DECIDE (Digitally Enabled Care in Diverse Environments) The Oxford University-RAND Europe centre for rapid evaluation of technology-enabled remote monitoring



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Summary

Background: There is growing interest in technology-enabled health and social care, including in the use of remote monitoring. The aim of using these tools is to respond to system pressures and improve access to, experience and quality of care. However, technology-enabled remote monitoring interventions are fairly new, with limited evidence about impact. There is an urgent need for process, outcome and impact evaluations of interventions at various stages of development and implementation to address questions around adoption, spread, sustainability and possible inequalities.

Aim: NIHR will fund a 3-year team to conduct rapid evaluations in this field. Our proposed Oxford-RAND Europe centre for rapid evaluation of technology-enabled remote monitoring is known as DECIDE (Digitally Enabled Care in Diverse Environments). It aims to support policy customers alongside service users, service commissioners and providers of remote monitoring services through evaluative evidence generation and shared learning that can enable high quality care.

Patient and public involvement and engagement (PPIE): A User Advisory Group with diverse voices will help shape evaluation design, implementation and dissemination. This will include institutional members and – at project level – those with lived experience. We will work with our PPIE lead and wider team, who will also be supported by a steering committee of experts in health and care services, policy and service innovation.

Approach and methods: DECIDE brings together expertise and a proven track record in health and care innovation, including adoption, spread and scale up, technology-enabled health and care, methodologically robust and rapid evaluations, prioritisation, co-production and stakeholder engagement.

Focused questions and evidence needs will emerge for each evaluation, in discussion with an identified policy customer, and be informed by established contributions to the theory and practice of understanding Non-Adoption, Abandonment and the challenges to Spread, Scale-up and Sustainability of technological innovation in health and care (NASSS framework). Specific evaluations will include set-up/scoping, main implementation and synthesis phases. Qualitative, quantitative and health economics methods will inform evaluations.

Example questions are:

- Is the technology-enabled remote monitoring innovation needed and if so, by whom?
- How does it work and what factors relate to the intervention, implementation process and wider context influence adoption?
- · What are associated outcomes and impacts and on whom?

• How does the intervention and its impacts mitigate and/or tackle inequalities and wider equality, diversity and inclusion considerations?

- What are the unintended consequences of implementing and using technology-enabled remote monitoring, and how are these mitigated?
- What are the opportunities and challenges for scale and spread?
- What de-implementation considerations matter?

Impact and dissemination: An overarching dissemination and impact strategy will be co-produced with steering committee and service-user input. Project-led dissemination and impact and learning across evaluations (e.g. on topics, methods) will provide timely and rigorous insights to inform decision making by policymakers, commissioners, providers, service-users, and researchers. This involves:

- formative and summative communications
- tailored outputs to different audiences and contexts
- at least one significant service user led output
- a mix of written, visual, audio and verbal activities (e.g. journal outputs, policy briefs, webinars, case vignettes, infographics, blogs, conference dissemination)
- in-person and virtual engagements

1. Background

1.1 What is the problem being addressed?

There is a growing demand for health and social care. This has led to increased interest in how we can improve the way health and social care is delivered, and how technology can help to ensure that people get the right care, at the right time, in the right place and in the right way. This is important in efforts to improve people's health, wellbeing and experiences of care in fair and equitable ways. It also matters for tackling the increased pressures that health and care services face, such as long waiting times to access care, workforce shortages and limited 'bed space' in hospitals.

Technology-enabled remote monitoring has the potential to improve care quality and service user experience, prevent unnecessary admissions to hospital and A&E, reduce length of stay in hospitals, prevent infection transmission and allow people to access care safely, at a suitable time and location. It involves the use of technology, devices or apps to support patients and other service users to actively monitor and manage their health or long-term conditions (e.g. asthma, heart failure), and enables the remote exchange of information, primarily between a patient or service user and a health or care professional, to assist in diagnosing or actively monitoring health or care status or promoting good health and care. Remote exchange is typically supported by consultations or other interactions (e.g. messaging) that enable sense-making of that information, enabling systematic review and monitoring, accompanied by (where needed) changes in the care being received. Examples include using apps, personal or medical gadgets (e.g. pulse oximeters) and 'virtual ward services' to monitor, review and support care at home; smartphones to share vital sign readings (e.g. blood pressure) with care providers.

Remote monitoring is being tested and used across the UK for many conditions (e.g. elderly care, diabetes, respiratory and heart diseases), especially since the COVID-19 pandemic. There is potential to use it to benefit more people and services. There is a growing evidence base, including in the context of rapid evaluation.¹⁻³ Yet there is still a lot we do not know about whether different types of remote monitoring work as intended; when they work and for whom, why and how; how they can be appropriately spread across health and care services; and what is needed to make sure they are helpful and do not disadvantage access to and quality of care for some people. There is an urgent need to rapidly evaluate promising remote monitoring practices to answer these questions.

1.2 Why is the research important?

Service innovation is often a response to the changing nature of demand on health and care services (e.g. growing burden of chronic conditions and co-morbidities) and associated pressures (e.g increasing demand, rising costs, widening inequalities).^{4,5} It is also a response to developments enabling innovation (e.g. science and technology advances, developments in IT and data infrastructure).⁶ Even before the onset of the COVID-19 pandemic, technology and digital transformation were priorities for the health and care system. Although the pressures of the pandemic have accelerated the scale and pace of adoption of digital care in some settings, pre-existing trends and challenges have intensified.

This means that care enabled by technology and the allied use of remote monitoring is a key part of the vision for improving value and access for patients and other service users, and recovery of the health and care system (refs).^{7,8} ⁹ However, while there is a significant policy and service-level push to develop technology-enabled care, and to use remote monitoring in ways that are meaningful and effective, there has been limited evaluation to date. Examples include a nurse-led service to monitor people living with COPD using pulse oximeters, and care home staff supporting residents using blood pressure monitors, pulse oximeters and thermometers to help recognise the deterioration of residents' health and improve care.¹⁰ These have typically been small scale, limited to a specific clinical or geographic focus, and provided limited evidence about outcomes that are meaningful for providers and patients and other service users, as well as those caring for them. As the pace of policy and innovation in this field increases, so there is an urgent need to rapidly evaluate emerging innovations and provide the evidence base that can best inform technology-enabled remote monitoring services across the UK going forward.

This is particularly the case given concern for health inequalities, i.e. avoidable, unfair and systemic differences in health between different groups of people.^{11,12} While there is growing interest in technology-enabled remote monitoring, this is accompanied by rising concerns over inequalities and

digital exclusion.^{7,8,13} Such inequalities are deep-rooted and widening, leading to disparate outcomes, varied access to services, and poor experiences of care, particularly for certain groups (e.g. sharing specific protected characteristics such as those related to race, gender, ethnicity, disability, socioeconomic status/deprivation, geography).^{12,14,15} This is compounded by issues of digital exclusion, where some people (e.g. on lower incomes, with learning disabilities) have continuing unequal access and capacity to use technologies that are increasingly essential to fully participate in health and social care.¹³ It is also compounded by issues of potential applicability of remote monitoring technologies (and the, sometimes limited, datasets on which they draw) to real-life clinical and care settings and populations. Evaluation is needed that can help to evidence and address this in the context of technology-enabled remote monitoring.

1.3 Why is the research needed now?

There is growing interest in technology-enabled health and social care, including the use of remote monitoring.^{7,8} Many long-standing implementation barriers were reduced with the pandemic, with various interventions launched across settings and service-user populations, and with some rapid evaluation in place to support this (e.g. on the use of pulse oximetry in care homes¹). However, remote monitoring interventions are fairly new, with typically limited evidence about their impact.¹⁶⁻¹⁸ There is an urgent need for process, outcome and impact evaluations of interventions at various stages of development and implementation to address questions around adoption, spread, and sustainability and inequalities. Rapid evaluation can provide timely, rigorous and evidence-based insights to inform decision making on remote monitoring.^{2,19-24} There is learning already from existing rapid evaluation teams, focused on the use pulse oximetry at home,² and in care homes;¹ and the use of remote AI monitoring in social care.³ The proposed Oxford-RAND Europe centre for rapid evaluation of technology-enabled remote monitoring extends this, focusing exclusively on technologyenabled remote monitoring as the core of it work. Known as DECIDE (Digitally Enabled Care in Diverse Environments), the centre brings together topic expertise in health and care innovation, with a proven track record of delivering cross-disciplinary and methodologically robust rapid evaluations. The aim is to support patients, service users, carers and those who commission remote monitoring services to enable high quality care and ensure decision-makers can make informed decisions.

1.4 Aims and objectives

Aim: to generate a strong evidence base on the potential and limitations of technology-enabled remote monitoring in health and care.

Objectives:

- To conduct formative, mixed-method evaluation of remote monitoring interventions and support their implementation by facilitating knowledge sharing across stakeholders.
- To perform summative assessment of the potential of remote monitoring interventions to improve outcomes for both services and service users, as well as produce economic benefits.
- To refine existing and inform new remote monitoring models in health and care through coproduction and with a specific emphasis on inclusion, diversity and equity.
- To draw transferable learning on the development, implementation and mainstreaming of technology-enabled remote monitoring in health and care.

2. Research Plan

2.1 Overall approach

Technology-enabled remote monitoring interventions are fairly new, with limited evidence about impact.¹⁶⁻¹⁸ The approach in DECIDE is to provide rapid evaluation of selected interventions using robust methods, a theoretically informed approach, underpinned by a set of guiding principles and with issues of equality, diversity and inclusion remaining central throughout.

2.1.1 GUIDING PRINCIPLES UNDERPINNING EVALUATIONS

Underpinning principles guiding the rapid evaluation work of the centre include:

A. Asking the right questions about relevant, priority interventions: working with an identified policy customer for each evaluation, and with a scoping phase for each project to build on the existing evidence base and stakeholder experiences, through desk research (e.g. rapid evidence assessments, scoping reviews) and early stakeholder consultation (e.g. with steering committee members, user experience panel, advisory group and additional project specific experts) to

ensure we assess evaluability of an intervention and focus in on questions that matter, evidence gaps and areas of uncertainty in a way that can provide rigorous and practically relevant insights.

- B. Theoretically and methodologically rigorous evaluation: (i) using tried and tested theoretical frameworks (see below) and a toolkit of methodologies applied in bespoke ways to a specific evaluation project to ensure rigorous outputs, alongside quality assurance reviews (see section 3); (ii) staffing each project with relevant skills, supporting (and costing) training needs (see section 3, also Justification of costs); and (iii) ensuring an additional layer of quality assurance via experts from the steering committee and advisory group.
- C. Flexibility in evaluation design supporting range in scope, scale, complexity: (i) awareness that rapid evaluation may be applied to interventions at diverse stages of development and adoption with implications on evaluation designs, e.g. evaluations of interventions at earlier stages of testing will differ from those designed to understand spread and scale; (ii) flexibility in operationalising evaluations (e.g. parallel versus sequential work); (iii) depending on scope, scale and complexity, investing in prioritising key questions to explore in a way that rapidly tackles key evidence gaps and uncertainties; (iv) building in modest time and resource contingencies to deal with emergence in an evaluation and planning for alternative methods to answer a question as a way of dealing with operational complexity (e.g. online versus in-person interviews); (v) flagging future evaluation needs (vi) flexibility in dissemination channels for formative and summative learning; (vi) flexibility in how we equip participants and contributors (e.g. user advisory group) to engage with evaluations (e.g. flexible engagement approaches for different types of contributors).
- D. Practically-oriented for usable insights, including de-implementation considerations: (i) asking questions that have practical value for those commissioning, delivering and using techenabled remote monitoring services (direct users and indirectly involved individuals/groups, e.g. carers); (ii) asking questions in accessible format and language that resonates with how evaluation participants relate to remote-monitoring enabled services and technologies; (iii) sharing and disseminating learning in formats suited to diverse users of the evidence; and (iv) sharing learning in timely ways both emerging and final insights.
- E. Attention to inclusiveness and inequalities: (i) designing evaluations and asking questions that address the needs of diverse stakeholders and populations; (ii) considering process and outcome measures that consider inequalities; (iii) ensuring that diverse voices are involved in evaluation design and implementation; (iv) disseminating learning to national, regional and local actors in ways that consider key structures and networks in the system, and organisations with a concern with seldom heard voices (e.g. advocacy groups representing underserved populations).
- F. Consideration of future scenarios, including intervention sustainability, spread, scale up and environmental sustainability: ensuring that evaluation questions and indicators engage with plausible future conditions, including environmental sustainability considerations, and that evaluation indicators seek to test findings in light of these issues. E.g. this might include:
 - engaging with evaluation participants around the **extent to which changes in the adoption context (e.g. changes in workforce capacity, funding mechanisms) are likely to influence the sustainability** of the intervention and its impacts,
 - considering features of the technology itself (e.g. user-friendliness, training requirements),
 - from an **environmental sustainability perspective** considering whether adoption contexts are collecting data on aspects like alignment with net zero policies.

2.1.2 THEORETICAL FRAMEWORKS

The focus of service innovation is on improving health and care service quality, efficiency, costeffectiveness and/or user experience, which typically entails novel models of care delivery, new technologies and products, (e.g. introducing new technologies often comes with needs for care pathway change and novel or adapted service organisation). It is a sociotechnical concept,²⁵ with the success of an intervention (e.g. new technology) intimately related to its interactions and fit with the conditions and actions in the broader adoption context and wider health system. The work of the Centre will be informed by the <u>N</u>on-adoption, <u>A</u>bandonment and challenges to <u>S</u>cale-up, <u>S</u>pread and <u>S</u>ustainability (NASSS) framework, an evidence-based framework developed by the Oxford team to guide thinking on sociotechnical implementation, roll-out and embedding of technology-supported innovations in health and care.^{23,26} NASSS allows researchers to surface and explain the multiple forms and manifestations of complexity which affect uptake and use of technology-supported services. The NASSS framework, designed as a widely applicable tool for any technology project, consists of 7 interacting domains. Partial failures and successes, unintended and unanticipated problems are explained by teasing out the multiple aspects of complexity across these 7 domains.

The NASSS framework has already proven useful in previous research on remote monitoring such as in the NIHR-funded SUPPORT-HF2 study on technology-enabled remote monitoring in heart failure and other cardiovascular conditions.²⁷⁻²⁹ We have recently developed an adapted version taking into account the nature of the clinical relationship, challenges of remote clinical assessment, as well as issues of digital inclusion and or practices' digital maturity in the context of remote consulting services.²⁰ We plan further work to adapt the NASSS framework to the specific context of social care.

To strengthen our focus on inequalities we will draw on a complimentary framework for the prevention of intervention-generated inequalities (IGI),³⁰ developed to support inclusive design decisions for increasing equity in access, adoption, meaningful use and effectiveness of digital health interventions and facilitating a focus on different types of inequalities (e.g. in access, uptake, adherence, effectiveness) and associated precautions.

2.1.3 EQUALITY, DIVERSITY AND INCLUSION

We aim is to ensure EDI features strongly in the context of remote monitoring, embedding equality, diversity and inclusion in evaluations of healthcare technologies, and ensuring multiple voices are heard. We have a track record on this (e.g. ^{31,32}), culminating in our recent systematic review compiling up-to-date research on intersectionality in digital health.³³ Drawing on insights from this and other work (including Core20Plus5¹⁵), the centre's **evaluation design and operationalisation** will be:

- Informed by a structured approach to sampling, with maximum variation (within the scope of each evaluation), including participants across diverse groups such as socio-economic and ethnic groups without geographical restrictions, and guided by relevant frameworks for recruiting/retaining individuals from minoritised and under-served communities.³⁴⁻³⁶
- Theoretically informed but practically oriented, being (a) **open to considerations of bias in technology design**, such as pulse oximeters and other sensors, including potential to generate false readings for certain ethnic groups and committed to scrutinising the origins and development process for such technologies; and (b) **supporting inclusive evaluation design decisions for increasing equity** in access, adoption, meaningful use and effectiveness of digital interventions.
- **Supported by wider governance structures** (section 4), with members of our steering committee and user group advisory panel providing oversight and guidance on equality, diversity and inclusion (in terms of evaluation design, operationalisation and dissemination).
- Sustained by wider Oxford-RAND Europe infrastructure and networks, enabling training and updates for core partnership staff on EDI, PPI infrastructure, and productive use of links across research/evaluation programmes.

2.1.4 USE OF EXISTING AND NOVEL METHODOLOGIES

The methodologies used by DECIDE will depend on the technology-enabled remote monitoring services evaluated. We plan to use established, and where scale and scope of evaluation and nature of questions permits, novel methodologies, balancing rigour and rapidity with methodological appropriateness and ingenuity. Approaches we will draw on range from rapid evidence assessments/reviews as well as systematic reviews, to web-crawling approaches to evidence reviews, surveys, case studies, interviews, observations and focus groups; through to use of HES data and other routine data sources, health economic analysis and modelling, quasi experimental designs, baseline and counterfactual analysis, prioritisation and consensus-exploration, as well as futures and foresight. We bring strong methodological expertise in realist review and evaluation³⁷ and use of case study research in evaluating complex interventions.³⁸⁻⁴⁰ Where appropriate we will consider rapid cycle evaluation and learning,⁴¹ crowdsourcing information from service users and/or workforce, and futureproofing evidence in the context of futures and foresight.

2.2 Approach to working

2.2.1 DELIVERING RAPID EVALUATIONS

For DECIDE rapid evaluation means adopting an iterative, intensive, robust and rigorous approach to evaluation with a focus on action-oriented outcomes that can rapidly inform policy and practice. Building on the principles outlined above), we will offer rapid evaluation through:

• Rapid response capacity: staff with appropriate methodological skills, expertise and flexibility to quickly begin projects (many of our staff already have established working relationships).

- Flexible delivery models and processes to support timely, rapid turnaround (e.g. parallel task work) capitalising on experience with evaluation and technology-enabled remote monitoring.
- Awareness that rapid evaluation is needed for interventions at diverse stages of development and adoption, involve short-term and potentially follow-up work through a responsive, flexible approach
- Capacity and reputation to help mobilise wider stakeholder networks
- Committed leadership and sound governance and management
- Open communication lines with the Funder, wider governance structure and evaluation participants balanced with processes supporting independence
- Commitment to rapid formative and summative learning, and to working closely with policy customers to deliver it
- Guidance and support for stakeholders to engage with rapid nature of evaluation (e.g. preparing service user contributors for involvement

DECIDE will operate on a 'hub and spoke' model, with a core senior team, an internal advisory group (largely co-investigators), and a pool of staff with diverse methodological and topic expertise.

We envisage a constructive relationship with the Funder that focuses on the priorities and work of DECIDE, is supported by good governance via our Steering Committee and User Advisory Group (see sections 4 and 5), and informed by discussion (with the DECIDE team and via the Funder) with potential policy customers. We plan early engagement in terms of (A) topic selection; (B) topic specification, scoping and protocol development, (C) quality control and (D) dissemination (Figure 1).

Figure 1: Input from stakeholders to evaluation of technology-enabled remote monitoring

	Topic identification and selection	Topic specification, scoping, protocol development	Quality control	Dissemination
User experience panel	Link with service users/publics Inform priorities Inform research questions	Review recruitment documents Inform service user-facing research tools/outcomes Support co-design	Review protocol Review reports / key outputs	Support development of accessible, service user facing summaries and resources
Participating sites	Inform focal areas in a research topic	Inform research questions to explore Access to services/sites	Interpret results	Inform appropriate audiences and formats of dissemination
External Steering Committee	Horizon scanning and prioritisation Identify potential innovations	Identify topic experts 'Light touch' review Connect with potential sites	Identify peer reviewers	Sighted for all reports Steer to relevant networks for sharing evidence/lessons

A. Topic Identification and Selection

Selection of topics will happen via two routes and involve close working with potential policy customers, the Funder, and other stakeholders. First, the DECIDE team will conduct rapid scoping desk based research, discussion with stakeholders and networks and review of social media/websites to identify topics of current interests. We will work with the Funder, External Steering Committee and User Advisory Group to develop a long list of potential projects and to develop (and intermittently review) a shortlist based on timeliness, strategic importance and evaluability/feasibility. Second, the team will engage Steering Committee members, other stakeholders and potential policy customers to identify key topics for rapid evaluation as they relate to priority TERM interventions and services (e.g. technology-enabled remote blood pressure monitoring, in-home sensors to support social care).

We aim to ensure that planned evaluations respond to unmet evidence needs as they relate to inequalities — including seeking critical and active involvement from the Funder, advisory groups and other stakeholders when ensuring that the overall portfolio of interventions selected for evaluation are relevant, not only to 'the majority', but also in consideration of inequalities.

B. Topic Specification, Scoping & Protocol Development

Once topics have been selected and confirmed by the Funder, each will require a rapid topic specification outline phase involving rapid evaluability assessment and informing development of an outline protocol (likely 2-3 pages) to be co-produced with the policy customer and submitted to the

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Funder within 3 weeks. This will be led by DECIDE co-directors, working closely with the Internal Advisory Group, ensuring input from senior academics with cross-methods expertise. It will be critical to have trusted connections to the health and care system. We will ensure early contact with the Steering Committee Chair and 2-3 committee members (depending on the focus of each evaluation) to feed into design and initial mapping of the relevant health/social care landscape (see Section 4.4).

Once the Funder confirms the commitment to DECIDE doing an evaluation, we will then further scope and produce a full protocol, including estimated budget, timescale and staffing, to be submitted within 6-8 weeks (i.e. the scoping phase). At this stage we will focus on finalising the evaluation design and protocol, conducting pre-assessment/scoping work and initial set up, including further specification and identifying routes of access to potential evaluation sites/participants. Depending on the focus of each evaluation this is likely to involve rapid, scoping desk research and stakeholder consultation to understand service user journeys and service processes related to the remote monitoring intervention, familiarisation with key stakeholders, and consideration of key process and/or outcome measures.

As evaluation projects are approved and progress, we will continue to revisit plans iteratively to ensure we remain well-placed to respond to shifting priorities and emerging learning. We will keep open lines of communication with specific members of the steering committee and user advisory group as relevant for each evaluation, inviting up to 3 members to join project specific advisory groups along with representation from the policy customer for each project.

C. Quality Control

We will put the following processes in place to ensure quality control:

- a) The lead for each project will maintain oversight, meeting with the project teams and reviewing progress on a monthly basis
- b) Monthly project management meetings, involving the co-directors and wider research team and programme management, will assess progress for every current evaluation
- c) All project deliverables to be reviewed by QA reviewers (RAND) and/or senior advisory group members (Oxford) who are not otherwise part of the evaluation team.
- d) Each project protocol, and subsequent final report, will be reviewed by an external expert before the start of each project. This will take the form of 'light touch' review to enable rapidity and timely evaluation and feedback.
- e) All deliverables will only be cleared for release if they meet RAND Europe's QA standards.

D. Dissemination

We will provide formative feedback and summative reports from each of the evaluations (section 8).

2.3 Research design and methods

Evaluation of technology-enabled remote monitoring innovations requires recognising the complexity of service innovation and seeing it as both a process (e.g. of establishing, implementing, sustaining and sometime scaling and spreading the innovation) and an outcome. The exact design and methods to be used by the DECIDE team will depend on the innovation being evaluated. We therefore provide the foundations for our approach below, acknowledging that different projects will require different methods, inputs and timescales. We will closely with relevant stakeholders (Figure 1) in designing and delivering evaluations. Each evaluation we will be guided by a set of co-produced questions.

Box 1: Example research questions for evaluations

- Is the technology-enabled/remote monitoring innovation needed and if so, by whom?
- How does it work and what factors related to the intervention, implementation process and wider context influence adoption?
- What are the associated outcomes and impacts and on whom (eg which end-user populations, service provider contexts)?
- How does the intervention and its impacts mitigate and/or tackle inequalities and widen equality, diversity and inclusion considerations?
- What are the unintended consequences of implementing and using technology-enabled remote monitoring, and how are these mitigated?
- What are the opportunities and challenges for the intervention to scale (within the local setting) and spread (more widely in health and care)?

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2.3.1 EVALUATION DESIGN

Multi-method evaluation across sites will generate actionable learning and in-depth understanding. We will employ a core set of tried and tested methods across evaluation projects, but will also retain flexibility for rapid tailoring of our approach depending on the needs of individual cases. The primary research method adopted for each project will depend on the time horizon agreed with the Funder, input from the policy customer and other stakeholders, diffusion of the technology being evaluated, availability of data (e.g. within electronic health records), and the results of scoping and literature reviews. We will proactively consider inequalities in designing and undertaking evaluations (section 2.1.1). We will use relevant theory (section 2.1.2) that enables explicit consideration of digital inclusion, and take into account CORE20Plus5.¹⁵ Each evaluation will evolve in 3 overlapping phases.

Phase 1 – <u>Topic specification, scoping and protocol development</u>: (a) rapid evaluability assessment to establish the most efficient and value-adding approaches to collecting qualitative and quantitative data (where possible at baseline and post-implementation or at different stages during spread and scale-up), (b) understanding service user journeys and service processes to gain a view of set-up in participating sites, and (c) familiarisation discussions with PPI representatives, staff and other stakeholders to establish initial programme theory (d) rapid review of the available literature, drawing appropriately on different types of reviews from restricted (or rapid) reviews⁴² through to living systematic reviews⁴³ (e) we will explore outcome measures that are meaningful in each context and agree data collection protocols with sites. PPI contributors will be involved in shaping evaluation plans. At the end of this phase, and following scoping with the customer, we would have a formal evaluation protocol for approval by the Funder.

Phase 2 – Finalising <u>co-design and formative evaluation</u>: data collection will focus on five core evaluation domains which will be adapted or extended depending on the needs of each project. Collection of service performance data and costs will align as far as possible with existing systems and will largely draw upon routinely collected data. The five evaluation domains will focus on:

- implementation process (quantitative service metrics, e.g. number of people using remote monitoring services, duration and qualitative metrics, e.g. workforce and service user engagement, contextual influences on implementation enablers and barriers e.g. funding and procurement processes)
- staff, patient, carer, and service user experiences (qualitative via interviews and focus groups, focused observation in clinical and home settings and/or quantitative via short surveys);
- service access and use (quantitative metrics, routinely collected data, e.g. hospital admissions, emergency attendances, and length of stay, may include capacity metrics such as bed availability and occupancy);
- clinical progress depending on condition/clinical area (e.g. service user outcomes, healthrelated quality of life – mostly quantitative, informed by routinely collected and/or via short bespoke surveys), and unanticipated outcomes (qualitative, case studies of significant events);
- economic outcomes, including resource use, economic costs and overall assessments of costeffectiveness/cost-benefit/cost-consequences.

We will conduct rapid and focused data analysis in parallel with data collection and will directly feed findings into iterations of programme theory and further co-design with partners, service users, and patient and public contributors. Evaluation timelines will vary depending on scope and scale of individual projects and the identified needs of each policy customer – we expect a typical rapid evaluation to last 4-9 months.

We have a set of piloted interview/focus group guides, consent forms and information sheets which we will adapt for different health and care settings. We will work closely with on-site clinical teams to set up data collection, and will use options for telephone/video interviews as well as face-to-face, thereby reducing logistical challenges. We will seek to use maximum variation sampling to recruit service users across sociodemographic and ethnic backgrounds, health needs and conditions, and with different levels of self-assessed digital literacy/confidence/access.

Any documentation, service protocols, significant event details or other relevant records (without identifiable details) will be retained for analysis. Acknowledging that health and care staff are under pressure, we aim to align with existing activities to minimise extra burden.

We are committed to rapid learning, through providing formative, emergent feedback with appropriate caveats in place, to ensure findings are shared throughout an evaluation.

Phase 3 – <u>Cross-case analysis, summative synthesis and formative legacy</u>: we will establish the summative impact of the technology-based remote monitoring service across qualitative and quantitative metrics, including in relation to sustainability and scalability. Process evaluation findings will be documented in narrative form, describing how the technology was implemented. By working collaboratively with the NHSE Digital Care Models team we will ensure our work supports policy priorities. We will feed back findings in real time through formal/informal opportunities for dialogue to strengthen organisational learning and contribute to sustainability while retaining critical distance.

2.3.2 TYPE OF ECONOMIC ANALYSES THE TEAM INTENDS TO UNDERTAKE

Primary research is likely to draw upon a range of economic research methods. Rapid evaluations of 4-9 months are likely to include economic evaluations based on individual-level observational studies and quasi-experimental designs (e.g. regression adjustment, difference-in-difference, propensity score matching) and economic evaluations based on decision-analytic models including value of information analyses. For more rapid evaluations, we will use alternative methods to facilitate that rapidity, including assessments of economic costs (using provider surveys, service user surveys, time/motion studies, other bottom-up costing approaches), budget impact analyses, and stated preference methods (e.g. discrete choice experiments, best-worst scaling). We anticipate drawing upon routine data sources in health care and complementing this with primary locally collected data in both health and social care settings. The host department for the proposed economic analyses (NDPCHS, University of Oxford) hosts four primary care databases (CPRD, QResearch, ORCHiD, OpenSAFELY) with linkages to Hospital Episode Statistics and Office for National Statistics data. We also have experience of accessing and analysing other datasets included in the HDR UK gateway. The choice of database will be informed by the evaluation question.

Accepted guidelines will be followed for methodology (e.g. the ISPOR guidelines for discrete choice experiments, CHEC for decision-analytic modelling based economic evaluations) and reporting (e.g. PRISMA for systematic reviews, CHEERS 2022 for economic evaluations). We will apply an equity lens within each evaluation, seeking to ensure that disparities in care provision and outcomes by geography, socioeconomic status, ethnicity and other protected characteristics are adequately addressed. For example, within economic evaluations, distributional cost-effectiveness methods will be used to assess trade-offs between efficiency and equity concerns.

2.3.3. HYPOTHETICAL EXAMPLE

To illustrate our evaluation methods and rapid approach, we provide a hypothetical example of a rapid evaluation of virtual wards for acute respiratory infections.

The intervention – According to NHS guidance (Jan-22),⁴⁴ acute respiratory infection (ARI) virtual wards provide an alternative to hospital admission or a pathway for safe early hospital discharge for patients with confirmed or suspected ARIs. Those who are stable or improving but still require acute care (rather than chronic disease management), receive technology-enabled remote monitoring and self-management advice in their usual place of residence (including care homes) as part of a time-limited 'admission' to the ARI virtual ward, instead of being admitted to hospital. Patients monitor their own health (e.g. temperature, pulse, saturations) using devices and communicate readings to the clinical team (e.g. using a tablet, also to submit responses to other monitoring questions). As an example, a multidisciplinary clinical team in Wolverhampton is running an ARI virtual ward to support patients at home with pneumonia, Covid, COPD, asthma and oxygen weaning.⁴⁵ The ARI virtual ward could be considered as two models, providing 1) step-up, alternative to hospital admission and 2) step-down care, pathway for safe early hospital discharge. Below we describe evaluation activities, noting that they may require separate activities for each model. We would coordinate with evaluation activities as part of the National Virtual Wards Programme to maximise synergies.

Evaluation questions (project-specific)

1. What is the feasibility and acceptability of ARI virtual wards (as an alternative to hospital admission or pathway for safe early hospital discharge)? What are their (perceived) implications for equity, satisfaction, efficiency and safety?

2. How do service users (e.g. patients, carers, and NHS staff) experience these new models of care, compared to hospital and other standard pathways? What is the organisational impact (including capacity) at different system levels across health and social care?

3. What is the clinical and cost-effectiveness of ARI virtual wards (as an alternative to hospital admission or pathway for safe early hospital discharge)?

4. What would be the optimal set-up of an ARI virtual ward in terms of workforce, training, care coordination, equipment (including technologies) and access to point of care diagnostics? How might this differ between areas depending on local service arrangements?

Topic specification, scoping and set-up (4-8 weeks) – To more closely specify the topic and tailor our evaluation for the example of ARI virtual wards we will follow a number of parallel processes:

a) <u>rapid review of documents</u> already collected to develop initial programme theory for the intervention (i.e. assumptions related to mechanisms of action and expected outcomes) and to identify key evidence gaps and uncertainties, drawing on policy and commissioning documents and high-quality research studies and prior evaluations, paying particular attention to equity and inclusion aspects (e.g. for ARI virtual wards NHS guidance mentions expected outcomes related to improved service user experience and outcomes, shared decision-making, improved patient flow by reducing admissions and length of stay, and reduced nosocomial transmission of infections)

b) <u>rapid identification of key stakeholders</u> through established networks (e.g. for ARI virtual wards this would include policy and ICS stakeholders, primary, secondary, urgent and community care providers including acute respiratory infection hubs depending on local implementation(s) and a set of PPI contributors who will support this project more closely).

c) <u>focused evaluability assessment</u> including feasibility of data collection methods, site selection/familiarisation and governance arrangements, data availability and reliability, and early identification of equity challenges. For quantitative data, we would assess the availability of service and resource utilisation data based on electronic health records from national or local data sources and speak to health or care professionals involved in care provision and data support professionals to understand how care related to virtual wards is represented in the data.

d) <u>assessment of alternative ways of measuring and expressing the economic value</u> of ARI virtual wards, including an assessment of data availability (see c) above), identification of appropriate sources of unit costs for potential resource consequences, assessment of how much primary costing research will be required for the main evaluation, and assessment of the best possible way of expressing the cost-effectiveness or cost-consequences of ARI virtual wards.

Our team is experienced in conducting rapid evidence consolidation (as we are familiar with much of the academic and grey literature already), stakeholder mapping and evaluability assessments (we have vast experience with rapid and long-term service evaluations).

Evaluation (7-8 months) – Scoping work will enable us to finalise our mixed-methods data collection and analysis plan which we anticipate will include the following:

A. Qualitative methods: instead of imposing unrealistic data collection demands on already burdened services, we will work closely with healthcare staff to align with their routines and workflows.

i. **Shadowing** ~3-5 staff members with different roles (e.g. nurses, doctors, pharmacists and administrators involved in running the ARI virtual ward) for ~1-2 days each to understand what works well or less well in terms of clinical management and technology-enabled monitoring. This will include shadowing in clinical settings but also home visits where relevant and feasible (including observations of service users using technologies provided).

ii. The information collected during shadowing will be used to focus interview questions and support more targeted and rapid data collection. We will conduct individual **qualitative interviews** (and/or small group interviews) with ~10-12 staff members (depending on team size and number of sites involved) and ~10-12 service users (including carers it is likely carers will play a significant role supporting care at home). By using maximum variation and snowball sampling we will aim to gather a wide range of views across staff members with different roles and service users with a different mix of

socio-demographic characteristics, health status, and IT literacy and ability. Interviews will be conducted online, on the phone or in-person depending on participant preference and time/logistics.

Focused data analysis will take place in parallel with data collection using a structured coding framework (drawing on NASSS and equity aspects) to enable rapid identification for practice and policy implications and to facilitate dialogue with other methods.

B. Quantitative methods: for quantitative analysis, we want to assess whether delivery of care via virtual wards is clinically and cost-effective.

i. Service utilisation and clinical outcomes: Whereas long term outcomes and impacts may unfold, primary outcomes of interest may be relatively short term, including indicators such as: length of stay, 30-day hospital readmissions, Emergency Department (ED) visits (if possible due to data availability), 30-day mortality.^{46,47} The study design for the proposed rapid evaluation will be guided by data availability, informed during scoping and set-up.

For relatively short evaluations (less than 1 year), alternative quasi-experimental study designs will be considered. These may include aggregated analysis at the Trust or area level, with econometric techniques such as matching and/or propensity score methods to create an appropriate comparison group and adjust for differences between groups. For longer evaluation periods (at least 1 year and would likely require additional resourcing) we would recommend a stepped-wedge cluster randomised controlled design in which units of observation (i.e. hospitals or clusters of hospitals) implement the virtual ward in a systematically staggered approach, allowing for comparisons of units that implemented the virtual ward to their own pre-implementation period, as well as contemporaneously to the pre-implementation period of other units. Other designs would be considered if virtual wards are already implemented or there is little support or engagement for a cluster randomised evaluation. Within each of these alternative study designs we would draw upon electronic health care records, extracted by NHS Digital, for example HES, and analysed in a secure data environment.

ii. Economic outcomes: an economic evaluation of ARI virtual wards will be conducted in accordance with the NICE reference case.⁴⁸ Primary research methods will estimate the costs of implementing the intervention, encompassing costs associated with support provided by multidisciplinary clinical team members, remote monitoring and follow-on management. For an economic evaluation built on a quasi-experimental design, our analytical strategy will be informed by recent guidance on accounting for selection biases within economic evaluations that rely on individual level observational data.⁴⁹ A key methodological challenge will involve generating expressions of cost-effectiveness amenable to broader cost-effectiveness comparisons by decision makers, i.e. incremental cost per quality-adjusted life year (QALY) gained. Alternative expressions of cost-effectiveness will be considered e.g. incremental cost per hospital readmission avoided. A range of economic values for avoiding adverse outcomes associated with acute respiratory infection will be informed by a review of the revealed and stated preference literature.

For longer evaluation periods, the underpinning study design would be a trial-based economic evaluation (see section B(i) above) using HES data and service user completed questionnaires. The duration of follow up will be determined by the final study design adopted but we anticipate a minimum of 30 days' follow up. Health Resource Group (HRG) codes extracted from HES will be matched to NHS Reference Costs based on diagnostic codes, procedure codes and lengths of stay to generate hospital inpatient and day-case costs. HRG codes will also be used to inform the cost of outpatient visits and accident and emergency attendances. Service user completed questionnaires will provide information on community health and social services resource use and health-related quality of life and well-being outcomes. Overall approaches to expressing the economic outcomes of ARI virtual wards in either cost-effectiveness or cost-consequences metrics will be informed by the scoping research (see Scoping and set-up, section d). A series of sensitivity analyses will explore the implications of uncertainty around incremental cost-effectiveness ratios.

C. Data synthesis: we will use NASSS as an overarching framework to integrate data, and surface multiple interacting complexities in an actionable way, with additional focus on digital exclusion and intersectionality. By creating synergies between qualitative and quantitative findings we can deliver a well-substantiated theory of change, including unanticipated implications in practice. We will be able to develop transferable learning to inform appropriate implementation, spread, scale-up and sustainability of virtual wards across settings.

3. Co-production

We view co-production as "*a way of working where service providers and users work together to reach a collective outcome. The approach is value-driven and built on the principle that those who <i>are affected by a service are best placed to help design it.*"⁵⁰ Guided by the aims and focus of each evaluation our focus will be on collaborative knowledge generation working alongside policy customers and other stakeholders, with the explicit aim of aligning policy priorities (particularly, but not only, for TERM), rapid evaluation, locally adaptive partnerships (e.g. between evaluators and users), rapid knowledge exchange and (where possible) service development.⁵¹ Guided by our principles (section 4.1) we recognise that **co-production may look different in rapid evaluation**, and plan to balance targeted co-production activities with prioritisation for timely evaluation and feedback.

We have a track **record of close working with evaluation participants to enable co-design** (e.g. use of Experience-Based Co-Design) and support co-production of technology-enabled services.^{31,32} This has informed new models of service delivery (e.g. multiple studies on remote consulting led by Oxford) and co-design with clinicians and service users of NHS badged resources to support video consulting during Covid-19 (ref). Building on this, we will follow a similar approach, **working with evaluation participants and clients to refine evaluation questions and designs, inform sampling and evolving analysis** (Figure 2).

In previous work we have **embedded co-design – of services and technologies – within projects, with the aim of working with stakeholders (patients, staff, providers and commissioners) to design and deliver high quality and equitable services**, and (where appropriate) to co-evolve technologies alongside clinical practices and organisational routines.³¹ We have practical experience working with organisations representing **seldom heard voices and marginalised groups** (e.g. those with mental health conditions, ethnic minorities). As per our recent work on co-design of digital health (a finalist in the prestigious Diana Forsythe prize, 2022), our focus is on (a) co-designing with service users, and with healthcare professionals, (b) including those who engage with the technology-enabled remote monitoring service/s directly and indirectly, (c) remaining sensitive to emergence and unpredictability in complex systems, (d) supporting healthcare staff to accommodate iterative change.

To facilitate co-production while maintaining independence we have planned principles, processes and systems to ensure clear evaluation objectives, robust study protocols, ethics and governance, quality assurance, peer review, effective relationships and open lines of communication.

4. Programme and project management

The Oxford-RAND partnership offers highly relevant expertise and infrastructure, combined with a flexible and responsive approach to working. Our team is experienced in rapid evaluation and evaluation of technology-enabled remote monitoring (e.g. evaluating the implementation and use of SUPPORT-HF2 remote monitoring and clinical decision support system for optimising heart failure treatment). We have demonstrated topic, method, management and leadership experience. Coupled with appropriate and feasible time commitments; alongside risk management arrangements for deputising and succession, this will support rapid delivery in feasible and high quality ways. This partnership will be supported by robust governance and management arrangements, with clearly identified roles at both programme and projects levels. Below we set out arrangements for how our core team, internal advisory broad, and steering committee with work together to deliver robust, effective and meaningful evaluations of technology-enabled remote monitoring.

4.1 Management of the overall programme

The DECIDE Director will have overall accountability for delivery of projects, devolving leadership on specific work packages as appropriate to other members of the senior team. Partner leads will meet regularly (online) along with deputies, to agree evaluations design/plans, ensure oversight at project and centre level, review progress and rapidly address challenges/issues arising. They will be supported by programme management (at both partners) and administrative support, as well as wider institutional structures (including research services, contract management, and post-award finance), thereby ensuring effective contract management, financial management and reporting and meeting of key agreed milestones.

4.2 Internal Advisory Board

The core senior team will be supported by a cross-partnership internal advisory group, ensuring topic and method-relevant advice, input into governance and operations, connection with the wider landscape, as well as evaluation/work planning. Membership will include senior Oxford, RAND and AHSN representation. The group will meet monthly, contributing to the identification, design, planning, implementation and delivery of the Centre's work, with ad hoc communication in-between to support planning, decision-making (e.g. re evaluation design/focus) and rapidity.

4.3 Project management

All evaluations will have senior oversight and then draw on the Centre's pool of staff to jointly staff projects. The DECIDE team combines senior level leadership and expertise with staff experienced in research and evaluation that is flexible, responsive and committed to high quality evaluation and impact. Responsibility for day to day delivery of each project will be allocated depending on evaluation focus, expertise (e.g. re social care), and capacity/timing. There will be clear lines of communication and accountability up to the core senior team.

Our programme manager (a senior social scientist with mixed method expertise who can provide ad hoc evaluation support) and administrator will support the team and individual evaluations. The Oxford-RAND partnership also brings with it additional resources from the wider institutional infrastructure in which the Centre will be based, including PPI/user experience infrastructure, junior staff training and support (e.g. on innovative methods) and access to existing data sets which will further support projects.

4.4 External Steering Committee:

A steering committee (12-15 members, including PPI representation) will advise on strategic and operational aspects of centre activity (e.g. refinement of evaluation questions, evaluation design and scope, inclusiveness and stakeholder engagement, dissemination), and oversee independence and quality. We will seek to involve the steering committee members in ways that maximise relevance and value of input but with due consideration of their time. The committee will meet every four months (mix of online and hybrid), to review programme and project progress and to feed into topic identification and prioritisation (Figure 1). Additional input will be sought at the evaluation-level. In the initial scoping phase for each project, this will involve ad hoc contact with relevant members, seeking input on current innovations and contacts, evaluation approach and focus and potential site identification. Building on this process (and once formally commissioned) we will then invite up to 3 committee members with relevant roles/expertise to contribute to a project specific advisory group for each evaluation, including (but not limited to) input to protocol development, specifics of evaluation design and conduct, and effective formative and summative dissemination of findings.

4.5 Working with the NIHR HS&DR programme

We want to ensure open communication lines with the NIHR HS&DR, governance structures and evaluation participants that is balanced and supports independence. In practical terms, this means we will have a clear contact point for engagement with NIHR HSDR through the DECIDE PI, the PM and administrator at Oxford. We will ensure relevant RAND Europe staff (e.g. DECIDE lead and PM at RAND) and specific project leads are engaged in key meetings with NIHR, where relevant.

5. Patient and public involvement and engagement

Meaningful involvement of service users, carers, patients, and members of the public is central to DECIDE, and will enable a strong rapid evaluation team, focused and relevant research and userfriendly outputs. We worked with patient and public collaborators in developing our proposal, and plan to involve service users, patients, and the public throughout. Those we have already connected with are keen to ensure DECIDE evaluates technology-enabled remote monitoring solutions that matter, asks the right questions, collects the right information appropriately, engages the right people, and interprets, communicates and shares learning effectively. To ensure that DECIDE not only holds issues of health and digital inequality as a central thread, but also looks at intersectionality when doing so, they have produced the underpinning principles in Box 2.

Box 2: Principles underpinning patient and public engagement in DECIDE

1. <u>D</u>IVERSE: Our oversight group will provide insights from a wide range of stakeholders including charities, care providers, and members of the public. For individual projects we will supplement our core oversight group with appropriate expertise, as relevant for that project

2. <u>EQUITABLE</u> ways of working: Participants of all types will be clearly informed of what will be expected and will be actively involved in co-creating expectations; work load will be defined and properly compensated; training will be provided

3. <u>CONTEXTUAL</u>: We will aim to be context sensitive and flexible. We are aware that different types of projects will require different levels and types of involvement, input and analysis. We will focus on relevance and intentional design, not quantity or tokenism

4. <u>INFORMED</u>: Communication will be clear and respectful at all times. We will be honest about what can and cannot be achieved and in what timeframes. We will be aware of and discuss the trade-offs between the need for speed and the need for granularity

5. <u>D</u>ELIBERATIVE: We will be considered in our approach, engaging with institutional and lay contributors, and seeking their views and dialogue on what types of data and sources we should consult, with whom we should engage and how

6. <u>E</u>THICAL: We will take into account a wide range of ethical issues, from questions of data equity and health inequalities to environmental impact and other forms of sustainability

5.1 Engaging with PPIE expertise

Co-investigator (and PPIE lead for DECIDE) Alvarez Nishio is an experienced public advocacy consultant with experience working with marginalised and vulnerable communities and interests in the use of digital technology in health and care. We will recruit 3 PPIE strategic advisors (provisionally from National Voices, Carers UK and People Street) to be part of a user advisory group, chaired by Alvarez Nishio, which will help to ensure that DECIDE evaluates solutions that matter, asks the right questions, collects the right information appropriately, engages the right people, and interprets, communicates and shares learning effectively. We will complement this (guided by the focus of individual evaluations) with project relevant voices, and work with relevant PPIE representatives on an ad hoc basis throughout our work.

Informed by our engagement with patient and public voices in developing our proposal, we have produced a comprehensive budget for PPIE covering time and contributions (in line with NIHR/INVOLVE guidance), training and development and expenses (including travel and subsistence for PPIE representatives and, where relevant, carers). We will work with PPIE advisors to ensure events, communications and interactions are accessible and appropriate for those involved.

5.2 PPIE contributions to DECIDE

At the programme level, Alvarez Nishio will bring the PPIE voice to the External Steering Committee, acting as equal partner in management, evaluation design, implantation and dissemination. She will attend SC meetings and, in collaboration with the Steering Committee Chair, play a key role in opening meetings with the service user voice. She will be supported by (and be in regular contact with) the User Group, enabling multiple voices to be heard.

Our user advisory group will work closely with Oxford and RAND Europe teams to inform the work of the centre, with advice sought via formal meetings and on an ad hoc basis. We will convene the panel twice each year and additionally consider (with User Group input) an annual review meeting that will include all members of the panel plus the core members of the research and evaluation team. The idea is to facilitate multi-disciplinary discussion of evaluations conducted and allow full stakeholder involvement in horizon scanning, prioritisation and planning for future evaluations.

Project-specific PPIE input has also been costed and will be sought for each evaluation. In line with Principle 3 above ('Contextual') we expect our PPIE contributors to assist (where skill set allows) with relevant, intentional rapid input and review of e.g. service user facing ethics documents or interview guides. The panel and additional contributors will play a key role in interpreting findings to support dissemination with a particular focus on patient/public facing outputs and impact. We have also costed for patient and public involvement to co-produce at least one publication from DECIDE.

6. Ethics and research governance

It is likely that individual evaluations will give rise to project-specific ethical issues (e.g. privacy, informed consent). All work will adhere to the UK Framework for Health and Social Care research. We have longstanding experience of liaising with sponsor representatives (Research Governance, Ethics & Assurance team at Oxford) and following HRA procedures and identifying service evaluations that only require institutional approvals or, where needed, seeking HRA/REC approval. Where projects are badged as service evaluations, we will seek approval from the Oxford Central University Research Ethics Committee for a programme of work focussed on evaluation of remote monitoring. Where/if one or more aspects of projects require HRA approval, we plan a similar approach, seeking HRA approval at the outset for a series of evaluations of technology-enabled remote monitoring and minor amendments as needed, on a project-by-project basis (we have done this successfully in other NIHR-funded studies, with minor amendments allowing rapid set up and start for allied studies).

For approvals and access to patient data, we will approach NHS Digital (now part of the NHS England and NHS Improvement Transformation Directorate) to obtain NHS secondary care activity data. Such data is highly likely to be useful in one or more of the evaluations that the DECIDE team conducts and having the approvals and access in place in advance will permit much more rapid evaluation than if a data application is made for individual evaluations as they arise.

6.1 Data access, management and storage

Oxford and RAND have institutional policies and infrastructure for storing, managing and sharing data, including NHS datasets. We have costed large data storage to support this.

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). Interview recordings will be sent to approved transcribers using approved methods of data transfer under wider information governance and data protection policies. Once the transcriptions have been checked, the original recordings will be destroyed. Transcripts (which will be anonymous) will be considered the primary data source and will be stored in secure, password access files. Field notes will be a mix of handwritten, digital, and photographic sources. Hand-written notes will be digitised as soon as feasible and stored with other digital media in password access files within the University of Oxford and/or RAND Europe networks. 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.
- <u>RAND Europe</u> 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.

Evaluation data sets are not intended for wider public access without specific permission. Third parties with a genuine reason to request access to the data sets will need to write to the Chief Investigator outlining their request, including details of how and why they propose to use and analyse the data. Data will not be withheld from those with reasonable requests. Any data shared beyond the core DECIDE team will need to align with relevant approvals (see above) and be governed by data sharing agreements.

Data provided by NHS Digital will not be available at any point in time for third parties who are not included in the specific DECIDE data sharing agreement with NHS Digital.

7. Timetable

Set up: NIHR contract and comms plan; Steering committee/advisory group/user panel, Ethics and data access, Staff recruitment (qual/quant postdocs); dissemination and engagement plan

On-going: agree project focus, aims and design with NIHR and stakeholder groups; secure service user input; review staffing; scope and operationalise evaluations; ensure formative and summative

feedback; dissemination and reporting; webinars and future-focused discussions; ad hoc policy engagement; co-production and co-design

To review at least 6 monthly throughout: staffing and training needs; anticipated time, overlap and capacity for evaluations; dissemination plan, outputs and impact

Whist the **precise timetable cannot be specified until NIHR selects projects for evaluation**, we anticipate approximately 6 evaluations over three years, with a mix of durations (e.g. some 6 month, some 9-12 month, and potentially one longer longitudinal evaluation).

8. Dissemination, Outputs and Anticipated Impact

We are committed to rapid formative and summative learning and to flexibility in channels for both (verbal, written, more and less formal, responsive, embedded in wider dissemination events in the system and in interactions with wider networks). In practical terms, this means we will (a) support diverse dissemination and engagement channels; (b) provide formative feedback to ensure evidence is shared in a timely way to support decision-making and learning cycles, with appropriate caveats in place; (c) engage early on with stakeholders to lay the foundations for active engagement and twoway communication, and (d) create opportunities for informal networking amongst target groups (e.g. virtual communication) to enable informal interpersonal communication alongside formal written outputs. Any interventions being evaluated can be subject to change through an evaluation. Dissemination therefore needs to be accommodating of emergence. We will balance interests in realtime formative feedback on emerging learning with caution in making final (summative and formative) inferences too soon. This may mean that formative learning may need to be confined to a subset of directly involved individuals/organisations, while final learning can be disseminated more widely. An overarching dissemination and impact strategy will be refined with steering committee and user group advisory panel input. The focus will be both on tailored dissemination and outputs specific to individual evaluations, as well as synthesis/learning across evaluations (e.g. on topics, methods, effective PPIE). This will build on our track record of effective dissemination and engagement, focus on written and oral communication, and make use of our networks and partnerships across a range of stakeholders (section 7). We envisage this will involve a mix of activities:

<u>For commissioners of technology-enabled services</u>: evaluation reports, evidence briefings and infographics/blogs, (formative and summative) presentations at seminars/events; ad hoc inperson and virtual engagements.

For providers and health and social care professionals: practical learning about remote monitoring, (formative and summative) presentations at seminars/events; case vignettes and resources that can support appropriate local adoption, use and spread.

<u>For patients, service users and the public</u>: a public-facing website, using plain English and visuals to set out the Centre's aims and work plan; at least one service user led publication, plus (where relevant, timely, and within available resources) co-designed service user facing resources to support adoption and use of technology-enabled remote care by different groups.

<u>For policymakers and funder</u>: evaluation reports and policy briefs, focused on the outcomes of each evaluation and methodological innovation across them; formative and summative communications via informal/ad hoc meetings, webinars, social media.

<u>For researchers</u>: a series of up to 6 journal papers, presenting evidence from evaluation along with theorisation of technology-enabled remote care; conference presentations/discussion.

We will work with Design Science (an applied design agency, <u>www.design-science.org.uk/</u>) to develop high quality materials and resources and tailor messaging across evaluations. Design Science bring expertise in co-production and co-design (section 3) and will provide additional, flexible and rapid capacity (e.g. communications, visual support, graphical resources) on which the core team can draw down to support knowledge translation and dissemination throughout. In our experience such support is highly effective in extending reach and impact.

9. Success criteria and barriers to proposed work

Our success criteria are set out below. These closely align with our guiding principles (section 2.1.1).

- Findings are of relevance and interest to diverse stakeholders meaning that relevant interventions are evaluated, relevant questions are asked, appropriate methods implemented, and high quality outputs produced

- Dissemination activities focus on communicating key messages in a timely, practical and useful way to targeted audiences through diverse learning channels to support impact
- Evaluations strike the appropriate balance between rapidity and rigour and are of high quality, guided by the commissioner, steering committee and lived experience user panel
- Evaluations are completed in a timely manner within the timeframe agreed on
- There is clarity and an alignment of expectations between commissioner (NIHR HS&DR), evaluation team and contributors and participants in the evaluations
- There is explicit pursuit of coproduction and consideration of diversity, equality and inclusion and inequalities in both design and implementation of evaluation

Table 1 sets risks to the Centre/work along with steps to mitigate against these.

Table 1: Risks, management and mitigation for DECIDE

Risk	Management and mitigation	
Data quality and access	 Establish data access agreements as soon as possible; timely arrangements with NHS Digital/NHSE Transformation directorate Gain upfront clarity on data availability and quality to inform design Triangulate across methods, data sources and types 	
Low participant engagement in evaluation or challenges to quick engagement	 Offer formative feedback (sustaining engagement, communicating value) Letters of support from influential individuals Tailor approach to local capacities, including scope/methods (see 4.1, C) 	
Reflecting inequalities in prioritisation criteria	 Include diverse voices on steering committee and user group advisory Explicitly consider inequalities in process and outcome measures 	
Challenges in delivering rapid work	 Establish approval processes and governance structures to support rapidity Align choice of methods and scale of work to timeline and resources Draw on flexible internal capacity, lean on wider networks as needed Invest in careful scoping, with stakeholder engagement 	
Staff appointments and turnover	 Initiate hiring processes well ahead of start date Ensure adequate cover and flexibility to cover for (junior/senior) staff absence 	
Low or reduced impact	 Secure early involvement and buy-in from relevant stakeholders Communicate throughout evaluation, not only at end Offer multiple communication/dissemination channels for different audiences Agree success criteria in evaluations to enable practical action 	

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