

Rapid evaluation of the NHS Health Check Online early adoption and local testing

Study protocol

Version 1.2

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Abstract

Background

Through early assessment of individual risk factors, the NHS Health Check (NHSHC) programme aims to prevent cardiovascular disease and assess the risk of developing other conditions such as type 2 diabetes. A recent review found that early assessment has contributed to increased detection of risk factors and morbidities [1]. Yet, between 2015/16 and 2019/20 only 41.3% of eligible people had an NHSHC [2][3]. To address low uptake, a 2021 review of the NHSHC programme recommended the development of a digital offer, with the aim to increase accessibility, effectiveness and efficiency of health checks. Development is currently underway with a view to implement and refine the digital service in 3 local authorities over a period of 6 months. The proposed rapid evaluation is intended to inform design, refinement and early adoption of NHSHC-Online (NHSHC-O) as well as further roll out and broader digital transformation in primary care.

Aims, objectives and research questions

The aim of the proposed evaluation is to examine the development, implementation and use of Digital NHSHCs during the local testing phase and to draw timely, transferable lessons that can inform and support wider roll-out. The objectives are as follows:

- 1) To develop a rich picture of the structures and support mechanisms underpinning successful adoption of NHSHC-O.
- 2) To surface and explore the numerous interacting influences on implementation and identify potential challenges for spread and sustainability.
- 3) To provide an in-depth understanding of staff and service user experiences, including in comparison with in-person health checks.
- 4) To examine service use quantitatively and explore economic costs and assessments of value of NHSHC-O for services and service users.
- 5) To capture and disseminate transferable learning for technology-supported care and its users, including wider roll out of NHSHC-O and feasibility of larger-scale evaluation.

Underpinning research questions for the evaluation are:

- 1) What structures, resources (organisational, technical, human) and support mechanisms are needed to achieve adoption? What adaptations are needed to existing practices?
- 2) What are the experiences of staff involved in delivering or introducing NHSHC-O? What are the experiences of patient users and non-users (as well as their care network)?
- 3) What is the patient experience in terms of quantitative service measures and how does this compare across patient groups? How can we assess uptake?
- 4) How can we assess process outcomes such as identification of risk factors and morbidities, treatments, etc.? How can we assess the economic value of NHSHC-O?
- 5) What can we learn about how sustained adoption at scale might be achieved?

Design and methods

This evaluation will take a multi-site, mixed-methods (qualitative and quantitative) approach with three implementation case studies, in order to build a rich picture of adoption of online health checks and the system-wide factors that influence and shape adoption.

Data collection and analysis will be guided by the NASSS (non-adoption, abandonment and challenges to scale up spread and sustainability) framework, in order to surface and explain the system-wide

challenges and complexities in the technology-supported service change, alongside more in-depth theoretical concepts.

The project will follow three overlapping phases.

Phase 1 (pre-assessment and groundwork) will focus on project set up, confirming study sites, and establishing the goals, projected benefits and concerns with regard to NHSHC-O. This will be conducted through a targeted literature review and evaluability assessment with the delivery team and study sites.

Phase 2 (data collection and analysis for process evaluation) will include qualitative and quantitative data collection, analysed iteratively and through engagement with our PPI and local sites. Qualitative data will include interviews with up to 50 staff across and beyond implementation sites, as well as system and policy stakeholders to explore the (inter)organisational resources, processes and challenges to implementation, as well as how the value of the in-person offer can be translated into the digital product. In addition, we will conduct interviews with up to a total 35 users and non-users of NHSHC-O (with members of their care network where relevant) to illuminate their experiences using (or not) the digital offer, their concerns and/or unintended consequences. A key element will be to capture the challenges for those with complex support needs and issues associated with inequalities in access, use and support. The quantitative evaluation will focus on measuring uptake rates, adjusting for patient and practice characteristics, to understand what factors influence uptake. We will also explore feasibility of comparing patient uptake between digital and non-digital NHSHCs. From an NHS perspective, we will explore the costs associated with NHSHC-O and the feasibility of a larger scale study that will look at their impact on identification of risk factors, morbidities, medications and other requirements needed to model their potential economic value.

Phase 3 (summative analysis) will involve data synthesis and cross-case comparisons to draw transferable lessons, report writing and dissemination. This will be supported by a stakeholder workshop and regular discussions with policy and delivery teams to explore the implications of the evaluation findings for national policy, and draw practical lessons for wider roll-out.

Timelines for delivery

Data collection started in April 2025 and will last to the end of 2025, to align with the timelines of the 'limited cohort' (early phase ahead of the main local testing period) and 'private Beta' phases. Overall the project will finish in March 2026.

Anticipated dissemination and impact

Outputs will include a final report with executive summary, including the case study narratives based on the qualitative and quantitative data, summative findings and key recommendations for policy, practice and future evaluations. The final report and executive summary will be made freely available through the DECIDE website. A lay summary will also be made available with the support of a project PPIE group. We will build interest and raise awareness more widely about the project from the outset, and work with our policy customer to inform ongoing national strategy in rolling out NHSHC-O.

Background and rationale

Through early assessment of individual risk factors, the NHS Health Check (NHSHC) programme, introduced in 2009, aims to prevent cardiovascular disease and assess the risk of developing other conditions such as type 2 diabetes. Local authorities hold responsibility for commissioning and monitoring the programme, which is primarily provided in general practice. Other types of providers include community pharmacies, major retailers and voluntary agencies. Funding for the NHSHC programme is provided to local authorities through the annual public health grant allocation. The programme invites everyone in England aged 40–74 who is not on one of the disease registers for vascular disease (although see [4] for full list of criteria) to a health check every 5 years. This primarily involves assessment of a number of risk factors including lack of physical activity, smoking, obesity and alcohol intake, as well as blood pressure and cholesterol levels. The outcome of the check is a 10-year CVD risk score and personalised advice, including follow-on referrals where relevant [5].

There has been significant debate on the effectiveness and value of NHSHCs (e.g. see [6, 7]). Results on effectiveness remain inconsistent, in part due to a large number of regional, smaller scale evaluations (although some large scale studies have also been conducted e.g. see [8]). A recent review found that early assessment has contributed overall to increased detection of risk factors and morbidities [1]. Qualitative research shows that health check attendees generally report positive experiences and high levels of satisfaction with the service [9]. They report benefiting from the experience and gaining increased awareness of so called ‘lifestyle-related’ diseases [10, 11].

Yet, between April 2017 and March 2022 (5-year cycle affected by COVID), only 28% of eligible people had an NHSHC [3]. In the 5-year cycle pre-COVID (2015/16 to 2019/20), only a marginally higher proportion of eligible people (41.3%) had an NHSHC [2]. Women and individuals ≥ 60 years old are among the groups most likely to attend [1]. Results are mixed in terms of the individual effects of ethnicity on uptake – some studies find no effect, while others report a mixed picture with higher attendance by some minoritised ethnic groups compared to others [12]. Findings related to deprivation are also mixed; one review found highest uptake among those from socioeconomically advantaged backgrounds [1] while another review reported the relationship between uptake and deprivation to vary depending on whether the analyses were adjusted for other predictor variables [12].

Several studies examine how invitation methods affect uptake. Opportunistic face-to-face and telephone invitation methods achieve significantly higher uptake compared to letter invitations [12, 13]. Given that letters are the most common and least expensive invitation method, a few studies have found that enhancements to the standard letter invitation, informed by behaviour science, can improve uptake rates [14-17]. Only one study examined both patient ethnicity and invitation approaches on uptake, finding that different invitation methods were more effective for different ethnic groups [18]. Consequently, more work is needed to increase the reach of the programme across population groups and further reduce cardiovascular mortality.

Qualitative research with those who had not taken up NHSHCs suggests that invitees do not necessarily see health checks as relevant to their situation, either because they perceive themselves as healthy or because they are already facing a significant burden of care for reasons unrelated to vascular disease or even because they are worried about the outcome [19-21]. Absence of perceived relevance or ‘candidacy’ is particularly pronounced in younger groups eligible for health checks [1].

Many non-attendees cite time constraints and competing priorities, as well as perceived difficulties accessing their practice to book an appointment [22]. Some practices require attendance at two appointments for those with high-risk blood results, which raises the likelihood of non-attendance and lack of follow up [10]. Studies also identify variability in public awareness and perceptions on why the health check is needed and what it involves with some patients expressing confusion around the scope and aims of the assessment as well as any follow-up needed [9, 19, 22].

Some have suggested that patients have difficulties interpreting their CVD score and its meaning tends to be ambiguous for people [9, 11]. Support, simplicity of messaging and personalised recommendations with a direct impact on individuals' own situation are received more favourably [11]. There are still open questions, however, around the longevity of any resulting behavioural changes, and the impact of inconsistencies in the delivery of health checks compared to what was originally envisaged in programme standards and specifications [10].

Previous research also suggests flexibility, convenience in terms of appointment times and access, personalised risk communication and messaging tailored to local community needs (rather than standardised impersonal postal invitations) and good patient-GP relationships, all have the potential to support uptake and engagement [10, 20]. Outreach and opportunistic approaches in community venues have been used successfully to reach underserved populations [13, 23, 24].

A 2021 government review of the NHSHC programme recommended the development of a digital offer to increase uptake, as well as embedding evaluation and monitoring as part of a 'learning system' to maintain quality [25]. Public Health England subsequently carried out a discovery piece that further demonstrated an appetite for an optional digital channel amongst some commissioners, providers and end users [26]. Development of this digital pathway is underway, with limited testing conducted currently in a newly introduced 'limited cohort' phase with 3 GP practices between March-June 2025, followed by a 'private Beta' phase (i.e. main period of local testing and refinement of minimum viable product) which will involve implementation across 3 local authorities over a period of 6 months.

Previous local efforts to deliver digital health checks include an initiative by Southwark council who were the first to offer online health checks in two pilot implementations in 2019 and 2023, primarily targeting those who did not respond to their invitation for in-person checks [27, 28]. Evaluation of the programme is due to report soon, including on reach, potential effectiveness and costs associated with the programme [29]. A similar pilot also took place in Cornwall in 2023 to inform the design and development of the national NHSHC-O programme [30].

The national NHSHC-O programme aims to increase the accessibility, effectiveness and efficiency of NHSHCs via an additional digital offer. Programme designers are seeking to achieve increased uptake of health checks overall (in-person and digital) across all groups including those from under-represented backgrounds. The plan is that GP capacity for in-person checks will then focus on early assessment and monitoring of high-risk individuals. The programme additionally aims to increase patient engagement with follow up pathways to manage risk factors and support healthy behaviours.

The proposed rapid evaluation is intended to inform the strategic ambitions for NHSHC-O but also digital transformation in primary care more broadly. To shape evaluation focus we have engaged closely with the DHSC, NHSE and technology supplier teams tasked with delivering NHSHCs. We will work further with implementation sites and the delivery team to gain a deeper understanding of online (and in-person) NHSHCs during the 'limited cohort' and 'private Beta' phases, generate

transferable lessons on the resources, systems, people and structures needed to achieve wider roll-out and explore feasibility for larger scale evaluation in the future.

EVALUATION PLAN

AIM, OBJECTIVES & RESEARCH QUESTIONS

The aim of the proposed evaluation is to examine the development, implementation and use of NHSHC-O and to draw timely, transferable lessons that can inform and support wider roll-out and potential future evaluation. The objectives are as follows:

- 1) To develop a rich picture of the structures and support mechanisms underpinning adoption of NHSHC-O.
- 2) To surface and explore the numerous interacting influences on implementation and identify potential challenges for spread and sustainability.
- 3) To provide an in-depth understanding of staff and service user experiences, including in comparison with in-person health checks.
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Underpinning research questions for the evaluation are:

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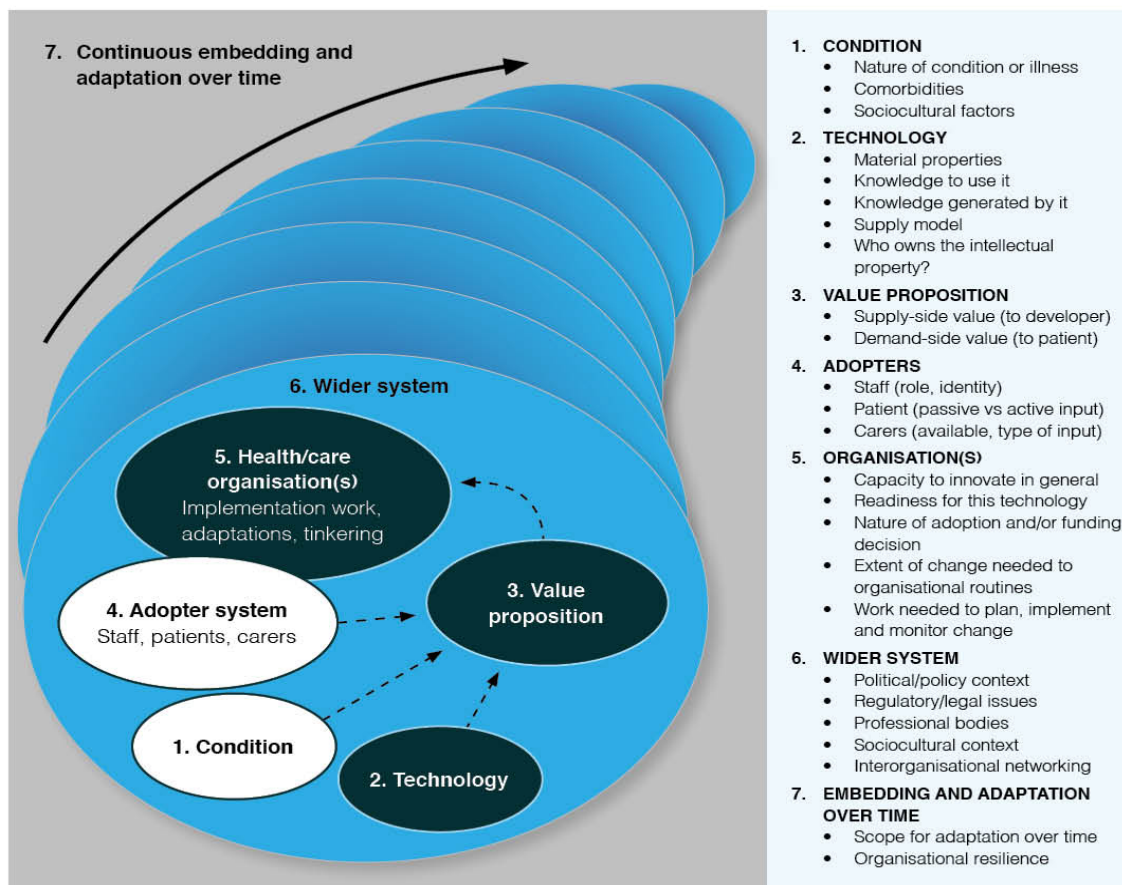
STUDY DESIGN & METHODOLOGY

Evaluation approach

The evaluation is positioned in the tradition of developmental, complexity-informed evaluation; an emergent, flexible approach to evaluating an initiative that captures data that can be fed back to the people leading the initiative to inform ongoing developments, and adapts to the particular needs and challenges of the service change [31]. Working in partnership with three implementation case studies in England (local authorities and collaborating organisations supporting NHSHC-O such as GP practices and community pharmacies), we will conduct an in-depth analysis of the multiple influences on the implementation and use of digital health checks, and draw transferable lessons for policy and practice.

Data collection will take a theoretically-informed, mixed-methods (qualitative and quantitative) approach guided by the NASSS (non-adoption, abandonment and challenges to scale up, spread and

sustainability) framework. The NASSS framework was developed by our team as an analytical tool to surface and explain the challenges and complexities in technology-supported service change.^[32] It includes seven interacting domains: the condition or illness, the technology, the value proposition, the adopter system (intended users), the organisation(s), the wider system (especially regulatory, legal and policy issues) and emergence over time (see Figure 1 below). These domains will initially guide data collection (including interview schedules and sampling strategy), thematic analysis and cross-case comparisons, with additional theoretical social science literature informing our approach such as candidacy theory [33], burden of treatment theory [34] and infrastructure studies [35].



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: NASSS framework

Study design and methods

This evaluation will take a multi-site, mixed-methods approach to understand influences on early adoption and inform wider spread. This will include three multi-level implementation case studies (described below), including at individual level (user and non-user interviews and observation), service level (GP, community pharmacy and other provider interviews, observation and programme outcomes) and wider-system level (local authority, regional and national stakeholder interviews and workshop).

The project will run in three overlapping phases:

Phase 1: Groundwork, Evaluability Assessment and protocol development (May 2024 – April 2025)

Confirm local authority sites and providers, links with delivery teams and suppliers, establish recruitment and data collection routes (e.g. through the app), engage key stakeholders • map underpinning rationale for the programme and product in development (i.e. its programme theory/theory of change – see draft in development in Figure 2), and the benefits expected to be delivered (especially, an agreed definition of what success will look like) • explore contextual influences that might emerge during implementation • Evaluability Assessment re data capture/measures (especially quantitative metrics) • service user involvement, including consideration re issues of equity and digital inequality • protocol development and revisions following revisions to programme implementation • establish local approvals and processes for data collection • confirm PPIE and project advisory group • regular engagement with policy partners and local authority representatives, contribution to user research and implementation planning, developing case narrative for programme through field notes from observation and participation in implementation meetings, other discussions • engagement with GP sites.

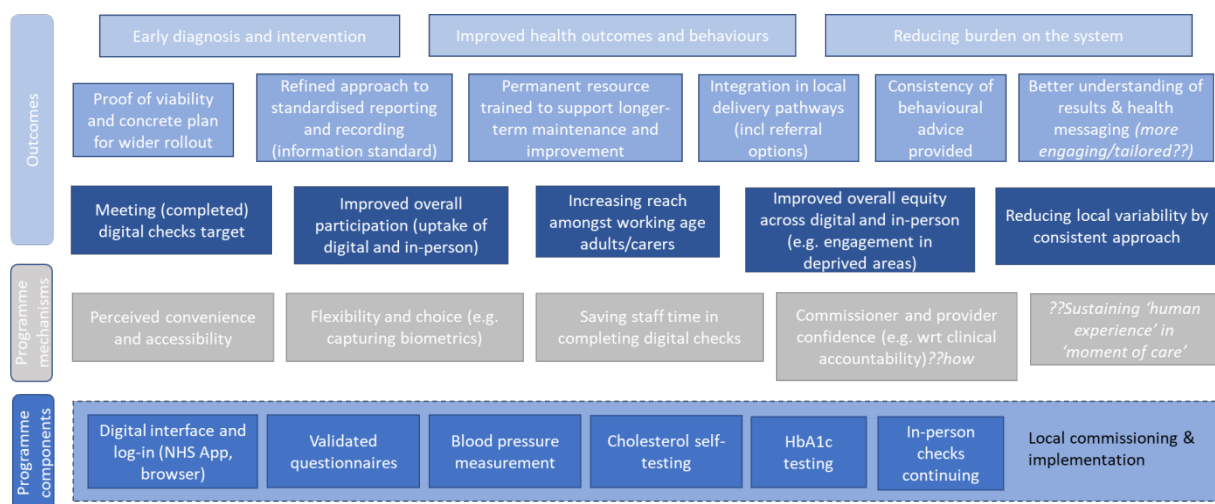


Figure 2: Programme theory in development (v0.2 draft)

Phase 2: Process evaluation data collection and analysis (April 2025 – Dec 2025)

Recruitment of patient users/non-users, local authority commissioners and programme staff, GP, community and pharmacy providers (depending on how implementation looks like locally), delivery team • qualitative and quantitative data collection and analysis examining how (and the extent to which) the digital service meet patients and service needs and expectations within and across sites (drawing relevant comparisons with the in-person option where feasible) • health economic data collection • formative analysis and feedback.

Phase 3: Data synthesis and output development (Aug 2025 – March 2026)

Data synthesis and cross-case comparisons across data sources and methods • theorisation of how introduction of the NHSHC-O programme worked, including contextual influences, to inform further roll-out and evaluation • summative reporting focused on the extent to which the programme

achieved its aims at ‘limited cohort’ and ‘private Beta’. Key findings will be shared and discussed in a stakeholder workshop, in order to explore implications and distil lessons for policy and practice.

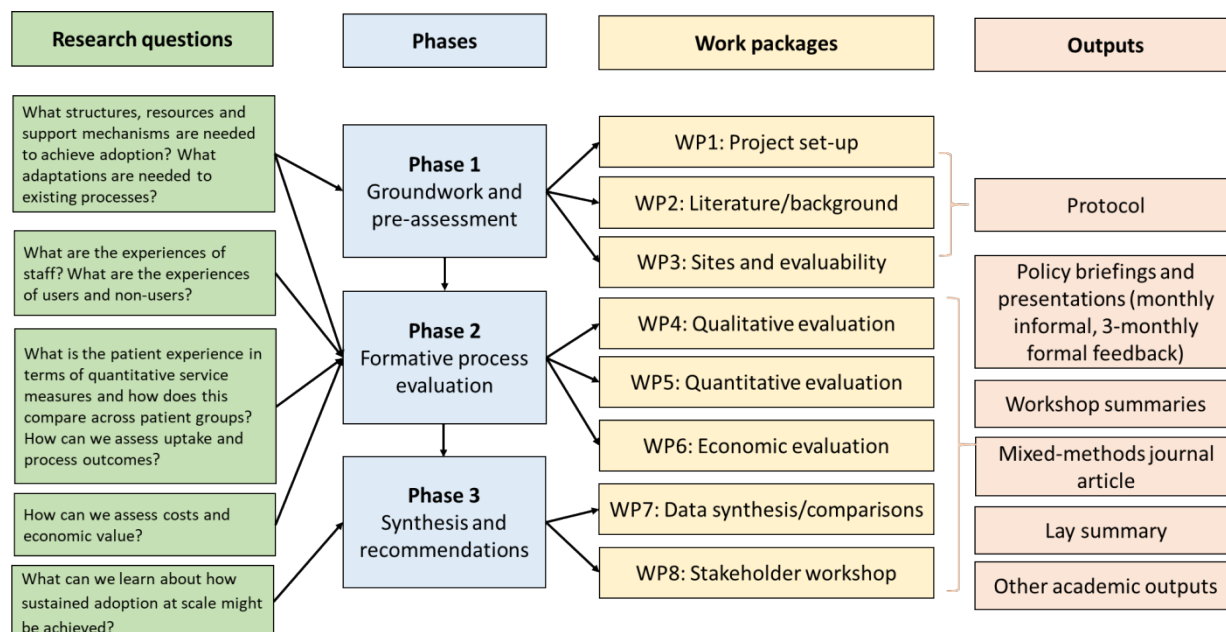


Figure 3: Summary of evaluation activities and links to research questions

Detailed plan

Phase 1: Groundwork, Evaluability Assessment and protocol development (May 2024 – April 2025)

This phase will include preparatory work for the rapid evaluation, such as project set up, a targeted literature review as part of background research, site selection and evaluability assessment, including being responsive to (and informing) changes to the implementation plan as the DHSC-led effort evolves, liaising with local authorities, PCN representatives and GP practices. The evaluation team will meet with key contacts within each site, in order to establish background information on NHSCH-O, expectations from participation in the ‘limited cohort’ and ‘private Beta’ phases and processes for data collection and formative analysis. Preparatory work is taking in account the recent change of government and allowing for shifting timeframes or priorities in policy plans.

WP1: Project set-up and governance

The first workpackage involves the establishment of project management and governance processes and approvals. This includes the following:

- *Project advisory group:* We are establishing a project advisory group to guide the project. This draws on membership from the DECIDE steering committee, and includes representatives from our policy customer (DHSC/NHSE). The meeting format and schedule will be agreed with the group, but we expect these to occur every three months over Teams; beginning with an inception meeting at the start of the project.
- *Project-specific PPIE group:* We are establishing a PPIE (Patient and Public Engagement) group specific to this project, drawing from the DECIDE user advisory group and plan to

complement this with 1-2 service user/carer representatives from the patient groups of participating GP practices, relevant LAs or local Healthwatch groups to address knowledge and experience gaps on the topic. The format and meeting schedule will be agreed with the group, but we expect each member will contribute one to two days over the course of the evaluation.

- *Governance and permissions:* We are in the process of gaining relevant approvals and data sharing agreements to access sites and data, and developing participant documentation.

WP2 Literature review and background research

A rapid and focused review of relevant literature (academic and grey) has been undertaken as part of background research to inform evaluability assessment and design this protocol. We have conducted targeted searches using PubMed to identify key sources of academic literature and identified relevant policy documents and other grey literature through Google searches and policy contacts. Analysis of this literature has helped familiarisation with previous research on in-person health checks as well as with broader lessons on technology-supported healthcare interventions, has informed research design in this protocol and sensitised us to different influences to implementation that we will need to consider in the evaluation. We will continue to update the literature review over the duration of the project (including grey literature) and will consolidate learning towards the final stages while developing outputs.

WP3: Site selection and evaluability assessment

Adoption of NHSHC-O is expected to take place across 44 GP practices within three local authorities (Lambeth, Medway and Norfolk). We will work closely with the local authorities (as already agreed in the MOU between DHSC and LAs) and providers supporting early adoption (e.g. GP practices alongside local community pharmacies). We will seek to recruit a purposive and maximum variation sample of providers with regard to GP practices, community pharmacies and any other healthcare organisations involved in the programme. Sampling criteria will include size, location (urban/rural), digital maturity, prevalence of CVD/other long-term conditions, deprivation index, as well as any differences in the implementation of in-person and digital NHSHCs. Phase 1 of the evaluation will confirm site selection, based on the sampling strategy above, combined with input from the advisory and PPI group. As the policy plan involves gradual implementation starting with a small set of practices (with specific planning and agreements currently in progress) before expanding to the 44 practices identified for early adoption, we anticipate the evaluation will follow a similar approach, recruiting 2 GP practices as part of the 'limited cohort' phase (out of 3 practices participating in total) and expanding to up to total 6 practices in the 'private Beta' phase.

Facilitated by DHSC as our policy customer, evaluability assessment will be conducted with each LA, in order to agree processes and engagement in the context of the evaluation. This will include an initial meeting over Teams with one or more members of the LA team leading on piloting of the NHSHC-O, followed by ongoing communication to refine plans. We will establish data collection plans, including participation in the qualitative component of the research, as well as establishing availability and developing protocols for sharing aggregated/pseudonymised patient-level quantitative and economic data for the evaluation. We anticipate this will take a phased approach, beginning with one LA, which will subsequently guide the approach/focus in the second and third LAs. We will also identify contact points and channels for communication between LAs and the evaluation team, in order to facilitate data collection and analysis of emerging data (during Phase 2). We will follow a similar approach to engaging GP practices and other local providers, working with LAs and DHSC to facilitate engagement. We have also been engaging with the technology supplier on

evaluability assessment and have confirmed a number of data collection routes (with data held by NHSE) as part of NNSHC-O.

Phase 2 – Process evaluation data collection and analysis (April 2025 – Dec 2025)

The second phase will involve a formative evaluation of NNSHC-O from the perspective of implementation and use. This will include qualitative and quantitative data collection and analysis of programme activities and outcomes, guided by the NASSS domains. As part of the formative component we will feed findings back to the policy customer and site teams for discussion and to guide further data collection. The formative channels will be agreed with stakeholders, but we expect these will include monthly (virtual/hybrid) meetings with pre-meeting materials/data.

WP4: Qualitative evaluation

Interviews with staff and system stakeholders

We will conduct semi-structured interviews with up to 50 staff and system stakeholders in total to understand the roles, experiences and perspectives of those who are involved in delivering and supporting the programme. The sample is likely to be highly emergent. However, we expect interviews to include the following groups:

- Local implementation: We will interview up to 35 staff (~10 in each case study) supporting implementation and use of NNSHCs (5 staff members in the ‘limited cohort’ phase and 30 in the ‘private Beta’ phase). This will include staff within the local authority, relevant staff (with different roles) at GP practices as well as community pharmacies or other healthcare organisations involved, depending on how implementation unfolds. Interviews will focus on aspects of their role in the context of NNSHCs (digital and in-person), the process of delivering NNSHCs (digital and in-person), experiences and challenges with regard to implementation and adoption (including unintended consequences to work practices), perspectives on the value of NNSHCs including clinical and service outcomes, and the operational and strategic aspects to achieving adequate uptake (and spread), including comparisons with in-person checks.
- Policy, decision-makers and delivery team: We will interview up to 5 members of the delivery team at policy and programme level, including policy leads, programme managers, technology suppliers etc. Interviews with this group will focus on the programme rationale, as well as key drivers and facilitators for NNSHC-O and operationalisation of (and potential blocks to) relevant policy. We will also interview up to 10 decision-makers with ICBs/PCNs locally as well as other relevant policy stakeholders at national level.

Interviews with staff and system stakeholders will be held at their place of work or conducted remotely by telephone/video, and may be conducted in pairs/groups where appropriate (e.g. colleagues within the same team). Sampling of staff and system stakeholders will be initially guided by the policy customer and LAs depending on how implementation unfolds locally, followed by ‘snowball’ sampling (asking interviewees who else we should be speaking to) to explore emerging topics and fill knowledge gaps.

Implementation case study 1	Implementation case study 2	Implementation case study 3
Local authority 1	Local authority 2	Local authority 3
1-2 GP practices	1-2 GP practices	1-2 GP practices
Relevant community provider	Relevant community provider	Relevant community provider
Methods		
Interviews with up to 35 GP, local authority and other provider staff		

Interviews with up to 35 users and non-users of digital checks
6-8 fieldwork visits (~2-3 per case study) for observation of digital and in-person processes
Quantitative data collection and health economics feasibility
Interviews with ~5 delivery team members and ~10 local/national decision-makers
Observation in programme and policy meetings

Table 1. Qualitative data collection overview.

To gain further detail on key processes, we will conduct on-site observations and naturalistic interviews (e.g. sitting with GP staff and asking them about their practices while they carry out NHSHC-related activity, as well as observation during in-person checks). We plan to conduct 6-8 fieldwork visits for such observations in total (~2-3 per case study, likely focusing on GP practices); including 2 days observation in total in the two practices we will be working with as part of the ‘limited cohort’ phase. We will also conduct observation in programme and policy meetings related to implementation processes.

Service user (and non-user) experiences

We will conduct interviews with up to 35 (~8 in each case study as part of the ‘private Beta’ phase and ~5 in each case study as part of the ‘limited cohort’ phase) users and non-users of NHSHC-O to explore their experiences and views of the programme (together with members of their care network as relevant). By non-users we refer to those who decide to only take up the offer of the in-person check and those who decide to refuse the offer altogether. By users we refer to those who complete the NHSHC-O as well as those who initiate the digital check but do not complete or complete in-person.

We will recruit patients directly from participating GP practices (e.g. patients invited by the practice, or completing part of the NHSHC-O in person), as well as to capture the perspective of non-users. Participants will be identified together with site staff, who will approach patients to explain the purpose of the evaluation and whether they are interested in being involved. If the participant expresses interest, the staff member will inform the evaluation team and arrange to introduce them. Patients completing their NHSHC-O will also be able to register interest to participate in the evaluation through the feedback feature on the digital service.

We will purposefully sample for a variation of service users that present a wide range of ethnicities, demographics and needs; and bearing in mind the range of experience, knowledge and skills relating to use of digital technology and the potential challenges of engaging with this service model. Efforts will be made to ensure the delivery and site teams supporting recruitment will be aware of these requirements, and we will continue to monitor our sample and sampling strategy with our project PPIE group.

Participants will be interviewed either in person (e.g. in their own home, at the GP practice) or remotely (phone/Teams) to enable wide recruitment. Where relevant and feasible, in-person interviews will involve think-aloud components, i.e. participants reviewing their responses to the NHSHC-O and discussing the process they followed to carry out the check (including if they had to stop at any point and why). Interviews will seek to surface a rich picture of users’ rationale for choosing the digital or in-person option, experiences with the digital offer (and previous experience with the in-person offer if relevant), aspects they found straightforward and those they found less easy to navigate, whether the check helps (or not) address what matters to them including communication of their risk score and engagement with further services as relevant, and concerns and/or unintended consequences for the individual. We will also explore key assumptions in the

developing programme theory, such as the role of flexibility, convenience and accessibility in the context of NHSHC-O. A key element will be to actively sample for and capture the experiences of users with complex needs to explore issues associated with inequalities in access and use.

The qualitative data will be analysed thematically, guided by the NASSS framework in the first instance, alongside other theoretical frameworks. We are building on a previous NIHR-funded national evaluation of the NHS App where CP led the qualitative component, as well as an ongoing rapid evaluation on blood pressure monitoring by the DECIDE team.

WP5: Quantitative evaluation

We are in discussions with the technology supplier to ensure relevant data (as described below) will be collected through the digital product. To this end, we have developed a data collection framework in collaboration with the supplier and DHSC to identify the required fields for inclusion into quantitative analysis. We will coordinate with the supplier to understand the ethics and research governance requirements to access the digital NHSHC data and will be seeking to secure necessary agreements with NHSE who will be holding the data.

The description of quantitative analysis below assumes pseudonymised patient-level data for the NHSHC-O. The scope of analysis outlined below will require revision if aggregate data, and not patient-level data, are available. Additionally, substantial delays to the implementation of NHSHC-O may impact on the availability of data at which point the timelines for the work outlined below may need to be revised again.

Quantitative data on the NHSHC-O include data on individuals that initiated a digital check, including service user demographics (age, ethnicity, gender, geography/postcode), completion patterns and time to completion, and types of results received (e.g. high- or low-risk, risk factors, risk score). We will use basic descriptive statistics to gather a picture of what completion of the NHSHC-O looks like. This would include understanding to what extent participants initiating the NHSHC-O complete each section, as well as the proportion of participants completing their blood sample (and, as relevant, proportion of results that are accepted, null or void). We understand that for patient deprivation, the Townsend score is currently available but that the Index of Multiple Deprivation (IMD) score will be implemented in the near future. Dependent on when the IMD score becomes available, we will either use the Townsend or IMD score in analysis of digital check data.

Assessment of uptake is not feasible within the scope of this evaluation currently as the digital service only includes data on those who have initiated the online health check, rather than all those invited. To inform potential future evaluations, we will explore feasibility of linking digital service data with invitation data held at the LA level for one LA in part based on how far along they are in developing processes for digital check invitations and the timing of their private Beta implementation. Alongside the invitation data, we will also explore feasibility of accessing invitation data on in-person NHSHC, required for comparison between digital and in-person NHSHCs, again for the single practice. We would begin by identifying the correct individual to speak to regarding data access and information governance at the practice level, liaising with them to understand who (GP surgery, primary care network, local authority) would conduct the data extraction (and at what level – aggregated or pseudonymised) from the GP system, and what approvals are necessary to secure at both GP and LA levels. The extraction would be basic during this feasibility stage, i.e. defining patients who had an in-person NHSHC (potentially also including those who initiated the digital check but completed in-person) and basic demographic information. This will demonstrate feasibility and help us to understand the process and timing involved to secure in-person NHSHC data for a number of pilot sites. We will also explore feasibility qualitatively as part of fieldwork conducted

with the rest of GP practices and LAs in WP4. The information will inform decision-making and planning for future analyses comparing digital and in-person uptake.

The quantitative data requirements and collection protocols, as well as related ethics and governance approvals required, will be established in discussion with the sites and delivery team during Phase 1, and adapted to local capacity and systems. We have developed the above plan following consideration of different options with the policy customer and will provide updates if evaluation needs and priorities change during the set-up period .

WP6: Economic analyses

Given adoption remains at an early stage, a full economic evaluation of NHSHC-O is beyond the scope of this project. Instead, the evaluation will focus on two research activities that are key to determining the cost-effectiveness and economic value of NHSHC-O in the future.

- 1) A primary research study will be undertaken to estimate the costs to the NHS and providers associated with the implementation of NHSHC-O.

We will collect data on the primary costs of NHSHC-O for the NHS and providers. Costs borne by the NHS will include the direct costs of the technology, costs incurred by providers administering the service, and costs incurred in following-up patients at GP practices, community pharmacies or local outreach providers as a result of their health check.

We will identify the costs to include via consultation with commissioners, providers and users (through engagement in three virtual workshops). Once these costs have been identified, we will undertake a survey using questionnaires to collect the appropriate information from relevant stakeholders.

Unit costs for each resource input will largely be derived from national secondary sources, for example, the Personal Social Services Resource Unit (PSSRU) unit cost compendia, or through Spinal Column Points Salary Scales for each local authority. All resource inputs will be valued in monetary terms using the latest and most appropriate UK unit costs or participant valuations estimated at the time of analysis. We will present unit costs and aggregated costs of the 'private Beta'. Mean cost differences between the NHSHC-O and the in-person health checks will be estimated (if comparative data is available). Evidence from NHS England and a literature review will be needed to inform this comparison. Measures of uncertainty (standard errors and confidence intervals) will also be reported for mean costs and, where possible, mean costs differences by resource category.

- 2) Feasibility research and development of a framework for a full economic evaluation.

The second element will focus on issues that would need to be considered if we are commissioned to do a full economic evaluation of the public beta. We will begin by identifying potential models in the literature such as the workHORSE model developed by the University of Liverpool, and assess their suitability for an evaluation of this nature.

We will start to generate the evidence that will allow the preferred tool for assessing the cost-effectiveness of NHSHC-O in the future. This will include: (i) literature reviews to update the evidence surrounding the values of model parameter inputs, including distributions surrounding parameter values, thereby informing probabilistic sensitivity analyses that are currently lacking within the workHORSE tool or any other relevant tools or models we identify through our literature

searches; (ii) an exploration of the type and magnitude of direct non-medical costs and indirect costs associated with NHSHC-O, such as the value of patient time attributable to the checks and follow-up, based on displaced activities, and travel costs and other expenses borne by patients such as child care costs that are a direct consequence of the health check and follow-up interactions with health-care providers; (iii) an assessment based on earlier phases of our proposed study of the uptake rates for digital and in-person NHSHCs that should be modelled; (iv) possible extensions to the range of downstream consequences that should be incorporated into the workHORSE tool or any other relevant tools or models, including labour market outcomes (and their economic values); and (v) guidance on how efficiency and equity concerns surrounding digital NHSHCs should be incorporated into an integrated distributional cost-effectiveness analysis framework. In the case of partial evidence in the published literature that can inform objectives (i) and (iv), we will work with policymakers and patient groups to appraise the relevance and quality of the evidence base. We have developed the above plan following engagement with the policy customer and will provide updates if evaluation needs and priorities change during the set-up period (end of 2024).

Phase 3: Data synthesis and recommendations (Aug 2025 – March 2026)

WP7: Synthesis within and across cases

The different data sources will be drawn together in detailed case narratives for each case study, with (anonymised and merged) service user case examples as well as key quantitative data. The quantitative and qualitative findings will be mutually informing to explore the challenges and outcomes in each setting. For example, quantitative data on changes and differences in use across sites will inform our qualitative study of local contingencies on provision and adoption. Conversely, qualitative data will highlight new ways of working and unanticipated consequences, which would be important to capture and monitor through quantitative measures in order to understand potential impact on service capacity and value for money.

A summative analysis and cross case comparisons will be conducted to draw transferable lessons on implementation and wider spread of NHSHC-O, the opportunities and challenges faced and the structures and resources required for sustained roll-out at scale. The final programme theory and lessons learnt will be refined in regular discussions with the delivery team and relevant policy stakeholders, as well as a dedicated stakeholder workshop (below).

WP8: Stakeholder workshop

Staff and system stakeholders from the three implementation case studies will be invited to a virtual workshop to share perspectives and discuss cross-case findings. The workshop will be structured to elicit shared experience and mutual learning on the challenges, impact and value of NHSHC-O. The workshop will be approximately 2 hours, with a plenary session setting out key findings within and across case studies, breakout sessions to share learning across organisational counterparts, and wider discussion to crystallise solutions to policy and practice challenges. A summary report of the workshop will be written up and shared among attendees to comment and feedback, with the final version shared for discussion with the policy customer to explore the implications (alongside summative findings) for national policy and feed into national guidance for national roll-out.

ANTICIPATED OUTPUTS, IMPACT AND PLANS FOR DISSEMINATION

Reporting

We will produce a final report with executive summary. This will include the case study narratives based on the qualitative and quantitative data, summative findings and key recommendations for policy, practice and future evaluations.

Public

The final report and executive summary will be freely available through the DECIDE website. A lay summary will also be produced and made available on the website with the support of the project PPIE group.

Policy makers

While retaining independence and critical distance, we are hoping to sustain close engagement with the delivery team throughout the evaluation to be able to use resources effectively, discuss emerging findings and inform the NHC-O programme as it develops. Given some of the policy work is characterised as official sensitive, we will build interest and raise awareness about the project in a manner appropriate to embargo limitations. As part of ongoing engagement with the delivery team, we will share drafts for comment ahead of submission, also inviting co-authorship with key individuals where relevant and appropriate.

Service providers

Through the formative component of the evaluation we will feedback and report to delivery and local teams on programme use, and patient and staff experiences. In addition, findings will inform wider adoption and roll out of the NHC-O across the country. Recommendations and learning will include operational and strategic aspects, which will also feed into national policy outputs (e.g. national guiding toolkit for implementation).

Researchers / evaluators

Open access publications and conference presentations.

PROJECT TIMELINES

Project set-up is expected to complete in April 2025, with the core data collection phase starting April 2025 and lasting to the end of 2025, to align with the timelines of the 'limited cohort' and 'private Beta' phases (see Table 2).

Table 2: Project timetable

	May	June	July	August	September	October	November	December	January	February	March	April	May	June	July	August	September	October	November	December	January	February	March
	Month																						
	-8	-7	-6	-5	-4	-3	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
PHASE 1 – Groundwork																							
WP1: Project set-up and governance																							
Establish the project advisory group																							
Establish the project PPIE group																							
Governance and permissions																							
WP2: Literature and background research																							
Literature searches																							
Review of literature and policy documents																							
Review informing evaluation design																							
WP 3: Site selection (incl. evaluability)																							
Engagement with LAs																							
Engagement & sampling of local providers																							
Assessing data availability																							
Developing data collection protocols and guides																							
PHASE 2 – Process evaluation																							
WP 4: Qualitative evaluation																							
Staff & system stakeholder interviews																							
Delivery and policy interviews																							
Fieldwork visits and observation																							
Service user (and non-user) experiences																							
Data analysis																							
WPS: Quantitative evaluation																							
Data collection																							
Data analysis																							
WPS: Economic analyses																							
Data collection and analysis on costs																							
Feasibility and framework development																							
PHASE 3 – Synthesis & recommendations																							
WP7: Synthesis within and across cases																							
Detailed case narratives																							
Summative analysis and synthesis																							
WP8: Stakeholder workshop																							
Run workshop																							
Write up workshop summary																							
Dissemination																							
Write up final report																							
Write lay summary and resources																							
Policy customer outputs/objectives																							
Academic publications/conferences																							

PROJECT MANAGEMENT AND QUALITY ASSURANCE

Quality Assurance

The study may be monitored, or audited by the Sponsor or funder in accordance with the current approved protocol, relevant regulations and standard operating procedures.

PLANS FOR SERVICE USER AND PUBLIC INVOLVEMENT

We have via the DECIDE user advisory group received inputs that will inform topics the evaluation will explore, and in particular those related to understanding the service users and carer perspectives, ethical implications and unintended consequences (e.g. privacy, consent).

We will form a project specific PPIE group, drawing from the DECIDE service user advisory group and complimenting with 1-2 PPIE representatives from other charity groups as needed to address knowledge or experience gaps on the topic. Members will contribute one to two days each over the course of the evaluation.

We will draw on the project PPIE group on activities such as: informing the design of materials to use in interviews and/or workshops to ensure relevance and accessibility, participation in research team meetings, data analysis, development of outputs and dissemination. The group will also raise items as a rolling agenda for ongoing discussion, including for example, wider ethical implications to NHSHC-O and how these should be considered in the data collection and analysis study.

RESEARCH TEAM

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

Table 2. Study team members

Team member	Role/contribution	Relevant expertise
Associate Professor Chrysanthi Papoutsis (University of Oxford)	Project leader providing topic, method, and team leadership. Project conception, design, analysis and synthesis, writing of reports/dissemination, project management oversight	Established academic bringing expertise in the evaluation of sociotechnical innovations, as well as ethnographic and qualitative methods. Experienced in leading large projects and working closely with policy and broader delivery teams. Deputy lead for the DECIDE centre at Oxford.
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.
Dr Sonja Marjanovic (RAND Europe)	Provide leadership support throughout the evaluation. Lead on RAND Europe team aspects. 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.
Dr Nikki Newhouse (University of Oxford)	Project conception, design, data collection, analysis and synthesis, PPIE lead, writing of reports/dissemination.	Expertise in conducting mixed-method and embedded research and evaluation, including ethnographic and qualitative methods and co-design to inform technology-enabled services.
Dr Jackie van Dael (University of Oxford)	Project conception, design, data collection, theoretically-informed analysis and synthesis, writing of reports/dissemination.	Expertise in theory-informed research on sociotechnical innovations as well as methodological expertise in ethnographic and qualitative methods
Dr Anne Ferrey	Data collection, analysis focused on behavioural aspects, writing of reports/dissemination.	Cognitive psychologist with a background in behaviour change and the use of qualitative methods for intervention development. Senior researcher and course director, MSc translational health sciences.
Dr Frances Wu (RAND Europe)	Lead on RAND quantitative analysis method, and team leadership. Project conception, design, quantitative 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.
Saoirse Moriarty (RAND Europe)	Project conception, data collection, and analysis. Writing	Experience in public health, health services research and evaluation,

	of reports/dissemination, project management and administrative support.	communications and project administration.
Dr Zuzanna Marciniak-Nuqui (RAND Europe)	Data collection and analysis. Writing of reports/dissemination, project management support.	Experienced in health services research and health technology research. Strong qualitative research skills, including interviews and ethnography
Ms Christy Wong	Data analysis and research assistance	Junior researcher with experience with research assistance, and training and experience with quantitative data analysis
Prof Stavros Petrou (University of Oxford)	Project conception, quantitative and methodological development, economic analysis, reporting	Highly established economist, with expertise in methodological development within health economic evaluation that directly impact health care policies at national level.
Dr Stuart Redding (University of Oxford)	Project conception, quantitative and methodological development, economic analysis, reporting	Expertise in health economics for health services and policy assessments using primary and secondary economics data.
Ms Shabira Papain (People Street)	Project design, writing, and dissemination – linking on this project from User Advisory Group.	Founder of People Street, an agile community development start-up making inclusive design achievable, extensive experience of designing and delivering innovations tackling inequity and exclusion
Dr 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 work packages in a number of NIHR funded research projects.
Ms 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, REGULATORY AND GOVERNANCE CONSIDERATIONS

Risks and their management

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

Risk	Impact	Likelihood	Mitigation

Risk	Impact	Likelihood	Mitigation
Delays with implementation of digital NHSHCs	Medium	Low	The delivery team (DHSC, NHSE, technology supplier) are currently planning for implementation to begin at the end of 2024. If there are any delays to this timeline we will need to adapt the evaluation plan and timeline accordingly.
Challenges to onboarding sites to participate in case studies	High	Low	The three local authorities where Digital NHSHCs will be implemented in the ‘private Beta’ phase have already been recruited by the policy customer (DHSC). These local authorities have identified 44 GP practices interested in taking part in ‘private Beta’ implementation. Evaluation activity has already been incorporated into the MOU with local authorities and there are plans in place to engage closely with them on data collection to meet evaluation requirements. We will maintain open lines of communication with LAs and provider organisations, and will retain a list of alternative provider sites in case any of the participating organisations has to withdraw. Experience from other DECIDE evaluations have shown that site payments facilitate recruitment and engagement – we have not been able to incorporate site or participant recruitment in our budget for this evaluation but will reconsider allocation of resources where necessary.
Demand pressures on local staff and system stakeholders and associated challenge to capacity to engage in timely ways	High	Medium	The evaluation requires support from the policy customer and field sites on diverse grounds such as local governance, helping recruit interviewees, and where applicable timely access to relevant data. We are investing in establishing early relationships with policy and case study stakeholders to help ensure support for the evaluation. We will be 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 be adaptive to the schedules and constraints on staff during fieldwork, including the timing and modality of interviews. There has been a high level of interest and engagement so far, and we will continue to maintain dialogue throughout the project assisted by the formative component.

Risk	Impact	Likelihood	Mitigation
Risks to researcher safety on field work and home visits	Low	High	We will follow the Oxford and RAND’s researcher safety policies, and develop internal protocols for minimising risk; including notifying colleagues of travel plans (location and timing) with check-out/check-in procedures, and ensuring researchers have key contact numbers, and maintain the option to travel with other members of the team.
Delays in local R&D approvals	High	Medium	All governance approvals to be undertaken as early as possible. 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, quantitative data from local authorities/GP practices) we will communicate these to the policy customer and NIHR in a timely fashion. Delays in obtaining approvals will affect the quantitative data we will be able to use for the evaluation, which will impact the strength of the evidence we will be able to generate.
Loss of key staff on project	High	Low	Oxford and RAND Europe’s staffing model allows for flexibility such that in the event of project staff turnover, we can tap into wider expertise. Senior staff at both Oxford and RAND have extensive experience needed to deliver on the evaluations.
Loss of data	High	Low	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 policies in place to safeguard data. We will put data transfer agreements in place with any third party (eg field 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 required approvals

We will submit a classification request to the Research Governance Ethics and Assurance (RGEA) team at the University of Oxford (sponsor) to confirm the appropriate approval process. This will either be classified as (a) service evaluation that does not require research ethics approval, (b) research not requiring NHS HRA ethical approval, or (c) research requiring NHS HRA approval.

- (a) Service evaluations are within the remit of the organisation commissioning the evaluation. In this situation we would expect to put agreements in place at each site participating in this piece of work. These agreements will cover expectations with regards to site and DECIDE team activities, responsibilities, and data access and use.

- (b) Research projects that do not require NHS HRA approval will be submitted for review by the Central University Research Ethics Committee (CUREC) in Oxford. Individual site agreements will also be required.
- (c) Research projects that require NHS HRA approval require an Integrated Research Application System (IRAS) application, and subsequent NHS R&D review/approval.

In line with the above we will contact the relevant local research and development (R&D) offices at each site where evaluation activities will take place 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.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

Informed consent

All participants will have capacity to provide informed consent. The participant must personally sign and date the latest approved version of the Informed Consent form before any study specific activities are undertaken.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing the nature of the study, what it will involve for the participant, the implications and constraints of the protocol, and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the study evaluation team or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent form will be given to the participant. The original signed form will be retained at the study site.

During the course of the study a participant may choose to withdraw early at any time. This may happen for several reasons, including but not limited to:

- The occurrence of significant distress during study interviews
- Inability to comply with study procedures
- Participant decision

Discontinuation/withdrawal

Participants may withdraw their consent at any time. Options for participants wishing to withdraw will be explained in the information sheet.

- 1) Participants may withdraw from all study communication but allow the study team to continue to access their medical records and any relevant data that has been recorded as part of routine

standard of care and is held by the study team; i.e., disease progression data, routine patient reported outcome data and quality of life questionnaire data etc.

- 2) Participants can withdraw from the study but permit data obtained up until the point of withdrawal to be retained for use in the study analysis. No further data would be collected after withdrawal.
- 3) Participants can withdraw completely from the study and withdraw the data collected up until the point of withdrawal. The data already collected would not be used in the final study analysis*.

*In cases where data have already been incorporated into analysis it will not be possible to exclude these data. It is also not possible to exclude data collected from any group discussions as an individual's data will likely be directly related to that of other participants.

The reason for withdrawal by researcher (and by participant, if this information is volunteered) will be recorded in a study file.

Data management and storage

Data Recording and Record Keeping

Datasets collected and collated for this service evaluations will include:

- Observational and ethnographic data from on-site field work. These will be primarily field notes, either completed in digital form at the time or hand-written and transcribed into digital format by the research team at a later date. It is possible this dataset could also include photographs and diagrams. It is difficult to be explicit about the volume/scope of these data but likely to be the equivalent of up to ~50hours of observation. Fieldwork data will be collected by a small number of the DECIDE centre team (~4/5). The resulting data files will be available for analysis by a larger number of people from the DECIDE centre team (~10). Electronic files will be saved on password-accessible areas of the University of Oxford network and remote access to these files will be granted to members of the DECIDE centre team as required for analysis and reporting purposes.
- It is likely that the research team will interview participants about their use of the technology under evaluation. These will generate interview recordings which may be audio only (conducted using digital recorder devices or Teams), or audio-visual (e.g., Teams). If transcription is required, these recordings will be transferred to professional transcriber services (using services and processes approved by the University of Oxford). During the transcription process any identifying information will be removed. Files for analysis will therefore be considered pseudonymised. The team will need to collect contact and basic demographic data from participants. The demographic data will be stored alongside a project ID and will not be directly linked to an individual's contact details. Interview data will be collected by a small number of the DECIDE centre team (~4/5). The resulting data files will be available for analysis by a larger number of people from the DECIDE centre team (~10). Electronic files will be saved on password-accessible areas of the University of Oxford network and remote access to these files will be granted to members of the DECIDE centre team as required. The original recordings will be deleted when transcribed files have been checked and there is no further need for the original recording.
- DECIDE will also collect contact details for key personnel involved in the evaluation where this information is required to arrange site activities or similar. This will consist of name, email address, and phone number. These data will be stored in the University of Oxford network files and remote access will be granted as required to those within the DECIDE team.

Data will be collected and stored in accordance with the University of Oxford (Sponsor) data policies.

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.

Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants’ personal data.

Access to data

Data will be accessible to the immediate team. This includes employees of The University of Oxford and RAND Europe who will be collecting and analysing the data for this evaluation.

Direct access to the data will also be granted as required to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

Archiving

Identifiable personal data will be deleted as soon as it is practical to do so. De-identified (pseudonymised) data will be stored for a minimum of three years after the end of the project in line with University of Oxford data management and storage policies.

Sponsorship, indemnity and insurance

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

The University of Oxford maintains Public Liability and Professional Liability insurance, which will operate in this respect.

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those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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