Central Public Health Interventions Responsive Studies Team (PHIRST): Evaluation of the move to remote models of service delivery by drug and alcohol services in Leeds during the COVID-19 pandemic (Leeds COVID-19 DASE Project)

Project summary

Study title	Central Public Health Interventions Responsive Studies Team (PHIRST): Evaluation of the move to remote models of service delivery by drug and alcohol services in Leeds during the COVID-19 pandemic (Leeds COVID-19 DASE Project)
Planned study period	16 months (September 2020 to December 2021)
Study design	Mixed methods
Research aim/s	To understand the impact that the required changes to drug and alcohol services in Leeds due to COVID-19 had on services, staff and service users in order to inform the optimised design of services in the future.
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Funder	National Institute for Health Research (NIHR) Award ID: NIHR131573
Protocol version number and date	v2.0 March 2021

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List of Abbreviations:

- ARC – Applied Research Collaboration
- AUDIT – AUDIT stands for Alcohol Use Disorder Identification Test. It is a well-established screening tool to identify unhealthy alcohol use (risky or hazardous) by answering a number of questions and obtaining a score (see Saunders et al. 1993, Haroon et al. 2018, Justice et al. 2018)
- A&E – Accident and emergency
- CCA – Cost consequence analysis
- COVID-19 – Coronavirus Disease 2019
- DASE – drug and alcohol service evaluation
- DMP - Data Management Plan
- DPIA – Data protection Impact Assessment
- GP – General Practitioner
- HED - HED stands for Heavy Episodic Drinking and refers to a pattern of heavy alcohol consumption over a short period. HED is associated with negative health outcomes (see Wechler and Nelson 2001, Jackson 2008)
- HIAT – Health inequalities Assessment Toolkit
- NDTMS - National Drug Treatment Monitoring System
- NIHR – National Institute of Health Research
- NHS – National Health Service
- PICO - stands for Population, Intervention, Comparator and Outcome. These are the key elements of a clinical research question and are usually the key guiding principles for a systematic literature review
- PHE – Public Health England
- PHIRST – Public Health Interventions Responsive Studies Team
- PIRg – Public Involvement in Research Group.
- PPI – Public and Patient Involvement
- UH - University of Hertfordshire
- WS (1,2,3,4) – Workstream (1,2,3,4)

1 Title and additional identifiers

1.1 Full title of the study

Public Health Interventions Responsive Studies Team (PHIRST): Evaluation of the move to remote models of service delivery by drug and alcohol services in Leeds during the COVID-19 pandemic (Leeds COVID-19 DASE)

1.2 Short title of the study

Leeds COVID-19 DASE

1.3 Registry

[add reference and date once registered]

1.4 Funding

Funding is provided by the National Institute for Health Research (NIHR) PHIRST initiative (Public Health Research funding stream).

Funders reference: NIHR131573

1.5 Research team

Investigators

Table 1: List of Investigators

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2 Background information

2.1 Overview of the intervention to be evaluated and contextual information

The Public Health Interventions Responsive Studies Teams (PHIRST) programme is a new initiative funded by the National Institute for Health Research (NIHR) to deliver public health evaluation research. Local authorities are invited to propose initiatives to be evaluated and if successfully selected by the NIHR, are paired with a PHIRST team (there are four PHIRST teams based within Higher Education Institutions across the country).

The University of Hertfordshire led PHIRST (known as Central PHIRST) is a consortium of four universities. The other consortium members are Ulster University, the University of Birmingham and the University of East Anglia. The Leeds COVID-19 DASE project is the first in a series of PHIRST projects allocated to Central PHIRST.

In line with the Health and Social Care Act (2012) Leeds City Council is responsible for commissioning local drug and alcohol treatment and recovery services in the city of Leeds. Since 2015, a partnership organisation comprising NHS and third sector organisations has been commissioned by Leeds City Council to deliver drug and alcohol support services on its behalf. Among the principles of the service are that drug and alcohol support services should be: integrated and easily accessible; responsive to changing local need; focused on promoting and enabling the recovery of individuals' while appreciating the uniqueness of each recovery journey. The partnership organisation is known as Forward Leeds.

To deliver drug and alcohol support services, Forward Leeds works in partnership with several local organisations, including charities, NHS providers such as GPs clinics and NHS trusts, pharmacies, and other local authority commissioned support services. Forward Leeds' work involves a wide range of service and holistic support. This includes: information and advice service; referral and signposting; harm reduction work; brief intervention work with service users; health screening, including sexual health; structured support and treatment, including pharmacological (such as opioid substitution therapy) and evidence-based psychosocial interventions; the offer of in-patient and community detox services; one-to-one support from a dedicated support worker; therapy; group work sessions; relapse prevention work; and specific support with sustaining recovery.

Forward Leeds also conducts targeted support work with specific service users groups, including: children and families affected by drug and alcohol use; young people aged 18-24 years assessed as 'vulnerable'; street sex workers; service users with mental health issues; service users recently released from prison; and those who are experiencing homelessness or in temporary accommodation.

Forward Leeds' drug and alcohol support services are housed within four locality-based community hubs across the city of Leeds. One of these hubs focuses on sustained recovery work with service users, and the other three deliver and coordinate the wider range of drug and alcohol support services, with key staff teams co-located within them. In addition to these hubs, Forward Leeds also delivers a significant amount of its support work through community based and outreach work. Various dedicated teams within Forward Leeds work in partnership to deliver specific components of treatment and support in an integrated manner.

2.2 The problem being addressed and why this research is needed now

The COVID-19 pandemic necessitated significant changes to the delivery of drug and alcohol support services across Leeds. This included cessation of, or significant reduction in, face-to-face support services, and a move to remote delivery of key drug and alcohol support functions. Prior to COVID-19, face-to-face delivery of drug and alcohol support services had been a core part of many of the drug and alcohol support services.

Since the original imposition of COVID-19 restrictions in March 2020, and as COVID-19 restrictions have varied, service delivery teams have adapted to the shifting COVID-19 context and the nature of remote delivery during the pandemic has also therefore changed. Remote delivery has included teams delivering some key support functions that had previously been face-to-face via telephone or video platforms. In addition, the reduction of face-to-face contact has meant the cessation of some key group work and psychosocial therapeutic interventions, home visiting, and outreach work. At certain points, this has meant restricting face-to-face delivery (in the limited cases where it has continued) to service users deemed to be particularly vulnerable, 'at risk' or in emergency situations.

COVID-19 has resulted in Forward Leeds and its partners significantly reconfiguring services while attempting to maintain appropriate levels of service user support and safeguarding. Particular challenges have been faced in remotely supporting certain groups of service users, including those with certain vulnerabilities (such as those who are homeless), and those for whom face-to-face contact would typically underpin their treatment (such as those requiring supervision to receive opioid substitution therapy, and those in need of in-patient detox). Existing structural health inequalities and factors such as 'digital poverty' have provided additional challenges to remote delivery.

Although there has been significant disruption to the usual mode and pattern of delivery, anecdotal evidence suggests that aspects of remote delivery have been experienced positively by some drug and alcohol support staff[1] and some service users. For instance, remote delivery has enabled some service users to engage with support without the need to travel to a hub building, and some staff members have valued the flexibility offered by remote working. Anecdotal evidence also suggests that both service users and staff members have had differential experiences of remote delivery, and that a range of factors may have impacted this experience.

[1] For brevity, throughout this document, the term 'staff' is used to refer to those employed by and volunteering at Forward Leeds and its partner organisations.

The local authority which commissions drug and alcohol services (DASE), the service providers and those who engage in service use will all benefit from this research, as the knowledge produced will provide an understanding of how drug and alcohol support services can be optimised, drawing on lessons learnt during the COVID-19 pandemic. Beyond the local service landscape, the wider national drug and alcohol service system will benefit from the translational knowledge produced. There will also be important learning for the effective remote delivery of services in sectors beyond drug and alcohol support.

2.3 Review of existing evidence

National drug and alcohol situation

This project is framed within the larger context of drug and alcohol service delivery and research in England. This context is perhaps best laid out through data obtained from the National Drug Treatment Monitoring System (NDTMS) (Public Health England, 2018), which provides standardized information from most providers of drug and alcohol treatment in England. For its reporting, the NDTMS divides people in treatment into four categories: opiate (people who are on treatment because of their use of opiates such as heroin), non-opiate (whose treatment relates to non-opiate drugs, such as cannabis, crack or ecstasy), non-opiates and alcohol (who are dependent or have problems both with non-opiates and alcohol) and alcohol only (who are dependent or have problems with alcohol but not with any other substance). Our project follows the NDTMS and uses these four categories of treatment (which we call 'pathways') to arrange our research of service provision and experiences. This will maximize the impact and relevance of our work for providers nationwide. According to the 2017-2018 NDTMS (PHE, 2018) individuals in treatment for opiate use account for 53% of all those receiving treatment; alcohol-only accounts for 28%, non-opiate and alcohol for 10% and non-opiate only for 9%.

The current project is framed within a decreasing trend in the number of people in treatment, as evidenced in the NDTMS (PHE,2018): in the 2017-2018 period, there were 268,390 adults in treatment, which is a 4% decrease from the previous year. The reduction was sharpest among people in treatment for alcohol-only. The number of new people entering treatment for both non-opiates and non-opiates and alcohol remained roughly the same despite a 18% increase in those being treated for crack cocaine (not opiates) which has been in an upward trend for several years. Most service users across categories are male (69%) and the median age for those in treatment for alcohol use was 46 years-old whereas, for those in treatment for opiates, it was 40 years-old. Most of people in treatment were white British (84%). For those starting treatment for whom a mental health status was recorded, 41% said they also needed treatment fora mental health condition. In 2017-2018, 121,332 people exited treatment, 48% after having successfully completed their treatment and being free of dependence. Among these, alcohol service users had the highest rate of successful treatment exits (61%) and opiate service users the lowest (26%). More than a third (35%) of service users had exits recorded as "dropped out/left", that is, they exited the system without having completed their treatment.

Drug and alcohol misuse poses a significant public health priority: in 2017-2018, there were over 338,000 estimated hospital admissions and, in 2017, over 5,843 deaths from alcohol-

related conditions (NHS Digital 2019), and since 1970, deaths from liver disease in England have increased 400% (British Liver Trust, 2019). This has led to significant policy efforts, such as the 2017 updating of the Government's Drug Strategy (HM Government, 2017). This project is framed within this context and seeks to provide guidance for the management, at public health and service delivery level, of drug and alcohol treatment needs in the aftermath of COVID-19.

Leeds has higher rates of adults in treatment at specialist drug misuse services (6.5 per 1000 population as opposed to 4.4 per 1000 in England in 2017/2018) and has higher rates of death from drug misuse (7.3 per 100 000 compared to 4.7 per 100 000 in England in 2018) [Public Health England, 2021]. This makes this project, with its scope, especially relevant.

The COVID-19 context

Both the COVID-19 pandemic and the measures put in place to contain it have profoundly impacted societies globally, so much so that queer philosopher Paul B. Preciado has argued that COVID-19 questions to what extent and under what conditions life is worth living (Preciado 2020). Whereas early reports portrayed the pandemic as a great equalizer, it soon became evident that its detrimental effects were unevenly distributed among populations (Timothy, 2020) and that existing vulnerable communities would be "likely to carry a heavier burden or what will be the devasting downstream economic and social consequences of the pandemic" (Hall et al., 2020, p. 1175-1176) That is, COVID-19 has deepened and exacerbated pre-existing inequalities. The significance of this project lies in exploring how drug and alcohol treatment, recovery and support services were delivered and experienced during the lockdown, a time when access to healthcare and support services became severely limited. In addition, because of the vulnerable nature of some of the service users of the organisations of relevance to this study, this project will also evaluate how these groups were uniquely and (perhaps disproportionately) impacted by limitations and changes to service delivery.

This project also evaluates whether the routes of drug and alcohol service delivery that were enacted during lockdown also proved more effective for reaching and engaging certain categories of service users and, thus, whether they are worth sustaining in a post-COVID-19 future. This is particularly significant because the COVID-19 lockdown not only severely limited the capacity of organisations to deliver services, but also provided "an opportunity for rapid regulatory change and programme innovation" (Church, Gassner and Elliott, 2020, p.523). This project evaluates this innovation to provide sound evidence as to whether the new ways of delivering services have been effective and are worth sustaining in a post-COVID-19 future.

2.4 What we have done so far

Following initial discussions with Forwards Leeds staff in September 2020, and the provision of service specification documents, a logic model of Leeds drug and alcohol services outputs and outcomes (Appendix 2) was developed by mapping the drug and alcohol services inputs, activities, anticipated impact on behaviour/other mediators of health outcome, health and quality of life outcomes, and the theoretical mechanisms through which this effect is hypothesised to occur. The activities aspects of the logic model was then assessed for accuracy and subject to validation by service providers. The wider logic of the model was then interrogated for soundness, a process that included explicitly considering the extent to which the service may be likely to achieve its stated impacts and outcomes and the extent to which it

had taken account of health inequalities in its conceptualisation, design and planned implementation. This process drew on resources from the Health Inequalities Assessment Toolkit (HIAT www.hiat.org.uk) and considered PROGRESS-plus (Evans and Brown, 2003) characteristics.

The logic modelling process formed part of a wider evaluability assessment that was conducted following guidance set out by Davies (2013) and involved working with the local authority and service providers to enable us to populate an evaluability checklist. The checklist assessed: 1) evaluability *in principal*, given the nature of the project design and logic model; 2) evaluability *in practice*, given available data and systems; and 3) the *practicality* and likely *usefulness* of an evaluation. The evaluability assessment informed our subsequent specification of research questions and evaluation design.

Since September 2020, and alongside the logic modelling and evaluability assessment, additional discussions have been ongoing with representatives from Forward Leeds and partner organisations to enable us to better understand the context of drug and alcohol service delivery in Leeds and the complex range of service providers, partner organisations, teams, and individuals involved in coordinating and delivering those services. Discussions have also enabled an understanding of the varied service user groups who receive drug and alcohol support, and the treatment pathways available (and how they relate to the four NDTMS substance use categories outlined in section 2.1). Diagrammatic representations of service providers' delivery processes and treatment pathways have been developed and validated through discussion with managers at partner organisations

This preliminary work has been invaluable in allowing us to develop and co-produce our research questions and methodology, in close collaboration with Forward Leeds and other partner organisations. 'Co-production' is a central tenet of the PHIRST initiative, with our PPI co-applicant, who chairs our dedicated PHIRST Public Involvement in Research Group. We will also collaborate closely with service users and other stakeholder members of the project-specific Advisory Group, and Leeds City Council representatives. Our co-production strategy has also been integral to the formulation of research questions and the overall methodology and design of the evaluation.

The research team has managed to secure strong buy-in and commitment to the evaluation from Leeds City Council and each of the partner organisations involved in the local delivery of drug and alcohol services, and the co-production process has facilitated this.

3 Study Information

3.1 Aims, objectives, and research questions

3.1.1 Aims and objectives

Aim:

The aim of the study is to understand the impact that the required changes to drug and alcohol services in Leeds due to COVID-19 had on services, staff and service users in order to

inform the optimised design of services in the future.

Objectives:

- To identify and critically appraise the extant evidence on remote delivery of support for alcohol and/or substance use issues and harm reduction and recovery interventions for adults

- To investigate how drug and alcohol support services have been impacted by COVID-19 restrictions and how services were delivered during the pandemic

- To explore staff and service user experiences of the delivery of drug and alcohol services during the COVID-19 pandemic

- To assess how outcomes for service users during the COVID-19 pandemic compare with pre-COVID outcomes

- To assess the economic implications of remote versus other forms of delivery for service providers

- To generate recommendations for how the design of drug and alcohol services in Leeds might be optimised in future, drawing on lessons learnt during COVID-19

- To communicate the findings of the evaluation to a range of appropriate stakeholders, including service users and providers, commissioners and policymakers

3.1.2 Research questions

1. What does the existing evidence tell us about the content and effectiveness of remotely delivered drug and alcohol interventions and therapies?

2. Prior to the COVID-19 pandemic what were the different drug and alcohol related activities that Forward Leeds and partners delivered and how were they implemented?

3. For each aspect of service delivery and activity identified, did implementation change as a result of COVID-19 restrictions, and if so, in what way?

4. How was change experienced? What did people find beneficial and what did they find less useful?

5. Prior to the COVID-19 pandemic, what were the outcomes of these different activities for service users?
5a. How did these outcomes change over the course of the pandemic?
5b. Were these differentially experienced by different groups (health equity)?

6. Pre-COVID-19, what was the cost of delivering the identified activities? How did these costs change with the changing implementation?

7. Drawing on evidence synthesis, and process and outcome evaluation findings , what can be recommended with regards to the organisation and delivery of drug and alcohol services in Leeds?

8. How might the findings be relevant to the wider system of drug and alcohol services nationally and internationally, taking account of contextual factors identified in the evaluation?

4 Study design and methods

4.1 Study design overview

To facilitate the management of the project and to generate operationally feasible units of work, this project has been divided into five distinct workstreams (WS) within a mixed methods framework. Each workstream seeks to answer specific research questions (RQs) or address questions in a different way to provide for a well-rounded and robust evaluation. The workstreams include:

- Workstream 1 (systematic review) involves conducting a systematic review of published evidence for remote delivery of drug and alcohol interventions. This review will be conducted throughout the length of the evaluation and its conclusions will serve to frame and contextualize the findings of the project.

- Workstream 2 (qualitative process evaluation with service providers) consists of qualitative data collection involving staff employed by the partner drug and alcohol organisations in Leeds and their volunteers. This workstream will be focused on gathering information about how service delivery and organisations changed during the COVID-19 lockdown as well as providers' experiences of it. This workstream will allow us to make informed and feasible recommendations about future service delivery that include providers' perspectives and will also serve to provide crucial information about the structure and operations of the organisation.

- Workstream 3 (qualitative process evaluation with service users) involves engaging current or former service users in qualitative data collection. The goal of this workstream is to explore users' experiences of accessing services during the COVID-19 lockdown to help assess what worked, for whom, and in what circumstances.

- Workstream 4 (quantitative outcome and health economic analysis) involves quantitative analysis of operational data collected by the partner organisations in Leeds. The data include staff activity, contacts with service users, service user characteristics and outcomes over time. This workstream will include an economic/cost evaluation of the different modes of service delivery (face-to-face, online, hybrid) for identified key elements.

- Workstream 5 (data synthesis and dissemination) seeks to synthesise the findings from Workstreams 1-4, and to develop recommendations about how to configure and deliver services in Leeds. We will also develop a range of communication outputs to share and mobilise the findings effectively with all relevant stakeholder groups.

Table 2 below highlights how the workstreams address the study's research questions:

Table 2. Research questions mapped to delivery workstreams

RQs	WS 1	WS 2	WS 3	WS 4	WS 5
1. What does the existing evidence tell us about the content and effectiveness of remotely delivered drug and alcohol interventions and therapies?	X				
2. Prior to the COVID-19 pandemic what were the different drug and alcohol related activities that Forward Leeds and partners delivered and how were they implemented?		X	X		
3. For each aspect of service delivery and activity identified, did implementation change as a result of COVID-19 restrictions, and if so, in what way?		X	X	X	
4. How was change experienced? What did people find beneficial and what was less good?		X	X		
5. Prior to the COVID-19 pandemic, what were the outcomes of these different activities for service users? 5a. How did these outcomes change over the course of the pandemic? 5b. Were these differentially experienced by different groups (health equity)?				X	
6. Pre-COVID-19, what was the cost of delivering the identified activities? 6a. How did these costs change with the changing implementation?				X	
7. Drawing on evidence synthesis, and process and outcome evaluation findings from WS1-4 what can be recommended with regards to the organisation and delivery of D&A Services in Leeds?					X
8. How might the findings be relevant to the wider system of D&A services nationally and internationally, taking account of contextual factors identified in WS2?					X

4.2 Co-production and Patient and Public Involvement (PPI)

4.2.1 Co-production

Co-production is a central tenet of the Central PHIRST initiative and our evaluation plans. The evaluationis being co-produced with the local authority, the PHIRST, and local partners and stakeholders, including service users, working together to plan, design, deliver, and disseminate the evaluation. This is being achieved through routine communication with the

partner organisations under evaluation, as well as the routine presentation of proposals and updates to the Independent Core Advisory Board (composed of relevant stakeholders in the field of public health and evaluations, including experts from academia, the third sector, government and the public) and the Leeds-COVID DASE-specific Advisory Group (similarly composed of key stakeholders but with specific expertise, relevant to the subject and area of the evaluation), which will provide feedback. This feedback will shape key decisions throughout the research process , including design, ethics, project delivery and dissemination.

4.2.2 PPI

The University of Hertfordshire is committed to involving the public in all stages of its research and has an existing Patient Involvement in Research group (PIRg) comprised of members of the public, service users and carers. PPI (patient and public involvement) involvement is key to the Central PHIRST and will be integral at all stages. All PPI activities will be co-ordinated by the PPI co-investigator (Amander Wellings), the academic PPI co-investigator Professor Julia Jones and members of the PHIRST team.

For this evaluation, PPI will be articulated in two ways through:

1. Central PHIRST Public Involvement in Research Group (PIRg), hosted by the University of Hertfordshire, which will collaborate with the research team across all projects; and
2. Local service-user involvement: this will take the form of consultation with service users in Leeds, who have lived experience of drug and alcohol use and are accessing drug and alcohol services in Leeds.

The PHIRST PIRg will provide public, service user and carer perspectives to all the public health evaluation projects conducted by the team. The eight members of the PIRg meet monthly to discuss key aspects of Central PHIRST evaluation work (for example, research questions, methodology, literature review, research tools, and dissemination), and between meetings work closely with the PHIRST to co-produce the evaluation.

The local service-user involvement will be undertaken in collaboration with Forward Leeds. Service users with lived experience of accessing drug and alcohol support services have been identified to advise on, and assist with, key aspects of our methodology, data collection, and implementation/impact work. These service users will attend three group consultations during 2021, which coincide with key points in the Leeds COVID DASE evaluation workplan, to provide input into the evaluation, providing a service user perspective on how we conduct the evaluation, making sense of the findings and to co-produce dissemination activities that will be accessible to service users, carers and members of the public.

Both PHIRST PIRg and the local-service user involvement groups will be involved in the dissemination of the projects and its impact strategy.

4.3 Workstream 1: Literature review and existing evidence synthesis

Objective

- To identify and critically appraise the evidence available on remote delivery of support

for alcohol and/or substance use issues, and harm reduction and recovery interventions for adults,

Design

Workstream 1 ('Literature review') involves a systematic literature review which will serve to frame our findings and to allow the research team to draw generalizable conclusions. The literature review will be conducted in parallel to the other workstreams.

The literature review is titled "Remote delivery of alcohol and/or substance use disorder interventions to adults: a systematic review". In particular, the review addresses the following questions:

- Are remote interventions for alcohol and/or substance use issues effective in promoting healthier lifestyles, improving mental health or wellbeing?
- What are the characteristics of remote service/intervention delivery and how does mode of delivery influence the content being delivered?
- What are the experiences of adult service users and providers and how are they related to positive or negative outcomes?
- Given the research design, what is the risk of bias of included studies?

We understand remote delivery as delivery of interventions that are mostly conducted over the phone or interactive internet-based platforms (e.g. smartphone apps, video chats, instant messaging, or social media) both synchronously (i.e. 'live') and asynchronous. Hybrid intervention delivery is defined as that which combines both face-to-face with significant remote delivery elements.

The review will include a summary of existing reviews of remote drug and alcohol service delivery (Ashford et al., 2020; Dick, 2019; Kaner et al., 2017). However, unlike previous work, this review will pay particular attention to the personalization of the remote interventions and its relationship to both effectiveness and user/provider experience.

The review will include studies published in academic platforms. In particular, it will search PubMed, Scopus, PsycINFO (ProQuest) and Cochrane. A full breakdown of PICO and the search strategy can be found in the published Prospero Record of the review (Garcia Iglesias et al., 2021). In general terms, PICO can be defined as:

- Population:
  studies whose population are adults (over 18 years old) accessing remote interventions for alcohol and/or substance use and/or receiving harm reduction or recovery support, recruited through a range of settings (e.g., primary or social care). For inclusion in the review, study participants should be screened for alcohol and/or substance use risk prior to taking part in the study and should meet the following thresholds: for alcohol, a score of 8 or above on AUDIT (3 or above on AUDIT-C). Similar measures such as Heavy Episodic Drinking (HED) will be accepted, and studies will be accepted if their inclusion threshold is lower but participants' baseline scores exceed the specified thresholds above. This review will exclude studies whose participants access remote

services only as additional components to face-to-face interventions, those who do not live freely in the community, or those who are mandated to access the intervention.

- Intervention: alcohol and/or substance use disorder support, harm reduction and recovery delivered remotely. The review will not consider tobacco or nicotine-based products but will include alcohol, illicit drugs, and substance use. To be included, interventions must have been delivered primarily remotely (i.e., phone, computers or mobile devices), synchronously or asynchronously, and must not consist or readily available libraries of content. Interventions targeting multiple behaviours or conditions (e.g. mental health) will be included if data is reported separately for alcohol or substance use. Studies will be excluded if the remote interventions are solely used to support a face-to-face intervention, if interventions are focused only on reducing alcohol/substance use in people in childbearing age or pregnant women, or if their remote component is delivered by post or mail.

- Comparator: a wide range of comparators, including no intervention, usual care, face-to-face interventions, and hybrid interventions.

- Types of studies: a wide range of study designs is expected, including qualitative, quantitative and mixed methods, randomised controlled trials, non-randomised controlled trials and quasi-randomised trials, and pre-and post-studies

- Outcomes: main outcomes will be measured by a range of self-reported and objective methods. Primary outcomes will be behaviour change such as quantity of alcohol and/or substance consumed, measures in alcohol units or similar, numbers of days of use; as well as changes in alcohol and/or substance-use related behaviours or outcomes, including accident and emergency visits, overdoses. Additional outcomes will include changes in outcomes such as depression, stress, anxiety, dependence, quality of life; as well as physical health outcomes, such as (perceived) severity of withdrawal, associated health conditions.

Screening will be conducted by two researchers independently. Data extraction will be performed by two researchers independently and moderated. A number of Risk of Bias Assessment Tools will be deployed (to account for the number of possible study types). The review will serve to complement the other workstreams, as well as leading to a stand-alone peer reviewed output. PPI feedback from the PHIRST PIRg will be sought at the design, analysis and summary stage. PPI members will be provided with training about conducting systematic literature reviews prior to seeking their feedback.

4.4 Workstream 2 (qualitative process evaluation with service providers)

Objectives

- To investigate how drug and alcohol support services have been impacted by COVID-19 restrictions and how services were delivered during the pandemic

- To explore staff experiences of the delivery of drug and alcohol services during the

COVID-19 pandemic

Design

The delivery of drug and alcohol support services in Leeds incorporates the work of multiple partner organisations and teams, and distinct components of support work that are tailored to individual need yet offer support based on broad treatment 'pathways' that align with the four substance use categories described in section 2.1. For this reason, Workstream 2 will utilise these substance use categories to frame recruitment and sampling of participants.

The broad range of drug and alcohol support services and the range of teams and partners involved in delivery, mean that it is likely that changes to delivery occurred in different ways and at different times for different services and teams. Indeed, our preliminary discussions with representatives from Forward Leeds and its partner organisations suggest that this was the case.

In order to capture the complexity of service delivery change across the wide range of services and teams, and to also allow for rich data to be captured about staff experiences of change, a process evaluation methodology is proposed that utilises three different methods of qualitative data collection: individual digital timelines, focus groups, individual interviews. Participants will be invited to participate in at least one, and up to three, of these data collection activities. The 'individual digital timeline' will allow for a broad range of service provider team members to describe how service delivery changed during the pandemic, while focus groups and interviews will allow for an in-depth exploration of how delivery has been impacted by COVID-19 restrictions, the ways in which remote delivery has been implemented, and how staff have responded to and experienced changes in delivery.

Recruitment and sampling

Participants will be recruited from current staff members or volunteers at Forward Leeds and third sector partner organisations that work in partnership with the organisation to deliver targeted drug and alcohol support services to various service user groups (for example, street sex workers). The recruitment process will be as follows:

- Emails will be distributed via internal mailing lists and staff will be invited to volunteer to participate (staff members will participate in the evaluation as part of their routine workload).

- Those interested in participating will be asked to provide basic details about themselves (job role, employment status, level of experience, and time working in organisation) using a secure online system.

- In the case of Forward Leeds, which has over 150 staff members, purposive sampling will be used: in conversation with senior management and considering the staff members who have shown an interest in the project by means of the survey, the researchers will identify subgroups of staff amongst whom to recruit in order to obtain a sample of job roles that will allow us to understand the changes in service delivery that occurred across the organisation's key drug and alcohol support functions.

- Identified potential participants will be invited to participate and sent the Participant Information Sheet and Consent Form via REDCap (Vanderbilt University 2021), a secure online platform. They will be given time to read this information and have any questions answered, before being asked to complete and return their consent form via the secure system.

Workstream 2 will recruit:

- Activity 1 - Individual digital timelines: Approximately 25 participants
- Activity 2 - Focus groups: Approximately 28 participants (across 4 groups)
- Activity 3 - Individual interviews: Approximately 15 participants

Further detail of sampling for individual data collection methods is presented in the sections below.

Activity 1 - Individual service provider staff digital timelines

Once consent procedures are complete, participants will be emailed a personal link to LucidSpark (Lucid Software 2021), an online portal where they will find an 'individual timeline' template to complete. They will be asked to generate a timeline of change at the individual level, indicating how service delivery changed before, during and after COVID-19 restrictions were introduced, and their experiences of this.

As stated in section 2, the four NDTMS substance use categories align with broad 'pathways' of treatment for service users. Our sampling strategy will ensure that participants invited to complete a timeline include staff members or volunteers who provide the different components of treatment and support present within the four pathways (for example, clinical staff, sustained recovery team members, 'key workers', and members of rehab teams). Timeline data will be captured for between five and seven staff participants per pathway (approximately 25 participants in total).

Once an individual timeline is completed by a participant, the timeline will be available for the research team to access in pdf format.

Activity 2 - Focus Groups with service providers

A sample of the participants who have completed an individual timeline will be invited to attend focus groups. In addition, some participants will be invited to attend where they have not participated in the individual timeline activity but carry out drug and alcohol support roles that are central to particular pathways and that would otherwise not be represented within focus groups.

Each focus group will include staff members who provide different components of treatment and support within a particular substance use pathway. One focus group will be conducted per pathway (with between six and eight participants per pathway, a total of approximately 28 participants).

Preliminary analysis of individual timelines will be conducted prior to beginning focus

groups with staff. This analysis will inform the prompts used in focus group discussions (for example, where participants raise particular aspects of service change or implementation of remote working), and may also provide the research team with additional information to inform decisions about which of the four focus groups to invite participants to attend.

Each focus group will explore changes in service delivery that occurred in relation to a specific pathway, including: whether and how services (that form a key part of specific substance use 'pathways') have changed or were disrupted; the ways in which remote modes of delivery were implemented; how change has been experienced by staff; the effectiveness of remote delivery; lessons learnt from the remote delivery of drug and alcohol services during the pandemic.

Focus groups will be held via an online video platform such as MS Teams or Zoom and will last between 50 and 75 minutes. They will be facilitated and moderated by members of the research team and audio-and-video recorded.

Activity 3: Individual interviews

Following the 'individual staff timeline' and 'focus group' activities, some participants will also be asked to take part in a one-to-one in-depth interview via a video platform (such as MS Teams or Zoom).

Participants will be selected to obtain representation of the job roles, teams, and support functions present within the four pathways. Three or four individual interviews will be conducted per substance use pathway (approximately 15 in total). The interview schedule will be informed by findings from the previous data collection activities and used to elicit information about subjective experiences of remote delivery during the COVID-19 pandemic, some of which participants might find difficult to discuss in a focus group. These will include:

- how changes in service delivery have been experienced by those delivering and those in receipt
- how individual circumstances have influenced the experience of change
- what has been effective and less effective in terms of remote delivery
- the provider-user relationship (for example, whether/how change impacted their relationship with new and existing service users)
- the provider-organisation relationship (for example, participants' relationship with their organisations and colleagues, and whether/how they were supported through the changes that took place)
- lessons for future configuration of drug and alcohol services in Leeds

Analysis

Focus groups and interviews will be transcribed and uploaded into NVivo (or a similar software) for coding and analysis. We anticipate that data will be analysed using framework analysis (Ritchie and Spencer, 2004) as this offers a structured, systematic approach to qualitative data analysis, and the possibility for PIRg and service user involvement in the analytic process. (Gale et al., 2013). Additional data will include the timelines, which will also

be uploaded to NVivo where relevant.

Piloting
Ahead of their use, we will pilot the individual timeline activity, focus group method, and interview schedule with the Central PHIRST PIRg**.** Piloting will also be conducted with representatives of the Central PHIRST Leeds COVID-19 DASE Advisory Group, and, where possible**,** a suitable cohort of Leeds staff members.

Research ethics
University of Hertfordshire ethics approval has been granted by University of Hertfordshire Health, Science, Engineering & Technology ECDA (Protocol number: HSK/SF/UH/04423, see section 6). Workstream 2 will be conducted in line with the research ethics procedures and protocols outlined in section 6 of this document.

4.5 Workstream 3: (qualitative process evaluation with service users)

Objective

- To explore service user experiences of the delivery of drug and alcohol services during the COVID-19 pandemic

Design

This workstream will provide insight into how service users experienced the changes in service provision, how their perceptions may have changed over time, and how these perceptions and experiences relate to their pathway, treatment status and other demographic context (including, but not limited to, age, digital literacy, etc.). The data generated will be qualitative in nature. Alongside the information obtained from service providers and staff in workstream 2, the data from workstream 3 will be a key element of the synthesis and conclusions of the report. This data will also be considered alongside the quantitative evidence provided by workstream 4.

Forward Leeds and its partners cater to a diverse population that includes service users who have completed treatment and are now being supported for their long-term recovery goals, people undergoing community detoxes, people without stable housing, street sex workers, and people recently released from custodial sentences. Therefore, the research design had to remain diverse enough to be inclusive of different populations, so that the data obtained could embody the wide array of experiences and contexts service users represent. To do so, the research team has worked in close collaboration with the PHIRST PIRg and the existing service-user involvement activities of Forward Leeds based within the organisation's sustained recovery team. In addition, the research design had to account for the social distancing and COVID-19 prevention measures put in place at the time of its design and potential future restrictions.

The design features a triple approach: interviews, focus groups, and a text-based conversation. By providing these three routes for involvement, we seek to meet service users' desires and

needs regarding their commitment to the research, personal context, digital capacity and capability, and overall capacity to engage. A breakdown of recruitment, methods and ethics can be found below.

Recruitment and sampling:
Given the variety of situations of service users (including those who do not have access to the internet or phone), email or mail recruitment directly with service users is not sufficient. Similarly, in conversations with service providers, it was deemed that it would be difficult to involve some service users because of their personal circumstances and/or because of where they were on their recovery journey (see below the section on research ethics). In addition, PPI input pointed to the fact that service providers may be best placed to help recruit potential service users, either at the group or individual level. Thus, recruitment will occur as follows:

- Providers will disseminate information about the evaluation and help identify service users who can be invited to participate.
- Service users will receive information about the research and opportunities to participate through routine communication channels (i.e., email, text, post, flyers and posters, etc.). These communications will be sent out by the service providers but will also include channels to talk with the research team directly.
- For service users who are not able to be approached in this way (for example, because they lack internet access), information about the project will be shared with them during routine contact with drug and alcohol support staff (for example, during appointments or meetings). This information will include a script approved by the research team with input from service providers.

Service users interested in participating will be provided with a Participant Information Sheet, Consent Form and Registration Form (which would request their name, pathway, current treatment status, and demographic information).

This workstream will recruit:

- 16 participants for the interviews, ideally four users per substance use treatment pathway.
- 4 focus groups, each ideally involving between 5 and 8 participants. Participants will be grouped based on their pathway, treatment status or other demographic characteristic.
- 16 service users for the text-based conversation

<u>Individual interviews</u>
Participants will be invited to take part in a semi-structured, in-depth interview. These will be undertaken by a member of the research team and focus on participants' experiences of change to service provision, with an emphasis on identifying potential barriers to access as well as examples of best practice/experience. In addition, interviews will also try to identify how the participants' context (e.g., demographic characteristics, pathway, treatment status, when they were referred to the service) influenced their experience. The interviews are expected to last between 45 minutes and 75 minutes. A safeguarding protocol will be place in collaboration with the partner organisations (see below, ethics).

Interviews will take place remotely: participants can engage in the interview online (using video-and-voice or voice-only platforms, such as MS Teams or Zoom), mobile or landline phone. Participants may use their own personal devices or, where available, access them at one of the partner organisations. In this latter case, organisations will, if possible and feasible given national or organisational Covid-19 restrictions, provide participants with a private space to conduct the interview, and may help setting up the interview platform or sorting out IT issues. Efforts will also be made to work with local digital inclusion organisations to enable participation from those without easy access to tablets, smartphones or adequate private space.

Focus Groups

Focus groups will take place online, facilitated and moderated by members of the research team. To participate in a focus group, participants will need to have access to a video-conferencing platform such as MS Teams or Zoom (either from their own device or from a device provided by the organisation in the latter case, they may be provided with a private space to participate in the focus group where this is possible and feasible given national or organisational Covid-19 restrictions). Participants may choose to participate using audio only, or video plus audio. Focus groups are expected to last approximately one hour. It is anticipated that this method might be particularly suitable for service users who have experience in engaging in group work sessions as part of their treatment and/or recovery.

Focus groups will aim to identify differences and commonalities in participants' experiences of services, and elicit views about obstacles and facilitators to access or engagement. . Participants will be invited to take part in focus groups based on the nature of their substance use (i.e., their substance use pathway), stage of treatment or recovery, and/or by virtue of their engagement with a particular partner service. Individuals will take part in focus groups alongside others sharing broadly similar characteristics in terms of these three criteria. We will also aim for variation among participants in each focus group in terms of factors such as age, sex, and time in treatment, where appropriate.

Text-based conversation

This option is presented as an engagement route for participants who would not be amenable to engaging in interviews or focus group for reasons including privacy concerns, perceived stigma about their experience/substance use, or lack of appropriate technology or private space . In this method, participants will be invited to engage in an asynchronous text-message conversation (e.g., via WhatsApp, SMS text-message, email, etc.). Participants will be sent a research question and they may reply at a time of their convenience, using text, voice, video, or image as part of their replies. Participants will not be expected to reply to the questions immediately and rather will be encouraged to reply at their preferred time. Researchers will seek to reply within a few hours of having obtained a response. This method seeks to be minimally invasive into participants' lives and thus, if participants do not reply to questions within 48 hours, only two prompts will be sent (one at the 48-hour mark and one at the 72-hour mark) before being considered as 'drop out'.

This method is expected to attract participants who would not engage in interviews or focus groups and thus will seek to obtain information about how participants' individual context

influences their engagement with remote service delivery, perceived barriers and experiences. The nature of the method will limit conversations to five to eight broad questions, with potential for more detailed follow-up questions based on participants' responses and perceived engagement. Participants who indicate they want to subsequently talk in more depth can be invited to participate in a focus group or interview, if appropriate or to continue a text-based conversation via email, if that option is available to them.

Analysis
Focus groups, interviews and text-based conversation data will be transcribed and uploaded into NVivo (or a similar software) for coding and analysis. As with WS2 data, we anticipate that data will be analysed using framework analysis (Ritchie and Spencer, 2004).

4.6 Workstream 4 (quantitative outcome and health economic analysis)

4.6.1 Outcomes evaluation

Objective

- To assess how outcomes for service users during the COVID-19 pandemic compare with pre-COVID outcomes

Design

We will investigate data from routinely collected service use contacts held in the records of Forward Leeds. Analyses will be performed in a cross-sectional manner by examining the records on a month-by-month basis and at points separated by six-month intervals. The four treatment pathways as defined by NDTMS (opiate, non-opiate, non-opiates and alcohol, alcohol only) will be analysed separately. The primary outcome variable will be use of (as relevant to each individual) opiates, use of non-opiates, and use of alcohol . In addition, client rated quality of life, psychological health, physical health, engagement in criminal activity, engagement in constructive activity (e.g., work, volunteering, education), and accommodation status will be evaluated as secondary outcomes.

The specific issues examined will be:

1. Changes regarding outcomes over time before and after the start of the pandemic.

2. An evaluation of the factors associated with outcomes, to ascertain whether the relative importance of potential explanatory factors (e.g., ethnicity, parental/caring status) changed as the pandemic evolved.

Numbers of service users will be presented graphically and summarised by tables. Changes in outcomes over time will be assessed by taking each outcome variable in turn and examining patterns across consecutive months. Values will be recorded as either higher or lower than expected relative to long-term trends obtained under the assumption that the pandemic has no effect.

To evaluate factors associated with the outcomes, multivariate methods will be employed on outcome variable data for time points at six-month intervals centred on the start of the pandemic. Covariates will include demographic factors. Other independent variables with information available above a pre-specified percentage will be selected.

Method

Data collected by Forward Leeds will be obtained from Humankind for the twelve months preceding and the twelve months following the start of Lockdown 1 (i.e., from 1/3/2019 to 31/3/2021). The sample size will be determined by the number of records available. As an indication, there are around 3500 service users at any one time with 300 entering and 300 leaving the system each month. Note that service use records with no data on the variables of interest will be excluded. Variables with observations present for at least 50% of cases will be selected for modelling.

As part of the data collected on service users, Forward Leeds routinely use the Treatment Outcome Profile (TOPS) Questionnaire. Outcomes will be selected or derived from items on this questionnaire. The substance use outcome variables, examined as binary, will be use over a period of 28 days (any v. none) of opiates, non-opiates, and alcohol. Quality of life will be assessed by the overall quality of life item on the TOPS, which addresses the individual's enjoyment of life and family relationships on a scale from 0 to 20. Independent variables will include age, gender, ethnic group, employment, marital status, accommodation need, and Index of Multiple Deprivation quintile.

Analysis

Numbers of service users per month over the two-year period will be presented graphically by gender (Nelson et al., 2020) for each treatment pathway group. Quantitative variables will be summarised by means and standard deviations or medians and interquartile ranges. Binary and categorical variables will be summarised by proportions.

To allow for the presence of long-term trends, linear regression lines will be fitted to the monthly data for each outcome variable. The sign of the differences between observed and predicted values will be recorded. To investigate the clustering of positive/ negative signs a runs test will be performed on each sequence of signs generated (Siegel and Castellan, 1988).

To adjust for covariates, multivariable analyses of the outcome variables will be performed at intervals of 6 months. These will be centred on March 2020, the month during which the pandemic began to have a serious impact on life in the UK, exemplified by the start of Lockdown 1. The other time points analysed will be March 2019, September 2019, September 2020, and March 2021. The first two points have been chosen in order to examine the work of Forward Leeds prior to the epidemic. The last two points will highlight the medium-term impact of the pandemic. Quantitative variables will be analysed using multivariable linear regression (Bland, 2015) and binary/ categorical variables by multivariable logistic regression (Hosmer et al., 2013). Where the degree of missingness is not excessive, sensitivity analyses will be performed. Stata Version 15.1 (Stata Corp, 2017) will be used for the analyses.

Research ethics

The data provided will have been anonymised; a data sharing agreement will be in place with the data provider.

4.6.2 Economic/cost evaluation

Objective

- To assess the economic implications of remote versus other forms of delivery for service providers

Method

The primary cost perspective of the analysis will be the local authority funder. If data allow, we will also include a health service perspective (including data on A&E attendances and primary and secondary care contacts), and an exploratory service user perspective (incorporating estimates of out-of-pocket costs from transportation). Unit costs will be drawn from a consistent price year, defined as the latest available at the time of analysis (most likely 2020 at time of writing).

Costs will be compared with the outcomes estimated above in a cost-consequences analysis (CCA). A CCA is a form of economic evaluation that does not calculate a summary ratio, representing the efficiency of one service format with another, but instead presents the costs and outcomes in a disaggregated manner. Conclusions will be drawn from these as to whether the virtual model represents good or poor value for money. It is likely that there will be no overall clear answer, but rather the analysis (and in particular, the sensitivity analyses) will attempt to identify at what stages and in which service users the virtual model represents an improvement in efficiency of the service, and where it is likely to be ineffective and/or counterproductive.

4.7 Workstream 5: Data synthesis and dissemination

Objectives

- To generate recommendations for how the design of drug and alcohol services in Leeds might be optimised in future, drawing on lessons learnt during COVID-19

- To communicate the findings of the evaluation to a range of appropriate stakeholders, including service users and providers, commissioners and policymakers, and the wider public

Method

Approaches to integrating qualitative and quantitative research procedures and data can be implemented at 'design', methods', and 'interpretation and reporting' stages of research (Fetters, Curry, & Creswell, 2013). For this study, qualitative and quantitative data will

primarily be integrated at the 'interpretation and reporting' level. Qualitative research data collected during Workstreams 2 and 3, and quantitative data from Workstream 4, will be separately analysed as standalone workstreams before being brought together (Brannen, 2005). While the four substance use treatment categories were used to frame recruitment and sampling of participants, the research team will analyse qualitative data for each workstream across whole datasets rather than within individual pathways to ensure pertinent themes are not overlooked.

Qualitative analysis of WS2 data (for example timelines) will begin prior to WS4 quantitative analysis commences. However, coding of some qualitative WS2 and WS3 data will be conducted concurrently with analysis of WS4 data. Data will be integrated using an 'integrating through narrative' approach (Fetters, Curry, & Creswell, 2013), where qualitative and quantitative findings are described in different sections of the same report. A mixed contiguous/weaving approach will be taken (Fetters & Freshwater, 2015), allowing the research team to integrate findings from the quantitative outcomes and health economic analyses with qualitative analysis of staff and service users' experiences of service delivery during COVID-19. This will allow, for example, for the generation of explanations for patterns of outcomes and differences in costs and for scrutiny of inequalities in access to services.

Our initial information gathering and logic modelling work has generated valuable contextual information about the structure and delivery of Leeds drug and alcohol services, including the various pathway service delivery components, staff teams involved in delivery, and the processes involved (for example, the nature of partnership, joint working, and colocation of services). WS2 and WS3 data collection will greatly enhance this understanding and generate contextual data that will be integrated during the interpretation phase to allow for findings and recommendations to be understood within Leeds-specific and sector-wide contexts. Conclusions from the systematic review of published evidence (WS1) will also be integrated at the interpretation phase to frame and contextualize the findings of the study.

Recommendations will be generated by the research team, through consultation with the Advisory Board, project-specific Advisory Group, and the local PPI consultation group. Recommendations will be further developed with key Leeds drug and alcohol service stakeholders at a stakeholder workshop comprising key Leeds drug and alcohol service stakeholders. This will help ensure that the recommendations for future optimisation of drug and alcohol services generated by the evaluation are appropriate and feasible.

In terms of dissemination, Central PHIRST impact, implementation and dissemination work will be driven through the development of an 'Impact Map', 'Dissemination Strategy' and 'Implementation Plan'. The Impact Map will outline the different levels of implementation that will be conducted with different audiences and map the short, medium and longer-term impacts. The Impact Map will be developed in partnership with Leeds City Council, PIRg members, and the project Advisory and Steering groups. It will consider the value of findings to the wider public health system and its stakeholders and how outputs can be effectively communicated and mobilised to other regions and sectors. The Impact Map will capture how the outcomes will be used by the local authority to inform planning and delivery in the short, medium and long-term, and once developed, will define the criteria for strategic impact work and how this will be delivered.

Following development of the Impact Map, we will work with guidance from implementation experts in the East of England NIHR ARC, and the UH Marketing and Communications (MarComms) team, to develop a 'Dissemination Strategy' and 'Implementation Plan'. In addition, a dynamic database of stakeholders is being created and we will convene a 'design group' to test ideas for effective implementation and dissemination.

Dissemination will occur through a number of key routes, including:

- PHIRST website, jointly managed by the four PHIRST teams
- Creative outputs such as video and interactive content, including a video lay summary
- A final evaluation report for NIHR (draft final report to be submitted in December 2021)
- Social media channels
- Traditional academic routes of conference presentations and peer-reviewed, open access journal articles
- Dissemination through professional networks, including drug and alcohol sector specific networks of which our project-specific Advisory Group are members
- Local Authority workshops and events such as the Leeds City Council 'Want to Learn More about....?' webinar series.

All outputs will be informed by consultation with the PIRg, local PPI service user group, and project Advisory groups. In addition, to organize the collaboration within the four PHIRST teams across England, a national-level PHIRST Communications Working group has been set up with representatives from each PHIRST as well as PPI members (supported by the PPI co-applicant and PPI expertise from University of Hertfordshire). This team will meet regularly and develop proposals for the approval of NIHR.

5 Research governance and project management

5.1 Central PHIRST governance and project management

Appendix 1 presents an organogram of the Central PHIRST showing the team structure and roles.

Project Leads
The project is led by the two PHIRST Chief Investigators, Professor Katherine Brown and Professor Wendy Wills.

Management Group
The Central PHIRST Management Group meets on a weekly basis to provide oversight and guidance to the Central PHIRST. The Management Group comprises the Chief Investigators and the eight PHIRST Co-applicants listed in section 1.6.

Central PHIRST Patient Involvement in Research group (PIRg)
The University of Hertfordshire is committed to involving the pubic in all stages of its research and has an existing Patient Involvement in Research group (PIRg) comprised of members of the public, service users and carers. In collaboration with our PPI co-investigator Amander Wellings, we have set up a dedicated PHIRST PIRg, which is chaired by Amander and supported by Professor Jones and members of the research team.

The PIRg will work closely with the Central PHIRST team and provide public, service user and carer perspective to all the public health evaluation projects conducted by the team. The eight members of the PIRg meet as a whole on a monthly basis to discuss various aspects of Central PHIRST evaluation work (for example, research questions, methodology, literature review, research tools, and dissemination), and between meetings work closely with the PHIRST to co-produce the evaluation.

5.2 PHIRST advisory and consultative groups

Central PHIRST Independent Advisory Board
An Independent Advisory Board (Central PHIRST Independent Advisory Board) has been convened to provide independent, external and policy-orientated advice to the Central PHIRST. The Board provides specific advice and support in relation to the strategic direction of the Central PHIRST and its allocated projects. It comments on the ongoing work plan and progress in line with study protocols, acts as a sounding board for new ideas and developments and advises on opportunities for wider dissemination and for translating research into policy and practice. It is an advisory only body and does not make decisions in its own right or report to any other group or committee.

The Board will meet up to three times per year and is comprised of experts in the fields of public health and evaluation from academic, third sector, governmental and public sector backgrounds. It is comprised of the following members:

Table 3. List of Independent Advisory Board Members

Name	Job title	Organisation
Mrs Helen King (**Chair**)	Former Deputy Director of Public Health / currently Independent Public Health Consultant	Solihull Public Health Department
Dr Nicola Armstrong	Programme Manager, HSC & R&D Division	Northern Ireland Public Health Agency
Professor Katherine Brown	Professor of Behaviour Change in Health	University of Hertfordshire (non-independent)
Mr Geoff Brown	CEO	Healthwatch Hertfordshire
Dr Tim Chadborn	Head of Behavioural Insights and Evaluation Lead	Public Health England
Dr Suzanne Connolly	Senior Health Improvement Manager	Public Health Scotland
Professor Steve Cummins	Co-Director of the Population Health Innovation Lab	The London School of Hygiene and Tropical Medicine
Dr Sarah Hotham	Senior Research Fellow & NIHR RDS SE Research Adviser	University of Kent
Professor Margaret Maxwell	Director of MHANP Research Unit	University of Stirling
Mr Alex Mendoza	PPI Expert by Experience on Central PHIRST Public Involvement In Research Group (PIRg)	Independent Member
Professor John Middleton	Professor of Public Health	Wolverhampton University
Professor Toby Prevost	Director, Nightingale-Saunders Clinical Trials & Epidemiology Unit at King's CTU	Kings College London
Mrs Genevieve Riley	Senior Researcher	Public Health Wales
Professor Richard Smith	Professor of Health Economics	University of Exeter
Professor Sarah Stewart-Brown	Professor of Public Health	University of Warwick
Mrs Amander Wellings	PPI Expert by Experience; Chair of Central PHIRST PIRg	University of Hertfordshire (non-independent)
Professor Wendy Wills	Director of the Centre for Research in Public Health and Community Care	University of Hertfordshire (non-independent)

In addition, Central PHIRST are in the process of adding a representative from local government to the membership of the Central PHIRST Independent Advisory Board.

Central PHIRST Leeds COVID-19 DASE Evaluation Advisory Group

A project-specific Advisory Group (Central PHIRST Leeds COVID-19 DASE Advisory Group) has been convened to offer specific advice and support in relation to the Leeds Covid-19 DASE evaluation. The Group is comprised of nine experts in the field of drug and alcohol treatment and support from across England and is chaired by Linda Harris (OBE), CEO of Spectrum Community Health CIC. It includes: a representative from Public Health England; a consultant psychiatrist; an 'Expert by Experience' with lived experience of accessing drug and alcohol services; a local authority drug and alcohol commissioner; a representative from a leading national drug and alcohol treatment alliance organisation; a research lead from an independent social change organisation; and two representatives from different leading national drug and alcohol information, evidence and resource providers.

The Advisory Group will meet up to six times per year for the duration of the Leeds COVID-19 DASE evaluation. It is comprised of the following members:

Table 4. List of DASE Advisory Group Members

Name	Job title	Organisation
Linda Harris (Chair)	Chief executive	Spectrum Community Health
Dan Burn	Health Improvement Principal (Drugs, Alcohol, Tobacco and Gambling)	Leeds City Council
Natalie Davies	Co-editor	Drug & Alcohol Findings
Sunny Dhadley	Consultant, Speaker and Advisor	N/A (Expert by Experience)
Will Haydock	Senior Health Programme Advisor	Dorset County Council
Michael Kelleher	Consultant Addictions Psychiatrist	South London and Maudsley NHS Foundation Trust
Andy Maddison	Health and Wellbeing Programme Manager	PHE - Yorkshire and Humber region
Harry Shapiro	Director	Drug Wise
Oliver Standing	Director	Collective Voice
Emma Wincup	Research Manager - Qualitative	Joseph Rowntree Foundation

Local PPI and service-user involvement

A local, Leeds-based service user PPI group with lived experience of accessing drug and alcohol support services has been convened, with the aid of Forward Leeds, to advise on, and assist with, key aspects of our methodology, data collection, and implementation/impact work. This group will convene on a minimum of three occasions, which coincide with particular points in the Leeds COVID-19 DASE evaluation workplan, to provide invaluable input into the evaluation and provide an additional route through which co-production can be realised.

6 Ethical considerations and approvals

Whilst an ethical framework guides the work of the PHIRST, ethical considerations for this project particularly relate to the qualitative process evaluation (Workstreams 2 and 3) and the following sections therefore relate to these elements of the study.

This project approaches ethics as an ongoing reflexive exercise relevant to all aspects of data collection, analysis and publication. While this protocol provides a description of the ethical issues identified, it is possible that unexpected ethical issues will happen in the course of the research. The research team will monitor and document ethical concerns arising during the course of the research which will be captured in the study's issue log. When necessary these will be discussed with partner organisations (in accordance with above provisions about confidentiality). PPI input will be sought in any discussion about ethical matters at all stages of research, both routinely during approval of different forms and data collection instruments, as well as when particular issues arise.

Service users will receive a voucher to thank them for their participation in the study.

Informed Consent and withdrawal

All participants will be adults over 18 years of age and this project will not involve vulnerable participants (in this document, we use the term 'vulnerable' to encompass both participants who meet standard criteria, such as being underage, and criteria specific to this project, such as undergoing intensive community detoxes). All potential participants will be provided with a detailed Participant Information Sheet, which will convey comprehensive information about the project to allow them to provide written consent. They will be requested to record this consent in an electronic Consent Form. Participants will be informed about their right to withdraw from the study at any time.

These documents will be written in a language that is accessible to participants with input from PIRg and Forward Leeds patient involvement groups. A telephone number will be set up for participants to contact the research team with queries.

Confidentiality

With the exception of potential harm or criminal activity described above, all personal information will be considered as confidential. Data will be stored and processed in line with GDPR and a Data Protection Impact Assessment (DPIA) will be developed.

This project will seek to maintain full participant confidentiality. Participants' contributions to the research will not be shared with service providers or their organisations and will be anonymized in publications, and focus group participants will be encouraged to consider their discussions confidential.

Risks, safeguarding and referrals

Given that the current project is interested in experiences of drug and alcohol services delivered during the COVID-19 lockdown and not experiences of drug and alcohol use disorders or of the lockdown more generally, it is not expected that the nature of the project will give rise to safeguarding concerns beyond those of any other project. Risk assessment and safeguarding protocols will be developed in collaboration with the partner organisations.

In particular, partner organisations have agreed to make available their standard safeguarding and referral pathways available to those seeking to participate in the research.

Staff members will have access to debriefing opportunities after their participation in the project—these will serve to identify any further referrals required.

Potential benefits for study participants

This project focuses on evaluating the characteristics and effectiveness of remote delivery of drug and alcohol services and will also provide recommendations for implementing hybrid delivery in the future. It is possible that organisations modify their service delivery based on the findings of this project. Thus, this is a rare opportunity for participants to see the effects of their participation in action. Participants will be informed that a report will be written and disseminated that will contain a number of recommendations.

Approvals

Ethics approval will be sought through the University of Hertfordshire Health, Science, Engineering & Technology ECDA.

Table 5. Ethical approvals

Workstream 2			
	Required?	Protocol number	Date obtained
Institutional approval	Yes	HSK/SF/UH/04423	07/01/2021
Workstream 3			
	Required?	Protocol number	Date obtained
Institutional approval	Yes	*Application in progress*	

7 Data protection and management

The PHIRST is an NIHR funded initiative and the University of Hertfordshire is leading a consortium involving Ulster University, the University of Birmingham and the University of East Anglia. Staff at the University of Hertfordshire will take full responsibility for organising data collection and the safe management and storage of data.

The University of Hertfordshire Data Compliance Officer has approved a Data Protection Impact Assessment (DPIA) for this study and this document is reviewed and updated regularly to meet University governance regulations. A copy of the DPIA is available on request from the Chief Investigators.

A Data Management Plan (DMP) will be produced specifying the types of data that will be generated by the study, how this data will be preserved, and how it will be shared. The DMP will reflect the University of Hertfordshire's commitment to open access science.

8 Plain English Summary

Why this study is needed

The Covid-19 pandemic meant that there needed to be substantial changes to the delivery of drug and alcohol support services across Leeds. This included stopping, or significantly reducing, face-to-face support services, and a move to remote delivery of key drug and support services. Remote service delivery means delivering services mostly over the phone or using technology such as smartphone apps, video chats or instant messaging, rather than face-to-face. Prior to Covid-19, face-to-face delivery had been a core part of many of the drug and alcohol support services.

Although there has been disruption to the usual way of delivering support services, there is some evidence that aspects of remote delivery have been experienced positively by some drug and alcohol support staff and some service users.

Overall aim

The aim of the study is to understand the impact of COVID-19 on the drug and alcohol services in Leeds, and the changes that staff and service users experienced, in order to come to an informed decision about how best to design services in the future.

Research questions

The study aims to answer the following, broad research questions:

- how did the Covid-19 pandemic affect the delivery of the various drug and alcohol support services?
- how were any changes in drug and alcohol support service delivery experienced by those delivering those services and those in receipt of them?
- what impact, if any, did remote delivery during the Covid-19 pandemic have on outcomes for service users

- what was the impact of remote delivery on the cost of delivering drug and alcohol support services, and what were the cost implications for service users?

Evaluation timescales
Start of evaluation work: September 2020
Draft final report completed: December 2021
Key dissemination activities completed: December 2021

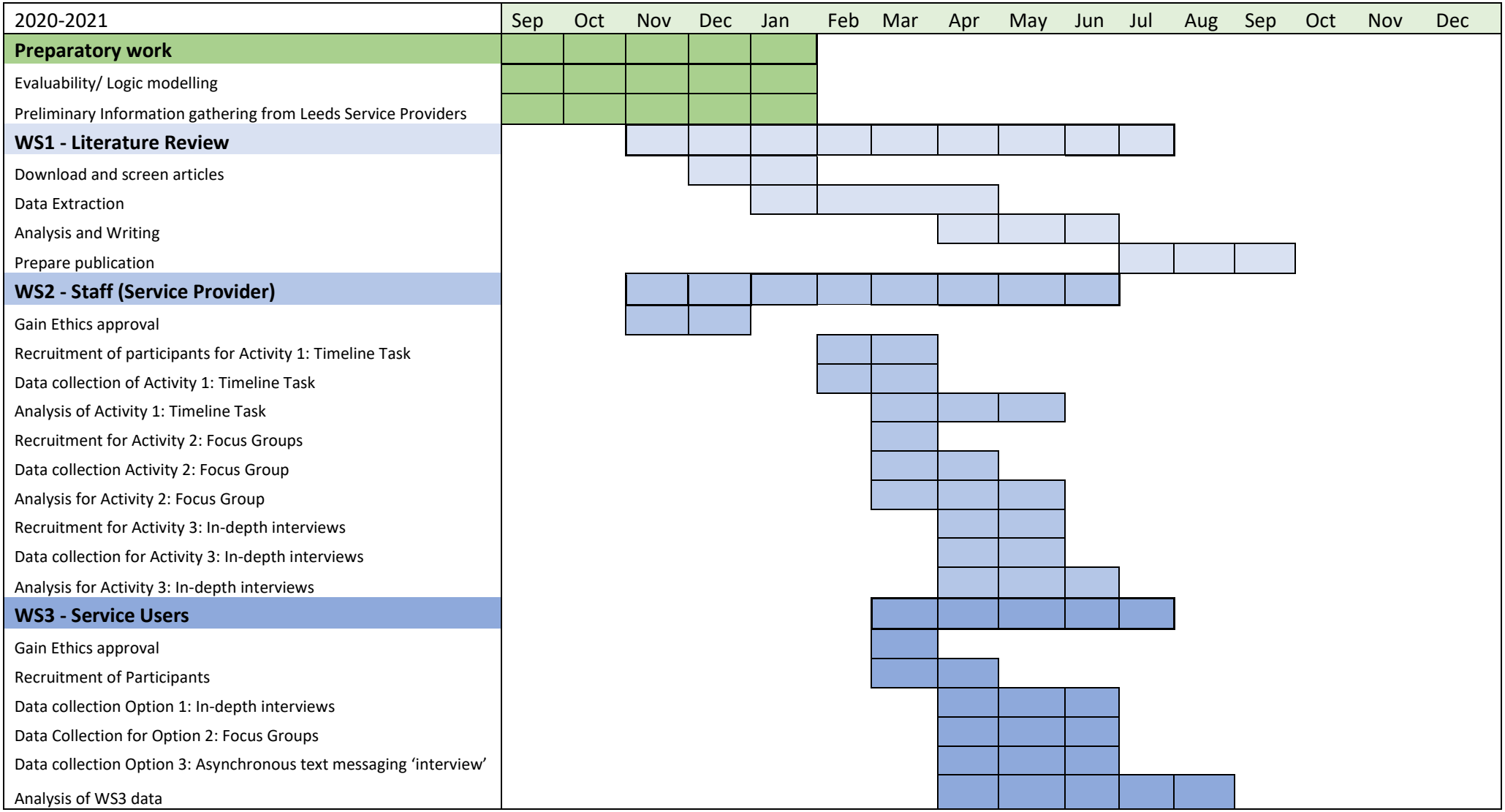
The value of the findings
The local authority which commissions drug and alcohol services, the service providers and those who engage in service use will all benefit from this research, as the knowledge produced will provide an understanding of how drug and alcohol support services can best be designed, drawing on lessons learnt during the Covid-19 pandemic. There will also be important lessons for the effective remote delivery of support service in sectors beyond drug and alcohol support.

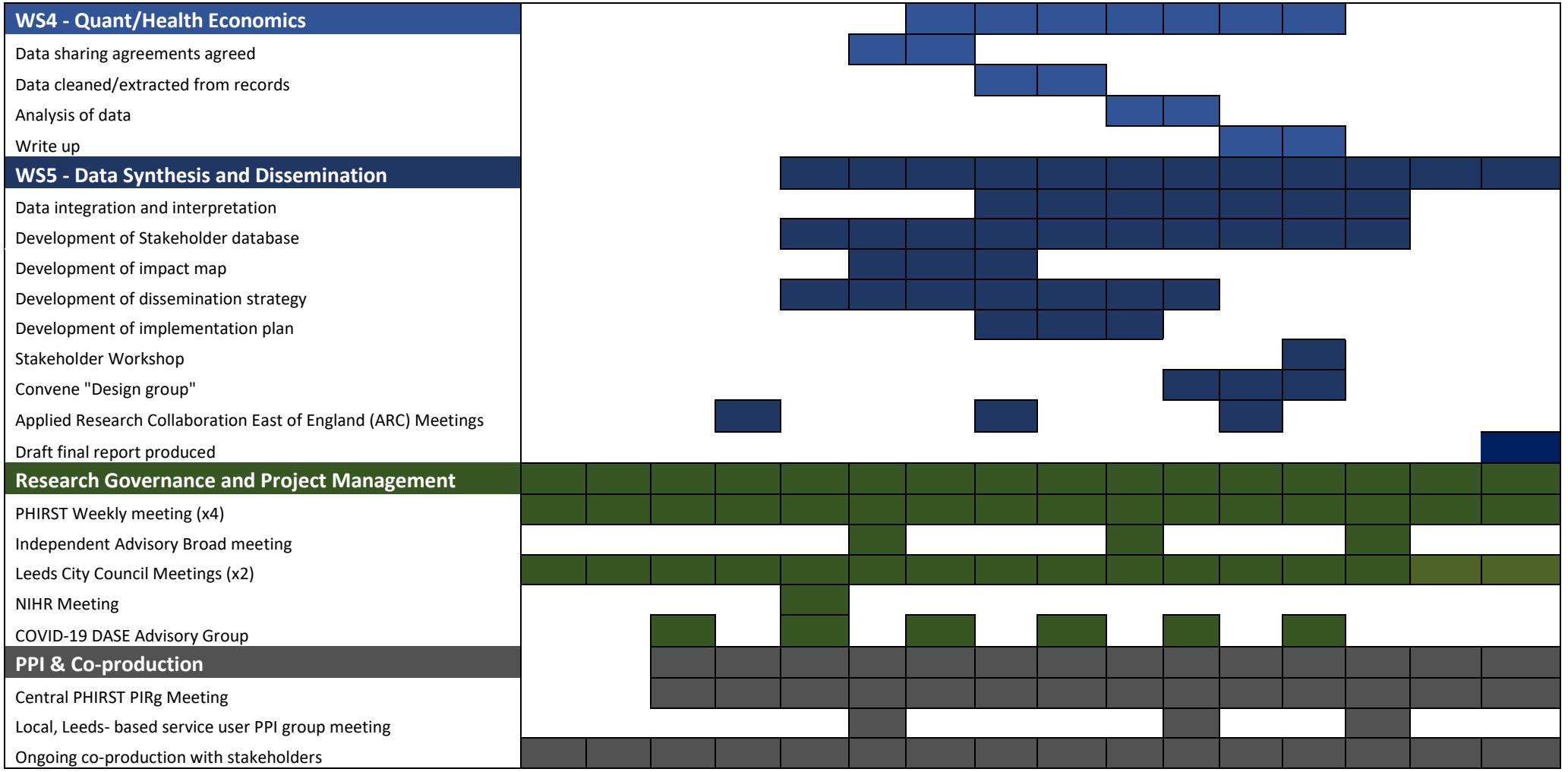
Research design

1) Looking at what has already been written about drug and alcohol support,
2) Asking drug and alcohol support staff to fill in a timeline, and take part in one-to-one interviews and group discussions
3) Group discussions, one to one interviews, and text messaging and email conversations with service users
4) Comparing past information (data) with new data that describes outcomes for service users before and after COVID-19
5) Looking at how much remote delivery costs (health economics)

Service users have been involved throughout the design of this project, adding their insight to help the researchers answer the questions important to them in an accessible way. They will also help with understanding the results of this evaluation and sharing them.

9 Project timescales/GANTT chart




WS4 - Quant/Health Economics
Data sharing agreements agreed
Data cleaned/extracted from records
Analysis of data
Write up
WS5 - Data Synthesis and Dissemination
Data integration and interpretation
Development of Stakeholder database
Development of impact map
Development of dissemination strategy
Development of implementation plan
Stakeholder Workshop
Convene "Design group"
Applied Research Collaboration East of England (ARC) Meetings
Draft final report produced
Research Governance and Project Management
PHIRST Weekly meeting (x4)
Independent Advisory Broad meeting
Leeds City Council Meetings (x2)
NIHR Meeting
COVID-19 DASE Advisory Group
PPI & Co-production
Central PHIRST PIRg Meeting
Local, Leeds- based service user PPI group meeting
Ongoing co-production with stakeholders

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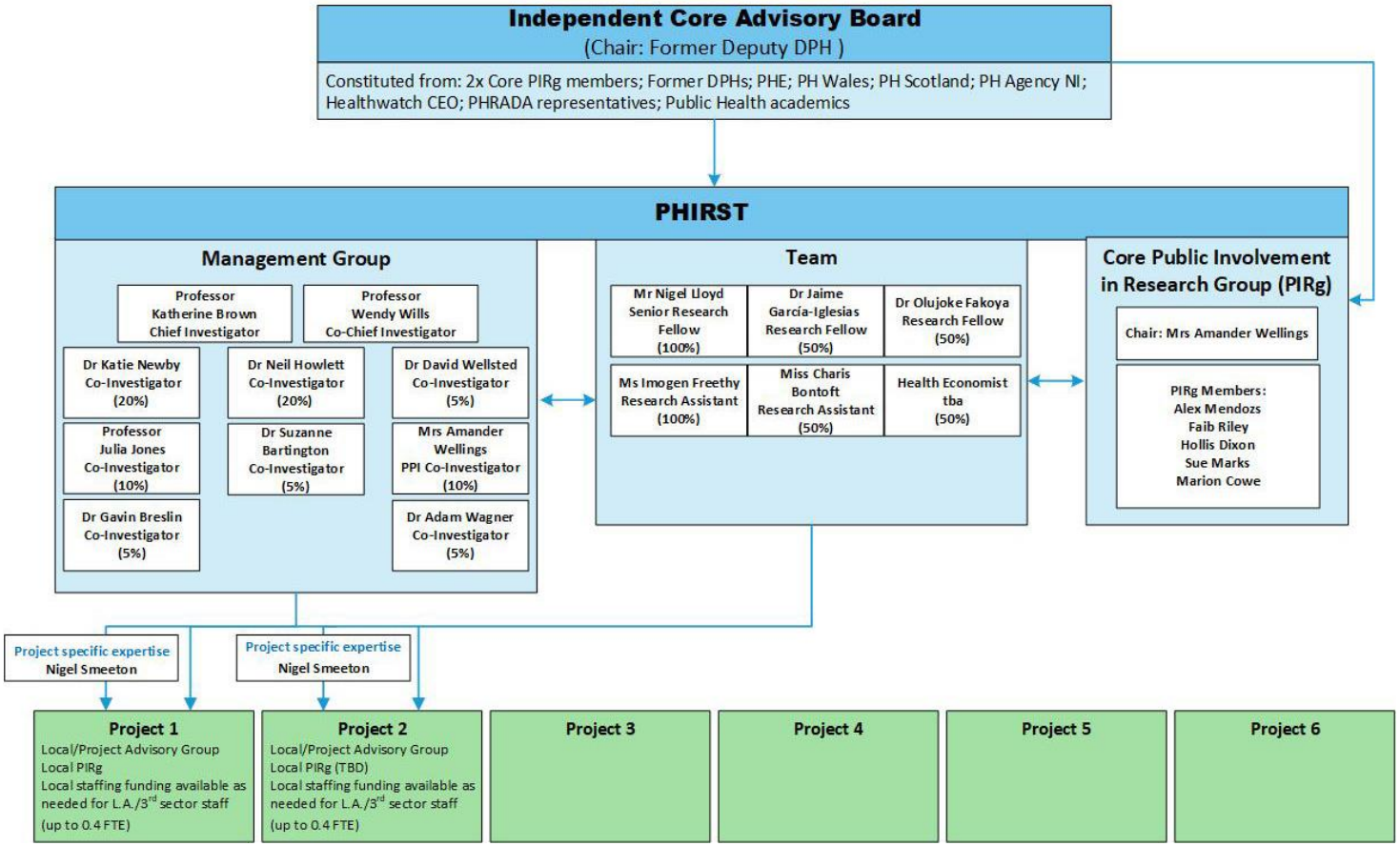
Appendix 1: Central PHIRST team organogram

Figure 2: Central PHIRST team organogram



Appendix 2: Forward Leeds drug and alcohol services 'output and outcomes logic model'

Figure 3: Forward Leeds drug and alcohol services 'output and outcomes logic model'