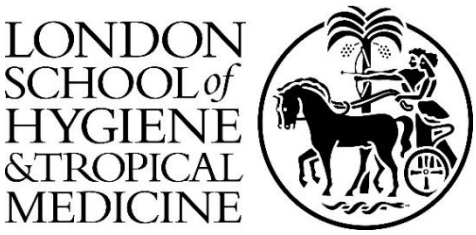

Winter Pressures

Impact and inequalities of winter pressures in primary care: providing the evidence base for mitigation strategies

Version 1.0 12th August 2024

SPONSOR: London School of Hygiene & Tropical Medicine
FUNDERS: NIHR NIHR158218
STUDY COORDINATION CENTRE: LSHTM

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the International Council for Harmonisation Good Clinical Practice (ICH GCP) and/or Medicines for Human Use (Clinical Trials) Regulations 2004 (SI2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, the Sponsor's (and any other relevant) Policies and Standard Operating Procedures (SOPs), and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the study as planned in this protocol will be explained.

Chief Investigator:

Name: **Michael Marks** **Date:** 12th August 2024

Signature : 

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Sponsor

London School of Hygiene & Tropical Medicine is the main research sponsor for this study. For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office:

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National Institute for Health Research – REF: NIHR158218

Problems relating to this study should be referred, in the first instance, to the study coordination centre.

This study will adhere to the principles outlined in the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines, protocol and all applicable local regulations.

Table of Contents

KEYWORDS
COVID-19, Influenza, Primary Care, Secondary Care, Winter Pressures

1. INTRODUCTION

1.1 BACKGROUND

NHS services come under increased pressure in winter, with effects on general practice, emergency care, and inpatient services. The burden on primary care providers during winter is intense but little explored, and there is incomplete understanding of the downstream consequences on patient health of these pressures. Interruptions to routine care can cause major collateral health impacts, as demonstrated by the Covid pandemic (1–3).

Respiratory viruses are a major cause of increased healthcare utilisation during winter which puts pressure on primary care. The impact of respiratory epidemics is unevenly distributed in the population, with lower socioeconomic status and ethnic minority groups bearing an excess burden. Epidemics are dynamic, with some population characteristics - such as a higher proportion of children - that increase epidemic intensity. Other factors that affect severity of infection - such as having pre-existing conditions - vary within the population. These risk factors for epidemic intensity and infection severity frequently cluster in the same groups, exacerbating the impact of respiratory epidemics. These groups also tend to have lower access to primary care (4), and it is possible that winter pressures on primary and secondary care are distributed unevenly with respect to these factors, potentially creating a synergistic worsening of health inequalities during winter.

Immunisations can blunt the impact of respiratory infections and are available for the major winter viruses influenza and SARS-CoV-2. Both active and passive immunisations are on the near horizon for respiratory syncytial virus (RSV). Additionally, pneumococcal vaccines can prevent post-viral bacterial infections. However, inequalities in vaccine coverage by socioeconomic status and ethnicity (5) prevent vaccines from attenuating the existing disparities.

This project will address socioeconomic and ethnic inequalities in experiences and consequences of winter pressures experienced in primary care. We will use administrative records to identify practices experiencing unusual pressure, infer the consequences for patient health and secondary care, and predict when a practice will experience pressure. We will quantify the role that immunisations could play in mitigating these effects.

2. STUDY OBJECTIVES

Our 4 major research questions are each addressed by a work package.

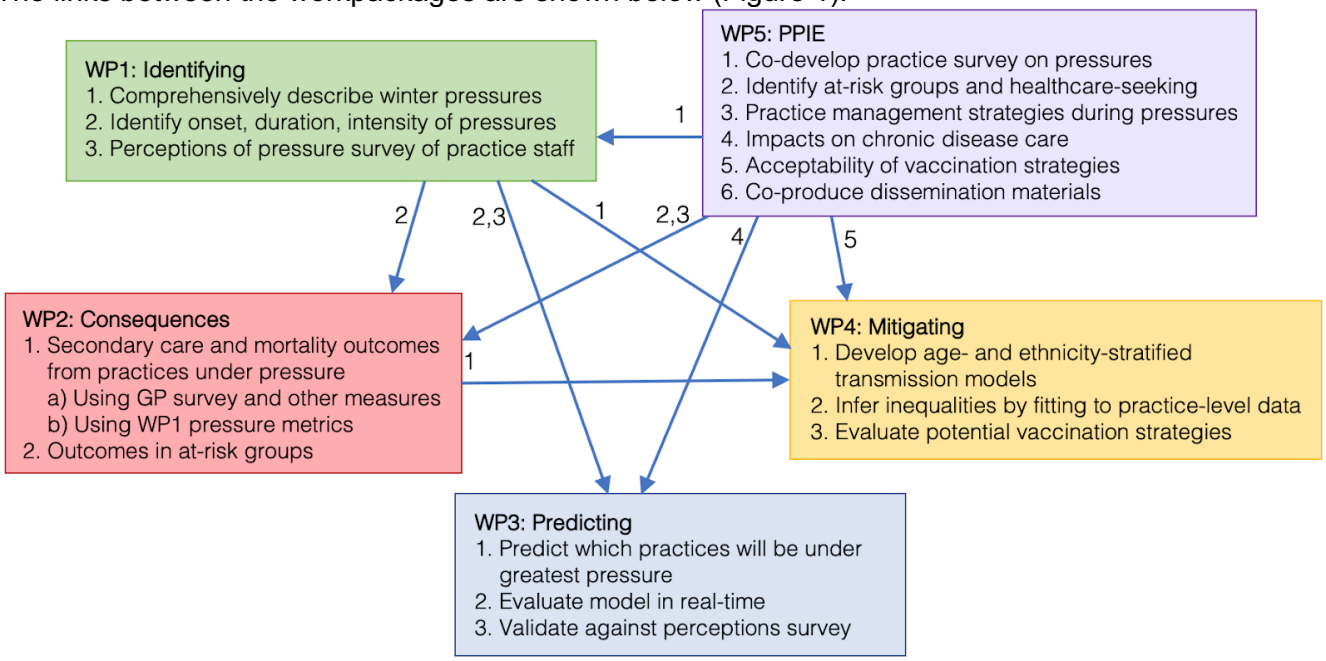
1. What causes winter pressure at the GP practice level and how do we measure onset, duration, and intensity of pressure?
2. What are the consequences of primary care winter pressures for severe health events?
3. Can we predict which practices are vulnerable to winter pressures?
4. How can vaccination be used equitably to mitigate winter pressures?

These are complemented by a fifth work package focused on Patient and Public Engagement.

3. STUDY DESIGN

This document acts as a master protocol describing the overall structure of the project. This includes a brief overview of the rationale and objectives of each of the work package. A set of linked protocols describes the specific methodologies for each of the work packages.

The links between the workpackages are shown below (Figure 1).



Data source and key variables: We will use the NHS England OpenSAFELY secure research platform for accessing and analysing electronic health records (EHR) data(29). OpenSAFELY has a permanent legal basis for ongoing access to NHS data, and support from NHS England for the duration of this project. Working in collaboration with our industry partner (the GP software provider TPP) we will maximise use of NHS data and generate new data linkages to enhance this research.

All studies in this project will use data from up to 24 million adults and children in England who are registered with a TPP SystmOne GP software. We will use data from 2015-2024 initially, however primary care data from TPP in OpenSAFELY are updated monthly, and secondary care and mortality data, quarterly. We will use the most up-to-date data throughout the project to ensure results are current, and reflect all possible winter seasons. We will separate winters during the Covid-19 pandemic during analyses.

OpenSAFELY currently contains GP health records, vaccinations, linked secondary care including emergency care, inpatient, outpatient and procedures. We will utilise extensive practice-level information on appointments, scheduling, types of appointments and staff roles. Additionally, we will link practice-level information from the GP workforce survey, the GP practice survey and the Quality and Outcomes Framework (QOF). We will also link Second-Generation Surveillance System (SGSS) tests on non-Covid-19 infections (Covid-19 tests and all hospital testing are already linked). These are new and exciting linkages, allowing the methodological advances needed for this project.

Table 1. Variables considered throughout the project

Individual Patient Variables	
Demographic	• Age • Sex • Ethnicity • SES measured through index of multiple deprivation (IMD) • Household size and composition (30) • Living in a care home

Health	• Health conditions (e.g. diabetes, coronary heart disease, kidney disease, liver disease), and the number of comorbidities (31)
	• Prescriptions
	• Vaccination status (date, type)
	  ○ COVID-19
	  ○ influenza
	  ○ pneumococcus
	  ○ RSV (if implemented)
	  ○ Any other vaccines
	• Date and cause of death from ONS
	• Electronic frailty index (32)

Healthcare utilisation	• GP visits
	  ○ Reason for visit (SNOMED code)
	  ○ Which staff member (e.g. GP, nurse, other)
	  ○ Time to appointment
	• Accident & Emergency (A&E)*[1]
	• Inpatient care
	• Outpatient care

Practice-level Variables	
Practice characteristics (33) These variables are factors that may affect or explain how a practice operates.	• List size • Demographic categorisations: e.g. % patients over 64 years, under 5 years, women, SES deciles, minoritised groups • Urban/rural categorisations • Number of FTE (full-time equivalent) doctors and nurses per 1000 patients*[2] • Patient-reported satisfaction from the GP patient survey*[3] • Quality Outcomes Framework (QOF) achievement score • Indicators for the Network Contract Directed Enhanced Service Investment and Impact Fund (34)

Epidemic potential of the catchment population
 	
These variables are factors that affect the expected size of an epidemic in a particular practice catchment.
	• Local relative reproduction numbers for influenza, RSV and Covid-19.
	Calculated from the dominant eigenvalue of the next-generation matrix*[4], using information on:
	  ○ Age and sex distribution
	  ○ Influenza vaccination uptake and effectiveness (adults and children)
	  ○ RSV vaccine uptake and effectiveness*[5]
	  ○ COVID-19 vaccine uptake and effectiveness*[6]
	  ○ Household size distribution

	• Potential number of infections of each pathogen per season. Calculated from the relative reproduction number, known estimates of the effective reproduction number of each pathogen, and pathogen-specific scenarios of susceptibility.
Factors associated with increased severity of infection in the practice catchment These are factors that affect the probability of severe outcomes following infection.	• Prevalence of morbidities that affect severity of respiratory infections, e.g. diabetes, heart failure • Pneumococcal vaccination uptake in adults and children (affects probability of community acquired pneumonia) • Smoking prevalence • Ethnic composition • Proportion of patients in the most deprived IMD quintile
Consulting behaviour These variables affect the likelihood and ease of seeking primary care.	• Median GP consultation rate per patient person year (telephone, e-consult and in-person) • Median nurse consultation rate per patient person year • Practice-level telephone (telephony) data: information on number of calls per day, average daily queue-time, will be available from a sample of practices from 2018-2023.

*[1] For all secondary care we have the full record including diagnoses and administrative codes, duration, and discharge type.
*[2] General Practice Workforce data: information on full-time equivalent (FTE) and headcount figures for GPs, nurses, direct patient care, and administrative staff for each practice. The data provides a snapshot of the practice workforce on a particular date. Between 2015 and 2021, information was collected quarterly. From July 2021, information has been collected monthly.
*[3] General Practice Patient Survey: a postal and online survey that collects information from a random sample of patients' capturing experience of healthcare services provided by GP practices, including experience of accessing primary care services and making appointments. Questions on length of time to make an appointment and experience of making an appointment have been included in the last five surveys, between 2018-2022.
*[4] Assuming social mixing matrix from POLYMOD(35)
*[5] potential impact of RSV vaccines (maternal, older adult), assuming uptake of maternal RSV vaccines will mirror maternal pertussis vaccine, and uptake/timing among older adults will mirror seasonal influenza uptake.
*[6] for years where COVID vaccine was recommended.

3.1 OUTLINE OF WORK PACKAGE 1

Rationale: There are major gaps in our understanding of how winter pressures affect GP practices and care provision. There is an urgent need to clarify what "winter pressures" means to primary care, whether through changes in number or availability of appointments, patient mix, reasons for attendance, or changes in chronic disease management. Determining when a practice starts experiencing excess pressure is critical to designing strategies to prevent downstream consequences of such pressure.

Objectives: This work package has three objectives:

1. Comprehensively describe the winter pressures experienced by general practice in England.
2. Develop metrics to identify onset, duration, and intensity of winter pressures at a practice level.
3. Conduct a quantitative survey of general practice staff to validate our metrics of pressures.

3.2 OUTLINE OF WORK PACKAGE 2

Rationale: The consequences of pressures in primary care may increase secondary care use, likely through three main routes: i) inability to access primary care causes patients to seek emergency care instead; ii) lack of treatment of an acute condition at an early stage results in worsening and a need for secondary care; iii) pressure at the GP displaces chronic disease management resulting in worse outcomes for those with chronic diseases.

Objective: Building on NIHR- and HDR-UK-funded research on winter pressures (grant: HDRUK 2022.0315), we will examine the effect of individual and composite measures of practice-level pressure (including those defined in WP1) on subsequent hospital admissions and mortality.

3.3 OUTLINE OF WORK PACKAGE 3

Rationale: Winter pressures are multifactorial, including the impact of: i) increased demand, driven by seasonal illness and worsening chronic conditions; and ii) capacity constraints in terms of number of available appointments, further impacted in winter by staff absence. Under the same winter conditions, there is likely to be variation in experience of pressure due to differences in the administrative characteristics of a practice, and its catchment population. Identifying predictors of vulnerability to pressure, and whether this is modified by vaccination, will generate targets for future intervention and support.

Objectives: i) To identify practice-level predictors of winter pressure; and ii) to evaluate whether achieving vaccination targets modifies the predicted effect of practice level factors on winter pressure.

3.4 OUTLINE OF WORK PACKAGE 4

Rationale: The size and timing of winter respiratory epidemics depends on the social mixing patterns of the populations they occur in, and the distribution of immunity within the population (from immunisation or natural immunity) (40). Social mixing patterns are affected by demographic factors, including household size and occupation. Uptake of vaccination against influenza and Covid-19 in the UK exhibits inequalities by SES and ethnicity, and it is likely that an RSV vaccine programme would have similar disparities. These same populations have lower primary care provision in England, and it is unknown if general practices serving those populations experience greater winter pressures (WP1-2). It is possible that vaccination strategies could be developed that decrease health inequalities caused by infections, and also decrease pressure on general practice.

Objective: This WP will use cutting-edge transmission modelling approaches to evaluate how demographic factors and unequal vaccination coverage affect respiratory virus transmission in different population groups and how these could be mitigated.

3.5 OUTLINE OF WORK PACKAGE 5

Work package 5 supports the activities of WPs 1-4 and is actively embedded within them at all stages of the project. This work package has two objectives:

- To involve patients, the public and other stakeholders (e.g. GPs and practice staff, e.g. practice managers, nurses) in the production and dissemination of this research.
- To communicate study findings in a way that is easily digestible for a general audience.

Establish a patient & public advisory group: To achieve this, we will establish a patient & public advisory group (PPI AG) who we will meet with at regular intervals throughout the project to provide strategic input into WP1-4 activities at various stages of the research life cycle, from research design, to recruitment, analysis and dissemination. We will also engage with GPs and practice staff throughout these stages to ensure the relevance and usefulness of the research to these groups.

3.6 RISKS AND BENEFITS

There is no direct benefit to participants in the research. There may be longer term, indirect benefits from a better understanding of pressures faced by the NHS which may help develop mitigation strategies. For the majority of the work packages the project consists of secondary analysis of routine data using the OpenSafely platform (see Section 4) without direct participant involvement. For work package one, we will be conducting a survey of practices to ascertain their subjective perception of work place pressures. This is a low risk activity with limited likelihood of harm beyond the time requirements for conducting the survey.

4. DATA MANAGEMENT

Data for this project will be accessed using the OpenSAFELY platform. OpenSAFELY is a secure, transparent, open-source software platform for analysis of electronic health records data. It has been deployed in collaboration with TPP to create a Trusted Research Environment (TRE), called OpenSAFELY-TPP. Alongside additional appropriate database, compute, governance, and administrative controls it forms a secure analytic platform, with strong additional privacy layers, to maximise patient confidentiality and privacy.

Patient data is de-identified within the OpenSAFELY-TPP database. Linkage of datasets involves pseudonymisation (typically of the NHS number) at source,using industry standard encryption standards, specifically the SHA 512 algorithm with a salt methodology. The approach is compliant with the advice for the disclosure of research data in the "NHS Code of Practice: Confidentiality" (Model B2 (6) / Medical purposes other than healthcare). There are several components to the process, compliant with the key techniques for anonymisation identified in the Information Commissioner's Office (ICO) Code of Practice "Anonymisation: managing data and protection risk" (2012)" and the guidance in the UK Anonymisation Network's "The Anonymisation Decision-Making Framework" (UKAN, 2016). This framework has been developed with the support of the ICO, following a series of consultations with the key stakeholders. Note that the approach taken in both the ICO's Code of Practice and the anonymisation framework are fully consistent with the General Data Protection Regulation (GDPR, 2018). The pseudonymisation process used to populate the

database is all automated, with no need for any manual intervention. It involves the following key steps:

- Partial Data Removal - this results in personal identifiers being removed from the database. It includes the complete removal of intentional unique identifiers (for example, NHS numbers and hospital numbers), associational unique identifiers (for example, mobile telephone numbers), transactional unique identifiers (for example, booking reference numbers for hospital referrals) and functional unique identifiers (for example, name and address details). There are no digitised unique biometrics for individuals stored on the database at all.

- Narrative Text Data Removal – there exists the possibility that narrative data within an electronic health record can act as a functional unique identifier for an individual. For example, the notes entered by a clinician during a face-to-face consultation may contain the patient's name or phone number, for example, and so identify them. This risk also extends to the identification of third-party individuals within narrative text if, for example, a patient has disclosed information about a relative or neighbour. Although narrative data is very content rich, a sophisticated approach is required to anonymise it successfully. For this reason, all narrative free text that could contain details of an individual is removed from the database. This extends to all other unstructured data including, for example, letters and communications.

- Pseudonymisation – this de-identifies data by attaching a unique identifier to each record in the data. It allows the data to be associated with a particular individual, without the individual being identified. For components of research, it is necessary to link disparate research data sources – for example, data from General Practice, Hospital data and personally –collected data. Unique pseudonyms facilitate any required data linkage, without the need to identify individuals. The process employs strong pseudonymisation. It uses an industry-standard, one way hash algorithm (SHA 512) with a secure salt to achieve this.

- Derived Data Items – this involves producing derived data that reflects the character of the source data, whilst removing the exact original values for anonymisation purposes. Derived data items include banded indices of multiple deprivation, the rurality-urban classification and geographic middle-layer super-output codes. The exact original values used to produce the derived data – for example, the postcode of a patient's address – are removed from the database. Pseudonymisation is necessary to protect patients' privacy, but it is not a sufficient safeguard on its own. Event-level healthcare data, combined with demographic factors, presents a re-identification risk. Because of this risk, our approach is that event-level pseudonymised health data should be handled as if it were identifiable. We have taken additional technical steps to prevent and detect misuse of the data. These include the following:

- OpenSAFELY-TPP does not move any patient data outside of the secure environments where it already resides. This includes pseudonymised data. Instead, trusted analysts can run large-scale computation across pseudonymised patient records in situ. The only data that is approved for

release is aggregated study results which have had disclosure controls applied *and* reviewed by two independent output checkers.

- No analyst / researcher has unconstrained access to view and manipulate pseudonymised data on a remote machine. Instead, they work on the data at "arm's length" using OpenSAFELY-TPP services.

- OpenSAFELY-TPP contains a range of flexible, pragmatic, but standardised tools that users work with to convert pseudonymised patient data into "research ready" datasets, and then to execute code across those datasets. Standardising the data management pathway in this way brings numerous security benefits.

- OpenSAFELY does not rely on an assumption of trust: it aims to be provably trustworthy, and transparent, by providing a full public log of all activity in the platform. This allows patients, professionals and the public to hold the entire system accountable, because it is their data being used for public benefit.

- The working methods, and the code in which they are embodied, mean that OpenSAFELY substantially exceeds current best practice around secure execution of analysis code on pseudonymised patient data, when combined with the other governance features of a strong TRE. After completion of each analysis, only minimally disclosure summary data is released outside the secure environment, such as summary tables or figures, after strict checks on disclosure and redactions, to ensure safe data, safe settings and safe outputs. When access to any TRE, including one using OpenSAFELY code, is considered to be appropriate, the dataset described by the study definition should also be justified and proportionate, in accordance with the Caldicott principles and the DCMS data ethics framework.

- As in all other research settings, OpenSAFELY users are expected to maintain the highest standards of research integrity as described by, for example, Universities UK's Concordat to Support Research Integrity and the UK Policy Framework for Health and Social Care Research; they must also pass a safe researcher course, such as that provided by the ONS. Research projects must be scientifically sound and guided by ethical principles: as with all other research work, gaining appropriate research ethics approval is a prerequisite for using the OpenSAFELY platform.

- All information governance for this particular instance of OpenSAFELY deployed in TPP is handled by NHS England. Research proposals submitted for possible execution in OpenSAFELY-TPP are assessed by NHS England and the OpenSAFELY collaboration in accordance with the process reviewed by the OpenSAFELY Oversight Board. This ensures that the platform is used for safe projects by safe people. All OpenSAFELY-TPP researchers must remain conscious of the level of responsibility required from all those analysing sensitive health data, and be cognisant of their obligations to respect the individuals to whom the data relates. The intention, design and process of the research should be appropriately described and justified in a research proposal or protocol, noting that the OpenSAFELY-TPP platform can currently only be

used to support research that will deliver urgent results related to the global COVID-19 emergency.

- It is important that research teams are accountable for delivering on their pre-specified aims: in addition to other mechanisms used by the research community to achieve this objective, all activity on OpenSAFELY-TPP is clearly logged, leaving a record of every analysis executed by each user. All code is made public at the point that results are shared, if not sooner. All results from OpenSAFELY TPP analyses must be shared within 12 months of execution (a code of conduct we require all researchers to sign up to) with a clear expectation of rapid dissemination in preprints, reports, and papers.

- Even though informed consent will be obtained from each participant, no researcher is required to access identifiable personal data during the study. Identifiable data will only ever be accessed by the patient / participant themselves and / or by their registered GP. A patient's registered GP clearly already has access to this data as part of the direct care team.

- The only data accessed by researchers will be de-identified, having been subject to the approved OpenSAFELY-TPP pseudonymisation and aggregation procedures outlined above. Further information is available at www.opensafely.org.

- This research-level data is also held in these secure data centres, as part of the OpenSAFELY-TPP platform. However, the storage mechanisms and security protocols remain as for the production EHR and PHR systems.

Identifiable data will not be accessed by the research team. The OpenSAFELY-TPP database only contains de- identified data; researchers will have access to view only the aggregated study outputs. The data generated by the study will be analysed by the research team at the London School of Hygiene and Tropical Medicine. All data analysis will be performed on the OpenSAFELY-TPP data platform.

5. STATISTICS AND DATA ANALYSIS

The analysis plans for each work package are described in the four linked scientific protocols for WP1-4.

Data and all appropriate documentation will be stored for a minimum of 5 years after the completion of the study, including the follow-up period.

6. MONITORING

This is a low risk observational study using already existing electronic health record data. Data use within OpenSafely is subject to a series of validation checks to confirm its accuracy.

7 REGULATORY ISSUES

7.1 ETHICS APPROVAL

The Study Coordination Centre will obtain approval from the NHS Research Ethics Committee, the LSHTM Research Ethics Committee, as well as any other appropriate Ethics Committees. The REC will approve all study documents. Substantial amendments to the study protocol will obtain a favourable opinion by the local REC before they are implemented.

7.2 CONSENT

The majority of the study consists of analysis of existing routine data. For participants in the GP survey conducted as part of Work Package one we will obtain specific additional consent. All participants will be free to withdraw at any time.

7.3 CONFIDENTIALITY

As described above in Data Management no identifiable participant data will be utilised.

7.4 INDEMNITY

London School of Hygiene & Tropical Medicine holds Public Liability ("negligent harm") and Clinical Trial ("non-negligent harm") insurance policies which apply to this trial.

7.5 SPONSOR

London School of Hygiene & Tropical Medicine will act as the main sponsor for this study. Delegated responsibilities will be assigned locally.

7.6 FUNDING

NIHR are funding this study.

7.7 AUDITS AND INSPECTIONS

The study may be subject audit by the London School of Hygiene & Tropical Medicine under their remit as sponsor, the Study Coordination Centre and other regulatory bodies to ensure adherence to GCP.

7.8 PROTOCOL DEVELOPMENT

This protocol was developed by the following investigators who are responsible for the development of, and agreeing to, the final protocol. Subsequent changes to the final protocol will require the agreement of the Study Management Group.

8. STUDY MANAGEMENT

A Study Management Group (SMG) has been appointed and will be responsible for overseeing the progress of the study. The day-to-day management of the study will be co-

ordinated by the Study Management Group at LSHTM , Bristol University and the University of Oxford. The team was created during protocol creation and will meet monthly. There will also be a three-monthly steering group meeting, including wider members of the study team and including our PPI representatives.

9. PUBLICATION POLICY

All publications and presentations relating to the study will be authorised by the Study Management Group and also follow the OpenSAFELY publication policy, https://www.opensafely.org/policies-for researchers/ and the NIHR Publication Policy. The first publication of the study's results will be in the name of the Study Management Group, if this does not conflict with the journal's policy. If there are named authors, these will include at least the trial's Chief Investigator, Statistician and Study Coordinator. Members of the SMG will be listed and contributors will be cited by name if published in a journal where this does not conflict with the journal's policy. Authorship of parallel studies initiated outside of the Study Management Group will be according to the individuals involved in the project but must acknowledge the contribution of the Study Management Group and the Study Coordination Centre.

10. REFERENCES

APPENDICES

- Work Package 1 Scientific Protocol
- Work Package 2 Scientific Protocol
- Work Package 3 Scientific Protocol
- Work Package 4 Scientific Protocol

APPENDIX 1: WORKPACKAGE 1 SCIENTIFIC PROTOCOL

VERSION HISTORY

V1	19/06/2024	Initial protocol draft

TITLE

Understanding the effects of inequalities of winter pressure in primary care on hospitalisation and mortality in England: a practice-level longitudinal analysis

RESEARCH QUESTIONS

1. Comprehensively describe the winter pressures experienced by general practice in England.
2. Develop metrics to identify onset, duration, and intensity of winter pressures at a practice level.
3. Conduct a quantitative survey of general practice staff to validate our metrics of pressures.

DATA SOURCES

This study will be conducted using OpenSAFELY-TPP with the following linked data:

- Primary care data (TPP) (imported once a week)
- Secondary Uses Services (SUS)
  - SUS Admitted Patient Care
  - SUS-Out-patient hospital appointments
  - SUS Emergency Care
- Office of National Statistics (ONS) death registry (latest import date: 12 December 2023)
- Practice-level telephone (telephony) data (if available)
- Second Generation Surveillance System (SGSS)

METHODS

OBJECTIVE 1: DESCRIBE PRESSURES

We will determine the weekly rate of primary care appointments, and the proportion of appointments attended, for each calendar year, stratified by broad cause, patient characteristics and practice characteristics (see Table 1). We will also stratify according to the type of staff member that the appointment was with (GP, nurse, other practitioner). For practices with digital telephony data linked to OpenSAFELY, we will measure within-practice changes in demand over time, by analysing call volume data.

Causes of primary care contact will be defined using Snomed codes and include causes likely to

be directly related to seasonal demand (e.g. influenza-like illness, bronchiolitis, vaccination, falls, chronic disease exacerbation) and those that may be collaterally reduced in times of increased pressure (e.g. chronic disease monitoring). We will look at measures both within and outside QOF to determine the impact of remuneration on services delivered at times of winter pressure.

OBJECTIVE 2: IDENTIFY PRESSURES

Building on NIHR- and HDR-UK-funded work (grant: WP0024) we will develop metrics to identify onset, duration, and intensity of winter pressures at a practice level. We will assess a range of metrics of pressure identified by clinicians as being realistic and valid indicators of winter pressures, including:

- Proportion of GP contacts relating to seasonal infections.
- Changes in monitoring of chronic conditions, e.g. cholesterol, diabetes and kidney function testing;
- Changes in volume of GP appointments (and in relation to capacity at a practice);
- Changes in the delay from appointment booking to appointment date;

Candidate metrics will be assessed by determining the degree to which they vary between practices, and seasonally within practices. Metrics that have more such variation are more likely to be usable as indicators of pressure. Subsequently, we will compare the metrics of pressure with the survey results generated in Objective 3.

Pilot work indicates substantial variation in these activities between GPs, and therefore the potential for use as indicators of increased service pressure. We will continue to develop these measures alongside clinician and patient groups, to ensure strong face validity in measuring service pressure. We will report the level of variation in each measure over time, including determining seasonality and correlation of measures within practices, and identify leading indicators that give early warning of a practice coming under pressure. We will create a summary measure of the degree of increased pressure, relative to a baseline for that practice which can be used as an input for other WPs. Individual measures can also be used in subsequent work packages.

OBJECTIVE 3: PERCEPTIONS OF PRESSURE

We will carry out a longitudinal survey of staff members in a 10% random sample of TPP practices (approximately 260 practices). The survey will be co-produced by our PPI AG and practice staff and take under one minute to complete. We will ask staff members (e.g. practice managers, nurses) to report current fluctuations in capacity (e.g. due to staff illness) and their experience of pressure on a 10-point scale each week. Among those who report increased pressures, we will ask them to choose the reason (e.g. increased demand, increased workload due to vaccination roll-out, increased staff absence, other). The survey results will be linked to OpenSAFELY, and changes in self-reported pressure will be used to validate the metrics of pressure developed above. For an expected prevalence of pressure (based on metrics calculated in objective 2) up to 80% of practices, this will allow us to estimate sensitivity down to 50%, and specificity down to 85%, with a confidence interval width of 0.10, at a confidence level of 95%.

SUMMARY

This will identify onset, duration, and intensity of pressure at a practice level, accounting for between-practice differences in operational methods and baseline pressure.

APPENDIX 2: WORKPACKAGE 2 SCIENTIFIC PROTOCOL

VERSION HISTORY

V1	07/05/2024	Initial protocol draft

TITLE

Understanding the effects of inequalities of winter pressure in primary care on hospitalisation and mortality in England: a practice-level longitudinal analysis

RESEARCH QUESTIONS

1. The effect of practice-level pressure (workforce) on secondary healthcare utilisation.

2. The effect of practice-level pressure (workforce) on morbidity and mortality.

DATA SOURCES

This study will be conducted using OpenSAFELY-TPP with the following linked data:

- General Practice Workforce – NHS Digital (**not imported yet**)
- GP patient survey (**not imported yet**)
- Practice-level telephone (telephony) data (**not imported yet**)
- Primary care data (TPP) (imported once a week)
- Secondary Uses Services (SUS)
    - SUS Admitted Patient Care (latest import date**: 28 November 2023**)
    - SUS-Out-patient hospital appointments (latest import date: 28 November 2023)
    - SUS Emergency Care (latest import date: 5 December 2023)
- Office of National Statistics (ONS) death registry (latest import date: 12 December 2023)
- Second Generation Surveillance System (SGSS)
- Index of Multiple Deprivation (IMD)

COHORTS

Our study will consist of six cohorts: a general population cohort and five cohorts of patients who may be vulnerable to disruptions in their care with: asthma; diabetes; hypertension; chronic obstructive pulmonary disease (COPD); and specific mental health conditions.

The study population for each cohort will include all individuals in OpenSAFELY-TPP starting from 30th Sep 2017 to 28th November 2023 inclusive with:

- A known age between 0 and 110 inclusive on the study start date (**30th *Sep 2017)***
- Alive on the study start date

- Registered for a minimum of 365 days prior to the study start date for individuals aged 1 year old or older. Registered since birth for those aged less than 1 year old
- Known sex, deprivation, and region
- For the specific patient cohorts, individuals are required to have a diagnosis of the condition of interest (identified in primary or secondary care) prior to the study start date
- Exclusion criteria for each cohort can be found in Appendix 2 - Table 1

Appendix 2 - Table 1. Inclusion and exclusion criteria for each cohort

	Primary Care (SNOMED CT)	**Secondary Care and Deaths (ICD-10)**	**Medication**	**Exclusion**
Cohort 1: Asthma	OpenCodelists: Asthma Diagnosis (SNOMED)	**Not applicable**	**Asthma medications (BNF)**	n/a
Cohort 2: Diabetes	Combine: Diabetes T1 SNOMED Diabetes T2 SNOMED Non-diagnostic diabetes SNOMED Other-Nonspecific diabetes SNOMED Gestational Diabetes SNOMED Opensafely: Insulin SNOMED Opensafely: Antidiabetic drugs SNOMED Opensafely: Non-metformin-antidiabetic drugs SNOMED	Diabetes T1 ICD10 Diabetes T2 ICD10	Opensafely: Antidiabetic drugs SNOMED Opensafely: Non-metformin-antidiabetic drugs SNOMED	Before the study start date: no history of coronary artery disease, peripheral artery disease, retinopathy, or chronic kidney disease
Cohort 3: Hypertension	Hypertension SNOMED	Hypertension ICD10	Hypertension Drugs DMD	Before the study start date: no history of heart failure
Cohort 4: COPD	COPD SNOMED	COPD ICD10	COPD medication (BNF)	Before the study start date: no history of heart failure, atrial fibrillation

Cohort 5: Specific mental health conditions				
- **Severe mental illness**	OpenCodelists: Severe Mental Illness	Combine: Bipolar and other mood related disorders ICD-10 Other psychotic disorders ICD-10 Schizophrenia ICD-10	Combine: OpenCodelists: Second generation antipsychotics, excluding long acting injections OpenCodelists: Prochlorperazine DM&D	Before the study start date: no history of severe mental illness
- **Self-harm**	Combine: OpenCodelists: Intentional self-harm (aged>=10 years) OpenCodelists: Intentional self-harm (aged>=15 years)	Combine: Self-harm (Intentional 10+ years) ICD-10 Self-harm (Undetermined Intent 15+ years) ICD-10	**Not applicable**	

EXPOSURES

Our main exposure will be the output from WP1, practice-level pressure. However, in the early stages of the project, we will define pressures using existing external data, including GP workforce data, GP practice surveys, and telephony data. Once measures of pressure in WP1 are identified, we will analyze these measures and compare the results with our findings based on the existing external data.

WORKFORCE

1. Staffing level in primary care using the NHS Digital General Practice Workforce data in England: General Practice Workforce – NHS Digital (1). Relevant variables:

FTE (Full-Time Equivalent) per 100,000 patients (calculable)
GP
Nurse
Total Direct Patient Care staff

The data resources of workforce variables are listed in *Appendix 2B*. The General Practice Workforce series of Official Statistics presents a snapshot of the primary care general practice

workforce. Before July 2021, data are available on a quarterly basis (a record as of 31 March, 30 June, 30 September, and 31 December). However, from July 2021, they are on a monthly basis (Last calendar day of each month including weekends and public holidays). The summary data across time can be found here (Table 5: GPW Bulletin Tables – January 2024.xlsx (live.com)).

2. Patient's experience in primary care: GP patient survey included experience of accessing primary care services and making appointments: Survey and Reports (gp-patient.co.uk) (2). The full list of questions in the survey can be found in Appendix 2. The summary question as follows can be considered to reduce the number of variables. Data collection dates can be found in Table 2.

Patient experience	**Overall, how would you describe your experience of your GP practice?** (Very good, fairly good, neither good or poor, fairly poor, very poor) **Response rate low (~50%)**

Appendix 2 - Table 2. Data collection dates for GP patient survey

Data collected period	**No of responses**
3 Jan – 3 April 2023	749,020
10 Jan – 11 April 2022	710,421
4 Jan – 6 April 2021	837,365
2 Jan – 6 April 2020	712,773
2 Jan – 5 April 2019	761,244
2 Jan – 6 April 2018	747,970
Jan-Mar 2017	795,150
Jul-Sept 2015 and Jan-Mar 2016	819,733
Jan-Mar 2015 and Jul-Sept 2015	837,583
Jul-Sept 2014 and Jan-Mar 2015	841,444

3. Practice-level telephone (telephony) data: information on number of calls per day, average daily queue-time, will be available from a sample of practices for 2018-2023.

OUTCOMES

PRIMARY OUTCOMES-SECONDARY HEALTHCARE UTILISATION IN ALL COHORTS

We will consider the following outcomes in all cohorts: secondary care health service use: defined as the weekly rates of A&E attendance and unplanned hospital admissions.

Categories	Sub_cat	Data source
Hospital admission	A&E	SUS (HES)
	APCS	
	Outpatient care	
Length of hospital stay	APCS	

Secondary outcomes-morbidity and mortality within patient cohorts

Any event in the 6-month period after a practice is defined as under pressure, specifically any hospital admission (planned or unplanned) and death.

Specifically, we will examine the following outcomes within patient cohorts:

1. Patients with asthma: exacerbations, or pneumonia

2. Patients with diabetes: new diagnosis of coronary artery disease, peripheral artery diseases, acute ischaemic stroke, retinopathy, neuropathy, or chronic kidney disease.

3. Patients with hypertension: new diagnosis of coronary artery disease, peripheral artery disease, acute ischaemic stroke, or heart failure

4. Patients with COPD: exacerbations, pneumonia, atrial fibrillation, or heart failure

5. Patients with specific mental health conditions: new diagnosis of severe mental illness or self-harm or death caused by suicide.

Appendix 2 - Table 3. Outcomes and data resources in each cohort

Outcomes	**Cohorts**	***Secondary Care and Deaths (ICD-10)***
Asthma exacerbations	Cohort 1 (asthma)	Asthma exacerbation – secondary care (ICD-10)
Pneumonia[ZZ1]	Cohorts 1 (asthma), 4 (COPD)	Pneumonia secondary care (ICD-10)

New diagnosis of coronary artery disease	Cohorts 2 (diabetes), 3 (hypertension)	*Appendix 3:* *https://www.opencodelists.org/codelist/user/ZoeMZou/coronary-artery-disease/086f1e63/*
Peripheral artery diseases	Cohorts 2 (diabetes), 3 (hypertension)	*Appendix 4:* *https://www.opencodelists.org/codelist/user/ZoeMZou/peripheral-artery-diseases/217e9198/*
Acute ischaemic stroke	Cohorts 2 (diabetes), 3 (hypertension)	*Including haemorrhagic and ischaemic: Stroke Secondary Care (ICD-10)
Retinopathy	Cohort 2 (diabetes)	*NA*
Neuropathy	Cohort 2 (diabetes)	*NA*
Chronic kidney disease	Cohort 2 (diabetes)	CKD ICD10
Heart failure	Cohorts 3 (hypertension), 4 (COPD)	*Cardiovascular Secondary Care (ICD-10) included myocardial infarction and heart failure
COPD exacerbations	Cohort 4 (COPD)	*NA*
Atrial fibrillation	Cohort 4 (COPD)	*NA*
New diagnosis of severe mental illness	Cohort 5 (mental health)	Combine: Bipolar and other mood related disorders ICD-10 Other psychotic disorders ICD-10 Schizophrenia ICD-10
Self-harm	Cohort 5 (mental health)	Combine: Self-harm (Intentional 10+ years) ICD-10 Self-harm (Undetermined Intent 15+ years) ICD-10
Death caused by suicide	Cohort 5 (mental health)	OpenCodelists: Suicide ICD-10
Fractures (3,4)	All	*Appendix 5:* *https://www.opencodelists.org/codelist/user/ZoeMZou/fractures/3d40c4c3/*
Concussion	All	S06.0 (tbc): https://www.opencodelists.org/codelist/user/ZoeMZou/concussion/2431518e/

*chronic diseases are marked in **bold**. More accurate codes to be confirmed are highlighted..

Negative control outcome (not related to winter pressure): hospital admissions due to fractures and concussion. Fractures and concussion may related to winter but not related to winter workforce pressure, so very sensible to use as NCOs.

Potential confounders

Appendix 2 - Table 4. Potential confounders

Confounder	Apply to Cohorts	Type	Definition	Data sources
Sex	All	Categorical	Male, Female	Primary care
Age	All	Continuous	Modelled as age in years using a restricted cubic spline with 3 knots at the 10th, 50th and 90th percentiles	Primary care
Ethnicity	All	Categorical	1: White 2: Mixed 3: South Asian 4: Black 5: Other	Opensafely-ethnicity
Deprivation	All	Categorical	10 categories from Index of Multiple Deprivation 2019	Index of Multiple Deprivation
Region	All	Categorical	East of England London Midlands North East and Yorkshire North West South East South West Scotland Wales	Primary care
Consultation rate	All	Continuous	Number of GP consultations 12 months prior to the start of the study	Primary care
Smoking status	All	Categorial	E: Ever smoker M: Missing N: Never smoker S: Current smoker	Opensafely – smoking
Obesity	All	Binary	1 if BMI>=30 or coded diagnosis for obesity; 0 otherwise	SNOMED CT ICD10
Healthcare worker	All	Binary	1 if healthcare worker; 0 otherwise	NHS England COVID-19 data store
Care home resident	All	Binary	1 if care home resident; 0 otherwise	Address matching CQC database
Dementia	All	Binary	1 if diagnosis present; 0 otherwise	Dementia SNOMED Dementia ICD10 Dementia Vascular SNOMED Dementia Vascular ICD10

Liver disease	All	Binary	1 if diagnosis present; 0 otherwise	Liver Disease ICD10 Liver Disease SNOMED
Cancer	All	Categorical	1 if diagnosis present; 0 otherwise	Cancer SNOMED Cancer ICD10
Hypertension	Cohorts 1, 2, 4, 5 (asthma,	Binary	1 if diagnosis present; 0 otherwise	Combine: Hypertension Drugs DMD Hypertension ICD10 Hypertension SNOMED
Diabetes	Cohorts 1, 3, 4, 5	Binary	1 if diagnosis present; 0 otherwise	Combine: Diabetes T1 SNOMED Opensafely: Diabetes T1 ICD10 Diabetes T2 SNOMED Diabetes T2 ICD10 Non-diagnostic diabetes SNOMED Other-Nonspecific diabetes SNOMED Gestational Diabetes SNOMED Opensafely: Insulin SNOMED Opensafely: Antidiabetic drugs SNOMED Opensafely: Non-metformin-antidiabetic drugs SNOMED
History of Chronic obstructive pulmonary disease (COPD)	Cohorts 1, 2, 3, 5	Binary	1 if diagnosis present; 0 otherwise.	Combine: COPD SNOMED COPD ICD10
Acute myocardial infarction	Cohorts 1, 2, 5	Binary	1 if diagnosis present; 0 otherwise	AMI SNOMED CT AMI ICD10 AMI Prior ICD10
History of Ischaemic stroke	All	Binary	1 if diagnosis present; 0 otherwise	Ischaemic Stroke SNOMED Ischaemic Stroke ICD10
All stroke	Cohorts 2, 3	Binary	1 if diagnosis present; 0 otherwise	Primary care, HES APC
Other arterial embolism	Cohorts 2, 3	Binary	1 if diagnosis present; 0 otherwise	Primary care, HES APC
Venous thromboembolism events	Cohorts 2, 3	Binary	1 if diagnosis present; 0 otherwise	Primary care, HES APC
Chronic kidney disease	Cohorts 1, 3, 4, 5	Binary	1 if diagnosis present; 0 otherwise	CKD SNOMED CKD ICD10

History of pneumonia	Cohorts 1, 4	Binary	1 if diagnosis present; 0 otherwise	See Table 3 https://www.opencodelists.org/codelist/bristol/pneumonia/44622d57/#full-list
History of asthma	Cohorts 1, 4	Binary	1 if diagnosis present; 0 otherwise	See Table 3
History of neuropathy	Cohorts 1,2 4	NA		
History of pulmonary fibrosis	Cohorts 1, 4	Binary	1 if diagnosis present; 0 otherwise	https://www.opencodelists.org/codelist/bristol/ild-snomed/2f3e3051/
History episode of depression	All	Binary	A diagnosis of, or symptoms of depression in primary or secondary care. 1 if present ≤6 months prior to index date; 0 otherwise	Combine: OpenCodelists: Depression (symptoms and diagnoses) Depression ICD10
History of a serious mental illness	Cohort 5 (not for SMH outcome)	Binary	Diagnoses of schizophrenia and other psychotic disorders, and bipolar disorders. (Sensitivity includes prescription of an antipsychotic or mood stabiliser). As above for SMI but occurring on or before index date 1 if present ≤6 months prior to index date; 0 otherwise	Combine: OpenCodelists: Severe Mental Illness Bipolar and other mood related disorders ICD-10 Other psychotic disorders ICD-10 Schizophrenia ICD-10
History of self-harm	Cohort 5	Binary	1 if present ≤6 months prior to index date; 0 otherwise	Combine: OpenCodelists: Intentional self-harm (aged>=10 years) OpenCodelists: Probable self-harm - Events of

				undetermined intent (aged>=15 years) Self harm 10 years ICD10 Self harm 15 years ICD 10

**Cohorts 1-asthma ; 2- diabetes ; 3-hypertension ; 4-COPD ; 5-specific mental health conditions*

STATISTICAL ANALYSIS

MAIN ANALYSES

Before getting the output from WP1, we will use workforce data as our exposure to get initial output. We will identify time-periods when practices were under pressure using the quarterly collected data from Sep 2017-Dec 2023 (data on 31st March, 30th June, 30th September, 31st December). We will use Poisson regression to compare weekly rates of A&E attendance and unplanned hospital admissions in patients registered with practice **under different degrees of pressure** (morbidity and mortality outcome is defined as any event in the six-month period after a practice is defined as under pressure), controlling for confounders listed in Table 4 and rates of the same outcome in prior periods when practices were not under pressure.

Extended cox proportional hazards model will be considered to investigate how level of workforce pressure impacts health outcomes. We will focus on a specific reasonable time period depending on the final winter pressure variable WP1 identified and acute/chronic outcome disease. Discussion within a wider group with clinicians involved would be preferable for choosing a reasonable length of study time.

Subgroup analyses

We will repeat the main analysis to estimate our estimates for the following subgroups unless specified otherwise in the outcome specific documents:

- Subgroups according to the influence Covid-19 pandemic (before/after January 2020)
- Subgroups according to age group (18-39 / 40-59 / 60-79 / 80-110)
- Subgroups according to sex (male / female)
- Subgroups according to ethnicity (White / Asian or Asian British / Black or Black British / Mixed / Other Ethnic Groups)
- Subgroups according to prior history of outcome subcategory (prior history of outcome subcategory / no prior history of outcome subcategory) depending on the cohort

SENSITIVITY ANALYSES

We will repeat the main analysis using the monthly collected data from July 2021-Mar 2024. We will repeat the main analysis where the morbidity and mortality outcome is defined as any event

in the 3-month period after a practice is defined as under pressure. Negative control study will be used to appraise causality in the association. We will examine the impact of confounders on the association by using fractures and concussion as negative control outcomes.

MISSING DATA

Individuals with missing age, sex, or deprivation are excluded from the study population. Multiple imputation might be used to deal with data missing at random, where appropriate.

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APPENDIX 2B. DATA SOURCES OF WORKFORCE VARIABLES

Workforce variable	Time period	Data sources
FTE per 100,000 patients	Monthly data July 2021-Mar 2024 (upcoming)	General Practice Workforce, 31 January 2024 - NHS Digital General Practice Workforce, 31 December 2023 - NHS Digital General Practice Workforce, 30 November 2023 - NHS Digital General Practice Workforce, 31 October 2023 - NHS Digital General Practice Workforce, 30 September 2023 - NHS Digital General Practice Workforce, 31 August 2023 - NHS Digital General Practice Workforce, 31 July 2023 - NHS Digital General Practice Workforce, 30 June 2023 - NHS Digital General Practice Workforce, 31 May 2023 - NHS Digital General Practice Workforce, 30 April 2023 - NHS Digital General Practice Workforce, 31 March 2023 - NHS Digital General Practice Workforce, 28 February 2023 - NHS Digital General Practice Workforce, 31 January 2023 - NHS Digital General Practice Workforce, 31 December 2022 - NHS Digital General Practice Workforce, 30 November 2022 - NHS Digital General Practice Workforce, 31 October 2022 - NHS Digital General Practice Workforce, 30 September 2022 - NHS Digital General Practice Workforce, 31 August 2022 - NHS Digital General Practice Workforce , 31 July 2022 - NHS Digital General Practice Workforce, 30 June 2022 - NHS Digital General Practice Workforce, 31 May 2022 - NHS Digital General Practice Workforce, 30 April 2022 - NHS Digital General Practice Workforce, 31 March 2022 - NHS Digital General Practice Workforce, 28 February 2022 - NHS Digital General Practice Workforce, 31 January 2022 - NHS Digital General Practice Workforce, 31 December 2021 - NHS Digital General Practice Workforce, 30 November 2021 - NHS Digital General Practice Workforce, 31 October 2021 - NHS Digital General Practice Workforce, 30 September 2021 - Provisional - NHS Digital General Practice Workforce 31 August 2021 - Provisional - NHS Digital General Practice Workforce 31 July 2021 - Provisional - NHS Digital General Practice Workforce - 30 June 2021 - NHS Digital

FTE per 100,000 patients	Quarterly data (March, June, September, December) Sep 2017-June 2021	General Practice Workforce 31 March 2021 - NHS Digital General Practice Workforce 31 December 2020 - NHS Digital General Practice Workforce 30 November 2020 - NHS Digital General Practice Workforce 31 October 2020 - NHS Digital General Practice Workforce 30 September 2020 - NHS Digital General Practice Workforce - 30 June 2020 - NHS Digital General Practice Workforce - 31 March 2020 - NHS Digital General Practice Workforce 31 December 2019 - NHS Digital General Practice Workforce 30 September 2019 - NHS Digital General Practice Workforce 30 June 2019 - NHS Digital General Practice Workforce, Final 31 March 2019, experimental statistics - NHS Digital General Practice Workforce Final 31 December 2018, Experimental Statistics - NHS Digital General Practice Workforce, Final 30 September 2018, Experimental statistics - NHS Digital General and Personal Medical Services, England: Final 30 June and Provisional 30 September 2018, experimental statistics - NHS Digital General and Personal Medical Services, England: Final 31 March and Provisional 30 June 2018, experimental statistics - NHS Digital General and Personal Medical Services, England : Final 31 December 2017 and Provisional 31 March 2018, experimental statistics - NHS Digital General and Personal Medical Services, England As at 30 September 2017, Final Experimental statistics - NHS Digital
FTE per 100,000 patients	Twice a year (March and September) Sep 2015-Mar 2017*[ZZ2]	March 2017 General and Personal Medical Services, England As at 31 March 2017, Experimental statistics - NHS Digital September 2016: General and Personal Medical Services, England 2006-2016, as at 30 September, Experimental statistics - NHS Digital March 2016 General and Personal Medical Services, England September 2015 - March 2016, Provisional Experimental statistics - NHS Digital September 2015 General and Personal Medical Services, England 2005-2015, as at 30 September, Provisional Experimental statistics - NHS Digital

*For December 2016 and June 2017, when quarterly extracts were first introduced, data is only available for GPs and not for the other three staff groups.

QUESTIONS IN THE GP PATIENT SURVEY

Section	Question

Your local GP services:	Q1 Generally, how easy is it to get through to someone at your GP practice on the phone?
	Q2 How helpful do you find the receptionists at your GP practice?
	Q3 Which of the following general practice online services have you used in the past 12 months?
	Q4 How easy is it to use your GP practice's website to look for information or access services?
	Q5 As far as you are aware, what general practice appointment times are available to you?
	Q6 How satisfied are you with the general practice appointment times that are available to you?
	Q7 Is there a particular GP you usually prefer to see or speak to?
	Q8 How often do you see or speak to your preferred GP when you would like to?
Making an appointment:	Q9 When did you last try to make a general practice appointment, with a GP, nurse or other healthcare professional, either for yourself or for someone else?
	Q10 Before you tried to get this appointment, did you do any of the following?
	Q11 When would you have liked this appointment to be?
	Q12 How did you try to book the appointment?
	Q13 Were you asked for any information about your reasons for making the appointment?
	Q14 Who asked you for information about your reasons for making an appointment?
	Q15 On this occasion, were you offered any of the following choices of appointment?
	Q16 Were you satisfied with the appointment (or appointments) you were offered?
	Q17 If you did not get an appointment, why was that?
	Q18 What did you do when you did not get an appointment?
	Q19 What type of appointment did you get?
	Q20 How long after initially trying to book the appointment did the appointment take place?
Your last appointment:	Q21 Overall, how would you describe your experience of making an appointment?

	Q22 When was your last general practice appointment?
	Q23 What type of appointment was your last general practice appointment?
	Q24 Were you given a time for the appointment?
	Q25 Did your appointment happen at the time, or during the slot, you were given?
	Q26 Who was your last general practice appointment with?
	Q27 Last time you had a general practice appointment, how good was the healthcare professional at each of the following?: Giving you enough time
	Q27 Last time you had a general practice appointment, how good was the healthcare professional at each of the following?: Listening to you
	Q27 Last time you had a general practice appointment, how good was the healthcare professional at each of the following?: Treating you with care and concern
	Q28 During your last general practice appointment, did you feel that the healthcare professional recognised and/or understood any mental health needs that you might have had?
	Q29 During your last general practice appointment, were you involved as much as you wanted to be in decisions about your care and treatment?
	Q30 During your last general practice appointment, did you have confidence and trust in the healthcare professional you saw or spoke to?
Overall experience:	Q31 Thinking about the reason for your last general practice appointment, were your needs met?
	Q32 Overall, how would you describe your experience of your GP practice?
COVID-19:	Q33 Have you, at any time in the last 12 months, avoided making a general practice appointment for any reason?
	Q34 Have you experienced any of the following over the last 12 months?
Your health:	Q35 Do you have any long-term physical or mental health conditions, disabilities or illnesses?
	Q36 Which, if any, of the following long-term conditions do you have?
	Q37 Would you describe yourself as having “long COVID”, that is, you are still experiencing symptoms more than 12 weeks after you first had COVID-19, that are not explained by something else?
	Q38 Do any of these conditions or illnesses reduce your ability to carry out your day-to-day activities?
	Q39 How confident are you that you can manage any issues arising from your condition (or conditions)?

	Q40 In the last 12 months, have you had enough support from local services or organisations to help you to manage your condition (or conditions)?
	Q41 Have you had a conversation with a healthcare professional from your GP practice to discuss what is important to you when managing your condition (or conditions)?
	Q42 Have you agreed a plan with a healthcare professional from your GP practice to manage your condition (or conditions)?
	Q43 How helpful have you found this plan in managing your condition (or conditions)?
	Q44 In the past 12 months, have you contacted an NHS service when you wanted to see a GP but your GP practice was closed?
	Q45 Considering all of the services you contacted, which of the following happened on that occasion?
	Q46 How do you feel about how quickly you received care or advice on that occasion?
	Q47 Overall, how would you describe your last experience of NHS services when you wanted to see a GP but your GP practice was closed?
	Q53 Which of the following best describes you?
When your GP practice is closed:	Q54 Is your gender identity the same as the sex you were registered at birth?
	Q55 What is your ethnic group?
	Q56 How old are you?
	Q57 Which of these best describes what you are doing at present?
Some questions about you:	Q58 Do you look after, or give any help or support to, family members, friends, neighbours or others because of either long-term physical or mental ill health / disability, or problems related to old age?
	Q59 Are you a parent of or a legal guardian for any children aged under 16 living in your home?
	Q60 Are you a deaf person who uses sign language?
	Q61 Which of the following best describes your smoking habits?
	Q62 Which of the following best describes how you think of yourself?
	Q63 Which, if any, of the following best describes your religion?

ICD10 DIAGNOSIS CODES FOR CORONARY ARTERY DISEASE

Code	Description

I21	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I22	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I23	Certain current complications following ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction (within the 28 day period)
I24	Other acute ischemic heart diseases
I25.1	Atherosclerotic heart disease of native coronary artery
I25.2	Old myocardial infarction
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.70	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris
I25.71	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris
I25.72	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris
I25.73	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris
I25.79	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris
I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris
I25.82	Chronic total occlusion of coronary artery
I25.83	Coronary atherosclerosis due to lipid rich plaque
I25.84	Coronary atherosclerosis due to calcified coronary lesion
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
Z95.1	Presence of aortocoronary bypass graft
Z98.61	Coronary angioplasty status
I20.0	Unstable angina

ICD10 diagnosis codes for peripheral artery disease

Code	**Data code definition**
I70.0	Atherosclerosis of aorta
I70.00	Atherosclerosis of aorta (without gangrene)
I70.01	Atherosclerosis of aorta (with gangrene)
I70.2	Atherosclerosis of arteries of the extremities
I70.20	Atherosclerosis of arteries of extremities (without gangrene)
I70.21	Atherosclerosis of arteries of extremities (with gangrene)

I70.8	Atherosclerosis of other arteries
I70.80	Atherosclerosis of other arteries (without gangrene)
I70.9	Generalised and unspecified atherosclerosis
I70.90	Generalized and unspecified atherosclerosis (without gangrene)
I73.8	Other specified peripheral vascular diseases
I73.9	Peripheral vascular disease, unspecified

ICD10 diagnosis codes for fractures (to be confirmed) (4, 5)

Code	Data code definition
M484	Fatigue fracture of vertebra
M495	Collapsed vertebra in diseases classified elsewhere
M80	Osteoporosis with pathological fracture
M843	Stress fracture, not elsewhere classified
M844	Pathological fracture, not elsewhere classified
M907	Fracture of bone in neoplastic disease
M966	Fracture of bone following insertion of orthopaedic implant, joint prosthesis, or bone plate
S02	Fracture of skull and facial bones
S12	Fracture of neck
S22	Fracture of rib(s), sternum and thoracic spine
S32	Fracture of lumbar spine and pelvis
S42	Fracture of shoulder and upper arm
S52	Fracture of forearm
S62	Fracture at wrist and hand level
S72	Fracture of femur
S82	Fracture of lower leg, including ankle
S92	Fracture of foot, except ankle
T02	Fractures involving multiple body regions
T08	Fracture of spine, level unspecified
T10	Fracture of upper limb, level unspecified
T12	Fracture of lower limb, level unspecified
T142	Fracture of unspecified body region

APPENDIX 3: WORKPACKAGE 1 SCIENTIFIC PROTOCOL

V1	31/05/2024	Initial protocol draft

TITLE

Understanding predictors of pressure in general practice in England

RESEARCH OBJECTIVES

i) Using risk prediction models, to identify practice-level predictors of winter pressure; and
ii) to evaluate whether achieving vaccination targets modifies the predicted effect of practice level factors on winter pressure.

DATA SOURCES

This study will be conducted using OpenSAFELY-TPP with the following linked data:

- General Practice Workforce – NHS Digital
- GP patient survey
- Practice-level telephone (telephony) data
- Primary care data (TPP) (imported once a week)
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  - SUS Emergency Care (latest import date: 5 December 2023)
- Office of National Statistics (ONS) death registry (latest import date: 12 December 2023)
- Second Generation Surveillance System (SGSS)
- Index of Multiple Deprivation (IMD)

METHODS

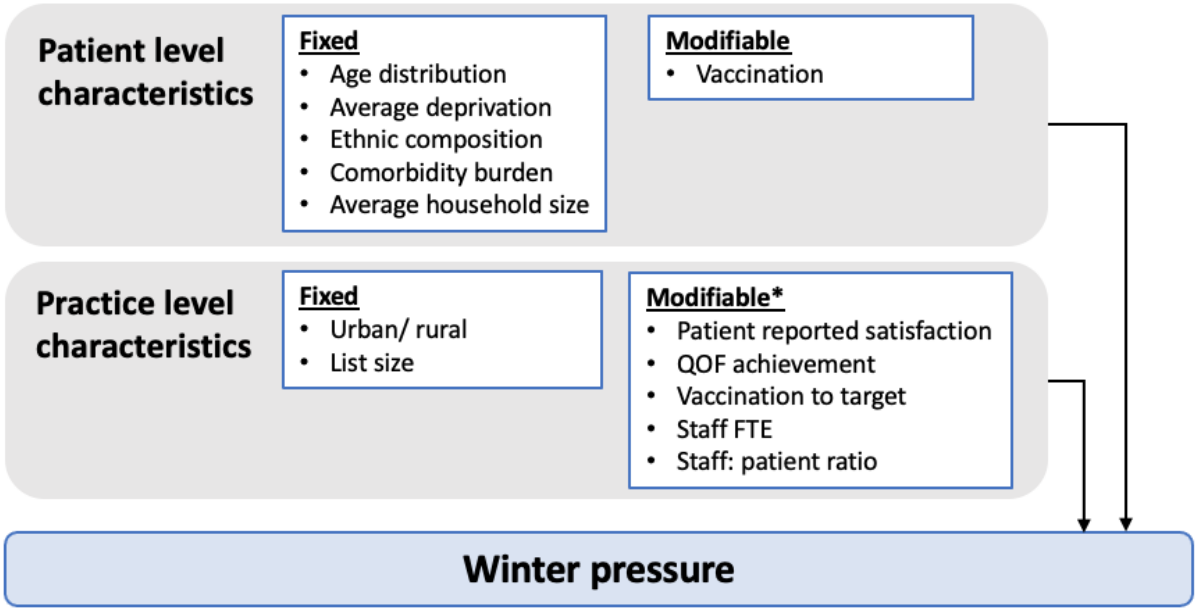
Our study will use data from all general practices (approximately 2600) in OpenSAFELY-TPP. Annual data from each winter season from 2015 onwards will be used to maximise power and train prediction models. We will also investigate whether predictors of winter pressure differ between the pre-pandemic and pandemic/post-pandemic periods (separating March 2020 - March 2021 from subsequent time).

OUTCOMES

Our outcome will be the output from WP1: practice-level pressure. However, in the early stages of the project, we will also look to define pressures using existing external data, including GP workforce data, GP practice surveys, and telephony data. Once measures of pressure in WP1 are identified, we will fit new models as appropriate.

CANDIDATE PREDICTORS

We will include practice characteristics that may affect or explain how a practice operates, factors related to the epidemic potential of the catchment population, and factors associated with increased severity of infection in the practice catchment. These will be in one of four categories. All of these factors might characterise a practice's vulnerability or resilience to increased pressure. Candidate predictors are described in more detail in Appendix 3 – Table 1.



Appendix 3 - Figure 1. Candidate patient and practice level factors included in the prediction model. *Some factors considered modifiable may need additional funding

Appendix 3 - Table 1. Candidate predictors and data sources.

Candidate predictors	Type	Example variable definitions	Data sources
Practice list size	Continuous or categorical	Raw list size, or deciles	OpenSAFELY
Urban/rural practice location	Categorical	A measure of whether the practice is within a rural or urban location	OpenSAFELY
Household size	Continuous	Average household size for patients in the practice	OpenSAFELY
Measures from the workforce data in England	Continuous	Full time equivalent per 100,000 patients for GP, nurse and total direct patient care staff.	GP workforce data
Measures of patient experience	Categorical	Patient experience of GP practice: Very good, fairly good, neither good or poor, fairly poor, very poor	GP patient survey
QOF achievement	Continuous	Summary of achievement in each domain	QOF
Measures from telephony data	Continuous	number of calls per day, average daily queue time.	Telephony data
Sex	Continuous	% women in practice	Primary care
Age distribution	Continuous	Average age of practice population, proportion under 5 years, proportion over 65 years	Primary care
Ethnic composition	Continuous	% non White ethnicity in practice	Opensafely-ethnicity
Deprivation	Continuous	Average deprivation score of patients in the practice,	Index of Multiple Deprivation

		or proportion in the most deprived group	
Region	Categorical	East of England London Midlands North East and Yorkshire North West South East South West Scotland Wales	Primary care
Smoking status	Continuous	Proportion of smokers in the practice	Primary care
Obesity	Continuous	Proportion of obese patients (BMI>30) in the practice	SNOMED CT ICD10
Care home residence	Continuous	Proportion of care home residents in the practice	Address matching CQC database
Measures of vaccination	Continuous	Proportion of eligible practice population vaccinated	OpenSAFELY
Morbidity burden	Continuous	Including dementia, liver disease, cancer, hypertension, diabetes, COPD, myocardial infarction, stroke, other CVD, chronic kidney disease, asthma, depression, severe mental illness; this will use either a morbidity index (e.g. average Charlson score for patients in practice) or will model the proportion of patients with each morbidity.	OpenSAFELY primary care and secondary care data

STATISTICAL ANALYSIS

We will follow best practice for risk-prediction model development including use of training and validation datasets. Broadly this will be developed by dividing the dataset into subsets (for example based on the NHS regions). We will perform internal–external cross-validation to concurrently examine between-region heterogeneity and assess generalisability. In this process, this process, each eight contributing NHS regions will be iteratively excluded from the development set with the model then developed and validated on the the remaining validation.

The outcome (metrics of pressure) will be ascertained monthly for each practice. For numerical winter pressure outcome measures, we will fit hierarchical multiple linear regression models accounting for clustering of patients within general practices and practices within years. For numerical predictor variables, nonlinearity will be modelled using cubic splines or quadratic terms).

Candidate models will be fitted in the training dataset and selected using: (a) a liberal p value threshold (0.2); (b) a stringent p value threshold (0.001); and (c) Akaike's information criterion. Selection

procedures will be extended including all possible pairwise interactions between predictors selected at the first stage. Model discrimination will be quantified using the area under the ROC curve (c-statistic). For each outcome, the final selected model will be that with best discrimination in the validation dataset.

Performance of the final selected models will be quantified using the proportion of variance in winter pressure explained (R^2). Calibration will be assessed by plots comparing predicted and observed metric of pressure.

The models will be externally validated against a range of external predictors including external workforce pressure data and prospectively validated against future winter-season data collected within the OpenSafely platform.

Power: With 1820 practices (using 70% of the 2600 practices for model derivation), assuming that 80% of practices fall under pressure based on our metrics from WP1, an estimated C-statistic of 0.755 our sample size calculations for a prediction model estimate that we would be able to accurately predict our outcome, including 28 predictors.

We will create a model that can predict ahead-of-time which practices are vulnerable to winter pressures. This will be used to develop a flagging system for policy makers.

MISSING DATA

Missing data for each variable will be described. Individuals with missing age, sex, or deprivation are excluded from the practice population when calculating the practice-level variables. Where appropriate multiple imputation will be used to deal with data missing at random.

APPENDIX 4: WORKPACKAGE 1 SCIENTIFIC PROTOCOL

VERSION HISTORY

V1	09/07/2024	Initial protocol draft

TITLE

Mitigating: Modelling vaccine-led mitigation strategies for winter pressures

RESEARCH QUESTIONS

Objective: This WP will use cutting-edge transmission modelling approaches to evaluate how demographic factors and unequal vaccination coverage affect respiratory virus transmission in different population groups and how these could be mitigated.

DATA SOURCES

This study will be conducted using OpenSAFELY-TPP with the following linked data:

- General Practice Workforce – NHS Digital
- GP patient survey
- Practice-level telephone (telephony) data
- Primary care data (TPP) (imported once a week)
- Secondary Uses Services (SUS)
  - SUS Admitted Patient Care (latest import date: 28 November 2023)
  - SUS-Out-patient hospital appointments (latest import date: 28 November 2023)
  - SUS Emergency Care (latest import date: 5 December 2023)
- Office of National Statistics (ONS) death registry (latest import date: 12 December 2023)
- Second Generation Surveillance System (SGSS)
- Index of Multiple Deprivation (IMD)

We will also rely on publicly available data at Local Authority District (LAD) level, with age profiles, household size distribution, ethnicity distributions and IMD quantiles defined at that level.

METHODS

Data aggregation: The modelling for WP4 will be based on aggregated data. The only data accessed by researchers will have been subject to the approved OpenSAFELY-TPP pseudonymisation and aggregation procedures (https://docs.opensafely.org/sdc/).

Data will be aggregated as follows:

- Weekly age- and risk-group and ethnicity-specific consultations for respiratory causes at practice level.
- The age, risk and ethnic composition of the practice catchment population.
- The vaccination rate, for the different age, risk and ethnic cohorts by GP.
- The hospitalisation rate for respiratory causes by age- and risk-group, and ethnicity as derived in WP2.

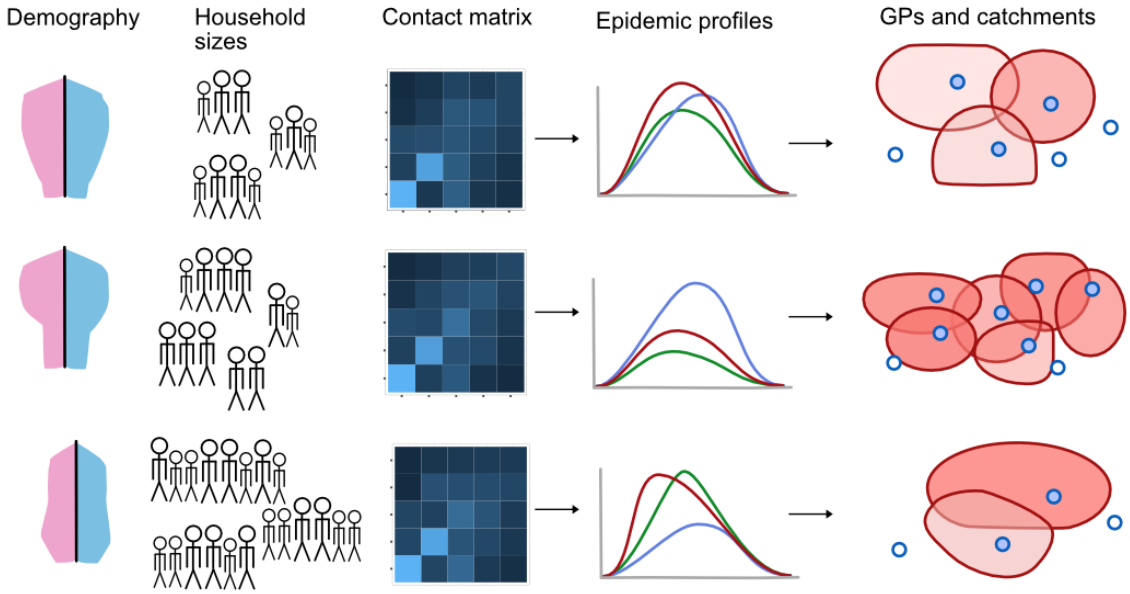
Model construction and parameterisation: We will extend existing dynamic transmission models for influenza, COVID-19 and RSV used previously in the UK for vaccine decision making (41–45), to include stratification by socioeconomic quintile. We will parameterise the transmission models using the age distribution of each SES quintile or ethnicity group, including local demographic differences and local variation in household size by SES and ethnicity. This will allow adjustment of the local

mixing matrix to match the demography of a geographic region. We have already created a proof-of-concept SES-stratified transmission model (senior author Jit, manuscript in preparation), and we will further extend this model to include the varying percentage of risk-groups by age in each SES quintile. These percentages can be extracted from data in OpenSAFELY.

We will then match vaccination coverage in each SES quintile (and by age) to that observed in OpenSAFELY, and use the transmission model to calculate and assess resulting inequalities in infections for influenza and COVID-19. For potential future RSV vaccination strategies targeting older adults, we will parameterise vaccination coverage as per influenza, and assess likely future inequalities that an elderly and risk-group targeted vaccination strategy could generate.

Model fitting: The transmission model will be parameterised at Local Authority District (LAD) level, with age profile and IMD quintiles defined at this level (Appendix 4 - Figure 1). GP practices within each LAD are the observation unit of each respiratory infection, and we will fit the models (RSV, influenza, Covid-19) to weekly age- and risk-group, and ethnicity-specific consultations for respiratory causes (WP1). We will account for small numbers at each practice by assuming reports occur as non-homogeneous Poisson processes proportional to the infection prevalence in each age- and risk-group. Separating the reporting of infections by practice allows two major advantages and innovations: i) the age, risk and ethnic composition of the practice catchment population can be included separately from the age-group composition of the transmission model allowing potential understanding of how epidemics may affect practices differently even locally; ii) we can then fit a different reporting rate per practice, which allows for differences in healthcare-seeking or care availability in the specific GP catchment population, which may be affected by similar factors.

We will also create an ethnicity-stratified model, and include information on differences in household size and composition, to allow those factors to impact on transmission rates as well as reporting rates. We will parameterise risk-groups and vaccination coverages as observed.



Appendix 4 - Figure 1. Demographic variation in the population, combined with household size distribution will affect the contact matrix in a LAD. This consequently affects the epidemic profiles of the three modelled infections (colours of lines). Data are fitted at the GP level where the catchment size and distribution of co-morbid conditions (shading) will be incorporated in the likelihood of reporting infection, and therefore into the fitting process. Not all GP practices are included in TPP (blue vs white circles) which we incorporate into the reporting model.