Title: Accounting for Unmet Need in Equitable Healthcare Resource Allocation

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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 Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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 investigation without the prior written consent of the Sponsor

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

Chief Investigator:

Signature: 

Date: **19/06/2020**

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Name: (please print): Professor Ben Barr

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Funder: National Institute of Health Research (NIHR)

STUDY SUMMARY

Study Title	**Accounting for Unmet Need in Equitable Healthcare Resource Allocation**
Study Design	**Secondary analysis of electronic health records.**
Study Participants	**Analysis will be based on the whole population of England.**
Research Question/Aim(s)	1. To understand alternative concepts of unmet need, its measurement, potential causes and their implications for NHS resource allocation and health inequalities. 2. To examine whether the methodology of the utilisation approach used in the national resource allocation formula can be enhanced to address unmet need. 3. To estimate variation in unmet need by assessing the healthcare costs of diagnosing and treating the estimated prevalent cases of undiagnosed chronic conditions in each CCG. 4. To estimate the heath impact and health inequalities impact of alternative adjustments for unmet need.

Study Steering Group:

The role of the steering committee will be to:

- Provide advice to the funder, Chief Investigator, the Host Institution and the Contractor on all appropriate aspects of the project
- To concentrate on progress of the project, adherence to the protocol and the consideration of new information of relevance to the research question
- To ensure appropriate ethical and information governance processes are in place.
- To agree proposals for substantial protocol amendments and provide advice to the funder regarding approvals of such amendments
- To provide advice to the investigators on all aspects of the project.

Plain English Summary.

The NHS in England uses various formulae to share out its budget of £87 billion between local areas. These aim to provide more money per person to areas with greater need for healthcare compared to areas with fewer needs. Currently the NHS uses information on how different groups of people have used health care services in the past to work out how much need they have. For example people at older ages and those living in poorer areas tend to use more NHS services than younger people and those living in more affluent areas, so these groups are assessed as having greater needs. There are concerns that the current approach does not take into account that some groups of people are less likely to use healthcare services even when they need them. That might mean the current approach underestimates need in some places. This research aims to calculate the amount of "unmet need" in different areas across the UK so that the formulae can be adjusted for this. This will mean that NHS resources can be shared out more fairly between places, so that places with more unmet needs receive more money to improve access for groups of people who aren't currently receiving the care they need.

In this research we will measure unmet need in two ways. First we will identify how the current formula can be changed to account for the fact that some population groups (e.g certain ethnic groups) use fewer health services than we would expect. Secondly using high-quality survey data alongside linked health service and mortality data, we will estimate how many people there are in each part of the UK with unmet needs for health care. Specifically we will estimate the number of people who have a chronic health condition but have not yet been diagnosed or received treatment. We will estimate how much it would cost to treat these people and propose an adjustment to the formula that would provide sufficient additional resources to each area to allow local health services to do this. Finally we will work out how making this adjustment will affect overall levels of health and differences in health between places in England.

The research will indicate improvements in the way NHS resources are shared out between places to better meet people's needs and demonstrate the impact these changes are likely to have on health and health inequalities. It is expected that this will lead to more investment in areas with higher unmet needs leading to improved health outcomes in those populations.

2. Summary of Research (abstract)

The NHS allocates a total of £87 billion to Clinical Commissioning Groups in England to fund healthcare using formulae that aim to estimate the level of need in each area. These formula largely use the historic patterns of utilisation as a proxy indicator of need. There is a concern, however, that these formulae do not sufficiently take into account the level of unmet need in a CCG. In other words people who could benefit from healthcare but do not currently receive it. Whilst premature mortality rates in each area are used to adjust funding to take account of this and address health inequalities, we do not know whether this adjustment accurately reflects variation in unmet need between areas. Better measurement of unmet need, would lead to more investment in areas with higher unmet needs leading to improved health outcomes in those populations.

Whilst there is evidence indicating that significant unmet needs for healthcare exists, a recent systematic review concluded that there is little useable evidence for measuring variation in unmet need between geographical areas that could inform resource allocation.[1] We will address the gaps in this evidence base using the best data and methods available to estimate the level of unmet need in each CCG in England. Firstly we will develop our conceptual understanding of unmet need for healthcare as it relates to resource allocation through a review of the literature and through engagement with members of the public, policy makers and health service experts to develop a typology of different approaches. Secondly we will systematically test out modifications to the current formula to develop approaches that better take account of unmet need. Thirdly we will use multiple high-quality nationally representative data sources alongside local data on risk factors and diagnosed prevalence to construct a

dynamic microsimulation model for key chronic conditions providing an adjustment for unmet need based on the additional healthcare costs required in each CCG to treat those previously undiagnosed. Recognising that an objective for resource allocation is also to contribute to the reduction in avoidable health inequalities we will use data on historical changes in funding to estimate the impact of increased funding on health outcomes. The will be used to estimate the effect of alternative adjustments for unmet need on health inequalities.

The research will produce a set of alternative and complementary adjustments for unmet need that can be used in resource allocation formulae. Alongside this we will produce a rigorous assessment of the uncertainties and assumptions of each approach and the likely health inequalities impact of these adjustments. The open source microsimulation model produced through the research will be available for use by local CCGs providing them with information on the populations most affected by unmet need, and the costs and benefits of addressing this problem.

3. Background and Rationale.

3a. Evidence explaining why this research is needed now

The current situation.

NHS England currently uses a set of resource allocation formulae to inform the distribution of its budget to local areas with the twin objectives of achieving equal access for equal need and contributing to the reduction of avoidable health inequalities.[2] There are 7 main funding streams, General and Acute (42%), maternity (2%), community (13%), mental health (9%), primary care(8%), prescribing(9%), specialised care (17%). For each of these funding streams specific formula are used to predict the needed level of healthcare expenditure in each area. These predictions are based on observed need variables (e.g. population size, age-sex structure, disease prevalence) and the estimated relationship between observed need variables and past utilisation of healthcare resources. The formulae first estimate healthcare expenditure as a function of need and supply variables and then apply the coefficients to predict expenditure as if supply variables were fixed at an average level across England. This means that any variation in the predicted expenditure depends on need variables only. This method is referred to as the "utilisation approach".

As these formulae are based on past utilisation, they may not adequately capture differences between geographical areas in unmet need for cost-effective healthcare. We use the phrase "cost-effective" here to emphasise the point that some unmet need for healthcare is inevitable in any resource-constrained system. What is not inevitable, however, and what can potentially be addressed by an adjustment to the geographical allocation of the limited available national healthcare budget, is unmet need for cost-effective care. There are likely to be people who are not receiving cost-effective healthcare that they would benefit from, either because their needs remain unobserved (a problem of incomplete diagnosis and reporting) or because their observed needs are not cost-effectively treated, or a bit of both. Unmet need for cost-effective care may vary geographically in ways that differ from existing patterns of utilisation.

To address this issue of unmet need, and also to contribute to the related but different objective of reducing avoidable health inequalities, a proportion of overall funding is currently allocated based on the under 75 standardised mortality ratio (SMR<75) for small areas within each CCG. This proportion varies between funding streams from 15% for primary care, to 10% for Core CCG funding (general and acute, community, mental Health, maternity and prescribing) and 5% for specialised care.

Why is addressing unmet need in resource allocation important.

Unmet need for cost-effective healthcare may arise because there are insufficient services available to some populations (supply side factors), or because despite the availability of services, they are not accessed (demand side factors).[1] In practice, however, many "demand side" factors will be influenced by supply side characteristics, such as the acceptability and quality of care. Both supply and demand side factors have consequences for resource allocation policy. Supply side factors are likely to be more responsive to the allocation of additional resources, whilst addressing demand side factors may have cost consequences, for example increasing awareness of a service will increase utilisation and increase costs. If a CCG does not have sufficient funds to cover these increased costs, this would disincentivise activities to increase access. The aim of addressing unmet need in resource allocation policy is to allocate sufficient resources to each CCG so that they can provide equal access for equal need. Better measurement of unmet need, will lead to more investment in areas with higher unmet needs leading to improved health outcomes in those populations. Our previous work has shown that improvements in NHS resource allocation policy can have a large impact on population health and health inequalities. [3]

Gaps in the current evidence.

There are a number of gaps in the evidence base, with a recent systematic review concluding that there is little useable evidence for measuring variation in unmet need between geographical areas that could inform resource allocation.[1] We do not know whether the current adjustment of the formulae using SMR<75 is effective as we do know how patterns of unmet need relate to the distribution of premature mortality.[4]

One approach to address this issue has been to better account for unmet need within the utilisation model, and some improvements have been made based on previous reviews.[5] For example by better adjusting for measures of healthcare supply, some supply induced unmet need can accounted for. The formulae also include some counter intuitively signed coefficients (e.g. a negative sign on ethnicity indicating that non-white individuals have lower utilisation than white individuals) that are thought to indicate unmet need. These coefficients are set to zero in the prediction model - a process referred to as sterilisation. This means that, for example, even though some ethnic minority populations have lower than expected levels of utilisation, they do not end up with lower needs weightings.[5] There is not however any systematic identification of population groups with consistent under-utilisation and the inclusion of these groups in the formula estimation could mean that the existing utilisation approach reinforces unmet need. Similarly if there is systematic under diagnosis amongst some population groups, the formulae may underestimate need in these groups. As Morris et al (2010)[5] highlighted, as the utilisation approach is based on the average relationship between need variables and utilisation, rather than the relationship in the best performing areas, the coefficients are likely to be a biased by under and over utilisation.

A second approach has been to directly estimate the prevalence of undiagnosed conditions and how this varies between places – referred to as the epidemiological approach. [6,7] These approaches have initially estimated the total undiagnosed and diagnosed prevalence of chronic diseases within small areas using representative national survey data (e.g The Health Survey for England). This has then been compared to the diagnosed prevalence of disease as recorded in clinical datasets (e.g the Quality and Outcomes Framework) to provide estimates of the undiagnosed prevalence.[6,7] There are, however, a number of major limitations with this approach for assessing unmet need. Firstly many of the population prevalence estimates available[6,7] derived from national surveys are based on self-reported measures that in turn will be influenced by a respondents access to diagnosis and treatment. Comparisons between these estimates and prevalence in clinical records will not therefore reflect the level of undiagnosed conditions. Work for the Advisory Committee on Resource Allocation (ACRA) exploring this[8] only identified prevalence estimates for depression, diabetes and hypertension, that could be used to estimate the prevalence of undiagnosed conditions in small areas. A

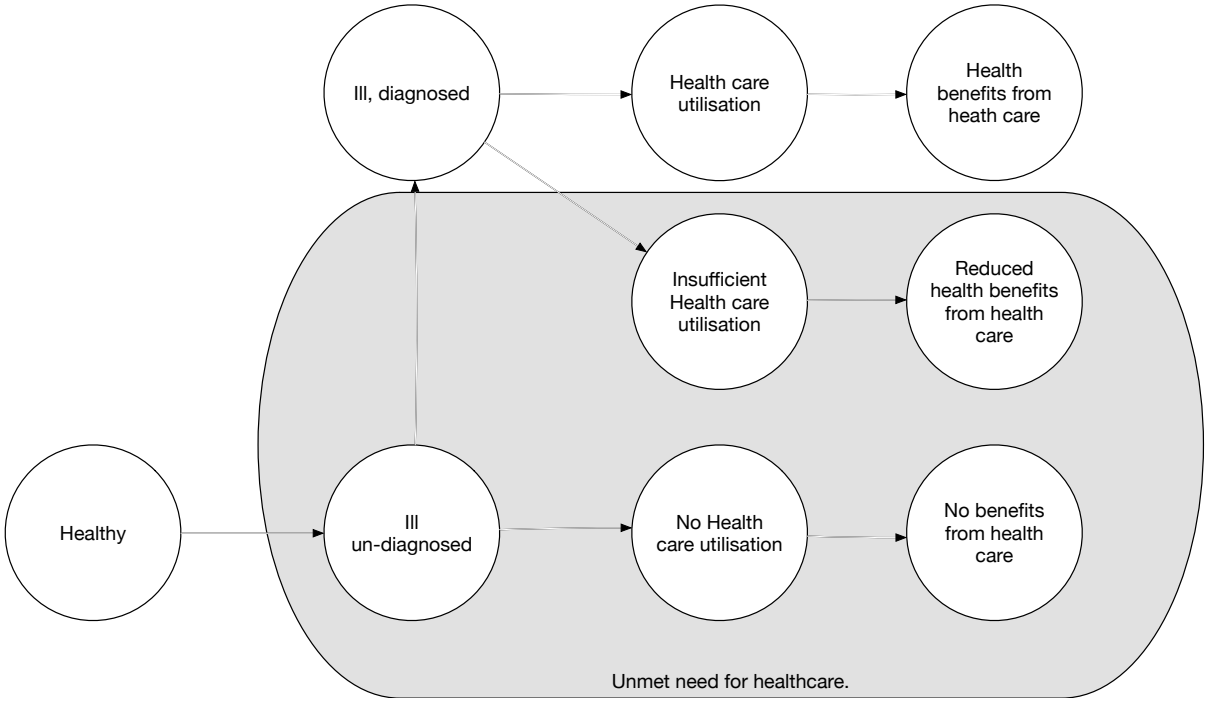
limitation of previous approaches is that they have not utilised recent advances in disease epidemiology modelling that triangulate between multiple data sources (e.g survey data, utilisation data and mortality statistics) to enable calculation of a complete and internally consistent description of disease epidemiology from partial data.[9] Whilst more recent methods using cross-sectional microsimulation methods[6] have led to more stable small area measures they have not reduced the biases related to the limitations of the source survey data. A further limitation is that it has not previously been possible to translate these estimates of undiagnosed prevalence into a measure of unmet need. People with undiagnosed diseases will have different needs for health care based on their undiagnosed health condition, the stage of the disease, comorbidities, their age and socioeconomic circumstances. In order to translate estimates of undiagnosed prevalence of multiple diseases into global measures of unmet need for particular populations a dynamic approach is needed to estimate the costs of diagnosing and treating previously undiagnosed disease and how this varies by diagnosis, stage of disease progression and sociodemographic characteristics.

Our approach:

Figure 1 outlines our basic conceptual model. We distinguish two main types of unmet need for healthcare during a given time period:

(1) under-diagnosed need which occurs when people are not receiving any effective healthcare because their needs have not yet been diagnosed and
(2) under-treated need which occurs when people with diagnosed needs are not receiving a cost-effective quantity of healthcare.

Figure 1. Conceptual model for unmet need for healthcare.



Both types of unmet need will be influenced by both “supply” factors such as the quantity of healthcare provision and the care-providing behaviour of health professionals and “demand” factors such as the socioeconomic, demographic, epidemiological and care-seeking

characteristics of the population. In accordance with the commissioning brief, we set aside cases of unmet need involving sub-optimal quality of care – for example, when people are not receiving cost-effective healthcare because their needs have been wrongly diagnosed or their treatment is poor quality. Unmet need in a given year can be measured in various ways, including (1) the proportion of the population undiagnosed or receiving an insufficient quantity of care, (2) the additional healthcare costs associated with diagnosing and/or treating these people's health conditions cost-effectively or (3) the additional health benefits of diagnosing and/or treating these people cost-effectively. The second and third metrics may focus on costs and health benefits in the current year only or also may consider long-run cost savings and health benefits. We will look at all three metrics, with and without consideration of long-run effects. The second metric is of primary interest, however, since the aim of NHS resource allocation policy is to allocate sufficient resources to each CCG so that they can provide equal access for equal need. For the purposes of resource allocation we are concerned with how unmet need differs systematically between places. For simplicity we focus primarily on unmet need for care provided through three funding streams:

(1) general and acute care (as it is the largest budget),
(2) mental health (as there is suspicion of high unmet need and the services are expanding), and
(3) primary care (as it is key to population health and in determining routes of access to other services).

The relationship between unmet need and health inequalities is complex. In general, unmet needs may tend to be concentrated among people who are worse off in terms of expected lifetime health – for example, socioeconomically disadvantaged people. However, this correlation is by no means perfect: people who are well off in terms of expected lifetime health may also have unmet needs (e.g. older and socioeconomically advantaged people). So reducing inequalities in lifetime health may require that some people's unmet needs are prioritised over others (e.g. younger and socioeconomically disadvantaged people over older and socioeconomically advantaged people). And indeed it is even possible that better allocation of resources to address unmet need could potentially *increase* inequality in the distribution health and well as decrease it.[10] It is essential, therefore, to examine the effect of any resource allocation adjustment for unmet need on social inequality in the distribution of health.

Our proposal builds on existing research, addressing the issue from a number of different but complementary angles.[5] Recognising that there is considerable debate concerning: what we mean by unmet need?, how it should be measured?, what are the main causes of unmet need? and whether some people's needs should be prioritised over others? we propose an process of engagement with members of the public, policy makers and health service experts to develop a typology of different approaches. (see work package 1). In deriving adjustments for unmet need we start with improvements that can be made to the current utilisation formula, building on the recommendations of Morris et al[5] and on recent methodological developments in risk-adjustment. (see work package 2). Building on the Academy of Medical Sciences report [4] that highlights the potential for longitudinal studies that combine activity data with modelling, we will use these methods to construct a dynamic microsimulation for key chronic conditions providing an adjustment for unmet need based on the additional healthcare costs required in each CCG to treat those previously undiagnosed (see work package 3) Recognising that an objective for resource allocation is also to contribute to the reduction in avoidable health inequalities we will use data on historical changes in funding to estimate the impact of NHS funding on health outcomes and use these to estimate the effect of alternative adjustments for unmet need on health inequalities (see work package 4).

4. Aims and objectives.
This programme of research will address the following objectives through 4 linked work packages outlined below.

5. To understand alternative concepts of unmet need, its measurement, potential causes and their implications for NHS resource allocation and health inequalities.
6. To examine whether the methodology of the utilisation approach used in the national resource allocation formula can be enhanced to address unmet need.
7. To estimate variation in unmet need by assessing the healthcare costs of diagnosing and treating the estimated prevalent cases of undiagnosed chronic conditions in each CCG.
8. To estimate the heath impact and health inequalities impact of alternative adjustments for unmet need.

5. Research Plan / Methods

Work Package 1 (WP1). Understanding unmet needs for healthcare. (Objective 1)
WP1 will develop the conceptual understanding of unmet need for healthcare as it relates to resource allocation between geographic areas and health inequalities. It will utilise a process of review and stakeholder engagement to iteratively develop our model of unmet need for use in resource allocation policy. We will initially conduct a review of the alternative theoretical perspectives relating need (unmet and met) and health inequalities to resource allocation policy, utilising methods used in previous systematic reviews of theory.[11] The review will follow a series of steps. Firstly we will develop an overall framework and concept mapping – based on our existing knowledge and known literature. This will identify broad theories and concepts and inform a systematic search of the literature, including database searches, citation tracking and consultation with key field experts. This literature will be used to clarify concepts in the overall framework and uncover theories and contrasting perspectives that may have been missed from the broad framework. The conceptual model will then be developed based on the review, highlighting causes and components of unmet need and their consequences for measurement, and the potential implications of alternative approaches for health inequalities.

Recognising that resource allocation decisions are a combination of technical decisions and value judgement, members of the public and a diverse group of policy makers and other stakeholders will be engaged in informing our research process from the beginning. This work has started with the establishment of a Public Involvement Panel (PIP) who have helped develop and inform this proposal. The membership of the PIP will be extended to include 10 members of the public from a diverse range of backgrounds, ages and localities, including representatives of patient groups that have previously had poor access to healthcare. They will be supported through our extensive public engagement infrastructure provided through the NIHR NWC ARC (see public engagement section). Our Expert and Stakeholder Advisory group (ESAG) will include representative from the PIP as well as academic expertise from diverse backgrounds (economics, epidemiology, history, philosophy), NHS England and local commissioners and providers.

Through a series of facilitated workshops we will refine and expand our conceptual model developed through the literature review. This will initially include 1 workshop with the PIP, one with the ESAG and a joint workshop. These workshops will be used to develop the logic model of pathways to unmet need that will inform the analysis and modelling in the subsequent WPs. They will explore potential trade-offs and synergies between using resource allocation policy to meet needs and reduce health inequalities, explore alternative approaches to measuring unmet need and the acceptability of weighting benefits in different populations to address health inequalities.[12] A final series of three workshops will take place following the analysis and modelling in work packages 2-4, involving the public and stakeholders in reviewing the

findings discussing the model assumptions, gaps in the evidence and how to best to communicate findings to the public and other stakeholders.

Work package 2 (WP2): Enhancing the utilisation approach to address unmet need.
The person-based formulae currently used for resource allocation are based on the utilisation approach. This approach uses regression techniques to derive estimates of needs based on national average relationships between utilisation and measures of socioeconomic status and morbidity, after controlling for supply. Differences in the extent to which needs are met across areas and population groups are currently addressed by sterilising the effects of sociodemographic variables with counter-intuitively signed coefficients and supply variables. These supply variables include fixed effects for each CCG, which removes differences across CCGs that generate differences in average levels of utilisation, for example historic levels of funding. However, concerns remain that the existing utilisation approach reinforces unmet need.

In WP2 we will consider whether unmet need can be better addressed within the utilisation approach by re-considering the three core elements of the utilisation approach:

- variations in levels of utilisation (the dependent variable)
- variations in the needs variables (the independent variables)
- variations in the effects of the needs variables on levels of utilisation (the coefficients)

We describe the methods we will use as if each is independent, but clearly they are interlinked and we will consider them in combination. The key feature of WP2 is that it is based on developing the current utilisation method. It will build on the Morris et al (2010) review[5] and exploits new datasets and new linkages at the person level, over time and across an extended set of services. We will apply these approaches to three formulae: General and Acute[13]; Mental Health[14]; and Primary Care.

*Adjustment 1: Unmet need in the dependent variable (*levels of utilisation)
Unmet need may appear in the dependent variable as atypically low values. We will examine whether utilisation is lower than expected through random chance by examining data over a long period and by looking for utilisation “holes” clustered by area or population group. This will be a development of the inconsistent way that sociodemographic variables with counter-intuitive signs (e.g. minority ethnic groups) have been handled in previous formula reviews. We will identify consistent under-utilisation in a variety of ways and by different groupings, including age groups, ethnic groups, GP practice types, and urban, rural and coastal areas. We will examine how the formula changes when the observations with consistent under-utilisation are removed from the regression estimation of the needs variable coefficients.

Adjustment 2: Unmet need in the independent variables (needs variables)
Some of the most important independent variables are the diagnostic indicators derived from primary and secondary diagnoses reported in hospital activity data. Unmet need may appear in these independent variables as unrecorded diagnoses. We will develop an adjustment to account for differences in diagnosis identification and recording across providers. If a provider does not diagnose or report secondary diagnoses then the extent to which chronic conditions and multi-morbidity influence need will be under-estimated.

We will use the approach proposed by Finkelstein (2017)[15,16] to measure differences in diagnostic intensity across providers. This approach uses patterns of movement of individuals across providers and areas of the country to separate true need and diagnosis differences between individuals from recorded differences generated by providers. We will use data on individuals who move between providers and geographical areas to estimate how utilisation and diagnosis records are affected. The matrix of effects defined by origin and destination

providers/areas shows whether particular providers/areas tend to under- or over-record utilisation and diagnoses. This approach will pick-up unmet need through changes in the completeness of the recording of secondary diagnoses in hospital records and referrals for elective procedures when individuals register with new GP practices. It could be used to generate provider- or CCG-specific adjustment factors for under-recorded diagnoses.

We will also use data from the Clinical Practice Research Datalink (CPRD), which includes de-identified patient data from around 20% of GP practices in the UK (~ 11 million patients) linked to Hospital Episode Statistics. This analysis will examine whether there are systematic differences between population groups (including gender, age, ethnic group, area deprivation and rurality) in the extent to which primary care diagnoses are reflected in the secondary care diagnostic flags used in the formula and have additional predictive value for variations in utilisation. This could be used to generate unmet need corrections for particular population groups in the short-term and will indicate the value of national data linking primary and secondary care utilisation in the longer-term.

Adjustment 3: Unmet need in the coefficients on the needs variables (the effects of the needs variables on levels of utilisation)

The inclusion of fixed effects for each CCG in the regression model used to estimate the coefficients on the needs variables ensures that the model only exploits within-CCG variation. The pooled national coefficients that are used in the formula are approximately the average values of the coefficients from each CCG. There will be variation between CCGs in the extent to which levels of utilisation respond to variations in need between areas and population groups. This may be because of inadequate resource allocation processes, poor planning of services or historical failure to engage with some population groups. We will explore the variation between CCGs in the needs coefficients because unmet needs may appear as unusually low coefficients in some CCGs.

To distinguish natural, random variation in the coefficients from systematic variation, we will systematically identify CCGs that may have higher levels of unmet need according to a range of process, quality and outcome indicators. We will select them based on the theoretical framework developed in WP1 and the associated discussion with stakeholders and patient groups. Examples of potential measures include indicators from: the CCG inequality monitoring framework; the CCG Assurance Framework; and the Right Care toolkits. We will rank CCGs based on each indicator separately and on a composite indicator. We will examine whether these CCGs that perform poorly on these measures have lower than expected needs coefficients and test how the exclusion of these CCGs from the national regression model changes the estimated coefficients used to calculate the needs shares for all areas.

Data
We will use person level data for five financial years (2013/14 to 2017/18) linked across a range of administrative data sources, including:

a) The patients registered with a GP in England at 1st of April of each year, their demographic characteristics, GP practice of registration and Lower Super Output Area (LSOA) of residence from the Personal Demographics Service (PDS)[17]
b) General and Acute secondary care service use from Hospital Episode Statistics (HES)[18], covering admitted patient care, outpatients and accident and emergency care;
c) Mental health and learning disability service use from the Mental Health Services Dataset (MHSD)[19] and Improving Access to Psychological Therapies Dataset;

These data will be accessed through the NHS Digital Data Access Request Service(DARS) and used with aggregate data for providers, GP practices and socioeconomic conditions in LSOAs, as used in the utilisation formula. This aggregate data is available as Open Data from NHS Digital and the Office for National Statistics(ONS). Whilst linkage between PDS and other

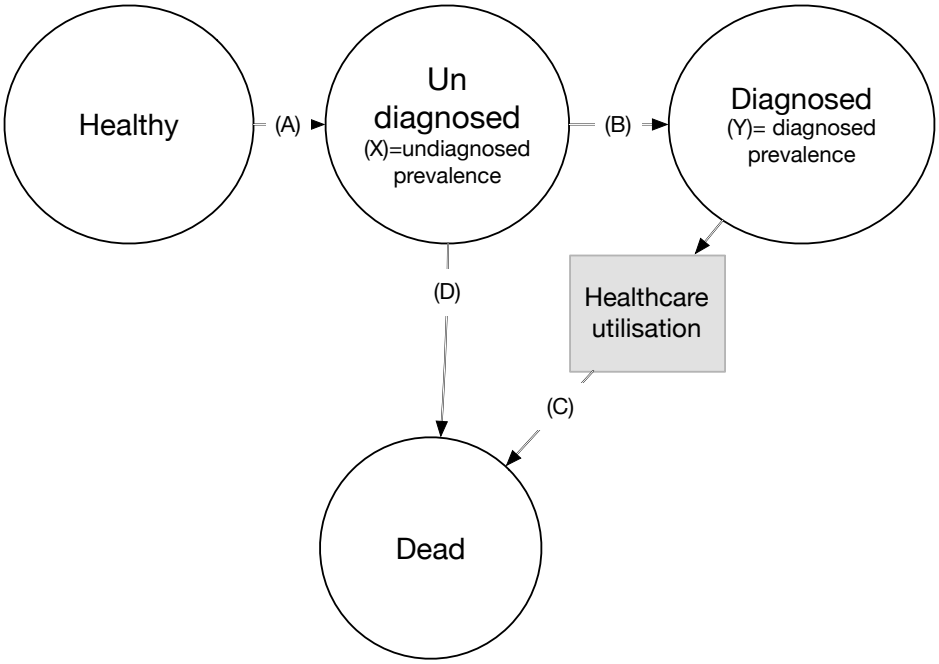
datasets is planned by NHS digital[20] if this is not available within the time frame for the project we will use aggregated registrations data (by age, gender, LSOA and GP practice), as we have done previously. In addition we plan a secondment with the NHS England Data Analysis and Intelligence Services (DAIS) which owns the National Commissioning Data Repository (NCRD) providing access to the datasets outlined above. Data from GP clinical records linked to Hospital Episodes Statistics will be obtained through the Clinical Practice Research Datalink (CPRD) using our existing Multi-Study user licences held by Manchester and Liverpool Universities.

Application of adjustments to the formulae.
The weighted capitation formula will be adjusted through the correction of the GP practice-age-gender need weights for unmet need. The adjusted weights will feed into the formula directly. These weights will be generated by using the coefficients produced from adjustment 1 and/or adjustment 3, implemented separately or together, and by imputing a corrected probability for each diagnostic flag produced from adjustment 2. The extent to which the three routes to unmet need currently affect the need estimates produced with the formulae, and the extent to which these overlap, will be tested as part of the project. Should unmet need affect the need estimates through more than one route, the adjustments will be applied simultaneously by using corrected coefficients and corrected probabilities for each diagnostic flag. These adjustments rely on the same utilisation datasets that are used in the main formulae. These can therefore be updated on the same basis and with the same regularity - i.e annually if necessary.

Work Package 3 (WP3). Estimating unmet need due to undiagnosed / late diagnosed conditions.

WP3 will significantly improve upon previous approaches[6] to estimate the extent of under diagnosis and late diagnosis, for chronic conditions in each CCG. Unlike previous methods we will use new techniques that triangulate multiple data sources (survey, utilisation and mortality data) to estimate undiagnosed incidence and prevalence across a wide number of diseases. We will focus our efforts on diseases with high burden on the UK population according to the Global Burden of Disease project, namely; CHD, stroke, COPD, diabetes mellitus type 2 (T2DM), dementia, asthma, breast cancer, prostate cancer, lung cancer, colorectal cancer, skin melanoma, depression, and hypertension.[21] By using dynamic, rather than crossectional[6] microsimulation techniques, we model transitions between disease and treatment states (see Figure 2), over time, estimating the likely healthcare costs of identifying and treating people with undiagnosed conditions. Essentially for each individual in the microsimulation model this involves estimating the probability that they develop a health condition (A) in each time period, the probability that these are diagnosed (B) and condition specific mortality risk in each state (C, D). People in the diagnosed state utilise healthcare resources (see Figure 2). Each of these probabilities varies by individual characteristics (age, sex, ethnicity, area deprivation, comorbidities) and area characteristics - including area based measure of historical risk factors (smoking, obesity), attributable mortality and local estimates of diagnosed prevalence. The advantage of characterising the extent of undiagnosed conditions in a CCG as a dynamic microsimulation model, as opposed to the static approach used in previous prevalence models[6], is that it enables the costs and benefits of diagnosing and treating previously undiagnosed cases to vary depending on sociodemographic variables, comorbidity and length of time that the condition has remained undiagnosed.

Figure 2. Four state chronic disease model.



Initial estimation of parameters.
For each of the conditions outlined above we will utilise the most appropriate sources to estimate their incidence, diagnosis rate, diagnosed and undiagnosed prevalence and attributable mortality rates (Table 1 below) building on the previous work of the Non-Communicable Disease (NCD) Modelling Group in Liverpool. We will further check these estimates for consistency using DISMOD II.[9] DISMOD II is a model designed to estimate epidemiological parameters of diseases where measured data are incomplete but most importantly to check the internal consistency of the observed epidemiological parameters. For example, when DISMOD II is informed by at least four of the observed incidence, prevalence, relapse, case fatality and mortality rates for a disease it can check their internal consistency and align them if necessary. When disease attributable mortality is among the inputs of DISMOD II, the aligned disease incidence and prevalence rate outputs from DISMOD II, are closer to the 'true' disease incidence and prevalence rates (including undiagnosed cases) because disease attributable mortality includes undiagnosed cases. For some conditions, undiagnosed prevalence can be directly estimated from the data where clinical measurements and/or validated screening instruments are included in surveys (e.g Hypertension, T2DM, COPD, Depression, Dementia – see Table 1). Where data is not directly available on undiagnosed prevalence (CHD/ Stroke/ Cancer), these will be estimated from DISMOD II as the difference between the estimates of the true incidence, derived from attributable mortality and case fatality rates and the diagnosed incidence found in clinical datasets (CPRD).

We can estimate the undiagnosed prevalence if we know Y (the diagnosed prevalence), C - the mortality rate in the diagnosed (case fatality rate), the overall disease specific mortality rate in the population and the mortality risk reduction associated with diagnosis and treatment. We will estimate Y, C and the overall disease specific mortality rate (Z) from our data. We will

use the mortality risk reduction associated with treatment derived from reviews of intervention studies to calculate D from C. Having calculated these for a particular population group we can then estimate the undiagnosed prevalence which can be shown to equal to: (Z-C*Y)/D). We will stratify all analysis by age, sex, deprivation, and ethnicity. The main data source in these calculations, CPRD has data on 45 million patients – this will provide sufficient sample within each subgroup (mean = 15,555) to meaningfully obtain estimates of the incidence of diagnosed cases within these groups. For example, for the condition with the lowest diagnosed prevalence – dementia (0.8%) – this would include an average of 120 cases in each sub group.

For diseases with high mortality rates (CHD/Stroke/Cancer) we will further utilise CPRD data linked to HES and mortality data to estimate the proportion of deaths from these that were previously undiagnosed (i.e. those without a prior clinical record of diagnosis in the data), and how this varies by sociodemographic characteristics, to refine our estimates of undiagnosed prevalence, using back calculation techniques.[22,23] Unlike previous small area prevalence estimates we will only use data on risk factors, biometric measurements, validated symptom screening instruments and mortality to estimate undiagnosed incidence and prevalence. By triangulating across multiple datasets our approach will provide more robust estimates of undiagnosed incidence and prevalence than previously possible.

Table 1. Data Sources.

Disease	Measure and sources
CHD/stroke	*Diagnosed incidence and prevalence* - Self-reported diagnosis Health Survey for England (HSE) Clinical Practice Research Datalink (CPRD), Quality and Outcomes Framework(QOF) and Hospital Episode Statistics (HES). *Attributable mortality* - ONS Mortality Registry
Breast, prostate, lung, colorectal and skin melanoma cancers	*Diagnosed incidence* by stage of cancer at diagnosis and 5- year survival - Cancer registry. *Diagnosed incidence and prevalence* – CPRD, QOF and HES. *Attributable mortality* - ONS Mortality Registry
COPD	*Undiagnosed prevalence* - Spirometry – HSE. *Diagnosed incidence and prevalence* - Self reported diagnosis(HSE), CPRD, QOF and HES. *Attributable mortality* - ONS Mortality Registry
Asthma	*Undiagnosed prevalence* - Validated asthma questionnaire – Millennium Cohort Study (MCS), Spirometry in Adults - HSE *Diagnosed incidence and prevalence* - Self reported diagnosis (HSE, MCS), CPRD, QOF and HES. *Attributable mortality* - ONS Mortality Registry
Dementia	*Undiagnosed prevalence* - Cognitive function test - English Longitudinal Study of Ageing (ELSA). *Diagnosed incidence and prevalence* - CPRD, QOF and HES. *Attributable mortality* - ONS Mortality Registry
T2DM	*Undiagnosed prevalence* - HbA1c - HSE *Diagnosed incidence and prevalence* - CPRD, QOF and HES. *Attributable mortality* - ONS Mortality Registry
Hypertension	*Undiagnosed prevalence* - BP measurements (HSE) *Diagnosed incidence and prevalence* - Use of anti-hypertensive medication – HSE, CPRD, QOF and HES. Attributable mortality - ONS Mortality Registry
Depression	*Undiagnosed prevalence* – The following validated depression scales: The Clinical Interview Schedule-Revised (CIS-R) - Adult Psychiatric Morbidity Survey(APMS). Mental Health Component Score (MCS) of the 12 item short form survey (SF12) - Understanding Society panel survey. The Centre for Epidemiological Studies-Depression scale (CES-D)-ELSA. *Diagnosed incidence and prevalence* – Self reported diagnosis (APMS,US,ELSA), CPRD, QOF.

Developing the microsimulation model

We will develop a dynamic microsimulation model for the population of England providing estimates at the CCG level. This creates a synthetic population for England with people moving between the states outlined in Figure 2 (replicated for each condition). The transition probabilities for this model are estimated using the various datasets and methods outlined above. These estimates will vary based on a individual's sociodemographic characteristics and the characteristics of the region and CCG where they live.

The data sources used to construct the model are available at various geographical levels. Due to the sample size most of the survey datasets can only be used to derive estimates for age, sex, deprivation, and ethnic groups within the 9 English regions. Initially we will

construct the model using these estimates of the transition probabilities, adjusting them to be consistent with regional estimates for diagnosed incidence, case fatality and attributable mortality derived from CPRD, HES and mortality data. We will then utilise techniques for small area estimation,[24] to apply these to CCG populations stratified by age, sex, deprivation, and ethnicity to provide an initial CCG model. In a final step we further calibrate the model for each CCG to be consistent with diagnosed prevalence estimates from QOF , the condition specific mortality rates for that CCG and local risk factor data. For example, our method will allow areas with higher historic levels of smoking to have higher diagnosed and undiagnosed incidence of COPD and other smoking related diseases based on well-established epidemiological causal links. Where areas have higher diagnosed prevalence rates estimated from HES and QOF, compared to that which would be expected based on their age, deprivation and ethnicity profile, our model will indicate greater diagnosis rates in those areas. The resulting model will be one that is consistent with all the available data at the CCG and the regional level. Our team has already applied these methods in a city level dynamic microsimulation for Liverpool[25] and is currently expanding the approach to other areas for the NIHR funded project workHORSE.

Estimating healthcare utilisation costs and deriving unmet need adjustments.
Within the microsimulation model we will calculate the utilisation of healthcare resources for people diagnosed, dependent on their health condition, socio-demographic characteristics comorbidities and time since diagnosis. Estimates of the costs of this healthcare utilisation will be calculated from CPRD data, linked to HES and MHSD. These costs will be broken down into those that would accrue to General and Acute Services, Primary Care and Mental Health Services. Based on the estimates of transition probabilities for each individual in the simulation model as outlined above, they can develop multiple conditions. We will explicitly estimate the costs associated with these patterns of comorbidity and how they change based on time since diagnosis using CPRD data. As CPRD includes 45 million patients it provides sufficient data to estimate how costs vary by time since diagnosis and for multiple conditions.

By modifying the diagnosis rates in the model so that all CCGs have the highest diagnosis rate observed, the increased healthcare costs calculated from the model, for each CCG, will provide an estimate of the additional healthcare costs required to treat previously undiagnosed cases of disease. This measure of unmet need, will provide an estimate of the overall proportion of each funding stream (General and Acute Services, Primary Care and Mental Health Services) that should be allocated to address unmet need, and the weight each CCG should be given in that allocation. By calculating the mortality rate for each disease state, the model will also provide an estimate of the health benefits of treating previously undiagnosed cases.

Calibration, validation and sensitivity testing.
Our initial model will then be further validated and calibrated. To ensure face validity the model will be developed and tested with key stakeholders building on our conceptual framework developed in WP1. Internal validity will be supported through the triangulation of estimates from alternative data sources as outlined above. Validation against external datasets will include, (1) a comparison between the pattern of diagnosed prevalence, derived from our model with those reported through the Quality and Outcomes Framework, (2) a comparison between predicted patterns of acute health care costs for these chronic diseases estimated from our model, with those calculated from HES data, and (3) a comparison between pattern of predicted health benefits from the additional treatment of previously undiagnosed cases estimated from our microsimulation model and the pattern of benefits of this increase in healthcare resource estimated from the instrumental variable analysis in WP4 (see below). These comparisons will be used to further calibrate the model. Finally, we will perform rigorous

one-way and probabilistic sensitivity analysis to ensure our estimates are robust enough to be used for policy making.[26] The model specification will be flexible to allow for it to be updated regularly as new data becomes available and to be modified for alternative geographies, as the configuration the health system changes.

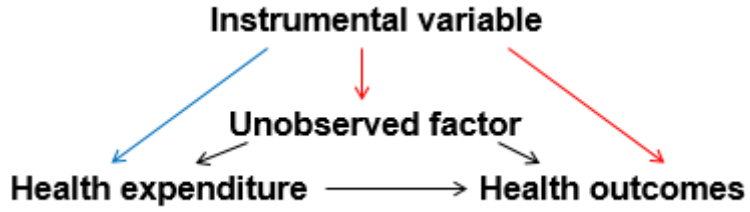
Updating adjustments
The microsimulation model utilises multiple datasets - household survey data, health care utilisation data (HES, CPRD, QOF), mortality data and sociodemographic data (census, population estimates). Updates for these are generally available on an annual basis (except the census). It will be feasible to update estimates on an annual basis, however as pooled data will be used for survey data, single year updates will probably make relatively small differences. We recommend therefore that the calibration of the model based on CCG diagnosed prevalence and mortality data is carried out annually and estimates from survey data are updated 3 yearly.

Work Package 4 (WP4). Estimating the health inequalities impact of unmet need adjustments.

WP4 aims to estimate the health impact and health inequality of proposed resource allocation adjustments for unmet need arising from WP 1, 2 and 3. It will do so by providing new estimates of the health impacts of NHS expenditure broken down by key equity-relevant characteristics (in particular, age and socioeconomic deprivation), and by applying those estimates to proposed adjustments for unmet need. It will also attempt to disentangle the differential health effects of NHS expenditure across two distinct funding streams - general and acute and primary care. Using a dataset of historical NHS budget allocations that we have developed for local areas across the UK covering nearly 2 decades (2001-2019) we will estimate the relationship between health gain and NHS investment for local areas defined by different population characteristics (in particular, age and deprivation). This estimated relationship will also be used to calculate the expected distributional impact of different resource allocation formulae with differing adjustments for unmet need to help inform equity-efficiency trade-offs when choosing between competing methodologies.

There are numerous challenges to overcome when estimating the relationship between health outcomes and healthcare expenditure. Two key challenges are that: 1. there are many determinants of health beyond healthcare that may be statistically associated with healthcare expenditure allocations; and 2. healthcare expenditure allocations are, by construction, a function of historical levels of health outcomes. In other words healthcare expenditure is endogenous. To account for endogeneity, previous work has employed instrumental variable strategies. Instrumental variables are required to be related with healthcare expenditures, but neither directly related to health outcomes nor some unobserved confounder (see Figure 3 – a blue arrow indicates a relationship that is required and a red arrow indicates a relationship that would invalidate the approach). Previous work considered a range of socio-economic variables as plausibly good candidate instrumental variables that were used when statistical tests indicated suitability.[27–30] More recent work has appealed to more theoretical reasoning exploiting exogenous variations in allocation formulae across upper-tier local authorities (market forces factor, age index and distance from target index).[31–33] These studies have analysed health outcomes, specifically mortality, by disease area within England and different types of health-related expenditures.

Figure 3. Conditions for good candidate instrumental variables



This analysis will employ the theoretically justified instrumental variable approach described above using data for 450 areas (lower tier local authority) across the UK over 20 years (more granular and over a longer period of time than previous research in this area). Unlike previous studies, outcomes beyond mortality will be considered, namely amenable mortality (ONS), health-related quality of life (GP Patient Survey), years of life lost, years of life disabled and disability-adjusted life years (Global Burden of Disease). Additionally analysis will investigate the differences in impact of different funding streams (primary care and G&A). The main analysis will consider the effects of these expenditures combined and of these funding streams individually. Also, a model where outcomes are related to both sources of expenditure included separately. Results generated over time will be analysed to consider how changes in the share that goes to primary versus secondary care has modified the effect of expenditure on health outcomes. Differential health effects by age and socioeconomic status will be estimated using three complementary approaches. First, by splitting the mortality outcome variable into separate components by age group and socioeconomic group to estimate how far NHS expenditure has differential mortality effects on different groups. Second, by using conditional average treatment effect models to estimate how far NHS expenditure in local areas with different population age structures and socioeconomic profiles has differential effects on the composite mortality outcome variable. Third, by conducting a simple modelling exercise that combines the average proportional health effect of expenditure with baseline mortality rates by age and socioeconomic group we will calculate the predicted differential health effect in absolute terms.

This proposed analysis presents further opportunities to be explored. First and foremost, panel data techniques will be used to better control for heterogeneity and improve the precision of estimates. In addition, over this time period a number of policy decisions were made to change the basis of the resource allocation formula, which provides a source of exogenous variations in healthcare expenditure over time ("natural experiments"). [3,34] Second, the length of panel enables time-varying and lagged effects of healthcare expenditure to be estimated. Third, more rigorous account of concerns relating to multiple testing can be taken by exploring joint estimation of outcome equations (using multivariate regression techniques)[35]. Fourth, the usual approach to estimating conditional average treatment effects is to stratify the sample into subgroups – for example, to see whether there is a difference in health effect between high deprivation areas versus low deprivation areas – using an interaction term. However, we will explore the potential of using more flexible methods for estimating conditional average treatment effects.[36]

These estimates of the effect of healthcare expenditure across different funding streams and how these differ by the sociodemographic characteristics of places will then be used to model the impact of alternative adjustments for unmet need on the distribution of health outcomes between CCGs and the consequences of this for health inequalities - in particular the difference in health between more and less deprived CCGs. Estimates of health effects will additionally be used to calibrate the estimate of the health benefits of treating previously undiagnosed cases, in the microsimulation model developed in WP3.

Dissemination, Outputs and anticipated Impact.
Our implementation strategy will take the findings from each work package through to changes in policy and practice. Three key target groups have been identified in this strategy. Firstly the public and their representatives who are affected by resource allocation decisions and who are able to influence policy through democratic processes. Secondly national NHS managers and analysts who are developing resource allocation policy. Thirdly local commissioners and providers who are seeking to identify and address unmet needs in their populations.

What we will produce from our research?
Firstly the research will produce several key outputs that will benefit the NHS through providing clear methodological indications on how to improve consideration of unmet need within CCG resource allocation and support local commissioners in addressing unmet needs. This will include

- A full research report detailing all the work undertaken and supporting technical appendices including an abstract and an executive summary suitable for use separately from the report as a briefing for NHS (health and social care) managers.
- A set of PowerPoint slides which present the main findings from the research designed for use by the research team or others in disseminating the research findings to the NHS.
- A cross-disciplinary conceptual typology for understanding unmet need for healthcare as it applies to resource allocation, outlining the consequences for measurement of each approach, in relation to the data available and current approaches, and the implications of different approaches for heath inequalities. This will include recommendations for improving administrative datasets to allow better analysis of need for healthcare. This will be produced as a policy brief for NHSE and as an academic paper.
- A set of 5 methods for adjusting the existing G&A, primary care and mental health resource allocation formulae, including:
    (1) Method for adjusting the formulae - when the population groups with consistent under-utilisation are removed from the regression equation used to estimate the formulae
    (2) Provider- and CCG-specific adjustment factors for under-recorded diagnoses.
    (3) Adjustments for particular population groups whose primary care diagnoses are not reflected in their admitted care diagnoses.
    (4) Method for adjusting the formula - when the observations from CCGs that may have higher levels of unmet need are removed from the regression equation used to estimate the formula.
    (5) An estimate from the microsimulation model giving a weighted population for each CCG indicating the distribution of the cost of diagnosing and treating previously undiagnosed cases of chronic disease.

  These methods will be outlined in 4 academic papers and one technical report for NHSE, including shareable statistical code that will allow the adjustments to be updated on a regular basis and for NHSE to replicate all analysis if necessary. In line with the allocations timeline, we will produce preliminary adjustments for 1-3 above by June 2021 that will be usable to inform allocations in 2022/23.
- An open source microsimulation model that can be used nationally and locally to provide estimates of (1) the level of unmet need in a population and (2) the likely costs and benefits of diagnosing previously undiagnosed conditions. The full code for the model will be published through the GitHub open source platform - https://github.com/, enabling the model to be easily updated as new data becomes available and adapted for alternative geographical configurations.

- We will produce an estimate of the population health impact of changes in NHS investment across key budget streams (G&A and Primary care) and how this differs for different age groups and deprivation levels. These will include estimates of the potential impact on differences in health between CCGs of alternative adjustments for unmet need. Full methods and findings will published in an academic paper and a policy brief to support discussion and decision making with respect to different adjustment options.
- Through our web-based data portal - https://pldr.org/ we will publish interactive data visualisations showing:
  - Age and sex specific estimates of the prevalence of common chronic health conditions for each CCG in England and the proportion that are undiagnosed.
  - The additional healthcare costs associated diagnosing and treating people currently undiagnosed chronic health conditions for each CCG in England.
  - Needs-weighted populations for each CCG based on the existing formula and alternatives using adjustments for unmet need derived from this research.
  - The potential impact on differences in health between CCGs of alternative adjustments for unmet need.
- Results will be further presented at national (Health Economics Study Group – HESG) and international (European Health Economics Association) conferences.

How will you inform and engage patients, NHS and the wider population about your work?
We will use our findings to change policy and practice by building on our strong engagement and networks with our three key target groups. Firstly with the public. Working closely with our Public Involvement Panel we will develop interactive web visualisations of our results enabling the public to explore the consequences of alternative adjustment approaches. These will be presented alongside public facing blogs explaining the findings to a wide public audience. We will support our PPI panel in co-producing all our dissemination output and developing their own dissemination – e.g through blog posts and through attendance as co-presenters at conferences. This will stimulate public debate about the potential trade-offs of alternative approaches. With our previous work we have found that such applications stimulate public debate in the national media. Alongside this we will produce a plain English guide to adjusting for unmet need and health inequalities in NHS resource allocation policy, including infographics, presenting these concepts in an easy adaptable form for a range of public audiences. We will produce briefs for elected representatives, and engage with parliamentary processes (e.g All Party Parliamentary Groups, Select Committees) to inform them of the research.

Secondly we will ensure that national NHS managers who are developing NHS resource allocation policy are engaged and informed about our work. Nationally our collaboration is well placed to ensure key decision makers are informed of the research with significant cross-membership between the project team and NHS England's Advisory Committee of Resources Allocation (ACRA) (Sutton, Cookson, Lake, Bentley) and its Technical Advisory Group (Chair: Bentley, member: Barr). The work will be further aligned with the needs of the NHSE resource allocation team through the inclusion on our advisory group of Stephen Lorrimer - Head of Analysis and Insight for Finance, NHS England and Robert Shaw, Lead Analyst- NHS England Data, Analysis and Intelligence Service. This will ensure that outputs are compatible with the requirements of NHS England. To support the integration of our analytical work with that of the NHSE's allocations team we will aim to arrange a secondment of one of the PDRAs with the team at NHSE to ensure methods and outputs are closely aligned. To support the translation of the findings into practice we will organise 2 Knowledge Exchange events in June 2021 and November 2022 with members of ACRA, TAG and key staff at NHSE Allocation team to present and discuss the findings.

Thirdly we will engage with local commissioners and providers who are aiming to identify and address unmet needs through our extensive networks with local NHS and public health organisations. Through the NHS long term plan all local health systems are required to set out how they are targeting funding to improve equity of access and outcomes, and they are increasingly looking for robust approaches for allocating resources across primary care networks. We will use our extensive knowledge translation and implementation infrastructure through the NIHR ARC NWC to adapt our utilisation formula methods and our microsimulation model to support the targeting of resources to better address unmet need within CCG populations.

Ethics.
The research only involves the secondary analysis of anonymised data there are still important information governance risks. The University of Liverpool Research Ethics Committee confirmed ethical approval was not needed. In order to use data from the Clinical Practice Research Datalink the research protocol will be submitted and reviewed by the Independent Scientific Advisory Committee (ISAC) (https://cprd.com/research-applications).

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