Full/long title of the study

Unlocking data to inform public health policy and practice: University of Sheffield

Short study title / acronym

Unlocking data: University of Sheffield

Protocol version number and date

Version 2 (Date: 17/05/21)

Research reference numbers

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RESEARCH REGISTRY Number: researchregistry6810

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.

For and on behalf of the Study Sponsor:

Signature:

Date:
13/05/2021

Name (please print): Dr Jennifer Burr

Position: Senior University Teacher

Chief Investigator:

Signature:

Date:
12/05/2021

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Study summary

Study Title	Unlocking data to inform public health policy and practice: University of Sheffield
Short title (Internal ref.)	Unlocking data: University of Sheffield (UoS Ref: 171949)
Study Design	Qualitative, Literature Review, Methodological
Study Participants	NHS CCG and Local Authority (LA; City Council) staff
Planned Size of Sample	N/A
Follow up duration	N/A
Planned Study Period	May 1st 2021 – February 28th 2022 (10 months)
Research Question/Aim(s)	To delineate the availability and potential of routinely collected administrative and service activity data to support commissioning decisions within and across sectors including LAs, CCGs, and Universities, in order to promote and protect health and prevent ill-health in local and regional settings.

Funding and support in kind

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
National Institute for Health Research (NIHR) Public Health Research (PHR) programme	£253,772
National Institute for Health Research (NIHR) Applied Research Collaboration Yorkshire and Humber (ARC-YH)	Non-financial support in kind

Role of study sponsor and funder

This study/project is funded by the National Institute for Health Research (NIHR) Public Health Research (PHR) programme (NIHR award identifier: 133634) with in kind support provided by the NIHR Applied Research Collaboration Yorkshire and Humber (ARC-YH; NIHR award identifier: 200166). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Roles and responsibilities of study management committees/groups & individuals

(1) Study Steering Committee (SSC)

The SSC will provide guidance on how the project is conducted and results disseminated. No financial reimbursement is provided to be a part of the SSC. All SSC members have been recruited through consultation with the key protocol contributors and chosen based on their knowledge, experience, or job roles pertinent to the study (e.g. public health, data analytics, health economics).

(2) Patient & Public Involvement (PPI) group

The PPI group has been recruited through consultation with our PPI Co-Ap (KS) with all PPI members funded by the NIHR based on the INVOLVE cost reimbursement framework.

Scientific abstract

Background

Routinely collected data is key to ensuring effective and responsive decision-making in Local Authorities' (LAs') commissioning of social care and some public health services, and in their collaborations with Clinical Commissioning Groups (CCGs) as the commissioners of most NHS services. Both parties are obliged to consider the within and cross-sector 'value for money' aspect of their commissioning decisions, including opportunity costs of alternative options in terms of beneficial outcomes relative to their costs - such aspects can be accounted for within economic evaluation (EE) frameworks. When using routine data to inform such decision-making there is a need to: (1) identify the data required to inform the commissioning process; (2) account for legal and information governance frameworks for storing, using, and sharing data, alongside other barriers and facilitators; (3) establish evaluation frameworks to enable the data to be used in transparent and useful ways, aligned to the requirements of the commissioning process.

Aim and work-packages (WPs)

To delineate the availability and potential of routinely collected data to support commissioning decisions within and across sectors including LAs, CCGs, and Universities, in order to improve public health in local and regional settings. Through four WPs and by fostering networks and partnership activities between academic research and public health practice, our objectives are:

- WP1: Mapping review of use and linkage of routine data in local/regional settings for commissioning decisions informed by LAs in England;
- WP2: Metadata specification and pilot metadata catalogue through stakeholder consultation;
- WP3: Workshops with stakeholder groups to explore the requirements of routine data to inform commissioning;
- WP4: Economic evaluation methods to analyse and present estimates from routine data to inform commissioning.

Methods

For WP1 we will search and then map the grey literature for examples of routine data being used to inform public health decision-making, used to inform WP2-WP4. In WP2, by working with key stakeholder representatives, we will develop a metadata specification and pilot metadata catalogue listing data assets from across all stakeholders with a focus on data and services associated with public health. Outputs from WP1&2 will inform WP3's series of workshops with stakeholder groups to explore the requirements, use, barriers, and facilitators of routine data to inform commissioning processes. Building on WP1-3, WP4 will explore and describe how quantitative methods informed by routine data can be applied to improve both the relevance and scope of EE to inform local commissioning. WP3&4 will focus on cross-sector commissioning of services specific to falls prevention.

Timeline & outputs

The project will be completed in 10 months. Outputs include: a report and slide deck; lay and technical executive summaries; metadata specification and pilot metadata catalogue; data extracts of the case studies.

Dissemination & anticipated impact

Findings will be disseminated locally, regionally and nationally through our extensive networks. This will initiate more evidence-based commissioning decisions through utilisation of routine data, stimulating joint working across LAs, CCGs, and universities, with support from NIHR infrastructure, with learnings for national change leading to more efficient allocation of scarce resources benefitting public health.

Plain English summary of research

Background

In England, many services that are paid for using taxpayers' money are decided on and funded by local government such as Local Authorities (LAs) and Clinical Commissioning Groups (CCGs). LA's are responsible for publicly funded social care (e.g. home-based services) and some public health services (e.g. sexual health services). CCG's are responsible for funding most NHS services in local areas. All local decision makers aim to fund services which promote and protect health and prevent ill-health in their locality. At the same time, they want to provide 'value for money' for the taxpayers. Such services and local decision makers often collect data to inform their processes. This data is used to support the services provided for individuals, but also for administrative reasons. This data could be used more often to help inform improvements to current services and funding of new services. This data could include potentially personal and sensitive information. As a result, it is important that such data is protected and only used or shared in circumstances when there is a clear and legal reason that would benefit the public.

What do we hope to achieve?

We hope to understand:
- what data is available to local decision makers;
- how they currently use it;
- how data could be used and potentially shared with parties who want to use it for public benefit.

We hope to explain how to best use and share data legally with clear reasons for its use. An example would be to help local decision makers calculate which services are considered 'value for money' and which are not. We hope that this will allow local decision makers to make the best use of money available to them.

How do we intend to achieve it?

We will first identify examples of when data has been used and legally shared to inform local decision making. We will then produce a detailed list of what data these local decision makers have available. These examples and data will then be discussed with people who work within the LAs and CCG – we have already identified people who are happy to be involved in our proposed project. This will allow us to further explore things to consider when using such data to inform local decision making. We will then explore and describe ways this data could be used to calculate what services are potentially providing 'value for money' when producing benefits for the public in local and regional areas. We will also explore and describe how the use of such information could be made more transparent and understandable for the public.

How long will this project take and what will we produce?

We will complete the project within 10 months in line with the National Institute for Health Research request. We will produce a report and slide pack in collaboration with the Universities, LA's, CCG's, and PPI members of this research group. We will be share findings nationally through our existing relationships and the NIHR groups.

Patient and the public involvement in the project

A lay co-applicant has helped to develop the research proposal and will be involved throughout the duration of the project. We will set up a public advisory group to meet with the research team and share their views.

How will this research change health and social care?

We believe that our research could start to change and improve how researchers and local decision makers use locally available data to decide which services to fund to benefit communities

Study protocol

1. Background and Scientific Rationale

Local Authorities (LAs) are responsible for commissioning publicly funded social care and, since 2013, some public health (PH) services. Routinely collected administrative and service activity data is key in supporting decision-making in LAs. Such routine data is vitally important for informing each stage of the yearly commissioning cycle (Figure 1 [1]). This is then used to determine which services will be commissioned/decommissioned, with associated impact on public health within a LAs local population.

Figure 1: The yearly commissioning cycle

The Better Care Fund encourages LAs to work with Clinical Commissioning Groups (CCGs), who have a statutory responsibility for commissioning most NHS services, by utilising joint working arrangements including integrated commissioning boards and pooled budgets. Due to the finite and restricted nature of the budgets available to achieve their within and cross-sector strategic planning objectives, evidence is needed on what services represent 'value for money' (i.e. what services are affordable within their budget while providing the most cost-effective option to achieve their strategic planning priorities). For example, in the remit of public health, areas of interest include health improvement/promotion, preventing ill-health, and protecting health [2, 3], the public health interventions for which are funded via finite budgets resulting in opportunity costs (i.e. which interventions to fund, or not, or even defund, based on the available budget). Although such 'value for money' considerations are explicitly built into some commissioning business cases, they focus mainly on costs (i.e. accounting processes) rather than consideration of opportunity costs alongside non-monetary outcomes, such as health gains and inequality impact. Also, due to organisational and technical barriers, there is a restricted capacity to share and analyse data which could inform these within and cross-sector commissioning processes. Subsequent consequences can include inaccurate and/or incomplete information informing commissioning decisions, resulting in unrealised future benefits, unrecoverable sunk costs once services have been procured, and difficult disinvestment decisions resulting in public, governmental, and political criticism.

Research evidence can support commissioning processes; however, as stated by Prof Whitty, CMO: "research carried out by academics at universities may not address the public health needs of the local authority where the research is being conducted. One of the best ways of tackling this issue is through the co-production of research". If local governments are to be engaged as full partners alongside researchers in the **generation** and **use** of evidence that informs commissioning decisions, the data and evaluation frameworks they use must be geared towards their local context and commissioning needs. In particular, there is a need to:

1. Identify the **data requirements** needed to inform each stage of the commissioning process, within and across sectors dependent on the scope of the commissioning decision and where short and long-term costs and outcomes may fall;
2. Account for **legal and information governance (IG) frameworks** for storing, accessing, and sharing data, alongside broader **barriers and facilitators** to access and use of data (e.g. staff skill and capacity, data systems) to help inform the commissioning cycle;
3. Establish **evaluation frameworks** to enable the data to be used in a transparent and useful way aligned with what is needed to inform each stage of the commissioning cycle.

1.1. Data requirements and legal and IG frameworks

The Data Protection Act 2018, which applies the General Data Protection Regulation (GDPR), was the first major change to UK data protection legislation since 1998. The GDPR formalises the notion of ‘data controller’ and ‘data processor’, including responsibilities when handling data. Beyond GDPR, there is a 'duty of confidentiality' based in common law that means that when someone shares personal information in confidence, it must not be disclosed without some form of legal authority or justification. The Eight Caldicott Principles apply to the use and sharing of personal information by clarifying the basic principles of the GDPR as applied to UK health and social care data. The aforementioned relates to “personal data”, but data can (and, under GDPR, should if possible) be de-identified. De-identified data shared with another party, under suitable legal/technical controls that ensure there is no reasonable likelihood of re-identification, may not be “personal data” to the recipient party. Data controllers may also act jointly to share and link data with one another, potentially with a ‘data processor’ to ensure the shared, linked data are “pooled” and only available in de-identified form under suitable controls with negligible re-identification risk.

A report in 2020 [4] identified particular areas of challenge for NHS Data services, which included: implementing new datasets; allowing easier access by users to its data; and improving the quality of data and extending the data collected. These issues are pertinent across all local government agencies, not just NHS Data services, particularly with the use of data playing an increasing role in designing, delivering and transforming public services to improve outcomes and drive efficiencies within current financial constraints [5]. However, sharing data raises issues of privacy, informed consent, de-identification, inequality, and research integrity. Public opinion holds a variety of views regarding data sharing, and while it has been reported that these are generally positive about the sharing of patient data, there are concerns regarding safety and the potential for personal data to be shared with unauthorised agencies [6]. **Trust**, **openness** and **transparency** are of key importance, with a need for clear communication regarding the **benefits of data sharing** to patients and the public. This is in order to overcome fears of data being used for commercial purposes, scepticism about the supposed benefits of data sharing, fear of being disadvantaged or discriminated against in some way, and little confidence in data security.

The Yorkshire and Humber (Y&H) region was awarded one of five exemplar positions on the NHS Local Health Care Record Exemplar (LHCRE) programme, which has led to the development of the Y&H Care Record (YHCR). The programme’s ambitious objective is to integrate health and care records across the region with the aim of improving care by providing timely and relevant information to care professionals and citizens securely and safely. YHCR works with: Humber, Coast and Vale Health Partnership; South Yorkshire and Bassetlaw Integrated Care System; West Yorkshire and Harrogate Health and Care Partnership; 74 organisations across the region; 725

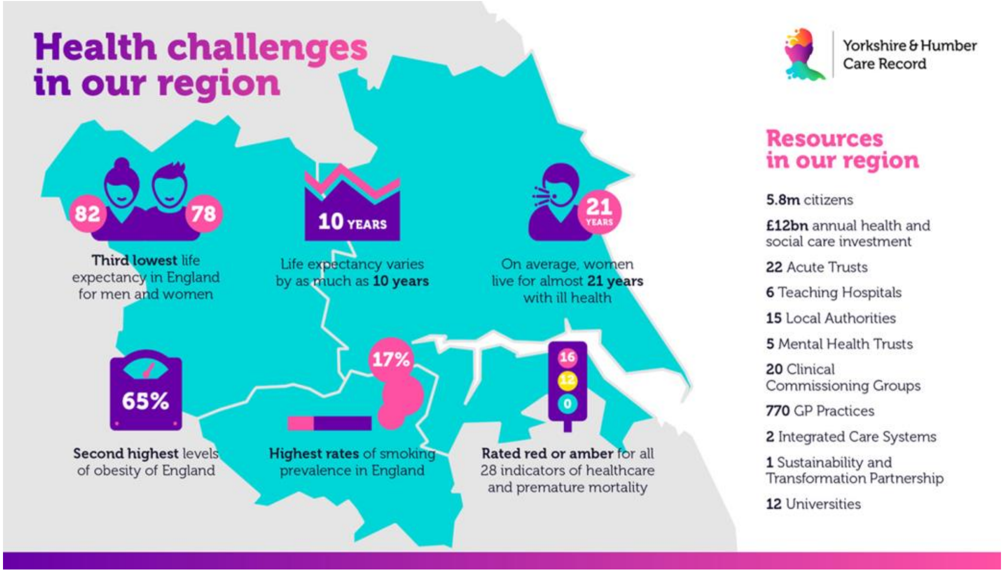

Figure 2: Health challenges within the Yorkshire and Humber region

individual GP practices. The YHCR could help inform the commissioning cycle within and across LAs and CCGs to tackle health challenges within the Y&H region (**Figure 2**).

1.2. Evaluation frameworks and economic evidence

One of the potential benefits to the public of data-sharing and data-linkage is to inform commissioning processes in the provision of cost-effective public health interventions, the merits of which are considered through evaluation frameworks. Alongside beneficial outcomes, there is a need to account for budgetary constraints. Funded services must represent ‘value for money’, as the NHS constitution states: “The NHS is committed to providing best value for taxpayers’ money”. Transparency and consistency in how data are used to inform commissioning services is a way to improve confidence in, and value of, data sharing within established legal and IG frameworks.

At a national level, economic evaluation (EE) is widely used for the appraisal of ‘value for money’ by comparing the ‘costs’ and ‘outcomes’ of relevant alternatives [7]. The use of EE evidence at the local level has increased over time in the UK [8, 9]; but many barriers to its meaningful application still exist. Significantly, there is a perceived disconnect between the evidence that informs national decision making, such as by the National Institute for Health and Care Excellence (NICE) [10, 11], and the evidence needed to inform localised commissioning [7, 9, 12]. A recent Delphi survey of public health decision makers by Frew and Breheny [13] suggested high-levels of agreement that EE evidence should incorporate an assessment of costs, health, well-being, and productivity changes, and that it should be local context relevant and transparent; this is not how local decision-makers perceive current EE frameworks. As a result, LAs and CCGs often do not use existing EE evidence. Reasons for this include local government agents: (i) not knowing where to find and access such evidence; (ii) not wholly understanding EE evidence due to a lack of clarity or training, and; (iii) not being able to translate this national-level evidence to their local-setting, which may be because the national-level evidence is in fact not wholly relevant to their localised setting. All the aforementioned are further complicated due to the tight timescales to produce business cases, and a lack of or constraints on necessary data, capacity, and skill sets.

The applicants of this proposal, which includes a collaboration between NIHR funded EEPRU and ARC-YH researchers, have explored and described a wide variety of considerations and ways to conduct EE analyses using routine data to inform local decision makers. For example, we (MF and JL) have produced an educational review [7] describing ways to utilise routine data, non-randomised study designs, and statistical methods to produce ‘value for money’ evidence pertinent to local decision making. This educational review was informed by a NIHR funded workshop titled “Interventional Studies as Service Evaluations” (Sheffield, June 2019) which brought together researchers (n=20) and commissioners (n=19). Our Co-Ap, SH [14], has explored the possible impact on local-level intervention effectiveness estimates dependent on use of different levels of locally available data and alternative statistical methods. Additionally, SH [15] used a case study of CCG’s limited commissioning of weight loss services, routinely identified as ‘cost-effective’ in the literature geared towards national decision makers, to identify four elements where the conventional EE framework differs from the reality faced by local decision makers, of which two aspects are pertinent to this funding call and proposal:
(1) ***Scope of included costs and outcomes:*** current EE frameworks often fail to incorporate and transparently present the full range of outcomes (i.e. beyond QALYs) and costs (i.e. non-NHS costs) relevant to local decision makers, while not accounting for inequality concerns [16].
(2) ***Implications of decision uncertainty and budgetary excess*.** Our collaborator, JL [17], has argued that, contradictory to the current EE approach, the estimation of the health opportunity cost of a service requires consideration of its budget impact, describing a solution to the “cost-effective but unaffordable” paradox often faced by local decision makers.

Although the work by SH focussed on CCGs, the suggestions align with that of Frew and Breheny [13] based on PH decision makers; the suggestion being neither sets of decision makers feel the current EE framework is aligned to their evidence needs. Some of the novel methods identified by MF and JL [7] could specifically address the concerns raised by SH [15], while aligning with the suggestions by Frew and Breheny [13]. Therefore, a more public health, local context relevant, and transparent EE framework could be developed to inform commissioning processes. These frameworks can be driven by local / regional datasets to inform within and cross-sector decision-making. Key local data of interest for EE would be: quantified outcomes of interest (e.g. clinical or person-reported health and well-being outcomes data, including impact on inequalities); resources consumed (e.g. use of NHS resources, such as clinical staff and capital, and non-health sector resources, such as social workers and care home beds); resource-based unit costs (e.g. NHS Reference costs); budget information and associated constraints (e.g. strategic targets and ring-fencing). Integrated data and evaluation frameworks are needed while accounting/overcoming barriers such as legal, IG, and public perceptions related to data sharing and processing.

2. Research Questions

Aim: To delineate the availability and potential of routinely collected administrative and service activity data to support commissioning decisions within and across sectors including LAs, CCGs, and Universities, in order to promote and protect health and prevent ill-health in local and regional settings. Through four work-packages (WP1-WP4) and by fostering networks and partnership activities between academic research and public health practice, our objectives are to:

WP1: *Mapping review of use and linkage of routine data in local/regional settings for commissioning decisions informed by LAs in England*

- Describe the current availability, linkages, and use of routine data for the purpose of within or cross-sector commissioning informed by LAs in England.

WP2: *Metadata specification and pilot metadata catalogue through stakeholder consultation*

- Develop a metadata specification and pilot metadata catalogue, including existing data flows within and across LA, CCG, and University partners;
- Develop guidance on the legal and IG frameworks to link data and enable data flows for research and practice based on the metadata specification and pilot metadata catalogue;
- Describe how linked datasets across health and non-health sectors, including the Yorkshire and Humber Care Record, can inform commissioning while accounting for legal and IG frameworks.

WP3: *Workshops with stakeholder groups (LAs, CCGs, Universities, YHCR) to explore the requirements of routine data to inform commissioning of services specific to falls prevention*

- Across all stakeholders identify the key organisational, technical, legal and resource barriers which need to be overcome to foster positive change to data sharing and linkage locally/ regionally, and what is required to overcome such barriers;
- Understand and describe public and stakeholder perception of the use of local and regional data to support commissioning decisions;
- Understand and describe how the Covid-19 pandemic may have been a catalyst for change.

WP4: *Economic evaluation (EE) methods to analyse and present estimates from routine data to inform cross-sector commissioning of services specific to falls prevention*

- Explore how to maximise the use of data to facilitate cross-sector working across LAs and associated bodies such as NHS commissioners.
- Describe EE methods to improve public health and commissioning by accounting for: cross-sector outcomes and costs; health inequalities; affordability, budgeting, and cost-effectiveness.

3. Research Plan / Methods

Building on examples from the identified grey literature (WP1), we will develop a metadata specification and pilot metadata catalogue which could help inform commissioning process including the legal and IG frameworks for consideration (WP2). The project will then combine qualitative methods to further explore the availability and potential of routinely collected administrative and service activity data to inform commissioning (WP3), with an exploration of what quantitative methods can be used to maximise the use of the data to support commissioning-based decision-making and its value to stakeholders and, subsequently, the public (WP4). Whereas WP1&2 will be a more general assessment of available data, WP3&4 will focus on a case study topic area of current cross-sector policy relevance (i.e. services specific to falls prevention) in order to help facilitate and focus discussions, with the generalisability to other commissioning areas being a point of discussion. The project has a strong emphasis on the involvement of key stakeholders throughout, with members of two LAs, two CCGs, and a patient and public representative involved as co-applicants and embedded in each WP.

WP1: Mapping review

We will explore the grey literature for case studies of routine data being used to inform public health decision-making specifically with the input of a LA within England. Case studies most pertinent to local government and commissioners will be in the grey literature (relative to published empirical literature) such as by local (LA, CCG) and national (Public Health England and NHS England) organisations. The mapping review will include three phases.

Phase 1: search the grey literature for case studies and compile a list, categorised by if a LA is working within or across sectors e.g. health, education, crime, transport. Sources will include GOV.UK, NHS Evidence, LA and CCG websites where appropriate, and general web searches. The list of sources will be discussed and agreed upon with all project Co-Aps. The search will be iterative, browsing and searching websites for a range of terms, and we will select the best available case studies that contain relevant data to be extracted in Phase 3 (based on predefined inclusion/exclusion criteria to be agreed upon across stakeholders). We will limit the search to case studies from the last 5 years (since 2016) with a preference for papers post-2018 (i.e. inception of GDPR). For pragmatic reasons, to ensure the following phases are achievable, we will cease searching once we have obtained a maximum of 100 case studies across the sectors of interest. If grey literature searching does not provide enough evidence, we will supplement this with focused database searching on Ovid MEDLINE and Science/Social Sciences Citation Indexes via Web of Science, and through conversations with all Co-Aps.

Phase 2: The list of potential case studies will be provided to all Co-Aps (and additional local government representatives as needed) to decide on a final list of case studies for data extraction. If the representatives know of additional relevant case studies not identified by the search, these will be added to the list. From this list, up to 30 case studies will be chosen for data extraction, equally split across the topic areas if available. For these included case studies, we will undertake "cluster" searching [18] to identify all the relevant information of interest for that study (including searching MEDLINE).

Phase 3: For the chosen case studies, we will extract the relevant data into a data extraction table. The finished data extraction table will be used to inform discussions with all relevant stakeholders to inform WP2-4. The data for extraction will include aspects such as: (i) data sources used, including if it is a single, bespoke or existing linked dataset; (ii) specified ‘data controller’ and ‘data processor’; (iii) any legal or IG frameworks / considerations specifically described; (iv) any described difficulties with obtaining or using the data; (v) examples of presenting routine data in novel /interesting/ useful / transparent ways. For case studies where there is missing data, we will contact corresponding authors.

WP2: Metadata specification and pilot metadata catalogue through stakeholder consultation

Working with key stakeholder representatives (LA, CCG, University, YHCR), we will develop a metadata specification and pilot this by creating a metadata catalogue listing data assets across all stakeholders, with a focus on data and services associated with public health (e.g. health and social care). The datasets and systems identified within WP1 will help identify relevant data assets to be included in the pilot. The value of the metadata specification standard will be demonstrated by advancing data asset discovery for-, and accelerating exploitation of data within-, WP3&4.

We will ensure the universality of the metadata specifications - to cover virtually any data asset from any domain - and accelerate its creation by adapting existing specifications, such as those implemented by data.gov.uk (a metadata catalogue listing open data held by central and local government and public bodies) and HDR UK’s Innovation Gateway (a published metadata catalogue listing UK health datasets for research and innovation). We will build on existing, open and well-documented metadata standards, taxonomies and controlled vocabularies, e.g. DCAT, and on the outputs of data mapping exercises previously conducted by our stakeholder organisations. Through explicitly identifying data controllers and data processors, we will be able to suggest existing data flows, but also data flows which don’t currently exist but would be preferable for informing commissioning processes (an output of interest from WP3). We will explore how specific existing data flows were enabled through legal and IG frameworks, among other technical aspects (e.g. data systems) if considered of specific interest by the commissioners (e.g. if there are local/regional differences which could inform cross-region and cross-sector learning). However, we will have a keen interest in specifying the potential for new data flows to inform commissioning and how these could be enabled (e.g. legal, IG, and technical) based on discussions from WP3.

The metadata specification for the metadata catalogue and the catalogue itself will be co-produced across all stakeholders. We will utilise online, joint working documents to co-produce this specifications and catalogue (e.g. Google Workspace) to allow simultaneous online working across the range of stakeholders, supplemented by bespoke stakeholder meetings to be held online via Google Meet (minimum of one meeting per month). Both Google Workspace and Google Meet have been used to successfully communicate and co-produce the development of this project plan, suggesting this will be a viable way to conduct WP2. As part of the planning process for this work, we have already identified relevant people across Sheffield and York LAs and CCGs who can aid with developing this metadata specification and pilot catalogue, who have already agreed to be a part of this work if funded and the pay grades for whom are included in cost estimates of this work.

WP3: Qualitative workshops focussed on the case study

A series of workshops will be carried out with key groups of stakeholders to explore current and potential data requirements, availability, and sharing processes, using a single area of commissioning as an exemplar. The workshops will explore what routine data is currently and potentially available, and challenges which may be encountered in unlocking data sources. These discussions will reflect on a current commissioning relevant area across all LA and CCG stakeholders (falls prevention) in order to help refine the discussions and allow a focussing of minds on a current relevant commissioning issue. Ten workshops will be carried out across:
- **Group 1:** Commissioners, directors, and clinicians (3 workshops)
- **Group 2:** Data analysts and researchers (3 workshops)
- **Group 3:** People with a legal or information governance role (3 workshops);
- **Group 4:** Representatives of the public (up to 4 workshops - this is separate to PPI meetings).

Workshops will be carried out online and will last around 1.5 hours. Participants will be selected to ensure diversity of participants in terms of organisation and role (a range of relevant roles have already been identified and included in the budgeting of this proposal). Members of the public will be recruited to ensure diversity in terms of age, disability, gender and health status, as examples. We will use a snowball recruitment method, encouraging identified participants to suggest others who should be invited with relevant expertise.

Local government and university stakeholders

Up to 9 workshops will run across 3 phases, with each phase consisting of 3 independent workshops running sequentially (one workshop per group within each phase) – see Table 1 for an overview of workshop phases, stakeholder groups, and running order. The workshops are designed to run sequentially in order for the thoughts and perspectives of each group to inform the next group. Workshops within phases will be spaced out by at least one week to allow the information from each workshop to inform the next workshop. These workshops will build on the findings from WP1, but will also form part of the iterative process of further developing the outputs from WP2. These workshops will also form the basis of what data should be considered as part of the evaluation framework within WP4. The workshop content and format will be developed through engagement with our stakeholder Co-Ap leads (i.e. via Google Meet). Our PPI group will inform development of the public representatives' workshop.

Phase 1 (Workshops #1-#3). Workshop #1 will include Group 1, with example questions being:
- What are the **relevant outcomes** of interest from commissioning falls-based services (e.g. health and non-health outcomes, determinants of ill-health, and associated inequalities);
- What are the **relevant costs** of interest from commissioning falls-based services and the relevant sectors/services (e.g. health and non-health sectors and services, and budgets)

- What are the **relevant data including sources** to quantify the outcomes and costs, building also on the grey literature (WP1), metadata specification and pilot metadata catalogue (WP2).

The suggestions by Group 1 in Workshop #1 will then be discussed by Group 2 in Workshop #2. Workshop #2's purpose is to further identify relevant data sources for the suggested outcomes and costs from Workshop #1, if these data sets are linked and how they could be accessed (if known), but also to discuss if these data have already been used for commissioning-related analyses and/or research purposes. Based on discussions from Groups 1&2, these data sources and possible data flows will be discussed with Group 3 in Workshop #3. Workshop #3's purpose is to discuss relevant current or proposed data flows, as well as the relevant legal and IG considerations for these data to be used by LA, CCG, and University partners (across Sheffield and York).

Phase 2 (Workshops #4-#6) will allow for further exploration of those topics discussed within Phase 1 as required, before **Phase 3 (Workshops #7-#9)** to describe our results in terms of findings across Phase 1 & 2, and WP1-2&4. Phase 3 will start with Group 3 and finish with Group 1 as the commissioners, directors, and clinicians who are key stakeholders when moving such findings and recommendations into practice (i.e. to inform the final commissioning decision).

Table 1: Overview of workshops across three phases and three stakeholder groups

Phases (P#)	**Group 1: Commissioners, directors, and clinicians**	**Group 2: Data analysts and researchers**	**Group 3: People with a legal or information governance role**
P#1: initial discussion	Workshop #1	Workshop #2	Workshop #3
P#2: further exploration	Workshop #4	Workshop #5	Workshop #6
P#3: present results	Workshop #9	Workshop #8	Workshop #7

Representatives of the public

A public workshop will take place following the first two phases of stakeholder workshops (i.e. after workshop #6) to explore any implications for members of the public from the suggestions or recommendations made during the first two phases of workshops (e.g. datasets of interest; suggestions to enable data sharing and/or linkage).

During the third phase of stakeholder workshops (#7, #8, #9) we will discuss and explore whether there are implications for any particular population sub-groups from our discussions and any developed plans for sharing/linking/accessing data. We will then carry out up to three workshops with public participants to discuss these plans. Three workshops are planned to ensure we engage with a range of sub-populations of interest to ensure that we have included any groups where data sharing may present particular challenges; for example, people with reduced capacity to consent or other groups identified during the workshops.

We will recruit 10 representatives of the public per workshop, the recruitment of which will be informed by our PPI group. We will provide an overview of the planned data to inform commissioning processes, including associated data flows as agreed upon within phase #2 and then phase #3. The workshops will explore public perceptions of the aforementioned aspects, including how any concerns might be best addressed through actions taken by any/all stakeholders, to ensure that changes are acceptable to the public.

Interviews

Up to 10 interviews will be held with key informants dependent on workshops' outcomes e.g. to gain a further and deeper understanding of key topics identified within the workshops.

Qualitative data analysis

Comprehensive notes will be taken by one of the researchers present. These notes will form the qualitative data for analysis. The notes will be analysed to develop a framework of key factors which influence the availability and potential of routinely collected administrative and service activity data. We will consider where changes at macro, micro and meso level may be required including within organisational systems, and legal and IG frameworks. The workshops and interviews will be recorded in order to check against the accuracy of the notes taken. Once these have been checked the recordings will be destroyed. The recordings will not be transcribed.

WP4: Quantitative EE methods focussed on the case study

Building on WP1-3 and two existing decision-analytic model case-studies of falls screening and prevention intervention as a cross-sector commissioning and policy-relevant area, we will explore and describe how quantitative methods informed by routine data can be applied to improve both the relevance and scope of EE evidence to inform local commissioning. The EE methods will focus on:

A. Decision making frameworks and criteria;
B. Quantifying and presenting the scope of outcomes and costs across sectors;
C. Accounting for health inequality considerations;
D. Accounting for affordability and budgeting-constraints relative to cost-effectiveness.

These areas of methodological development have been identified for both their potential to inform local decision-making deliberations, being aligned with the legislative roles and practical restraints placed on them, as well as their requirement for rich, local-level data to inform the analyses [7, 13, 19]. The methods and resulting outcomes will be presented to all stakeholders to discuss further developments of the frameworks, and the extent to which the evidence as presented could inform commissioning processes.

As part of this quantitative process, no individual-level data will be sought. Through use of existing decision-analytic modelling frameworks, it is possible for us to use aggregated and/or simulated data (e.g. we can simulate how the data could look and be used, if it could be obtained in the future) to explore how the data could be analysed and presented to decision makers to inform commissioning processes.

The purpose of WP4 is not to solve all the issues with current economic evaluation methods more commonly used to guide NICE-based decision making than local commissioning. Instead, it is to understand the disconnect between the aforementioned, including how methodology and commissioning reality can better align. Our intention is to identify possible solutions and areas for future research so that cost and outcomes are able to be explicitly accounted for in the same framework to inform commissioning, drawing directly on the rich and highly relevant local data that will be identified in WP1-3. An overview of these methods are now described including why they have been chosen as commissioning relevant challenges which need to be overcome, focussing mainly on new and novel ways to present and process cost and outcome data.

Case study models: falls screening and prevention interventions

Two existing decision-analytic model case-studies of falls screening and prevention intervention were chosen as they represent two different ways to model the decision problem and care pathway. One is a published cohort-based Markov model developed by our PI [20] based on the Public Health England (PHE) falls-commissioning return-on-investment tool currently promoted by PHE for use in terms of: "Local authorities and Clinical Commissioning Groups (CCGs) can use results from the tool to protect and improve the health of their local populations when making commissioning decisions". Although relative to the PHE model, our PI's model accounts for falls-risk screening (rather than just prevention interventions) and is stratified by age-groups (ages: 65-69; 70-74; 75-89; 65-89; 70-89). The other model is a patient-level simulation currently under development as part of existing research funding (a schematic has been provided alongside this DRP which visually represents the model); this model has been specifically designed to take into account system constraints related to falls-prevention services, having been co-produced by a Wellcome Trust PhD student, NIHR-ARC, and representatives of the Sheffield LA and CCG.

A. Decision making frameworks and criteria

For descriptive purposes we suggest there are three categories of relevant decision making frameworks and associated criteria which could inform resource allocation decision making [2]: health technology assessment (HTA); multi-criteria decision analysis (MCDA); programme budgeting and marginal analysis (PBMA).

The criteria and decision making frameworks associated with HTA are those most commonly associated with NICE: cost per QALY and the use of a cost-effectiveness threshold (e.g. £20k-£30k per QALY) [10]. These HTA methods are not commonly used, understood, nor fully 'accepted' as criteria to guide localised decisions from the perspective of the commissioners [12, 13]. Cost per QALY is a form of cost-utility analysis, which is also associated with other forms of economic evaluation including cost-effectiveness analysis and cost-benefit analysis; similarly, the aforementioned methods are synonymous with return-on-investment analyses such as is reflected in the current PHE promoted tools.

Compared to HTA associated methods, MCDA and PBMA are alternative frameworks to guide resource allocation particularly in regards to public health interventions and where multiple decision perspectives and fixed budgets are part of the decision making framework [2]. MCDA allows for a range of outcomes and costs to be accounted for within the same framework which are decided upon through stakeholder engagement (e.g. WP3), but has known complications within its suggested framework (e.g. subjective preference weighting). PBMA is based on reviewing resources allocated to specific programmes with a subsequent assessment of added/foregone benefits and costs from that/alternative programme(s); however, it has been regarded as 'outdated' and is rarely used based on the experience of our LA and CCG co-applicants, despite accounting for explicit budgets which is of interest to WP4.

Related to these three overachieving decision making frameworks (HTA, MCDA, and PBMA) and associated criteria, we will explore their relevance for guiding commissioning-based decision making in terms of their components (e.g. inputs to include and outcomes presented), processes (e.g. stakeholder engagement and discussions), relevance (e.g. QALYs relative to other outcomes), and data requirements.

B. Quantifying and presenting the scope of outcomes and costs across sectors

EE frameworks focussed on national decision makers in the UK often only focus on an NHS and social care perspective for costs and health outcomes (i.e. QALYs). Such a perspective has been argued to exclude the broader impact on, and required inputs of, non-NHS services, such as those broader services which contribute to public health (e.g. environmental interventions) [12, 13]. We will utilise the 'extended impact inventories' framework [21] to overcome this criticism of the limited scope of EE by accounting for, and then presenting, a range of outcomes, costs and associated opportunity costs relevant to multiple decision makers in a transparent way [13, 19].

Building on the workshop discussions (WP3), metadata specification and pilot metadata catalogue (WP2) and other examples from the grey literature (WP1), we will explore the potential to quantify the cross-sectoral outcome and cost which would be of relevance to the commissioning of services for falls prevention. We will seek to populate the case-study impact inventory with local level data relevant to the commissioners, as descriptive statistics at the aggregate level and/or simulated data based on expert opinion as required.

C. Accounting for health inequality considerations

Despite the important role of inequality considerations in care decision making including public health, inequality considerations are not always built into EE frameworks. There is an increasing trend to include inequality aspects in EE, particularly with emerging recommended methods to do so including Distributional Cost-Effectiveness Analysis (DCEA) [16]. Through WP2 and WP3, and further stakeholder engagement as required (e.g. via Google Meet), we will identify data available to the local decision makers that would be pertinent to estimating the inequality impact of public health interventions focussing on the commissioning services for falls prevention.

The exact aspects of tacking inequalities, definitions and/or inequality considerations, and how these aspects can/could be quantified will be key points of discussion within WP3; this could include, for example, relevant prevalence estimates and rates of local deprivation (e.g. measured through the Index of Multiple Deprivation [IMD]) to inform the use of local-level DCEA.

D. Accounting for affordability and budgeting-constraints relative to cost-effectiveness

EE evidence is recommended to advise decision-makers on the best use of available resources, often focussing on allocative efficiency when there is a finite budget. There is a general suggestion (e.g. NICE's methods of technology appraisal [10]) that decision makers should fund some new activity if the benefits it produces exceed its opportunity costs; however, budget restrictions are not always explicitly taken into account, with a focus often on what is 'cost-effective' relative to what is also 'affordable' within budget constraints [17]. The concept of 'affordability' relative to 'cost-effective' will be a commissioning relevant consideration explored in WP3, with outcomes, costs, and budgets being a point for consideration.

Through WP2 and WP3, we will establish the availability of locally available data on commissioning relevant outcomes and costs, including data related to budgets. Explicit budget information, relative to other data, will have additional complications for consideration including restricted access to only specific job roles (e.g. Finance Managers) who may not be the analysts of the other data for consideration. Through stakeholder engagement (WP3 and bespoke meeting via Google Meet), we will discuss and establish the potential fixity of relevant budget constraints, and the consequences of overspends and underspends. This will require consideration of ex-ante uncertainty in funding new programmes including the extent to which they may deviate from expected costs. Given the rigidity of local government budgets, we anticipate that concerns regarding budgetary impact - specifically that larger potential budgetary impact may cause more highly valued services to require defunding - to be of concern [22]. We will discuss and describe considerations for applying EE to the local decision-making context, including presenting and communicating the importance of opportunity costs and how it relates to finite local budgets.

4. Dissemination, Outputs and Anticipated Impact

Outputs. The project report will be 5000 words with a 20 slide deck, in addition to the peer-reviewed publications detailed below. We will develop a two-page summary aimed at key LA and CCG stakeholder audiences, together with a briefing co-developed with our public advisory group aimed at a public audience. We will produce a short multimedia presentation suitable for a range of audiences which we will disseminate through our extensive networks, both within local commissioning groups as well as the NIHR Academy (see dissemination plan below).

Our outputs in terms of open-access, peer-reviewed publications will include a series of four papers which encapsulate the outputs from each of the four WPs as well as drawing on the cross-cutting nature of this project:

- **Article 1: Unlocking data to inform public health policy and practice: development and use of a metadata catalogue and specification to better inform research and commissioning using real-world data** (Journal target examples: Lancet Public Health / BMC Public Health / BMC Implementation Science). This article will reflect on the information generated across all WPs, with a specific focus on WP1&2. The main focus will be describing how we collaboratively developed an open and accessible metadata specification and populated a pilot metadata catalogue, its importance, and how it can be used to better inform research and commissioning related to public health, health and social care. We will highlight the importance of metadata standards and metadata catalogues to drive data discoverability, identify relationships between different datasets held within and across organisations, and how this can be harnessed to support better research and commissioning.
- **Article 2: Unlocking data to inform public health policy and practice: the local authority, clinical commissioning group, and public perspective** (Journal target examples: Lancet Public Health / BMC Public Health / BMC Implementation Science). This article will reflect on the information generated across all WPs, with a specific focus on WP3. The main focus will be to

describe the information and feedback generated from all of the workshops and interviews from WP3. Key aspects to be described will be the identified barriers and facilitators of sharing/linking/using data, specifically to inform commissioning process, including how these aspects could be overcome and what still needs to change/develop.

- **Article 3: Unlocking data to inform public health policy and practice: the role of economic criteria and frameworks to guide local decision makers based on real-world data** (Journal target examples: Journal of Health Economics / Health Economics / Applied Health Economics and Health Policy). This article will reflect on the information generated across all WPs, with a specific focus on WP2-4. The article will reflect on the various criteria (e.g. cost-effectiveness thresholds relative to budgeting/affordability; QALY maximisation relative to equality) and frameworks (e.g. cost per QALY, return on investment, multi criteria decision analysis, and programme budgeting and marginal analysis) which could be used to guide localised commissioning, what aspects are of use or not (from a research and commissioner perspective), and how they could be guided through current data collected including what data is missing/unavailable/inaccessible to support the commissioning process. This article will combine current suggested health economic methods with the needs of local commissioners and how these aspects could be supported by real-world data sources.
- **Article 4: Unlocking data to inform public health policy and practice: the use of real-world data and modelling methodology to support localised commissioning** (Journal target examples: Applied Health Economics and Health Policy / Age & Aging / Medical Decision Making). This article will reflect on the information generated across all WPs, with a specific focus on WP2-4. This article will revolve around the case study of fall-prevention commissioning and associated decision-analytic models; although, it will explore and discuss the use of modelling methodology to inform commissioning in a broader sense (e.g. the input and outputs, including how these aspects are trusted by commissioners). It will focus on what information has been traditionally included in such models, what inputs have been included and outputs presented, and how this aligns with the actual needs of local decision makers to use such models to guide commissioning decisions. We will describe the potential disconnect between how current models are developed and presented, and the needs of commissioners when supported by localised real world data; this includes: scope of costs and outcomes; accounting for inequalities; assessing and describing cost-effectiveness relative to affordability and accounting for explicit budgeting constraints.

Dissemination. *Locally*. We will circulate our outputs to council staff, elected members, and academic partners. We will use our existing networks (EEPRU, ARC-YH, RDS-YH) to stay connected and make ongoing plans for the outputs to local colleagues. ***Regionally*.** We will share the outputs with other LAs/CCGs within the region including those in the wider Y&H region via ADPH. MF has been commissioned to provide PHE-YH a ‘Public Health Economics’ course, within which this work can be disseminated next year (2021/22). We will seek guidance from our PPI group regarding opportunities for dissemination to public audiences. ***Nationally*.** We will use our NIHR networks (EEPRU, ARC-YH, RDS-YH) to share our outputs, including via mailing lists and social media (Twitter and blogs). We will disseminate our outputs via the PaRC to the LARK that is managed by our Co-Ap (AH) and has representation from all LAs across Y&H. We can also use this forum to test out our findings in order to identify if these resonate with a wider local authority network. We will present the outputs via ARC-YH related conferences. We will publish a report summary in the LGA First magazine and Local Government Chronicle.

Anticipated impact. This work will explore the benefits of ‘unlocking’ existing and further data collection and flows, including its potential use to inform commissioning and how this connects through to public benefit through better use of EE evidence in commissioning decisions. It will initiate more evidence-based commissioning decisions through utilisation of such routine data, stimulating joint working across the LA, CCG, and universities, with support from NIHR infrastructure, with learnings for national change.

5. Project / research timetable

TIMESCALES: Ten month (M1-10) project from May 2021. ***Ethics***: during contracting process. ***WP1:*** *phases 1-3* **(***M1-2)*. ***WP2***: iterative development process (M1-9); initial metadata specification for WP3 phase 1 (M3); final draft version for review in WP3 phase 3 (M8). ***WP3:*** *phase 1 (M3-4), phase 2 (M5-6), phase 3 (M8-9)*. ***WP4*****:** iterative process and development (M1-9), with outputs for review as part of WP3 phase 3 (M8-9). **Report**: iterative process (M1-10) for final report and presentation (M10).

6. Project management and governance

MF will lead the project supported by monthly meetings across all Co-Aps. We will recruit people to a Study Steering Committee (SSC) from organisations such as ARC-YH, EEPRU, SPHR, SIPHER, PaRC/LARK, and PHE. Our PPI Co-Ap will also be involved in the SSC. The SSC will meet four times online (via web-based video conference), once every 3 months: initiate the project (M2), discuss progress (M4-7), and inform the report (M9/10). In addition, a public advisory group will be established to oversee the study - further details provided in the PPI section.

7. Ethics / Regulatory Approvals

We will obtain university ethics approval for the workshops. We will apply for provisional ethics approval during the review and contracting period to ensure that work is ready to start promptly. Use of software including Google Meet is already agreed as part of our ScHARR IG policy.

8. Project / research expertise

The co-applicants of this proposal represent a diverse and interlinked group of researchers and local government agents. This includes three universities (Sheffield [UoS], York [UoY], and Leeds [UoL]), three NIHR infrastructures (EEPRU, ARC-YH, RDS-YH), four local government agencies (Sheffield City Council, City of York Council, Sheffield CCG, Value of York CCG), and representatives of YHCR and LARK, with existing and ongoing relationships to co-develop research activities with a focus on informing commissioning process across the Y&H region.

MF (PI) is a Senior Health Economist, ARC-YH, Director of the Health Economics and Decision Modelling MSc and Knowledge Exchange lead for Health Economic and Decision Science, UoS. **MF** will lead the overall project including inputting into all WPs, given extensive previous experience in successfully utilising localised (i.e. raw health record & SUS data) and national care data (i.e. HES & CPRD), utilising existing and bespoke data linkages for both research and service evaluations. MF specialises in the use of routine data for the purpose of EE, including running workshops and searching/writing about methods/considerations when applying EE to inform local decision-making. **KS** will act as PPI Co-Ap - see online 'PPI' section for role. **WP1** will be led by **MF** and **TS** (Data Architect and Senior Data Manager, ARC-YH), with input from two Information Specialists (Anthea Sutton and Mark Clowes, UoS). **WP2** will be led by **TS** and **SuM** (Professor of Emergency Medicine, ARC-YH). **WP3** will be led by **SB** (Senior Research Fellow, mixed-methods) and **AH** (Research Fellow, and Manager of the PaRC YH). **WP4** will be led by **SH** (Health Economist, ARC-YH & RDS) and **DH** (Senior Health Economist), with input from **JL** (Health Economist, EEPRU). **MJ** (Chief Data Officer of YHCR) will act as representative for the YHCR. Our local government organisation leads include: **LB** (Head of Public Health Intelligence / Public Health Caldicott Guardian, Sheffield City Council), **JS** (Public Health Practitioner, City of York Council), **MH** (Deputy Director of Research, Sheffield CCG), and **GS** (Deputy Head of Analytics, Value of York CCG). Alongside these organisation leads, we have identified and funded research participation from the following job roles across the LAs and CCGs: Caldicott Guardian for the CCG, Caldicott Guardian for Public Health, Assistant Director Legal Services, Head of Legal and Governance, Data Protection Officer, Health Economics and Research Manager, Head of the Business Intelligence Hub, Head of Commissioning in Adult Social Care, Deputy Director of Care Out of Hospital, Head of Joint Commissioning, Head of Contracting and Analytics, Better Care Fund Finance Manager, Finance Manager. We will also link in with two projects being led by the UoS (PI: Peter Bath, Professor of Applied Health Data Analytics & Informatics): one NIHR funded, the AIM (Artificial Intelligence for tackling Multi-morbidity) project, and the other working with the Rotherham CCG. Both are exploring the availability of local data to implement data mining and AI technology, including mapping reviews similar to that in WP1 but from an NHS perspective.

9. Success criteria and barriers to proposed work

Success will be defined as delivering the project report and slide deck in the 10 month timeframe. We also consider success in terms of producing findings and outputs which are perceived to be of relevance and value to stakeholder audiences (i.e. researchers, local government agents, and the public). We anticipate that the inclusion of workshops with stakeholder participants in varying roles will add to the relevance and usability of the research findings, and their involvement in co-producing outputs will also enable communications to be in optimal forms for enabling action. Barriers could include engagement with the LA and CCG during a pandemic, during which their workload has increased and their time restricted. We are anticipating carrying out the workshop component online, rather than in-person, which we have found from other ongoing work minimises the time burden despite potential technical difficulties. Alongside a long standing and good working relationship between the LA, CCG, and UoS; our LA and CCG Co-Aps (JS, MH, GS, LB) as Organisation Leads will facilitate the ongoing work. Also, we have refined and discussed our proposed bid to make it flexible to the needs of the LA and CCG during this complicated time. In the time of COVID and social distancing, we will utilise online working practices to enable the success of the project during a difficult time.

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