Potential for scale and spread of technology-enabled remote monitoring of blood pressure at home: a rapid evaluation

Study protocol

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Summary

Background

Hypertension is a key public health issue, given its prevalence and links to risks of cardiovascular disease. There is compelling evidence for the benefits of controlled blood pressure on cardiovascular disease outcomes, and a growing interest amongst health system decisionmakers and care providers in innovative approaches to supporting patients with hypertension. This includes an interest in technology-enabled remote monitoring and its potential to help manage demand and pressures on health services capacity. The establishment of various national programmes, such as the NHS England BP@home programme and the ConnectMe programme in Scotland, is illustrative of this growing focus on the role that remote care can play. In addition to national programmes, many regional health system decision-makers and care providers have rolled out remote blood pressure monitoring care pathways.

There is relatively well established evidence in support of the effectiveness of remote blood pressure monitoring on controlling blood pressure in patients with hypertension. However, there are also significant evidence gaps related to understanding which types remote monitoring BP approaches can support optimal patient outcomes and service impacts in specific contexts, how and why. More specifically:

1. *There is a need to better understand the diversity of remote blood pressure monitoring care pathway models, their constituent components and mechanisms of action, and how these may relate to realisation of desired outcomes and impacts*. Such understandings are central to efforts to inform future pathway design, sustainability, scale and spread. There appears to be substantial variety in diverse aspects of remote blood pressure monitoring. There is a need to learn from the variety of approaches in order to understand how implementation may relate to outcomes and impacts, and implications for scale, spread and sustainability.
2. *There is also very limited evidence on how considerations of inequalities relate to remote BP monitoring care pathway design, implementation, outcome and impacts*. The literature currently does not touch on how multiple categories of disadvantage may interact and play out in the area of BP remote monitoring.
3. *While the challenges to implementing remote monitoring pathways are relatively well understood, there is little systematic learning across studies about how challenges can be effectively addressed* to support implementation and the achievement of desired outcomes, under specific conditions and in specific implementation contexts. This impeded efforts to arrive at practical and actionable insights for decisionmakers.
4. *There are relatively few well-designed studies that examine impacts of remote blood pressure health service utilisation (for example, using quasi-experimental approaches),* as well as cost-related evidence. In part, this is related to challenges to the ability to access such datasets and in part to an evolving data landscape.

Aims, objectives and research questions

Against this context, and in discussion with NHS England (specifically the BP@home team within NHS@home as the policy customer) and the National Institute for Health Research (NIHR) Health and Social Care Delivery Research (HSDR) programme, the DECIDE centre for rapid evaluation of technology enabled remote monitoring will conduct an evaluation of remote monitoring of blood pressure.

Building on insights gained through prior work in this space, *our core overarching aim* is to, through robust yet rapid evaluation, improve the evidence base on what works, how, why and in which contexts, as it relates to services involving remote blood pressure monitoring. More specifically, DECIDE's evaluation aims to provide novel perspectives and insights to inform implementation decisions focused on scale, spread and sustainability of remote blood pressure monitoring care pathways.

Our core evaluation question will be to examine: **How can interventions focused on the remote monitoring of blood pressure be designed, implemented, spread, scaled and sustained to optimise patient outcomes and impacts on health services in the United Kingdom (UK)?**

Key associated questions include: (i) How is tech-enabled remote monitoring of blood pressure implemented (i.e. examining variety in approaches taken)? (ii) How can implementation challenges be navigated and effectively addressed? (iii) How do different implementation approaches contribute to and affect patient uptake and experience, outcomes and health service impacts (i.e. teasing out contribution stories)? (iv) Do (and how do) considerations of inequalities impact on decisions to implement, spread and scale specific approaches and what impact do the chosen approaches have on efforts to address inequalities? (v) What are the key considerations for those looking to scale, spread and sustain technology-enabled remote monitoring of blood pressure at home?

Addressing these questions will allow us to build a better understanding of implementation processes and their relationships to observed outcomes and impacts across a variety of contexts. This learning is a pre-requisite for further exploring and drawing out key criteria for sustainability, scale and spread that can inform future decision-making. A multi-stakeholder perspective on our questions of interest is also key to arriving at well-rounded understandings of spread and scale.

The rapid evaluation will address the urgency of finding innovative ways to support high quality patient care and respond to demand and capacity pressures on health systems, as well as help national and regional/local decision-makers make better informed decisions about future efforts related to remote blood pressure monitoring, in a changing health systems, technology and policy landscape.

Design and methods

The rapid evaluation will adopt a range of qualitative methods, building on literature and document review to understand the current evidence base, establishing an understanding of the intervention logic and 'theory of change' for remote blood pressure monitoring services, in-depth case studies, and refining and testing learning from the case studies for applicability to a wider range of sites and contexts. The evaluation will focus on learning from the experiences of diverse stakeholders (as introduced above) through individual level and interactive fora for data gathering and knowledge exchange.

The evaluation will be rooted in tried and tested theoretical frameworks which will serve as sensitising devices to ensure we consider a diversity of influences on implementation, spread, scale and sustainability in our enquiries, with inequalities being an integral consideration. More specifically, we will use the Non-adoption, Abandonment and challenges to Scale-up, Spread and Sustainability (NASSS) framework, complemented with the

Consolidated Framework for Implementation Research (CFIR). We will also draw on the Intervention-Generated Inequalities framework to underpin our understanding of the role of BP remote monitoring in mitigating or exacerbating inequalities.

The evaluation will unfold in four core phases:

1. In the first inception phase, we will build on initial scoping work done in preparing this protocol and conduct further groundwork to understand the theory of change/intervention logic(s) for remote BP monitoring care pathways, including the variety at play. This will help nuance the issues to consider in the formative evaluation phase, as well as support efforts to select and onboard key case study sites. The inception phase will be implemented through literature review and analysis of key programme documents at intended case study sites and consultation with candidate case study site leads to finalise selection of sites and identification of key individuals to engage in further phases of evaluation.
2. The second key phase is a formative evaluation based on learning from in-depth qualitative case studies of sites implementing technology enabled remote monitoring of blood pressure. The case studies will focus on four general practitioner (GP) practices in approximately 3−4 system footprints (e.g. primary care network and/or integrated care boards/systems). Case studies will place an emphasis on understanding intervention complexity, implementation realities and ways in which challenges can be navigated, as well as approaches to sustainability and perspectives on scale and spread. They will be implemented through desk research and interview based methods. Case studies will be complemented by opportunities to share emerging learning and refine insights on scale and spread, through collective fora (workshops) bringing together stakeholders from across the case study sites. Cross-case analysis will begin to tease out commonalities and differences across contexts to inform spread and scale considerations.
3. The third phase will focus on learning form cross-case comparisons and testing case-study insights for wider applicability across a broader range of contexts, with a particular emphasis on scale and spread considerations. We will bring together stakeholders from different organisations and geographies through workshop formats (one focused specifically on a diverse service-user voice; and another on the broader set of stakeholders from professional communities), to reflect on the learning gained from the case study settings, to help identify the critical scale and spread requirements which are likely to apply across diverse contexts and those which may be more context specific, and to explore the feasibility of enacting spread and scale criteria. We will also consider the learning gained in the context of potential future developments, such as potential new blood pressure monitoring technologies.
4. The final phase will focus on cross analysis, synthesis, reporting and dissemination. At this stage, understanding spread, scale and sustainability requirements will be further advanced through triangulating learning gained against key existing relevant insights from the analysed literature and/or our conceptual frameworks. We will produce a quality assured and message driven final report.

We will pursue a thematic analysis approach. Aligned with principles of rapid evaluation, simultaneous data analysis and initial synthesis of learning will take place as the project evolves to allow formative learning to be shared in timely ways, rather than only at the end. Final synthesis will reside on triangulating insights across data sources and methods.

We will engage Digitally Enabled Care in Diverse Environment's (DECIDE's) governance structures including members of the steering committee with relevant expertise and interests, our service user advisory group for the project, and DECIDE's internal advisory group in key aspects of the work, such as input into data collection materials to ensure relevance and accessibility, potential assistance in recruitment of participants and in informing the dissemination approach. We will maintain open lines of communication with case study sites, NIHR HSDR and NHS England.

Timelines for delivery

The project is anticipated to start in early spring 2024 and complete over a period of 11−12 months, as detailed in the protocol.

Anticipated impact and dissemination

The findings from this evaluation aim to produce nuanced, in depth understandings of the complexity of remote blood pressure monitoring service pathways in terms of how they are designed and implemented, how challenges that unfold over time can be addressed, and practical and actionable learning related to criteria for sustainability, scale and spread. They should be of particular relevance to national policymakers and regional decisionmakers (e.g. at integrated care board/system, primary care network and GP practice levels) concerned with supporting and rolling out innovative, effective approaches to hypertension management across populations in the UK. By better understanding whether and how promising approaches can be scaled and spread, the evaluation will be directly relevant to efforts to address capacity pressures and demand for health services. We also hope that charities active in the hypertension and cardiovascular disease, as well as digital inclusion space will also find the insights on implementation, service user experience and outcomes, and inequalities directly relevant to their awareness raising, outreach, engagement and research funding activities. The findings may also be of interest to an international audience of both scholars and health system decisionmakers, given the growing interest in remote care.

We anticipate disseminating findings from the evaluation through a variety of ways, including through the final report for the NIHR, web-based resources with links to the report and summaries of key insights and social media dissemination. In addition, we will consult with NIHR, our policy customer, steering committee and user advisory group to prioritise other bespoke outputs, which could range from slide sets and infographics with key messages for specific audiences, blogs, webinars or presentations at conferences/events and/or journal publications (which would be costed once decisions on desired outputs are made).

Background and rationale

There is a need to systematically understand what works for remote blood pressure monitoring, in order to support patients with hypertension, a key public health issue

Hypertension is an important public health issue given its prevalence and links to risks of cardiovascular disease (CVD). According to Public Health England (PHE), 11.8 million adults aged 16 years or older in England have hypertension, approximately 26.2% of the adult population[1]. PHE also estimates that for every ten people diagnosed with hypertension, another seven are undiagnosed and untreated [1]. Hypertension is a primary risk factor for several cardiovascular diseases such as coronary artery disease, congestive heart failure, and atrial fibrillation [2].

Given its clear link to CVD, hypertension is considered by the World Health Organisation (WHO) as one of the most preventable causes of premature death[3]. There is compelling evidence for the benefits of controlled blood pressure (BP) on cardiovascular disease outcomes[4-6] . For example, a 2016 meta-analysis including 123 studies and 613,815 participants provided strong evidence on the links between lowering BP and reducing cardiovascular-related health outcomes[4]. A decrease of 10 mm Hg in systolic BP was found to reduce the risk of major cardiovascular disease events by 20%, coronary heart disease by 17%, stroke by 27%, heart failure by 28%, and all-cause mortality by 13%[4]. Yet several studies suggest that it is challenging to adequately control BP[7-9]. For example, a 2021 UK-based study found that only two in five adults between ages 40 and 69 on hypertension treatment have their BP adequately controlled[8], and globally, the WHO estimates that only one in five are adequately controlled [9].

Given the potential that controlling BP holds for improving cardiovascular disease outcomes, coupled with growing public interest in taking actions to support their own wellness [10], health system decisionmakers and care providers are interested in innovative approaches to supporting patients with hypertension[11-14] including in approaches which can help manage demand and pressures on health services capacity. This includes an interest in using technology to enable remote monitoring of BP in home settings[15-20]. For example, the BP@home, BP optimisation and CVD Prevent audit focus on various services and aspects of improving blood pressure control and cardiovascular outcomes in England. Additionally, Scotland has been working on remote BP monitoring through the Scale-Up BP programme, from 2019 to 2021[21] and more recently through ConnectMe[22]. In addition to such national programmes, many regional health system decision-makers at primary care network (PCN), integrated care board/integrated care system (ICB/ICS) level and care providers have rolled out remote monitoring programmes [11, 13, 23].

All BP monitoring relies on monitors and so all remote monitoring is to some extent tech-enabled, although to different degrees. A distinction can be made between lower and higher levels of tech enablement. In '*low-tech' remote BP monitoring* patients use a BP monitor in a home setting, communicate their BP values to clinicians in traditional ways (e.g. by post or phone) and practice staff manually input values into the general practice system. *Higher-tech remote BP monitoring* not only uses blood pressure monitor, but also involves the transfer of BP values from the patient to a general practice electronic health record system via a data/digital platform either with patients actively inputting the data or (potentially) the data being automatically communicated. The scale of automatic transfer of data is currently unclear.

Prior research and evaluations of remote BP monitoring are helping build an understanding of the potential in remote monitoring care pathways to improve patient outcomes and health system impacts. There is relatively strong evidence in support of the effectiveness of remote BP monitoring on controlling BP in patients with hypertension. However, as we expand on in the contents that follow, there are also significant evidence gaps related to understanding which types remote monitoring BP approaches can support optimal patient outcomes and service impacts in specific contexts, how and why. This impedes efforts to draw out practical learning that can help health system decisionmakers make informed decisions about how to sustain, spread and scale remote care pathways.

The DECIDE rapid evaluation centre will provide novel insights to inform implementation decisions focused on scale, spread and sustainability of remote blood pressure monitoring care pathways

Against this context, and in discussion with National Health Service (NHS) England (specifically the BP@home team within NHS@home as the policy customer) and National Institute for Health Research (NIHR) Health and Social Care Delivery Research (HSDR) programme, the Digitally Enable Care in Diverse Environments (DECIDE) centre for rapid evaluation of technology enabled remote monitoring will pursue an evaluation of remote monitoring of BP. Building on insights gained through prior work in this space, we will use robust yet rapid evaluation to contribute to wider knowledge and advance the evidence base, to help inform decisions about care pathway design, implementation, scale, spread and sustainability.

To better understand key evidence gaps and decision-maker needs that rapid evaluation could help address, the DECIDE team conducted early-stage scoping activities, which included desk research and consultations with people who have had a role in establishing and/or implementing programmes of tech-enabled remote monitoring of BP at home. The aim has been to better understand the nature of evidence gaps where rapid evaluation could make an important contribution, and to explore possible localities/implementation sites we could engage with in an evaluation, ideally with quantitative data sources that we could draw on.

At the time of writing this protocol, we have consulted 30 individuals spanning (i) members of DECIDE's advisory and steering committees; (ii) individuals with relevant research, clinical or patient and public involvement and engagement (PPIE) expertise and perspectives; and (iii) experts advising decisionmakers or making decisions related to remote blood pressure monitoring roll out (e.g. experts in the NHS England team, Health Innovation Network (HIN) landscape, industry experts). We also spoke to regional health system decision-makers and care provider representatives involved with implementing technology-enabled remote blood pressure monitoring pathways (e.g. leads from ICBs, HINs, Primary Care Networks (PCNs), GP practices). Consulting this large number of individuals proved essential in light of limited scope for gaining direct access via a policy customer to care pathway or system leads with insights into remote BP monitoring realities at local and regional levels. This meant that we had to establish initial links with regional system leads and informed experts by mobilising our wider networks and DECIDE's governance structure, and to then follow up from those initial leads with individuals who could speak more directly to remote BP monitoring care pathway implementation and connect us with potential case study sites. This snowballing approach was facilitated through our rapid response capacity

but was labour intensive. Given that NHS England (as the policy customer) could not meet to discuss this specific work before 20 December (which was the last day in the office for research team staff before annual leave), staff returning in the second week of January, and the deadline to produce this draft protocol, this large-scale scoping work activity alongside draft protocol production was accomplished in approximately four to five weeks (rather than anticipated six to eight weeks for protocol development).

This scoping work led us to identify the following evaluation needs, focused on building an understanding of the implementation of remote monitoring pathways and the links between diverse implementation approaches and outcomes and impacts, as a foundation for examining and understanding sustainability, spread and scale considerations.

1. *There is a need to better understand the diversity of remote BP monitoring care pathway models, their constituent components and mechanisms of action, and how these may relate to realisation of desired outcomes and impacts*. Such understandings are central to efforts to inform future pathway design, sustainability, scale and spread. There appears to be substantial variety in diverse aspects of remote blood pressure monitoring care pathway design and implementation, such as in the levels of tech-enablement; nature of interactions and roles of service users and healthcare professionals; in how care pathways are governed and financed, and in how patients are selected into care pathways. Diversity in itself is not seen as an issue, but there is a need to learn from the diversity of approaches in order to understand how implementation may relate to outcomes and impacts.
2. *There is also very limited evidence on how considerations of inequalities relate to remote BP monitoring care pathway design, implementation, outcome and impacts*. The literature currently does not touch on how multiple categories of disadvantage may interact and play out in the area of BP remote monitoring.
3. *While the challenges to implementing remote monitoring pathways are relatively well understood, there is little systematic learning across studies about how challenges can be effectively addressed* to support implementation and the achievement of desired outcomes, under specific conditions and in specific implementation contexts. This has impeded efforts to arrive at practical and actionable insights for decisionmakers.
4. *There are relatively few well-designed studies that examine impacts of remote blood pressure health service utilisation* (for example, using quasi-experimental analysis), as well as cost-related evidence. In part, this is related to challenges to the ability to access such datasets and in part to an evolving data landscape.

We expand on these evaluation needs and evidence gaps below.

Remote monitoring of blood pressure at home has been found in randomised controlled trials to be *effective in improving blood pressure control* in patients with hypertension[14, 16, 24]. One study (TASMINH4) that specifically compared usual care vs. tech-enabled (i.e. involving digital/data platforms) vs. low-tech enabled monitoring (i.e. relying just on use of monitor at home) found that remote monitoring in general was effective, regardless of whether remote BP monitoring is tech-enabled or not[17]. A cost effectiveness study of TASMINH4, suggested that tech-enabled monitoring could be more cost-effective compared to usual care and low-tech enabled monitoring, though results varied based on model assumptions made [24]. The impact of remote monitoring in real world implementation contexts (outside of trials) is less clear.

The evidence on the impacts of remote monitoring of BP on *service utilisation* is mixed. For example, a study that looked at remote monitoring-based service redesign found that supported self-monitoring at home was associated with an increase in use of NHS resources (telephone calls, surgery and home visits carried out by GPs, practice nurses, district nurses, and attendance at out-of-hours service, accident and emergency, and hospital admission)[25]. In addition, a cost-effectiveness analysis found that the telemonitoring intervention also resulted in additional GP and nurse time, in part due to higher dosages of medication issued[20]. Conversely, an implementation study in Scotland found that participants in remote monitoring care pathways made fewer face-to-face appointments and used less consultation time than non-telemonitored patients[19]. A case study on the Bridges Medical Centre in Dorset based on a time and motion analysis also found that remote of monitoring of BP resulted in a 45% reduction in appointments in Year 1, and 73% reduction in Year 2[23]. There is currently an ongoing service evaluation of the telemonitoring intervention, Hypertension Plus, to understand how well the device is working in GP surgeries, and the impact on GP workload[26].

Our consultations revealed perceptions of high variation in practice and little standardisation with regard to implementation, making challenging any systematic learning of how best to implement services in a range of contexts. For example, the BP@home programme was initiated during the COVID-19 pandemic and primarily involved the provision of BP monitors to specific sites and clinical commissioning groups. Our early scoping suggests that practices locally had significant autonomy in deciding who received such monitors and in developing the care models/approaches to supporting patient monitoring. This autonomy seems to be accompanied by diversity in terms of decisions about the frequency and duration of obtaining readings from patients, organisation of labour within GP practices for engaging with and acting on monitoring data and levels of engagement and support from local and regional bodies such as PCNs and ICBs. Scoping consultations also suggest that following the initial provision of BP monitors via the BP@home programme, the BP Optimisation programme focused on continued support for remote monitoring, prioritisation of patients, identifying undiagnosed patients and addressing health inequalities through the Proactive Care Frameworks developed by University College London (UCL) partners[15]. The uptake of BP Optimisation at the PCN level was relatively high at just under 50%[13], but whether and how practices utilised the BP Optimisation tools appear to vary widely. There is diversity in how the relations and interactions between these two national hypertension-focused programmes (BP@home, BP Optimisation programme) unfolded across different regional and local health systems footprints and GP practices and their respective impacts on desired outcomes. Funding for BP Optimisation ended September 2023; thus, current activities related to BP monitoring at home are based on local ICB/ICS funding and decision-making.

Conversations with stakeholders in our early scoping activities revealed key challenges that affect remote BP monitoring implementation, many of which are also covered in the literature[21, 27, 28]. They identified challenges including (i) *technical features* such as those related to data conveyance to GP practices[11,19] and data integration with GP electronic health record systems[27]; (ii) *human factors* such as patient and clinician accessibility, acceptability, experience, skills and capacities to engage[28]; and (iii) wider *governance arrangements* affecting purchasing and distribution of monitors, nature of support around the tech in terms of patient-clinician engagement in care pathways or selection of eligible patients into remote monitoring efforts[11]. Specifically with regard to service user challenges, lack of guidance on

submitting BP readings to a GP, lack of awareness about why they should monitor their BP and uncertainty around follow-up processes have been documented [28].

Early scoping activities highlighted the importance of considering inequalities and their relations to the implementation and outcomes of remote BP monitoring pathways. The DECIDE rapid evaluation centre has committed to exploring the theme of inequalities as a cross-cutting theme across evaluations, and the importance of exploring inequalities in the context of technology-enabled remote monitoring has been validated in conversations with NIHR HSDR. Specific to remote BP monitoring, there is limited evidence overall on how uptake and in outcomes of remote BP monitoring vary based on diverse patient characteristics. In randomised controlled trials,[12,29] patients had similar BP-related outcomes across individual characteristics: sex, deprivation, though the HOME BP study found differences by age. Studies to date have not said much on differential effects based on ethnicity or inclusion health groups. While existing evaluations and case studies have highlighted example of approaches to address inequalities, for example due to digital exclusion[11, 21] or language barriers[13], the literature does not touch on how multiple categories of disadvantage may interact and play out in the area of BP remote monitoring[30].

Why this research is important and needed now?

The scoping phase desk research and consultations identified that **there is a limited understanding of how remote monitoring of BP interventions can be designed, implemented, spread and scaled to optimise impacts** on both patient outcomes and on health service utilisation in the UK. We conceptualise *spread* as entailing efforts to transfer successful interventions beyond the original adoption context; *scale-up* as establishing the infrastructure that can support widespread adoption, and *sustainability* as maintaining an intervention (in its original or adapted form) over time, where that is merited and supports desired outcomes [31]. Related to this, there is a need to better understand the variety of pathways including different levels of tech-enablement and how this relates to implementation and outcomes, as well as how implementation challenges in tech-enabled remote monitoring pathways can be effectively addressed. A better understanding of implementation realities and their effects is a pre-requisite for exploring and drawing out key criteria for sustainability, scale and spread that can inform future decision-making.

The need for rapid evaluation in this space is particularly important in light of (i) the **importance of hypertension and relatedly cardiovascular disease as a public health issue**, (ii) the **urgency of finding innovative ways to support high quality patient care and respond to demand and capacity pressures** on health systems; and (iii) **the need for robust evidence to help national and regional/local decision-makers** make informed decisions about implementation, spread, scale and sustainability in a changing health systems landscape. This is all the more pertinent given that the early waves of the COVID-19 pandemic provided the impetus (and resources) for rapid roll-out of remote monitoring pathways, raising questions and the needs for evidence that is applicable to decision-making in a 'new normal' context.

Who is the research aimed at?

The evaluation findings will be of particular relevance to national and local NHS decision-makers who are involved with decisions about programme design, implementation, scale and spread. This ranges from leads at local and regional levels, for example in GP practices, PCNs, HINs, ICS/ICBs, and health boards across the UK, as well as national decisionmakers

in NHS England (e..g NHS@home team) and Department of Health and Social Care (DHSC), as well as wider decisionmakers in the devolved nations including in Scotland, Wales and Northern Ireland, relevant to hypertension management, and national programmes such as BP@home and CVD Prevent. We hope that charities active in the hypertension and cardiovascular disease space (e.g. the British Heart Foundation and Blood Pressure UK) as well as charities involved in digital inclusion (e.g. TechAngels and the Good Things Foundation) will find the insights on implementation of remote monitoring pathways, service user experience and outcomes and inequalities directly relevant to their awareness raising, outreach, engagement and research funding activities. The findings should also be of interest to patients and people with hypertension, people important to them, carers, and the public, including to engagement structures such as HealthWatch and Citizen Panels. We believe that the findings will also be of interest to an international audience given increased interest in remote care. Finally, the insights should be of interest to scholars form diverse disciplines in the social and natural sciences, including health services, innovation studies, digital health, cardiovascular disease research and methodologists with an interest in rapid evaluation.

Project plan

Aims

To increase understanding of how interventions focused on the remote monitoring of blood pressure can be designed, implemented, spread, scaled and sustained to optimise patient outcomes and impacts on health services in the UK.

Research questions for the evaluation

Towards this aim, the primary research questions (RQ) are:

RQ1: How is tech-enabled remote monitoring of blood pressure implemented?

RQ2: How have known implementation challenges been navigated and effectively addressed?

RQ3: How do different implementation approaches contribute to and affect patient uptake and experience, outcomes and health service impacts?

RQ4: Do (and how do) considerations of inequalities impact on decisions to implement, spread and scale specific approaches and what impact do the chosen approaches have on efforts to address inequalities?

RQ5: What are the key considerations for those looking to scale, spread and sustain technology-enabled remote monitoring of blood pressure at home?

Design and Methodology

The evaluation design and approach (also methods, see below) has been informed by scoping desk research and consultations (as introduced earlier) as well as on-going discussion about the intended direction and focus of the evaluation of BP remote monitoring services, with the BP@Home team at NHS England. To date this has involved three meetings and email discussion with varied members of the team. These interactions have confirmed the importance of an evaluation focused on better understanding implementation realities in remote monitoring of blood pressure services and the use of technology, and the emphasis on spread and scale up, as this has proved challenging. Engagement with the team at NHS England has been welcome and helped inform the approach conveyed in this protocol. Changes at national level, in terms of clinical director and team make up have, at this stage,

also impacted on what has been feasible in terms of timely engagement with clinical leads and sites, and the extent to which NHS England as a policy customer input to establishing connections with potential study participants. The research team has thus mobilised networks via DECIDE governance structures and existing contacts to establish links and connect with diverse potential study participants at scoping stages, at pace. We plan a strong working relationship with NHS England going forward, on-going connection with potential sites and wider stakeholders to inform the evolution of the evaluation.

Study design overview: approach and methods

The evaluation of BP remote monitoring services will adopt a multiple qualitative methods approach (e.g. document review, multi-level case studies, interviews workshops). Given the diversity of approaches to BP remote monitoring, our focus is on learning from the experiences of a diverse stakeholders and enabling both individual level and interactive fora for data gathering and knowledge exchange. The term stakeholders in its broadest sense refers to the following types of groups relevant to this study: (i) healthcare professionals and support staff; (ii) service user and/or carer perspectives; (iii) regional/local system leads such as ICBs/ICSs, PCNs, HINs; (iv) national decision makers/policy-related bodies; and (v) industry. Whilst we will engage with a limited number of individuals and organisations within the scope of a rapid evaluation, we will seek rounded perspectives from a variety of voices. Engaging with the expertise and experiences of those *directly involved with delivering remote monitoring care pathways* (e.g. healthcare professionals and support staff, community pharmacists, care coordinators, technology suppliers); *those with a role in establishing and shaping the pathways* (e.g regional system leads and national policy bodies); and *those using services* (e.g. patients and/or indirectly carers) will allow us to consider implementation, scale and spread from the perspectives of a variety actors who jointly interact to determine how these care pathways unfold, are sustained, spread and scaled (or not) over time.

Core primary data will stem from in-depth qualitative case studies of 4 GP practices implementing technology enabled remote monitoring services of blood pressure pathways in 3−4 system footprints (PCNs, ICSs/ICBs). This will be complemented by opportunities to share emerging learning and refine insights through collective fora bringing together stakeholders from across the case study sites, as well as wider stakeholders in the tech-enabled remote blood pressure monitoring space across the UK (see methods section for further detail).

Case studies will focus on understanding service intervention complexity and mechanisms of action, implementation realities and ways in which challenges can be navigated, and key aspects of relevance to sustaining interventions over time. Cross case analysis will tease out commonalities and differences in insights across contexts to inform spread and scale considerations. Understanding spread and scale requirements will be further advanced through engaging stakeholders from a wider set of contexts (organisational, geographical) and triangulation against key existing relevant insights from the literature and our conceptual frameworks that will inform the evaluation. This comprehensive design reflects the breadth of the evaluation to include learning from implementation and understanding scale, spread and sustainability.

Case study sites will be selected in consideration of our aim to learn from diverse types of technology-enabled remote monitoring service approaches (e.g. more and less tech-enabled, entailing different technology platforms); diverse implementation contexts and populations served (with inequalities being a key theme of interest); and ability to engage with evaluation.

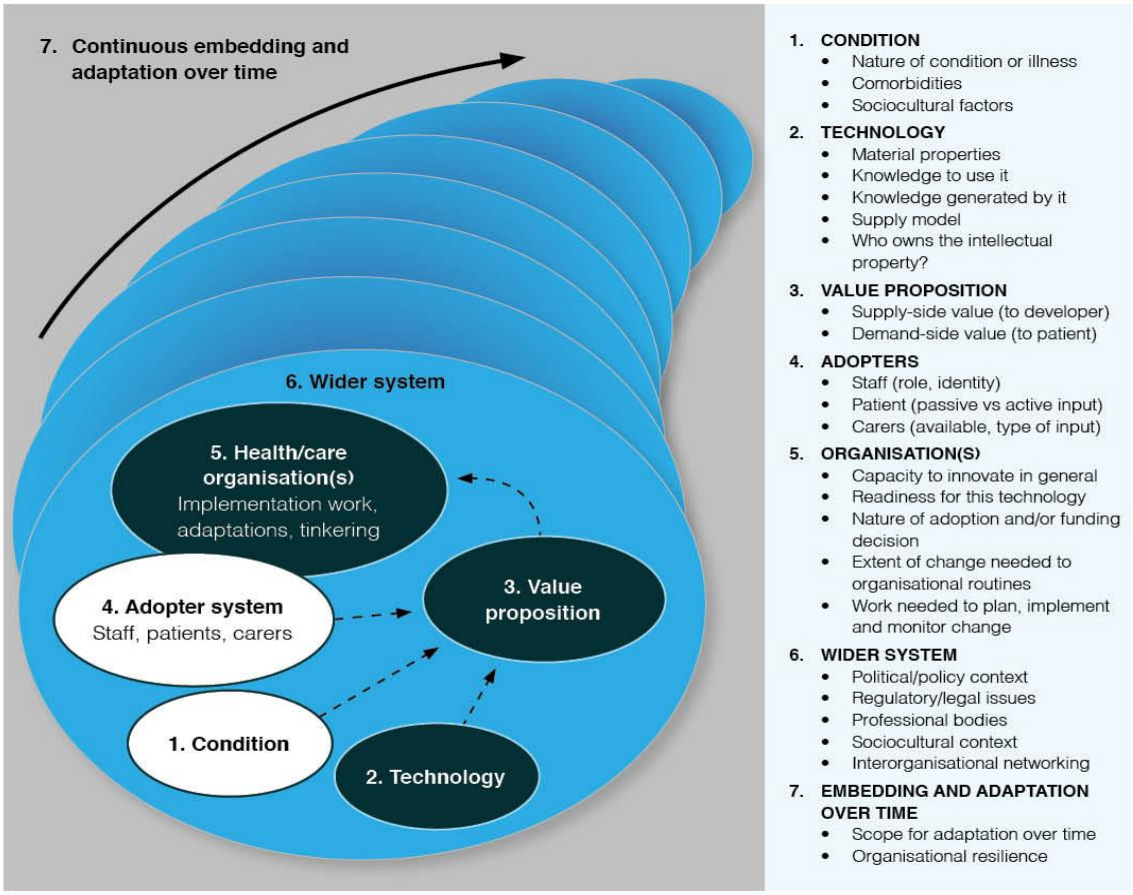
We aim to focus on learning from 'mature sites' who seem to be navigating implementation challenges with relative success (based on insights from scoping consultations) and with scope for offering learning of relevance to decision-making about spread and scale-up to a broader range of sites and contexts.

This protocol does not include a quantitative component. In discussion with our policy customer we are considering the feasibility of quantitative evaluation aspects and the readiness of potential sites for such evaluation given data availability, access constraints, and rapid evaluation timelines. Should this prove possible we would submit the work as a separate study phase.

Conceptual Framework

Our underpinning approach to evaluation is guided by a social science and complexity lens, acknowledging the sociotechnical nature of technology adoption in health care settings, and the uncertain and emergent ways in which technology is understood, adopted, spread and scaled[31]. To this end, we use NASSS framework (Non-adoption, Abandonment, and challenges to Scale-up, Spread, and Sustainability) as a primary sensitising device to understand the various factors that affect implementation, spread and scale [31, 32]. We will supplement this with use of the Consolidated Framework for Implementation Research (CFIR) and work on Intervention Generated Inequalities to allow us to more fully consider the complexities of implementation and equity[33].

The NASSS framework has been used to understand adoption, non-adoption, spread and scale across a variety of settings[31–34]. It is informed by complexity and social science perspectives, embracing of emergence and uncertainty, and sensitises those studying, evaluating or pursuing innovation and improvement efforts to consider seven domains, each of which can come with different levels of complexity (i.e. simple, complex or complicated). The domains are related to: (i) the **nature of the health condition** (including both physical and sociocultural factors); (ii) **technology type** (including both material/physical properties and associated knowledge needed for it to work, supply models and commercial/IP considerations); (iii) **the value proposition** (for developers, patients, health service); (iv) **the role of adopters** (e.g. healthcare staff, system decisionmakers, service users and carers) ; (v) **organisational and wider support** (capacity for innovation, support structures and processes framing innovation decisions and implementation and monitoring over time); (vi) **the wider system** (e.g. sociocultural, political, regulatory) and (vii) **potential for adaptation over time.**



Note: Adapted from Greenhalgh T, et al. 'Beyond adoption: a new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies'.[1]

Figure 1 The NASSS framework (Non-adoption, Abandonment, and challenges to Scale-up, Spread, and Sustainability) to understand various the various factors that affect implementation, spread and scale.[34]

We will use the CFIR as a complementary framework [35]. The CFIR framework enables us emphasise the implementation process in the context of multilevel interactions between different domains and levels in a system that are involved with implementation, spread and scale efforts – these are the (i) **intervention characteristics** (e.g. considering factors such as strength of evidence behind intervention, design quality, relative advantage, adaptability, cost considerations and others; (ii) **inner setting** (e.g. structural and social characteristics of the adoption setting, culture and implementation climate) (iii) **outer setting** (e.g. unmet needs, resources, policies and incentives and social forces), (iv) **participants individual characteristics** (e.g. knowledge, beliefs, attitudes, skills/self-efficacy and other personal attributes) and (v) **process of implementation** (e.g. planning, engaging, executing, reflecting and evaluating). CFIR explicitly offers a series of constructs having to do with individuals, inner and outer settings – i.e. individuals, organisations and the wider system, and the updated framework[35] adds a considerable number of constructs to improve relevance to a breadth of implementation contexts.

Specifically related to inequalities, we will draw on the Intervention-Generated Inequalities framework to underpin our understanding of the role of BP remote monitoring in mitigating or exacerbating inequalities[33]. Together these frameworks allow us to engage with the complexity of technology-enabled remote monitoring of blood pressure care pathways and consider the structures, resources, processes, knowledge, behaviours, attitudes and interactions needed for implementation, spread, scale and sustainability in a way that

accommodates for emergence, recognises the differing levels of complexity in different domains framing how interventions unfold and the interdependence and interactions of different levels in the system (and associated stakeholders) on the success of implementation, scale, spread and sustainability efforts.

Methods

The evaluation will be comprised of five distinct but interrelated work packages (WP), each with a distinct focus, set of activities and outputs. Figure 1 provides an overview of work packages, with detail provided in the sections below.

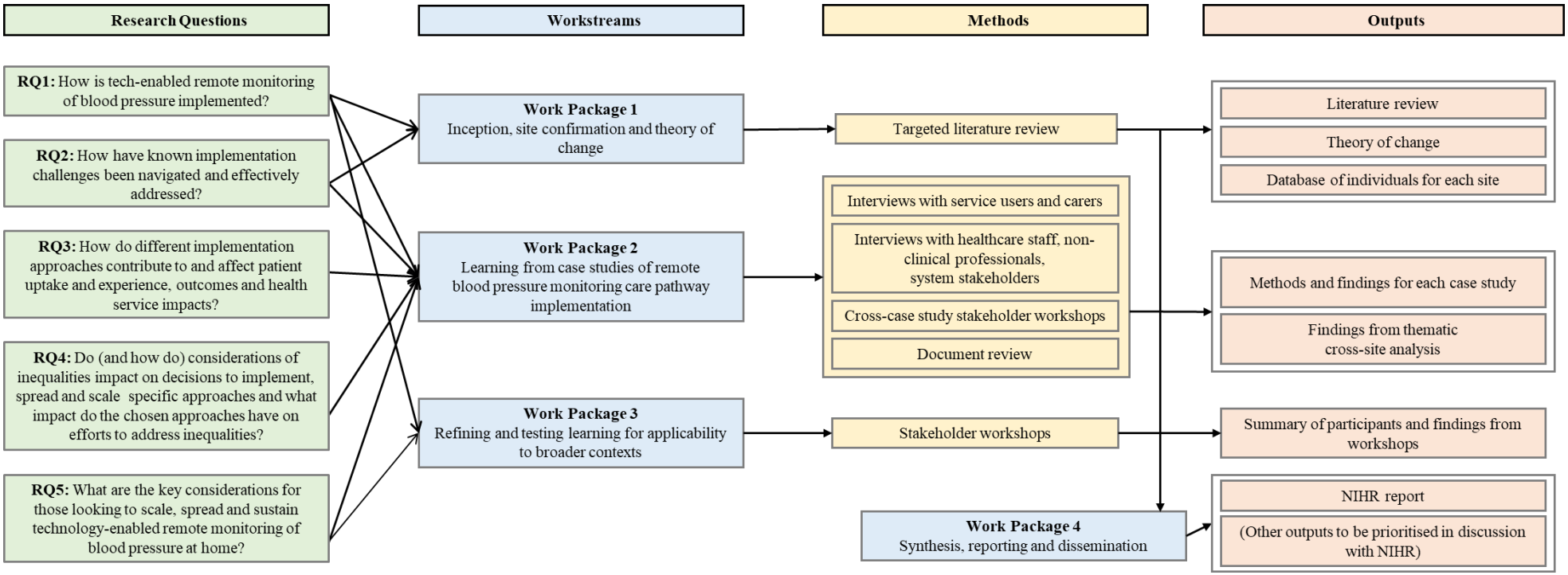


Figure 2. Summary of evaluation activities and links to research questions

WP1: Inception, site confirmation and theory of change *(months 1-2)*

Aim: To lay the initial groundwork for the evaluation.
Approach: This work package involves various activities to lay the initial groundwork to conduct a successful evaluation as detailed below.

1) **Task 1 - Inception meetings**

Inception meetings will be online amongst the evaluation team, and between the evaluation team, NIHR and NHS England (as the policy customer) and will serve to confirm a shared understanding of the evaluation focus, aims and implementation plan.

2) **Task 2 - Establishing the project PPIE group and kick off meeting**

We will draw from one to two members from the DECIDE advisory group of service users and representatives of patient charities, to establish a project specific user advisory group. We will complement this with additional representation from one to two PPIE representatives with specific experience in the hypertension space. A kick off meeting with this group will help nuance our approach to service user engagement, the issues to consider in implementing evaluation and inform the service user participant recruitment approach.

3) **Task 3 - A targeted literature review**

A rapid and focused literature review will be undertaken to summarise key existing literature based on thematic analysis, including both peer-reviewed literature as well as grey literature focused on BP remote monitoring in the UK. The review will help identify common elements of remote monitoring pathways and sensitise us to variables to consider in implementing the evaluation. We will conduct a targeted search strategy using PubMed to identify key sources of academic literature and Google to identify recent, local evaluations of BP monitoring programmes, aiming for approximately 20 documents to include in the literature review. The literature review will inform our theory of change (see fifth bullet below) for technology enabled remote blood pressure monitoring programmes in the UK, within which to locate further evaluation activities.

4) **Task 4 - Initial consultations with candidate case study site leads to recruit and confirm case studies for the evaluation**

This will build on early scoping activities which explored a range of possible sites to engage in the evaluation and evaluability, and will help us identify and focus in on 4 case studies (GP-practice site as entry unit of analysis) spanning diverse system footprints (ICB/ICS). We will use a purposive and maximum variation sampling strategy to select case study sites, with the aim of ensuring a mix of geographic area, low vs. high tech implementation of BP remote monitoring, types of staff supporting BP remote monitoring, and service user population characteristics such as age, socioeconomic deprivation and ethnic diversity.

In the earlier scoping phase (see above) we identified a number of potential regional health systems (e.g. ICS/ICB level) with GP practices that may be potential case study sites. At the time of writing this protocol, two sites (GP practices) have expressed an interest in being case study sites and we have also had promising signals of potential interest from experts (mainly regional and local health system decisionmakers) in five health system footprints where potential case study sites (i.e. GP practice level) are being identified. We have been discussing and/or have scheduled conversations to explore potential participation in the following health systems (and seek to follow up with potential GP practice site leads): Dorset ICS, Surrey Heartlands ICS, Frimley ICS, Cornwall and Isles of Scilly ICS, Hampshire and

Isle of Wight ICS, North West London ICS, South East London ICS, NHS Lothian, Scottish Deep End Project practices. Candidate GP practice case study sites include:

- Bridges Medical Centre in Weymouth and Portland, Dorset ICS: This site has three years of experience with BP remote monitoring; the remote monitoring care pathway approach is led at the practice level primarily by an experienced nurse practitioner (other areas in the ICS use a PCN-led approach). Initially, Bridges targeted patients by risk category; they have since expanded the offering to all patients with hypertension and offer the service to newly diagnosed patients. Monitors are provided free as part of the service at present. They use the VISO system by Omron.
- Deep End practice in NHS Lothian: Deep End is a consortium of the 100 most deprived practices in Scotland. We are targeting a practice within NHS Lothian, which covers NHS organisations within the Lothian area (which was evaluated by Hammersley et al 2020[19]) that is part of the Deep End consortium, but which is yet to be identified. The Scottish Government in the last one to two years have stopped providing free monitors to patients. Practices have moved recently to the InHealthcare system (the initial pilot used Flo).
- A practice in Sout East London ICS (contact yet to be established via the local HIN): This GP surgery was identified as a potentially interesting site to learn from by a local HIN representative, who is yet to put us in touch with the practice. The surgery was one of the last in the ICS footprint to receive BP monitors as part of the initial BP@home programme roll out in the region, and thus had the opportunity to leverage learning from earlier implementations of BP@home. We are currently being connected to this group via HIN South London.
- St. Austell Healthcare is one GP practice within the two-practice St. Austell Healthcare Group PCN. The service model is a centralised model primarily implemented by seven pharmacists. St. Austell's offer home monitoring to everyone with hypertension and loan out home monitors for patients who need a diagnosis. St Austell's offer digital drop-in sessions for patients who need help with at-home monitoring. They use the VISO system by Omron.

Other areas we have initiated conversations with but are yet to establish contact at the GP practice level (or finalise efforts to confirm which GP practice would be most appropriate for a potential case study) include: Surrey Heartlands ICS, South East London ICS, and Mid Dorset PCN in Dorset ICS. We will conduct consultations with case study site leads to confirm feasibility/evaluability assessment, building on earlier scoping activities – looking at readiness of the intervention for evaluation, willingness of participants to engage in case studies, and utility. These consultations will also confirm primary areas of enquiry for the case studies and identify stakeholders to engage in case study implementation – both individuals to interview for the case studies and possibly wider stakeholders in a system footprint with whom it might be helpful to engage with as part of wider evaluation activities (see WP2 and WP3). We envisage up to 12 consultations (complementing those carried out pre-protocol development) to allow us to finalise case study site selection.

While we plan to use GP practice sites as the entry point level of analysis for the case studies, we recognise that there is a diversity of approaches to remote blood pressure remote monitoring across the country, in terms of the level and nature of practice led versus system led (e.g. PCN, ICB-led) approaches. We will consider these differences in our enquiries and sampling approach.

Task 5 - Developing an overarching theory of change and intervention logic to guide evaluation activities

Guided by findings from the literature review and consultations with candidate case study site leads, we will establish an overarching theory of change and intervention logic for tech-enabled remote monitoring of blood pressure services[36]. Our aim here is to formulate an understanding of what tech-enabled remote monitoring is meant to achieve and how, as a foundation for informing further evaluation inquiries. Specific domains from the study frameworks (e.g. NASSS) will complement insights from the literature and consultations, and be used to help identify important dimensions to consider in a theory of change and intervention logic(s) for remote BP monitoring pathways.

We plan to use this overarching theory of change and intervention logic model as an organising structure and a tool to help make sense of how localities may have developed localised intervention logics given diverse social, political, and economic contexts as well as differences in service user population makeup and needs. The theory of change will tease out the key categories of inputs needed in remote BP monitoring pathways; key types of elements/components of relevant to process implementation (acknowledging that there will be variety in how the key components play out in specific contexts); desired outputs and outcomes/impacts. It will also consider key influences in external context that influence implementation and allow us to, based on the literature and initial consultations, assess the types of challenges that can affect implementation of planned theories of change. This in turn will provide a foundation for enquiries into how challenges can be navigated, for later phases of the evaluation.

5) **Task 6 - Developing data collection tools**

We will develop the data collection tools for case study implementation. These will primarily be the semi-structured interview guides for healthcare staff, system level stakeholders, and service users who are involved with BP remote monitoring and accompanying resources (e.g. project information sheet, informed consent and privacy form). We will seek some form of input on the project information and data collection materials from our project user advisory group to ensure relevance and accessibility. See also section on Plans for service user engagement and public involvement.

6) **Task 7 - Ethics, data and R&D governance**

We will ensure in this phase that we have the appropriate ethical approvals from the University of Oxford (see section below for detail on Ethics).

Outputs: Key outputs from this phase will include:

- Literature review, including methods and findings
- An overarching theory of change and intervention logic to guide evaluation enquiries
- A database of individuals and organisations to engage in case studies for the evaluation
- Co-designed project information (e.g. participant information sheet, informed consent/privacy form) and data collection tools for the case studies

WP2: Learning from case studies of remote blood pressure monitoring care pathway implementation (*months 3-7)*

Aim: To understand and learn from diverse approaches to remote BP monitoring care pathway implementation, to inform efforts to spread and scale.

Approach: This work package will be based primarily on case studies of implementation of remote blood pressure monitoring at a sample of case study sites, complemented with cross-case study learning and exchange.

The case studies (individually and through cross-case comparative learning) will explore the implementation, scale, and spread of remote monitoring of blood pressure pathways in detail to improve our understanding of how different approaches play out in local contexts, with a particular interest in examining how known social and technical challenges are addressed. We will learn primarily from the perspective of those involved in delivering care pathways and will complement learning from those of service users/carers. The study design will not be able to attribute specific outcomes to specific process changes, but the case studies will seek to tease out 'contribution stories'[37] – i.e. how different elements of tech-enabled remote monitoring pathways and their constituent mechanisms of action interact with each other to contribute to the pursuit and realisation of desired outcomes of interest, considering both intended and unintended consequences of implementation. Case studies will be informed by multiple methods, including document reviews of local programme materials, interviews with local stakeholders, and a stakeholder workshop to complement and refine interview findings:

1) **Task 1 - Document review**

Once case study sites are confirmed, we will seek to obtain key programme-level documents including local evaluation reports (if applicable). We will analyse these in light of the overarching theory of change and intervention logic (see WP1) in order to refine it/establish localised intervention logics for each case study sites, support local evaluation enquiries and understand how local approaches relate to the overarching intervention logic. This will help us explore variation in how key elements of the overarching intervention logic are pursued across a sample of local contexts/case study sites (e.g. different levels of tech enablement pursued, different approaches to governance and implementation of tech-enabled remote monitoring pathways, different approaches to service-user selection into pathways, different conditions in implementation contexts). As a result, we will specify an intervention logic model for each case study site, which will evolve as case study learning accrues and help us nuance the overarching theory of change over time.

2) **Task 2- Interviews with healthcare staff, system stakeholders and service users**

We seek to learn from the expertise, experiences and perspectives of those who are involved with delivering, shaping and using remote BP monitoring services. This includes: (i) healthcare staff, such as GPs, nurses, pharmacists, care coordinators, (ii) service users; (iii) system stakeholders, such as those from the ICS/ICB/PCN/HIN; (iv) and technology suppliers/industry.

The interviews will be semi-structured and will cover questions related to understanding:

- **The intervention** itself, such as *key components and mechanisms of action* (for example those related to the levels and nature of tech-enablement; where onus of responsibly for flagging abnormal readings lies- on patient or healthcare professional; means of engaging with data from readings; workforce organisation; frequency of BP

monitoring and reading submission, duration of monitoring and other process/implementation factors); (ii) *how patients are selected into care pathways* (e.g. eligibility, different approaches to enrolment, consideration of inequalities and population diversity); and (iii) *governance arrangements* (e.g. finance, oversight and management of implementation)
- **The wider implementation contexts** (e.g. social, political, economic and environmental contexts, wider local, regional and national programmes).
- **How different aspects of the intervention and wider implementation context interact with each other to determine how the care pathway unfolds and observed outcomes and impacts**, including how different elements support each other or challenge implementation
- **How implementation challenges have been navigated**
- How **consideration of inequalities** influences implementation decisions
- Key considerations when thinking about **sustainability, scale and spread.**

The interviews will first seek to understand the complexity of the intervention and experiences with implementation, in order to engage with drawing out insights of relevance to learning about sustainability, scale and spread considerations.

We envisage approximately ten-fifteen interviews within each case study site, as follows:
- *Healthcare practice staff*: Within each participating case study site, we envisage up to six interviews with healthcare staff. This could entail a mix of 1-2 GPs, a practice manager, receptionist, and other relevant staff that lead or are involved with BP remote monitoring such as nurses, pharmacists and care coordinators. We understand that individuals with such roles are busy and may have limited time to engage; we will provide flexibility in terms of scheduling and maximise ease of participation.
- *Service users perspective*: We plan interviews (2-4) with service users and if possible and as appropriate will seek to interview their carers. We recognise that with this approach, we are limited in terms of the number of perspectives we are able to gather but feel that with the one-on-one approach we may be able to build some rapport during the interview session and can cover some topic areas more in-depth.
- *System stakeholders:* We envisage approximately three to four interviews with system level leaders at ICB/ICS, PCN and HIN levels.
- *Industry:* The technology supplier relevant to the case study

Recruitment of interviewees from health professional and system leads stakeholder groups as well as industry will be enabled through support from case study local site leads and system stakeholders secured as part of initial evaluation groundwork (see WP1) and prior scoping conversations. We will seek to engage a variety of perspectives and will also incorporate an element of convenience sampling in the first instance to recruit system stakeholders, including initial contacts from the HIN/ICB who may have been involved and/or identified during early scoping conversations. From there we will use snowball sampling to identify other relevant stakeholders. For each participant, we will provide a participant information sheet and request written informed consent prior to the interview.

Recruitment for the interviews and focus group will be secured via local healthcare professionals and if needed, local/regional patient panels. Service user selection will be important given the scope of this specific task; we will seek to involve service users identified by local healthcare professionals in consideration of diversity (and to the extent possible considering those being initially reluctant to uptake remote monitoring or having a

more diverse perspective. We will be transparent in any limitations of the approach, including as related to the constraints of rapid evaluation. For example, we are cognisant that issues of trust, historic relationship to surveillance, fear about access to care and cultural issues and not only time and resource constraints related to rapid evaluation can impact on efforts to ensure optimal levels of diversity. We will try to seek carer input to help understand the service user perspective, as we find they have additional insight into the service user perspective and have their own perspective as the carer of the service user. If it is not possible to engage a carer perspective within the scope of the limited number of individual interviews, we will try to include them in a service user and carer-focused workshop (see below).

Interviews will be conducted via MS Teams and recorded (with consent). For participants without access or unable to utilise the software for any reason, we will offer other means for a video call or a telephone interview. Interviewees will take detailed notes during the interview and write up key learning points in support of rapid evaluation (rapid generation of key learning) which will inform on-going analysis. Given the rapid nature of this evaluation, we will utilise the built-in transcription software within Microsoft Teams to complement interviewee notes to summarise responses to questions in the interview topic guide and to draw out key findings and themes within and across the case study sites over time. To enable this we will use templates and tools such as Rapid Assessment Procedure (RAP) sheets to help summarise and/or organise findings in near 'real-time'[38]. We will adapt our tools to allow for emerging themes not necessarily captured in the template, allowing for both deductive and inductive themes to be developed.

3) **Task 3 - Cross-case study stakeholder workshop with service users and carers, in consideration of inequalities**

We seek to learn from perspectives of service users and carers who have experience with remote blood pressure monitoring care pathways. We will invite the individuals interviewed but also seek to expand participation through recruitment via the case-study related via local healthcare professionals and if needed, local/regional patient panel. Depending on learning emerging from the case studies, we will consider additional representation of the service-user and carer voice from voluntary organisations/charities with patient representatives who may be appropriate to involve, and if appropriate gauge the views of our user advisory group as to who to invite to these workshops. To the extent possible, we will foreground considerations of inequalities in the design, invitees, implementation of this workshop which will focus on service user and carer experience with remote monitoring blood pressure care pathways but also perspectives related to improvement opportunities in a future-focused, forward outlook. We will also be transparent in the limitations of the approach as they relate to the types of participants we can secure and will seek to triangulate insights against wider research on inequalities and digital disparities currently taking place in the research team at Oxford and involving Prof Trisha Greenhalgh (a member of DECIDE's internal advisory group).

4) **Task 4 - Cross-case study stakeholder workshop**

A cross-case study online workshop will be held among professional stakeholders (e.g. clinical, non-clinical, system leaders) to discuss findings from the case studies, and will include sharing, discussing and refining learning at both case-study level and cross-case level thematic learning. We have found that tacit and informal stakeholder knowledge captured in these types of approaches to be valuable sources of data. Bringing together stakeholders form different communities and case-study sites will help in identifying key scale and spread considerations that may apply across contexts, as well as those which may be more context specific.

We also plan to invite participants from the localities in which case study sites are located but which had not participated in the evaluation at case study level (i.e. in the interviews or focus group) to the workshop (e.g. individuals from other GP practices implementing remote BP monitoring in the region, and PCNs in the same ICB footprint). This can help us begin to tease out how well the learning gained resonates with other stakeholders in the same health system footprint and help us identify key scale and spread relevant considerations. Reflections and feedback would be incorporated as findings into the final write up.

Individual case studies will be based on thematic analysis and will draw on the NASSS framework, to enable learning of scale and spread of BP remote monitoring across diverse contexts as well as learning related to technology-enabled remote monitoring more generally. The structure of the case studies will be informed by the research questions and intervention logic model, and sensitised by our theoretical/conceptual frameworks. While yet to be worked out, to illustrate, this could entail: context; evolved intervention logic (with a detailed section on process/activities and their contribution to observed outcomes and impacts, nuancing the components and mechanisms in the approaches taken and how they play out in terms of the implementation processes and realities experienced); and analysis of approaches to navigating implementation challenges; an analysis of how the chosen approach tackled and impacted on considerations related to inequalities (this would inform RQ1−4 of our evaluation).

In addition, drawing on cross-case comparison and insights from the cross-case study stakeholder workshop, we will draw out key thematic learning of relevance to supporting effective implementation and addressing implementation challenges, with a view to drawing out also insights of relevance to understanding requirements (success criteria) related to scale-up and spread of effective practice in particular, which will be further refined in WP3.

Throughout our analysis, the team will undergo a process of sensemaking in the form of bimonthly research meetings to share reflections and preliminary thoughts and impressions of early findings throughout primary data gathering as applicable to WP2. Key themes will be drawn out during the analysis phase, and summaries of themes will be developed by research team members as the evaluation progresses. Relationships between and across themes will be discussed and incorporated into final findings.

A combination of factors prohibit a comparative evaluation design or establishing a counterfactual scenario (i.e. including sites not doing remote monitoring, or collecting data before the intervention was implemented). These include: (i) the inherent diversity and complexity of remote monitoring of blood pressure care pathways as service interventions, combined with (ii) our focus on learning about and from implementation processes; (iii) the rapid nature of the evaluation (within a specific timeframe and resources); and (iv) limited availability of quantitative data to allow for comparative analyses. To address these limitations, we will seek to in our qualitative enquiries gauge stakeholders' reflections on how BP monitoring and patient engagement has changed since the implementation of the remote monitoring pathway.

Outputs:

- Write up of methods and findings for each case study site

- Write up of thematic cross-analysis across case studies

WP3: Refining and testing learning for applicability to broader contexts (*month 8-9)*

Aim: To test and further develop findings from prior work packages with a broader set of stakeholders and settings, with an explicit focus on examining key requirements for scale, spread and sustainability of promising approaches

Approach: Stakeholder workshops

1) **Task 1 - Stakeholder workshop: engaging with a broader set of stakeholders and implementation contexts**

We will convene two online workshops to engage a wider set of stakeholders across diverse ICB/ICS/PCN settings to (i) test our case-study based findings for wider applicability across a diversity of sites and contexts; (ii) examine key requirements to support the spread and scale, as well as sustainability, of seemingly promising approaches (e.g. intervention components and combinations, approaches to addressing/responding to implementation challenges and whether some are more tractable to scale and spread requirements than others). We will also examine stakeholder perspectives on the feasibility of securing necessary requirements and conditions for scale and spread, including in consideration of not only current but potential future technological and health system landscapes.

We will convene one workshop including 1) healthcare providers, non-clinical staff, and local decision makers (e.g. at the PCN, ICB, HIN level) from other non-case study sites; 2) industry and 3) national policy stakeholders (e.g. NHSE, DHSC). A separate workshop will be convened for service users and carers. We will use findings and feedback from the workshops to help apply findings and understand implications related to implementation scale, spread, and sustainability.

Outputs:

- Summary document of participants and findings from online workshop

WP4: Synthesis, reporting and dissemination (*months 9-11)*

Aim: To bring together findings from all work packages into a final summative evaluation report based on learning about implementation approaches for tech enabled remote blood pressure monitoring, how they contribute to the pursuit of desired outcomes and impacts, how implementation challenges can be addressed and key requirements for scale and spread of promising practices. To also provide learning of practical and formative value for system stakeholders considering how to scale, spread and sustain promising approaches.

Approach: Synthesising learning will be based on triangulation of insights from prior work-packages across methods and stakeholder perspectives.

1) **Task 1 - Cross analysis and synthesis research team workshop**

For the final synthesis and reporting phase, the research team will hold an internal workshop to discuss the report structure, key themes that have emerged from learning across the different work packages, and key messages of relevance for different types of stakeholders

who are likely to be involved with decisions around spread, scale and sustainability (e.g. messages for healthcare providers, local system leads, messages for national policymakers and messages for service users). We will invite members of the project user advisory group, and internal expert advisory group members, to input into the discussion.

During one of the regular progress meetings with NHSE, we will discuss findings and approach to final reporting/dissemination.

2) **Task 2 - Synthesis and reporting**

We will synthesise outputs from prior work packages (working documents/outputs from workshops) to write the final NIHR report.

Outputs:

- NIHR report
- Other – see section on expected outputs and plans for dissemination

WP5. Project management, customer engagement and quality assurance (*months 1-11*)
Aim: To ensure effective project management and administration, timely sharing of learning and the policy customer, open lines of communication with the policy customer and quality assured final outputs.

Approach:

1) **Task 1 - Customer/client engagement**

Throughout the evaluation, we will maintain open lines of communication with NIHR HSDR and NHS England as the policy customer. Given the nature of rapid evaluation, we will hold monthly or quarterly (to be discussed with policy customer) online progress meetings with NHS England (possibly alongside project advisory group) and share emerging learning at the end of key work packages.

2) **Task 2 - Continuous analysis and sharing the learning with case study leads**

We will at the mid-point in WP3 seek to feedback learning to participating case study sites and will build in fora for more informal communications (email, calls throughout case study implementation with case study site leads) for knowledge exchange on emerging themes with key contacts at case study sites.

3) **Task 3 - Internal project management and administration**

A designated project leader and project manager will oversee delivery according to plan, with research administration support at both RAND Europe and Oxford. Clear project plans, designated staff roles and supportive management and operational processes will ensure effective delivery (please see section on project management and quality assurance (QA) for further information).

4) **Task 4 - Quality assurance**

QA will take place throughout the project, as well as through review of final deliverables (please see section on project management and QA for further information).

Expected outputs and plans for dissemination

We will ensure that awareness about the project is raised early on in the study (e.g. project pages on website; social media; using our networks and governance structures to help raise awareness; early communications with NHS England as the policy customer, NIHR, and case study site leads).

We will ensure that emerging evidence and insights are shared in a timely way, with appropriate caveats in place. For this project, we will share emerging formative learning with relevant individuals and organisations directly involved with the evaluation as case study site leads through an emerging insights workshop and through less formal communication channels (emails, calls). We will also share and disseminate early insights with the policy customer (NHS England) through regular progress calls and accompanying working project documents such as a summary of key learning themes or a presentation to use in meetings. We will maintaining open lines of communication with stakeholders directly involved in the project, e.g. site leads, policy customer and NIHR, to enable timely dialogue throughout the project. A workshop with a wider range of stakeholders towards the end of the project will both serve to test emerging learning and refine it, as well as to share key emerging insights.

We will share final learning with a broader range of stakeholders across the UK more formally and widely through the final report and associated dissemination materials. We are committed to tailoring dissemination approaches and outputs to intended audiences. Based on consultations conducted in establishing the dissemination approach for DECIDE and as discussed with our Steering Committee, we will in addition to the final NIHR report, including lay and scientific summaries, consider additional outputs for specific stakeholder groups. We are also mindful of the need to balance the variety of possible dissemination mechanisms with resource constraints. In light of these considerations, we propose producing an infographic (or separate infographics) with key messages based on the learning targeted and (a) care providers; (b) service users; and (c) systems leaders at regional and national policymaker levels. We will also consider a journal publication and dissemination at a conference, but these will be costed separately (i.e. are not costed for in current estimates). We will also mobilise our internal advisory group, steering committee and user advisory group to support the nature of our final outputs and dissemination. We will work with our experienced communications professionals at the University of Oxford and RAND Europe, as well as Design Science (an organisation specialising in effective design of communication materials with expertise in co-production and co-design).

Table 1. Project Timetable

	Month											
Work Package/ Task	1	2	3	4	5	6	7	8	9	10	11	12
WP1: Inception, site confirmation and theory of change												
Inception meetings												
Project service user group establishment												
Literature review												
Case study confirmation												
Development of theory of change												
Development of data collection tools												
Ethics, data and R&D governance												
WP2: Case studies												
Document review												
Interviews												
Cross-case study workshops												
Analysis												
WP3: Refining and testing learning for applicability to broaders contexts												
Stakeholder workshops												
WP4: Synthesis, reporting and dissemination												
Research team workshop												
Synthesis/ report writing												
WP5: Project management, customer engagement and quality assurance												
Client engagement												
Project management and administration												
Quality assurance												

Planned activity Contingency

Project management and quality assurance

Project management

We see project management as an important and continuous effort in performing this evaluation, and have established both staff roles, processes and structures to support effective delivery.

The project leader at RAND Europe (Dr Frances Wu) will lead on ensuring effective delivery to time and budget will be supported with designated project management and administration support at University of Oxford (Dr Julie Darbyshire, Mrs Charlotte Thompson-Grant and wider administration support in the unit at Oxford) and research assistant support at RAND Europe (Ms Saoirse Moriarty). Overall project delivery will also be supported by oversight by centre leads for DECIDE at RAND Europe (Dr Sonja Marjanovic) and input from Oxford (Prof Sara Shaw).

We suggest holding meetings at regular intervals between the DECIDE Team and policy customer (NHS England) to update on the progress of the project and next steps for the research (through quarterly catch-up calls with NHS England). We will also establish an expert advisory group for this project, complementing our internal advisory group for DECIDE with approximately two individuals from our steering committee with particular expertise and experience relevant to this project. We are happy to discuss with NIHR whether they would like to participate as an observer in these meetings. Our service user advisory group for this evaluation will comprise representation from the DECIDE service user advisory group and will be complemented with PPIE representatives with particular experience with hypertension. We will maintain open lines of communication with NIHR and NHS England throughout the project.

Both RAND Europe and The University of Oxford are experienced in delivering projects of this nature. The direct team will be supported by a robust infrastructure that includes appropriate policy documentation and procedures that underpin all aspects of academic activity.

We also apply additional management processes such as:

- An internal kick-off meeting, to review the project plan for ensuring high quality and timely delivery; and
- Internal team meetings and catch-ups, ensuring clarity in team roles and responsibilities and good internal communication, and maintaining a project vision.

Quality assurance

RAND Europe and Oxford have rigorous QA processes, enabling all project deliverables to be reviewed by QA reviewers not involved in the project. For QA, DECIDE will draw on either our internal advisory group or other senior researchers at RAND and Oxford not involved with the project, and potentially Steering Committee members with relevant expertise. All deliverables will only be cleared for release if they meet DECIDE's QA standard. Engaging with the user advisory group, internally advisory group and steering

committee as part of wider DECIDE structures will provide an additional continual layer of quality assurance.

The protocol has also been reviewed by a senior member of the DECIDE centre internal advisory group and by the chair of the user advisory group.

Plans for service user and public involvement

We have via the user advisory group received inputs that will inform the questions the evaluation will explore, and in particular those related to understanding the patient perspective and inequalities.

As outlined in WP1, we will form a project specific service user advisory group, drawing from one to two members from the DECIDE service user advisory group and complimenting with two PPIE representatives with particular experience with hypertension. Members will contribute approximately two days each over the course of the evaluation.

The user advisory group chair has reviewed this project protocol. We will draw on the project user advisory group on activities such as: informing the design of materials to use in interviews and/or workshops to ensure relevance and accessibility, design of the cross case study workshop with service users and carers, participation in the research team workshop and in dissemination.

Research Team

Table 2 presents the team members and their corresponding roles and expertise.

Table 2. Study team members

Team member	Role and contribution in research team	Relevant expertise
Dr Frances Wu, Senior Analyst, RAND Europe, and Deputy Lead for DECIDE at RAND Europe	Project leader providing topic, method, and team leadership. Project conception, design, qualitative data collection, analysis and synthesis. Writing of reports/dissemination, project management	Experienced in conducting mixed-method and embedded research and evaluation, including quantitative analysis using administrative, electronic health record and survey-based quantitative data. Experienced in project management.
Dr Sonja Marjanovic, DECIDE Lead at RAND Europe (Senior Research leader in Health and Wellbeing, Director of healthcare innovation, industry and policy portfolio)	Provide support and DECIDE leadership oversight throughout the evaluation. Project conception, design, data collection, analysis and synthesis, workshop facilitation, writing of reports/dissemination	Experienced in health services and healthcare innovation research and evaluation of complex interventions; wide ranging portfolio of work on role of innovation in service delivery; experienced in leading large and rapid projects involving public, third sector and industry stakeholders and collaborative research partnerships.
Ms Saoirse Moriarty, Research Assistant (RAND Europe)	Project conception, data collection, and analysis. Writing of reports/dissemination, project	Experience in public health, health services research and evaluation, communications and project administration.

Team member	Role and contribution in research team	Relevant expertise
	management and administrative support.	
Prof Sara Shaw (PI for Decide, Professor at Oxford University);	Project conception, design, analysis and synthesis, writing of reports/dissemination.	Highly established academic bringing expertise on technology-enabled health care, qualitative, case study and mixed methods design and delivery, and knowledge exchange/impact. Experienced in rapid evaluation and oversight of large research projects and evaluations; overall oversight of all projects under NIHR Decide centre.
Hampton Toole, Analyst (RAND Europe)	Project management, data collection, and analysis. Writing of reports/dissemination, project management and administrative support.	Experienced in health technology research, understanding landscape for innovation in health services and analysis of policy initiatives.
Ms Anica Alvarez Nishio	Project design, writing, and dissemination	Experienced public involvement and engagement consultant, served on and chaired a number of boards/committees (eg NICE, NIHR), interests in the effective usage of data and technology in care delivery, in tackling inequalities, working with marginalised groups.
Dr Joe Wherton (University of Oxford)	Project conception, design, analysis and synthesis, writing of reports/dissemination	Experienced in ethnographic and participatory design methods to inform the development and implementation of technology-supported services for health and social care.
Julie Darbyshire (University of Oxford)	Project Management and PPIE liaison	Experienced in academic project management including multi-site international drug trials, large data analysis studies, and use of digital tools to support healthcare management and delivery. Has led patient/carer stakeholder workpackages in a number of NIHR funded research projects.
Charlotte Thompson-Grant (University of Oxford)	Project Co-ordination and PPIE liaison	Experienced in academic administrative processes including contracting, budget monitoring, meeting logistics, and liaison across teams.

Ethical and Regulatory Considerations

Risks and their management

See Table 3 below for our assessment of potential risks and mitigation strategies

Table 3. Potential risks and mitigation strategies

Risk	Impact	Likelihood	Mitigation
Challenges to onboarding sites to participate in case studies	High	Medium	We have two verbal confirmations of interest to participate in our scoping consultations but need to identify additional suitable sites. We will seek to minimise risk by having approached more potential sites and locations than needed and by maintaining open dialogue and following up on conversations. We have also produced a two page document on the project and the benefits of participating to assist with recruitment. We have established good links with the policy customer but there has been staff turnover and changes in leadership at NHSE, which has impacted on their ability to support recruitment at rapid turnaround. We will maintain open lines of communication with NHS England and NIHR HSDR.
Demand pressures on NHS staff and health system decisionmakers and associated challenge to capacity to engage in timely ways	High	High	The evaluation requires support from case study sites on diverse grounds such as any needed local governance approvals, helping recruit interviewees and workshop participants, and where applicable timely access to relevant documents and data. We are investing in establishing early relationships with candidate case study sites and local decisionmakers to help ensure support for the evaluation. We are sharing summary documents on the evaluation and what is required from participants in case studies to support upfront clarity on needs, and what the benefits from participating might be. We will seek to ensure 'back-up' participants for interviews where possible (i.e. ask of study leads to suggest more than the number of individuals we hope to interview, to provide options and support contingency plans). We will maintain open lines of communication throughout and offer flexible times for study participants to contribute. Should there be challenges to timely engagement, we will maintain open lines of communication with the policy customer (NHS England) and NIHR HSDR to ensure discussion around contingency planning.
Delays in local R&D approvals	High	Medium	Should there be delays in obtaining any local potentially needed R&D approvals, which impact on timelines for primary data gathering (e.g. interviews for case studies) we will communicate these to the policy customer and NIHR in a timely fashion.
Loss of key staff on project	High	Low	RAND Europe's staffing model allows for flexibility such that in the event of project staff turnover, we can tap into wider expertise in the team at RAND. Senior staff at both Oxford and RAND have extensive experience needed to deliver on the evaluations.
Loss of data	High	Low	This is unlikely but both Oxford University and RAND Europe have robust, secure and well tested data and IT systems with data backed up in multiple locations to support recovery efforts in the event of data loss. Both The University and RAND Europe have robust

Risk	Impact	Likelihood	Mitigation
			policies in place to safeguard data. We will put data transfer agreements in place with any third party (eg evaluation sites) to ensure safe and secure transfer of information. Any transfer of data between researchers at RAND and Oxford University will be in accordance to GDPR.

Ethical issues and approvals required

This project has been reviewed by the Oxford Joint Research Office classification committee, which determined that this is service evaluation. The Oxford Central University Research Ethics Committee subsequently confirmed that projects determined as service evaluation need not undergo additional ethics review.

Information Governance: The University of Oxford requires all projects to register project data sets as 'information assets'. The DECIDE programme reference is IAR 561. This register supports obligations under General Data Protection Regulation (GDPR) and links to 'data protection by design' policies which include initial screening to confirm the level of data protection documentation required. Results of the screening will indicate that either a Data Protection Assessment (DPA) or, for data sets that include special category data, or where activity is likely to result in high risk to those individuals whose personal data are being processed, a Data Protection Impact Assessment (DPIA) form needs to be completed.

Any data generated from this piece of work will be processed in line with this protocol and stored in secure environments at the University of Oxford and RAND Europe. These secure environments are hosted within each institution and are accessible through a dual-authentication password process. As the primary award holder, the University of Oxford will act as the data controller for DECIDE. The University of Oxford data storage servers will therefore be the primary repository for all data. Members of the team who are employed by RAND Europe will be granted remote access to these files. As per any data storage clauses in the individual site agreements, RAND Europe may also store data files pertaining to this piece of work.

R&D Governance: We will contact the relevant local research and development (R&D) offices for advice regarding the local requirements for approval and/or registration of service evaluations. As required, we will put agreements in place with individual sites participating in this piece of work. These agreements will include clauses that cover activities to be undertaken at the site, including (but not limited to) recruitment of participants, transfer of funds, physical access to the site, and access (and use and subsequent storage of) data required to support outcome findings.

Participant consent

We will provide information sheets to all participants taking part in our evaluation which we summarise aim, study design, risks, benefits, who to contact for further questions, and their right to withdraw from the study at any point. Participants taking part in interviews will receive an invitation and information sheet via email (or by post if email is inconvenient) and will need to provide informed written consent.

Data management and storage

The University of Oxford has taken responsibility as data controller for the DECIDE programme. RAND Europe will therefore be a data processor.

Data collected for evaluations will be anonymised at the earliest opportunity and stored in secure locations as per policy and guidance at each individual institution (see below). All data files will be stored for a minimum of three years according to the host institution data management policy.

- In Oxford data will be stored on a secure project folder in accordance with the University of Oxford Data Protection policy. This system is ISO 27001 compliant and the Nuffield Department of Primary Care Health Sciences (NDPCHS) meets the standards of the Data Security and Protection Toolkit administered by NHS Digital. Access is provided by an encrypted remote desktop application. No individual-level data will leave the Oxford servers. Access is restricted by strong individual passwords and to staff that have undertaken appropriate training.
- RAND Europe maintains a strong security governance framework aligned with ISO 27001. All research projects are required to comply with internal quality management systems, in line with RAND's ISO 9001:2008 certification. RAND Europe adopts good industry practices regarding the protection of personal data as part of its obligations as a Data Controller under the DPA1998. Data will be held on a server located in RAND Europe's Cambridge, UK office. Backups taken for disaster recovery purposes will be encrypted and stored in a secure offline site. All records will be kept in compliance with the UK General Data Protection Regulation (GDPR) 2018. Further information about RAND Europe's overarching privacy policy can be found here: https://www.rand.org/randeurope/privacy.html.

The University of Oxford has a robust integrated data management and information governance policy to safeguard data. All electronic files relating to DECIDE evaluation topics will be saved on password-accessible areas of the University of Oxford network and remote access will be granted to members of he DECIDE centre team as required for analysis and reporting purposes. This will include employees of RAND Europe.

Both The University of Oxford and RAND Europe operate in compliance with GDPR.

- The University of Oxford data protection policy can be found here. The Department of Primary Health Care Sciences also has a suite of policies relating to information governance, data management, and data security.
- RAND Europe has a company wide Information Security Management System (ISMS) and a senior management team that supports the continuous review and improvement of the company ISMS.

Indemnity and insurance

The University of Oxford holds the relevant insurance cover for this study, as confirmed via our DECIDE contract with NIHR.

Sponsor

The University of Oxford will act as the main sponsor and guarantor for this study.

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