long term. Evaluating (changes in) patterns of documentation and values of BP and lipids in the primary care records prior to and during the COVID-19 pandemic together with ongoing analyses of prescriptions and dispensing of CVD risk factor medication could be used to determine the potential future impact on CVD burden and identify valuable opportunities to address suboptimal care.

As many countries, including the UK, have reduced testing of key risk factors during the COVID-19 pandemic and related restrictions, it would be necessary to examine the indirect impact of the pandemic towards the population's risk factor distribution. It has been repeatedly observed in clinical settings that people had worsened risk factors, e.g. weight gain, poorer liver function, but it is unknown to which extent these occur at the population level and how these differ by different sub-populations.

Research question(s)

1. General population evaluation:
   - Are BMI, BP, lipid levels, and liver functions being checked/documented less frequently, and do such patterns differ by sociodemographic or ethnic characteristics?
   - Did the pandemic alter the temporal trend of these risk factors?
   - If risk factor trends have changed, can they be shown to be inter-related in some cases e.g. change in LFTs linked to weight or BMI change?
   - If risk factors have worsened, to what extent can such changes be explained by reduction in prescriptions of statins or blood pressure medicines?

2. High CVD risk population evaluation (those with hypertension, diabetes mellitus, >10% estimated 10-year risk of CVD events, coronary artery disease, peripheral vascular disease and cerebrovascular disease):
   - Are BP and lipid levels being checked/documented less frequently in these patients?
   - Has there been a change in the prescribing and dispensing of antihypertensive drugs in these patients (proportion of patients treated; drug categories; drug doses; number of drugs prescribed/dispensed)?
   - Has there been a change in the effectiveness of BP control according to National Institute of Health and Care Excellence (NICE) guidance recommendations in these patients?
   - Has there been a change in the nature of statin prescribing (proportion of patients receiving statin treatment and statin dose intensity) in these patients?
   - Has there been a change in the effectiveness of lipid management in these patients?

Patient/public contributor involvement

The BHF DSC works with patients and the public to ensure transparency, and to build trust in the use of health data for research. Please complete the relevant section below, to indicate your plans for involving patient/public contributors throughout your project.

Please contact bhfdsc@hdruk.ac.uk if you would welcome an initial conversation with the BHF DSC team and patient/public contributors, or any other support regarding patient/public contributor involvement in your project.

The research team **has not yet** consulted with public/patients on plans for this project.

Please provide brief details on how you intend to do this for the project (e.g., plans to connect with PPIE support at your host institution or other groups/input).

There has been a rapid design and creation process for this proposal, so to date we have not had the opportunity to directly involve patient and public members in the development of this proposal, but we will seek input from patients and the public during the conduct of the study. We will welcome the involvement of patient and public representatives from the BHF Data Science Centre, HDR UK and other suitable networks, to review and provide feedback on study progress as well as providing input into the future direction of the wider programme of this work.

Methods

*Provide a **brief overview** of methods to be used - a detailed plan is not required.*
Please also complete the table on the next page for information on TRE(s), datasets and years of data required and the analyst(s) who you propose will work with the data in the TRE(s)

In this proposal, we will use routinely held primary care and secondary care data extracts to estimate the changes in patterns of measurement, documentation and control of BP and lipid levels according to National Institute of Health and Care Excellence (NICE) and European Society of Cardiology (ESC) guideline recommendations in the UK population between 2018 and the first quarter of 2021.

We will firstly determine whether there has been any change in the frequency of BMI, BP, lipid, HbA1c, FBG, and liver function testing and in the rate of new diagnoses of hypertension and identification of those at >10% 10 year risk of CVD events in the general population, as well as in the population subgroups, e.g. by age group, sex, ethnicity, deprivation quintile.

We will then explore in more detail the frequency of measurement and evidence of effective control of BP and lipids in those with documented hypertension, diabetes mellitus (DM), increased CVD risk (>10% Estimated 10 year risk of CVD Events), coronary artery disease (CAD), peripheral vascular disease (PVD) and cerebrovascular disease (CVD). We will then consider these data together with the relevant data for antihypertensive and lipid lowering drug prescribing and dispensing that will be obtained from our recently approved CVD-COVID-UK study examining the prescribing of drugs used for CVD and its major risk factors.

Patients for analysis will be identified from secondary care and primary care records. Primary care data extracts will be analysed for documentation of BP and lipid measurements. Evidence of achievement of NICE-guideline and European Society of Cardiology guideline target recommendations for BP and non-HDL cholesterol levels will be considered as the main outcome measures for risk factor control.

Comparisons will be made between data from 2 years preceding the pandemic (2018-19) and matched periods during 2020-21. Multivariable modelling will then be undertaken to explore potential associations between changes in risk factor testing and control and relevant demographic, socioeconomic and clinical factors of interest. We are particularly interested in whether certain groups (e.g. age, sex, deprivation, geographical location, ethnicity [where data are available]) are more or less likely than others to have had their CVD risk factors tested and/or effectively treated during the COVID-19 pandemic.

The time trend of the measurements and the actual levels of the risk factors would also be explored by modelling the time trend 5 years pre-pandemic (2014-2019). Both immediate change due to the pandemic and the trend change would be examined. Various covariates would be accounted, e.g. the number of COVID-19 cases during that time, any population-level restriction, and the number of measurements (for the level of risk factors), as well as the population structure. In addition, a sensitivity analysis would be conducted by including only people who had at least two measurements of risk factors, one prior to the pandemic and one after the start of the pandemic.

Mediation analyses based on change of coefficients and counterfactual frameworks would be used to examine whether we can explain the changes in risk factors might be related to the changes in prescriptions.

These outputs should allow us not only to begin to estimate the potential longer-term effects on CVD outcomes, but also promptly to identify areas in which suboptimal care standards are of greatest concern and consider potential ways by which these could be addressed most effectively through care pathway optimisation and health policy recommendations.

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Trusted Research Environments (TRE)
England: NHS Digital TRE for England
Scotland: Scottish National Data Safe Haven *(for more information, view the COVID-19 Research Database Dataset and Variable Specification)*
Wales: Secure Anonymised Information Linkage Databank (SAIL)
Northern Ireland: Northern Ireland Honest Broker Service

***** FOR COVID-IMPACT[4] PROJECTS, PLEASE COMPLETE THE ANALYST AND DATA SOURCE DETAILS FOR ENGLAND ONLY *****

DATA ANALYSTS

	PLEASE COMPLETE THIS COLUMN
TRE	**Analyst(s) requiring TRE access – please provide name, institution, and email if not already in the consortium**
England	Fred Ho
Scotland	Fred Ho
Wales	Ashley Akbari, Fatemeh Torabi, Hoda Abbasizanjani, Daniel Harris
Northern Ireland	

DATA SOURCES

						PLEASE COMPLETE THESE COLUMNS		
TRE	**Category**	**Dataset Name**	**Year data available from**	**Time lag**	**Available in TRE**	**Required (X)**	**Years of data required (ALL or range)**	**Brief justification of why you need each dataset / date range**
England	Primary care	GDPPR: GPES Data for Pandemic Planning and Research	From the start of each individual's records[5]		Yes	X	All	All primary care data will be required to ascertain risk factors and comorbidities before and after the covid pandemic.

[4] COVID-related research projects not directly linked to cardiovascular disease
[5] Includes patients with active, current registrations at participating practices and deceased patients with a date of death on or after 1 November 2019. Note: prescriptions and numeric values (e.g. BP, laboratory test results) only go back two years.

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England	Secondary care	HES: Hospital Episode Statistics **- Admitted Patient Care**	1997		Yes	X	From 2010	Hospital admission data will be required to ascertain risk factors and comorbidities before (10 years) and after the covid pandemic.
England	Secondary care	**- Adult Critical Care**	2013		Yes			
England	Secondary care	**- Outpatients**	2019		Yes	X	All	All outpatient data will be required to ascertain risk factors and comorbidities before and after the covid pandemic.
England	Secondary care	**- Accident & Emergency**	2007		Yes			
England	Secondary care	SUS: Secondary Uses Service	2019 / earlier		Yes	X	All	All outpatient data will be required to ascertain risk factors and comorbidities before and after the covid pandemic.
England	Secondary care	**SUS/Uncurated Low Latency Hospital Data (Admitted Patient Care, Outpatients, Critical Care)**			Yes			
England	Secondary care	Emergency Care Data Set (ECDS)			Expected TBC			
England	COVID testing	COVID-19 SGSS: Second Generation Surveillance System[6]	From start of records (2020)		Yes	X	All	This would be used to estimate the trend by Covid-19 positivity.
England	COVID testing	Pillar 2 Antigen	April 2020		Yes	X	All	This would be used to estimate the trend by Covid-19 positivity.
England	COVID testing	Pillar 3 Antibody	September 2020		Yes			
England	COVID testing	**Variant strain data (COG-UK)**			Expected TBC			
England	COVID vaccinations	Vaccination Status	December 2020		Yes			
England	COVID vaccinations	Vaccination Adverse Reactions	December 2020		Yes			

[6] Pillar 1 and 2 positive tests

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England	Deaths	**Civil Registration – Deaths** (ONS guidance / NHSD mortality data review)	1993		Yes	X	From 2010	This would be used to calculate the population size
England	ITU	**ICNARC: Intensive Care National Audit and Research Centre**			Yes			
England	ITU/HDU admissions	**COVID-19 SARI-Watch (formerly CHESS: COVID-19 Hospitalisation in England Surveillance System)**	From start of records (2020)		Yes			
England	Prescribing/ dispensing	**Medicines Dispensed in Primary Care (NHS BSA)**	April 2015		Yes	X	All	This would be used to ascertain risk factors and medicine use
England	Prescribing/ dispensing	**Secondary Care Prescribed Medicines (EPMA)**			Yes	X	All	This would be used to ascertain risk factors and medicine use
England	NICOR CVD audits	**NICOR – MINAP: Myocardial Ischaemia National Audit Project**			Yes	X	All	This would be used to ascertain comorbidities
England	NICOR CVD audits	**NICOR – PCI: Percutaneous Coronary Interventions**			Yes	X	All	This would be used to ascertain comorbidities
England	NICOR CVD audits	**NICOR – NHFA: National Heart Failure Audit**			Yes			
England	NICOR CVD audits	**NICOR – NACSA: National Adult Cardiac Surgery Audit**			Expected TBC			
England	NICOR CVD audits	**NICOR – NACRM: National Audit of Cardiac Rhythm Management**			Expected TBC			
England	NICOR CVD audits	**NICOR – NCHDA: National Congenital Heart Disease Audit**			Yes			
England	NICOR CVD audits	**NICOR – TAVI: Transcatheter Aortic Valve Implantation**			Expected TBC			
England	Stroke audit	**SSNAP: Sentinel Stroke National Audit Programme**			Yes	X	All	This would be used to ascertain comorbidities
England	National Vascular Registry	**National Vascular Registry Audit**			Expected TBC	X	All	This would be used to ascertain comorbidities
England	Other	**Diagnostic Imaging Dataset**			Expected TBC			

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England	Other	Improving Access to Psychological Therapies (IAPT)	April 2012		Expected TBC			
England	Other	Maternity Services Data Set			Expected TBC			
England	Other	Mental Health Services Data Set			Expected TBC			
England	Other	**Mental Health of Children and Young People**			Expected TBC			
England	Other	Patient Reported Outcome Measures (PROMs)			Expected TBC			
Scotland	Primary care	Primary care[7]			Yes	X	All	All primary care data will be required to ascertain risk factors and comorbidities before and after the covid pandemic.
Scotland	Secondary care	Outpatient Appointments and Attendances - Scottish Morbidity Record (SMR00)	1997		Yes	X	All	All primary care data will be required to ascertain risk factors and comorbidities before and after the covid pandemic.
Scotland	Secondary care	General Acute Inpatient and Day Case - Scottish Morbidity Record (SMR01)	1997		Yes	X	All	All primary care data will be required to ascertain risk factors and comorbidities before and after the covid pandemic.
Scotland	Secondary care	Accident & Emergency	2007		Yes			
Scotland	COVID testing	COVID-19 laboratory and lighthouse testing (ECOSS)[8]	From start of records (2020)		Yes	X	All	This would be used to estimate the trend by Covid-19 positivity.
Scotland	COVID testing	**Covid Tests**[9]			Yes	X	All	This would be used to estimate the trend by Covid-19 positivity.
Scotland	COVID testing	Variant strain data (COG-UK)			Yes			
Scotland	COVID vaccinations	**Vaccination data**			Yes			

[7] Data provided comprises a single cut of the data as at June 2020 with no current updates. Based on data used in the EAVEII project.
[8] Contains the first positive test result per person or earliest test result if they have never tested positive (dataset not updated after August 2021 – replaced by Covid Tests)
[9] Contains all test results (positive and negative) and replaced the ECOSS dataset from August 2021.

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Scotland	Deaths	Deaths			Yes	X	From 2010	This would be used to calculate the population size
Scotland	ITU	Intensive care data - Daily (SICSAG)[10]			Yes			
Scotland	ITU	Intensive care data - Episodes (SICSAG)[11]			Yes			
Scotland	Prescribing/ dispensing	Dispensed/Prescribed/Paid (Prescribing Information System)	2015		Yes	X	All	This would be used to ascertain risk factors and medicine use
Scotland	Stroke audit	**Scottish Stroke Care Audit**	TBC		Yes	X	All	This would be used to ascertain comorbidities
Scotland	Other	**Diabetes covariates**			Yes	X	All	This would be used to ascertain comorbidities
Scotland	Other	**Scottish Renal Registry**[12]	2019		Expected TBC			
Wales	Primary care	**GPCD: Welsh Longitudinal General Practice (Daily COVID codes only)**	2020		Yes			
Wales	Primary care	WLGP: Welsh Longitudinal General Practice	2000		Yes	X	From 2010	This would be used to calculate the population size
Wales	Secondary care	CCDS: Critical Care Dataset	2007		Yes			
Wales	Secondary care	EDDD: Emergency Department Dataset Daily	2010		Yes			
Wales	Secondary care	EDDS: Emergency Department Dataset	2009		Yes			
Wales	Secondary care	OPDW: Outpatient Dataset for Wales	2004		Yes	X	From 2010	This would be used to calculate the population size
Wales	Secondary care	OPRD: Outpatient Referral Dataset	2009		Yes	X	From 2010	This would be used to calculate the population size

[10] Additional approval process required for this dataset.
[11] Additional approval process required for this dataset.
[12] Contains data to identify patients receiving hospital based renal replacement therapy – haemodialysis – only (from January 2019).

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TRE	**Category**	**Dataset Name**	**Year data available from**	**Time lag**	**Available in TRE**	**Required (X)**	**Years of data required (ALL or range)**	**Brief justification of why you need each dataset / date range**
Wales	Secondary care	**PEDW: Patient Episode Dataset for Wales**	1995		Yes	X	From 2010	This would be used to calculate the population size
Wales	COVID testing	**PATD: COVID-19 Test Results (Laboratory Information Management System [Pillar 1&2 NHS/Lighthouse Labs Results & Pillar 3 Antibody Results])**	March 2020		Yes	X	All	This would be used to estimate the trend by Covid-19 positivity.
Wales	COVID testing	**CTTP: COVID-19 Test, Trace and Protect**			Yes			
Wales	COVID testing	**CVSP: COVID-19 Shielded People List**	May 2020		Yes	X	All	This would be used to ascertain comorbidities
Wales	COVID testing	**CVSD: COVID-19 Sequence Data**[13]			Yes			
Wales	COVID vaccinations	**CVVD: Covid Vaccination Dataset**			Yes			
Wales	Deaths	**ADDD: Annual District Death Daily (ONS Deaths)**	2016		Yes	X	All	This would be used to estimate the trend by Covid-19 positivity.
Wales	Deaths	**ADDE: Annual District Death Extract (ONS Deaths)**	1996		Yes	X	From 2010	This would be used to calculate the population size
Wales	Deaths	**CDDS: COVID-19 Consolidated Deaths**	2019		Yes	X	From 2010	This would be used to calculate the population size
Wales	ITU	**ICCD: ICNARC – Intensive Care National Audit & Research Centre *(COVID-19 only admissions)***	March 2020		Yes			
Wales	ITU	**ICNC: ICNARC – Intensive Care National Audit & Research Centre *(All admissions)***			Yes			
Wales	Prescribing/ Dispensing	**WDDS: Wales Dispensing Dataset**	2015		Yes	X	All	This would be used to ascertain risk factors and medicine use
Wales	NICOR CVD audits	**NICO: NICOR Audits and Registers**			Expected TBC	X	All	This would be used to ascertain comorbidities

[13] Additional approval process required for this dataset

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TRE	**Category**	**Dataset Name**	**Year data available from**	**Time lag**	**Available in TRE**	**Required (X)**	**Years of data required (ALL or range)**	**Brief justification of why you need each dataset / date range**
Wales	Stroke audit	**HQIP: HQIP Stroke Audit**			Expected TBC	X	All	This would be used to ascertain comorbidities
Wales	National Vascular Registry	**NVR: National Vascular Registry**			Expected TBC			
Wales	Other	ADBE: Annual District Birth Extract	1996		Yes			
Wales	Other	MIDS: Maternity Indicators Dataset	2014		Yes			
Wales	Other	NCCH: National Community Child Health			Yes			
Wales	Other	CARE: Care Homes Index	2018		Yes			
Wales	Other	CENW: Office of National Statistics Census (2011)[14]	March 2011 only		Yes	X	All	This would be used to ascertain population size
Wales	Other	RTTD: Referral to Treatment Times	2012		Yes			
Wales	Other	SDEC: SAIL Dementia e-Cohort	March 2019		Yes			
Wales	Other	WASD: Welsh Ambulance Services NHS Trust	2013		Yes			
Wales	Other	WDSD: Welsh Demographic Service Dataset	1990		Yes	X	All	This would be used to ascertain population size
Wales	Other	WRRS: Welsh Results Reporting Service			Yes	X	All	This would be used to ascertain population size
Northern Ireland		**TBC**			Expected TBC			

[14] Additional approval process required for this dataset (4-6 week lead time).