Study Title: Evaluating the national rollout of the NHS App in England

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1. LAY SUMMARY

The National Health Service (NHS) in England has introduced a new smartphone app for patients, called the 'NHS App'. There are a number of different apps associated with the NHS, the one we are referring to is shown in Figure 1, and is not the NHS Covid-19 app/track and trace app. This app has been available to everyone in England from July 2019. People are able to use the app to see their medical records, book appointments, order repeat prescriptions, set their organ donation preferences, have online consultations and undertake other tasks related to their health and care.

NHS App	selected scre	eenshots		Digital
	NTES 8 Ny appointments	NIES 8 Book an appointment	My repeat prescriptions	CTES 8 Order a repeat prescription
NHS	Upcoming appointments Ciscl in the appointment if you need to cannol it Wednesday 25 June 2016 Of CO am	Type of appointment Deneral appointment Levation	Approved Paul Two months Order date: 19 March 2018	Medications currently available for repeat prescription: Amostollin Clanulanate Creato be taken each day - 28 tablet
How are you feeling right now? Check your symptoms Want to book a GP appointment or order a repeat prescription?	S & Donal Dyte Past appointments Past month Past mont	Bit Martine Practice DectaryNarse There no preference Show appointments from	Anostollin Glavulante One to be taken each day - 28 tablet Bedolmer. 1 146 gef Apply tils pm - 100 gram Tameslukei 400nicorgram modified- release capaules One to be taken twice a day - 56 tablet	Distolenze 1.15% gel Apply tils pm - 100 gram Tamsuledin 400niongram modified-velases capsules One to be taken twice a day- 56 tablet
Sign In with your Mid account	10:00 am Book new appointment 0 10:00 am 0 10:00 am	Moning Adamson Evening	Order a repeat prescription	Special requests relating to this order (sprime)
				11111

Figure 1: The NHS App

This research, funded by the National Institute for Health Research (NIHR), will look at what people think about the NHS App, whether they use it to do the things it was designed for, and whether it changes how people use the NHS.

This research is important because it will potentially provide the only national evaluation of the official NHS App, and thereby, a major part of digitally transforming the NHS. By understanding how people are or are not accessing and using the app, and why, we can inform efforts to support digital access to NHS services.

We will use interviews and discussion groups (either virtually – due to safety concerns around Covid-19, or face-to-face, if possible) with people who use the app, and with doctors and other staff who work in the NHS (such as receptionists, practice managers, those involved in the development of the app and those informing NHS policy). These interviews and discussion groups will try to understand what these people think about the app, how they use it or tell others about the app, and what impact it has on their lives and their work. We will also spend time (either virtually or face-to-face, if possible) with participants and watch how they use the app in real life. We hope to gain understanding of the implications of the app (and other digital health tools) and to consider how it has, and could be, best put into practice.

We will also use statistics to measure how often the App is used, including its different functions, how usage of the App changes over time, and how it relates to measures of practice population (such as they average age or ethnicity of patients) and how usage compares to measures of patient satisfaction with the practice.

We will work closely with the NHS Digital and NHSX teams who developed the app so that we can learn from their experience, and we can feedback our findings to help them improve the app. We will also work closely with a group of patient and public contributors to help design and undertake this study. For example, we will ask this group what questions to ask in the interviews and discussion groups, and how to ask these questions when we talk to patients and NHS staff. We will ask our public members to help with understanding what we have found out from the interviews and discussions groups and how to share these findings with others. There will be opportunities for writing up the work in different formats. We will work with our public group to help communicate our findings to NHS staff, patients, policymakers and the public.

We will communicate the findings by going to events where we can talk about the work, preparing presentations for people to use to explain our work in their own practices, and also by writing about it on the NHS App's web pages.

2. BACKGROUND AND RATIONALE

2.1 What is the problem being addressed?

This study intends to identify and understand the use and acceptability of the NHS App, measure the extent to which it improves patient experience and influences health service access, and understand patterns of early take-up and participation. The app was being rolled out in 2019 across the NHS in England at the direction of the Secretary of State for Health and Social Care (1).

NHS England's goals for the app are to 1) improve access to primary care services, 2) improve patient experience, 3) save time in GP practices and 4) promote self-care. There is no planned national evaluation of this app which is being introduced as a policy priority and constitutes a novel complex intervention with potentially wide-ranging impacts on the use of healthcare services. This qualitative study protocol aims to evaluate how the NHS App is used by patients and healthcare staff and whether it meets their needs in accessing and organising healthcare. We will also look for other effects, including unanticipated consequences (2).

The delivery of the NHS App has been led by NHS England and built by NHS Digital (3). A new organisation - NHSX - has now been formed to take over technology leadership at a national level for the NHS. Responsibility for the NHS App has been taken on by NHSX, with NHS Digital remaining the main delivery partner.

The app was user tested in a series of small private beta tests in late 2018 and was released on the Google and Android App stores on January 1st 2019. Initially, it was planned that there would be a gradual stepwise roll out, CGG by CCG, but political decisions initially led to a more rapid rollout plan, to have full national usability by July 2019 in England. However, the Covid-19 pandemic has had some impact on this national rollout, with other competing apps (such as the NHS Covid-19 app) at the forefront of NHSX's delivery campaign. Presently, it is estimated that 95% of GP surgeries in England are able to deploy all features of the NHS App.

The functions of the NHS App are:

- 1. Symptom checking and triage
- 2. Patient record access
- 3. GP appointment booking
- 4. Repeat prescriptions online
- 5. Set data sharing preferences for the national data
- 6. Set organ donation preferences
- 7. Provide advice about coronavirus

Some GP surgeries also offer additional services, such as:

- Messages to the GP surgery, doctor or health professional
- Consultations with a GP or health professional
- Access to health services on behalf of someone else
- Viewing hospital and other healthcare appointments
- Useful links shared with patient by their doctor or health professional
- Booking initial secondary care appointments

2.2 How does the existing literature support this protocol?

A scoping review of the existing literature was undertaken to inform the development of this protocol. We did not identify any literature which evaluated smartphone tools with equivalent functionality to the NHS App. However, other kinds of literature are relevant to inform our evaluation, including that around 1) patient portals, patient health records, patients' access to notes and the other features in the app, and 2) technology adoption in health systems.

Recent reviews on patient portals show their widespread use in other countries and that patients' interest and ability to use them is influenced by age, ethnicity, education, health literacy, and health status (4). They also show there are issues around trust, security, communication and interoperability with these new technologies (5). Work by the OpenNotes team in the US suggests that offering patients access to doctors' notes is acceptable, improves communication and patients' confidence in managing their care, but also finds many clinicians are still resistant to the idea (6-8). National PHR programmes have been established in Denmark, Estonia and Australia, with data available on use, but there is still uncertainty on the impact on patient outcomes and service use of these initiatives (9).

The literature on technology adoption and diffusion of innovation tells us that this process is difficult and complex. Adoption is not just based on the technology, but a complex mixture of how the public and staff interact with it, what they see as the benefits, organizational culture and wider influences on the system including the policy and regulatory context (10). This literature includes previous work undertaken by members of the study team, including the Non-adoption, Abandonment, and challenges to Scale-Up, Spread, and Sustainability (NASSS) framework (11).

2.3 Why this research is needed now

This project is important and timely as it is providing the only national evaluation of a major component of the central plan to digitally transform the NHS, which is being rolled out without prior evaluation and at considerable cost to the NHS. It will also inform other initiatives to harness patient-facing digital tools in the NHS and elsewhere, as many countries are currently seeking to harness 'digital health' solutions as patient-centred and efficient approaches to addressing the challenges of limited resources and aging populations with increasing levels of chronic disease.

The NHS has a problematic record when it comes to the central development and rollout of new technology. Policy think-tanks have questioned whether the single product, NHS-developed approach is a sensible way to deliver this app (12). It is therefore important to understand whether and how this initiative meets its goals, and what other possible unintended effects are. The study team will work closely with the delivery team to allow findings to inform future developments, but will also ensure this project retains critical distance from these organisations.

Information from this evaluation could help decision-makers decide whether and how to improve the existing programme, and potentially influence future funding decisions. This work will also be of interest to those leading similar initiatives in other countries as health systems seek to make better use of digital interventions to reduce costs and manage demand.

The role of the NHS App has been clearly stated in the NHS Long Term Plan (13) - where it is mentioned 13 times. It describes the app as a "digital front door to the NHS" and that the "NHS App will create a standard online way for people to access the NHS". It also contains a commitment that "we will continue

to develop the NHS App to create a consistent way for people to access the NHS digitally" including using it as an open environment to allow developers to add their own content. Blogs by the new leadership at NHSX have highlighted its role in creating an open platform for innovation from the private sector (14), and listed the NHS App first in its list of priorities (15). In addition, as this programme is made available to all patients in the NHS in England, it will lead to changes in practice that will have a significant impact on a large number of patients across England. To that end, we will be diving deeply into case studies in practices in different and diverse areas of the country.

While this research focuses on one particular technology intervention, its findings on adoption and use will have transferability to other newly introduced digital technologies in the NHS and how to drive effective national adoption.

This study aims to inform the design and deployment of other digital services across the NHS and elsewhere as transferable findings about the uptake and use of consumer-facing digital health services are generated. The NHS environment is complex, with multiple competing and interacting agendas - including financial, political and cultural factors all at play simultaneously. The design of this study, using the many lenses of the NASSS framework to understand the NHS operational environment, will focus on understanding this complexity in the NHS and more widely. We anticipate that this impact in terms of addressing some of the generalisable evidence gaps around the uptake and usefulness of digital tools and apps in healthcare, particularly in the busy and pressurised primary care environment, could be substantial.

Due to the current Covid-19 pandemic we have adapted the study design, participant documents and analysis. While Covid-19 restrictions are in place we will not be undertaking face-to-face interviews or observations. Video/telephone engagements provide a safer option for patients, carers, healthcare professionals, other stakeholders and research staff during this time.

3. QUALITATIVE STUDY

4. AIM / RESEARCH QUESTIONS / OBJECTIVES

Aim / F	Research Questions / Objectives
Aims:	
1.	To understand the role of the NHS App and its different functions in the context of
	technology-enabled access to primary care
2.	To develop the evidence base on roll-out and routine use of technology-supported options for
	accessing primary care and other health services
Resear	ch Questions:
1.	How and why do patients and carers use (or not use) the NHS App and what are their
	experiences with technology-enabled access to primary care?
2.	What are the experiences of healthcare staff with the NHS App and its integration in the
	service?
3.	What background work and ongoing adaptations are needed to accommodate the impact
	of technology-enabled access to primary care?
4.	What is the role of local commissioning groups and NHS delivery teams in successfully
_	mainstreaming technology-enabled options for accessing primary care and other services?
5.	What are the perceived implications of the NHS App for access, efficiency, safety and
	overall experience in primary care over time?
6.	What transferable learning can we draw from the example of the NHS App to inform the
	implementation, national roll-out and routine use of health technologies?
Operat	ional objectives:
1.	To carry out qualitative research on the use of and experiences with the NHS App
2.	Through formative findings, to inform ongoing development of the NHS App
3.	To support widespread and sustained use of technology-enabled access to primary care

5. STUDY DESIGN

5.1 Methodology

The study will use a qualitative approach to undertake a process evaluation on the perceptions and experiences of patients, the public, NHS staff, commissioners and NHS delivery teams. We will use a comparative case study design to develop an in-depth understanding of the introduction, implementation and routine use of the NHS App in (at least) 5 GP practices across England. This will allow us to compare and contrast between practices with sufficient variation in different characteristics: geographical location, population served, list size, number of GPs and organisational structure, digital readiness and rates of NHS App adoption/use, electronic systems used in GP surgeries (including both TPP SystmOne and EMIS) and other patient access portals being used in parallel, number of appointments being booked through the app etc.

Given current Covid-19 related circumstances, our primary methods will initially include remote (on the phone or online via MS Teams) semi-structured interviews and focus groups, as well as the participant demonstrating their use of the technology (think aloud interviews) as part of video interviews or virtual platforms, where feasible. At later stages if Covid-19 restrictions allow, we will also carry out face-to-face interviews and focus groups, as well as ethnographic observation (of patients and organisational settings).

5.2 Sampling Strategy

We will follow a staged approach in the recruitment of GP practices to ensure we cover a wide range of characteristics and patterns of technology engagement. We have been liaising with the delivery team at NHS Digital to develop our recruitment strategy drawing on their learning so far and have identified potential sites for recruitment. We will identify participants via our professional networks and via recruited surgeries, and potentially 'snowballing' from our initial contacts (especially staff participants, commissioners and delivery teams) to others in their organisations.

We will cover a number of criteria including location (urban, rural, coastal), ethnic diversity, socioeconomic status, digital maturity and practice size. We believe that by carefully and purposive selecting, we should be able to identify practices that capture variation across these criteria. This will allow us to extract rich learning from close engagement with case sites, rather than attempt to recruit a large number of practices at the expense of explanatory potential. For example, the list below represents a hypothetical balance of practices of the sort we would hope to gain for the study.

- Practice 1: Urban, higher deprivation, small list size, high digital readiness, low ethnic diversity (Northeast)
- Practice 2: Urban, mixed deprivation, large list size, low digital maturity, high ethnic diversity (London)
- Practice 3: Suburban, mixed deprivation, large list size, mid digital maturity, high ethnic diversity (Midlands)
- Practice 4: Rural, mixed deprivation, smaller list size, lower digital maturity, low ethnic diversity (Oxfordshire)
- Practice 5: Coastal, higher levels of deprivation, large list size, lower digital maturity, low ethnic diversity (Northwest)

5.3 Methods of Data Collection

We will involve the following groups in longitudinal qualitative research: a) patients and members of the public (users and non-users), b) NHS staff (clinical and non-clinical) in GP practices, c) local commissioners and policy-makers and d) development and delivery teams at NHSX, NHS Digital and NHS England (or other organisations as relevant). Longitudinal data collection will allow us to investigate the NHS App as an evolving technology in a fast changing context (given the new functionalities and upgrades planned during our evaluation by the NHS Digital team following an agile development process) and will enable us to study the processes of socio-technical change that accompany its implementation (e.g. changes in administrative processes, professional roles, norms around access to primary care, patient expectations, implications of the pandemic etc.). In qualitative interviews with patients, staff and commissioners, we will also consider the potential for additional functions within the

app, to gain their views on practicality and usefulness. Relevant policy documents, internal reports, public-facing materials (such as NHS App promotion and further information) and other communications will be collected for analysis.

For the virtual elements of the study (interviews and focus groups), Microsoft Teams (MS Teams) will be used combined with Open Broadcast Software (OBS), with the recordings saved onto an encrypted, university owned computer, so that we are GDPR compliant.

5.3.1 NHS patients, carers and members of the public

We will carry out semi-structured, qualitative interviews with patients, carers and members of the public to explore their views and experiences. Interviews will be carried out virtually using an appropriate remote platform (MS Teams) where Covid-19 restrictions do not allow face-to-face contact or where participants prefer to be interviewed online. All participants will be invited to a follow-up interview 12 months later to reflect on longitudinal changes – we hope to be able to carry out many of these follow-up interviews face-to-face at participants' homes, their GP practice or another location of their choice, if the Covid-19 situation permits this at a later stage. Participants are not obliged to undertake a follow-up interview but this is an option in addition to the original interview. All interviews will follow a flexible topic guide and will last 45-60mins.

Alongside qualitative interviews, we will carry out ethnographic observations to better understand the wider context of participants' lives; how they cope with own healthcare needs or their caring responsibilities, and wider engagement with technology (where relevant). This means we will spend time engaging with participants in their homes (if feasible), or we will ensure to have more time when engaging people on interviews through video, so that we can ask them to tell us more about their situation, given we will not be able to observe their surroundings as we would do in a face-to-face interview. We appreciate the potential ethical implications of this so we will explain to participants that if we are using video interviews, to consider if members of their household (or other setting) may be captured on video as well. We will ask participants if they expect other household members would like to be involved and if so we will apply the same principles for involvement in the study (providing information leaflet, the opportunity to read the leaflet and ask questions about the study, and acquire consent forms) from said household members who may otherwise also be involved in the interview.

With a small sample of patients and/or carers (up to 5), we are planning to develop video diaries (e.g. using the camera on their smartphones or bespoke technology provided by the project) to record how they manage their everyday activities, how they engage with the app, or how they are accessing healthcare. These video diaries will be de-identified (pixilated) and participants will be requested to send these via the secure Oxfile system, where attachments are encrypted.

As part of our interactions with participants, we will employ interactive methods, such as think aloud protocols, where we will observe patients booking their appointments on the app, ordering repeat prescriptions, checking their symptoms or looking at their GP records, and will ask them to articulate how they accomplish each of these tasks and any particular challenges they encounter. These tasks will be undertaken over telephone, video call or video diary if we are not able to observe face-to-face. We will capture these interactions in field notes, photos, screenshots, and videos, with participant permission. Given we are not looking to replicate user testing work carried out by the development teams at NHS Digital already (19), we will focus our enquiry on situating use of the technology in the

wider context of living with chronic conditions or caring for family members (including those who care for children with chronic conditions and also people who care for elderly or grail parents/partners or other family members), rather than purely aim to provide design suggestions.

While interviews and observations will explore individual patient and carer experiences in depth, we will additionally use focus groups to allow participants to collectively debate their views and perceptions about the NHS App. Half of the focus groups will involve technology users and half will involve non-users. Discussions will take place on virtual discussion platforms (Microsoft Teams), or face-to-face at GP practices or voluntary/community organisations (at later stages if this becomes feasible). The discussion will last 60 minutes and will be led by an experienced moderator using a topic guide to maintain focus on predetermined questions, while allowing flexibility to explore topics that are important to participants.

5.3.2 NHS Staff

To understand how the NHS App affects organisational routines and work practices, we will gather feedback from NHS staff: health professionals (GPs, trainees, practice nurses, healthcare assistants), practice and IT managers, and reception staff. We will unpack how different GP practices make decisions about how to integrate the app in their processes (e.g. preparation for connecting to the app, deciding which appointments will be bookable online, etc.), how responsibilities for operationalising necessary changes are distributed, what is the impact on existing technical infrastructures and other patient portals operating in parallel, and how access to clinical care and service provision are affected (e.g. impact on workload) – this will also include an emphasis on how use of the NHS App changed during Covid-19 (e.g. where practices had to restrict appointment booking through the app). We will develop a detailed understanding of good practices in service integration and will also generate transferable lessons for technology-enabled access to primary care.

Interviews will last 30-45mins and will be carried out either virtually or face-to-face. An indicative topic guide will be followed, tailored to different types of NHS staff. Although the app would have been rolled out nationally before planned initiation of staff recruitment, we expect different GP practices will integrate the app into their service at different rates, therefore will aim to capture this diversity of experiences and staff exposure to changes over time. We will take into consideration current and fluctuating Covid-19 related pressures in GP practices. Covid-19 pressures could impact on HCPs time commitments, capacity and motivation to take part in the study. We will try to ensure we are sensitive to these needs by providing flexible opportunities to take part, build in enough time to anticipate delays and participants disengaging in our timeline, ensure we have back-up options for participants, provide a menu of opportunities of ways to take part (telephone calls/face-to-face or video), including being flexible with when HCPs take part, and what times of the day participation occurs (offering evening engagements if this fits best).

We will also carry out face-to-face (when feasible) ethnographic observation on back-end operational and technical processes required to integrate the app in the service, to promote the app with patients and to manage competing priorities. Observations will be planned so that they cover every day routine work but also relevant internal activities (e.g. appointment planning sessions, operational meetings, troubleshooting with NHS Digital etc.). Acknowledging that NHS staff are under pressure, especially in the Covid-19 context, we aim to align our research with existing activities to minimise any extra burden on their work.

5.3.3 Stakeholders

5.3.3.1 Local Commissioners

Local commissioners have been a key part in the implementation process where the NHS App has been rolled-out already. We will use qualitative methods to draw on this learning and to consolidate our findings from research with patients and staff in the 5 main case studies. We will carry out semi-structured interviews with commissioners. Interviews will last 45-60mins and will be carried out either face-to-face (if feasible) or by telephone/video. Commissioning insights will allow us to understand the wider impact on service planning and access. Given the move towards Primary Care Networks we will closely follow developments and adjust our recruitment plans accordingly in this changing environment.

5.3.3.2 Delivery teams

We will draw on specific qualitative data collection methods, including semi-structured interviews with the development and delivery teams at NHS Digital, NHS England and other organisations as relevant. These will last 45-60mins and will be carried out either face-to-face (if feasible) or by telephone/video.

We are also planning to virtually observe key delivery meetings, workshops, 'app clinics' (delivered by NHS Digital to troubleshoot problems together with patients) and other interactions. Observations inperson will occur later on in the project when there is a possibility that Covid-19 restrictions may be lighter. Covid-19 pressures could impact on stakeholder time commitments, capacity and motivation to take part in the study. We will remain sensitive to these needs by providing flexible opportunities to take part, build in enough time to anticipate delays and participants disengaging in our timeline, ensure we have back-up options for participants, provide a menu of opportunities of ways to take part (telephone calls/face-to-face or video), provide flexible options for when stakeholders (commissioners and members of the delivery teams) take part, and what times of the day participation occurs (offering evening engagements if this fits best).

Relevant policy documents, internal reports, public-facing materials and other communications will be retained for analysis. Data collection will focus on key milestones (e.g. app updates) to examine opportunities, obstacles and unintended consequences in the development, implementation and roll-out processes.

5.4 Methods of Data Analysis

Interviews and focus groups will be audio or video recorded, with participant consent, and the recording of the audio will be professionally transcribed. Field notes will be taken during observation, and images and videos will be collected through video call to illustrate use of the technology (e.g. participant showing their app on the video call and how they use it) and through video diaries, with any identifiable information pixelated to ensure de-identification. Video diaries will be sent via the secure Oxfile system, where attachments are encrypted. All data will be uploaded onto NVivo 12 to aid data management. Following data familiarisation and guided by our research questions, we will take a systematic approach to coding the data derived from each of the 5 case studies, and from additional data sources. We will compare and contrast findings between cases, to develop a detailed, theory-driven understanding of participant experiences and the socio-technical processes required for underpinning the introduction, implementation and routine use of the NHS App. Thematic analysis, following an inductive and deductive approach, will allow us to identify issues that matter to participants, paying attention to emergent as

well as anticipated themes. This means we will follow an inductive approach to identify 'bottom-up' themes that reflect the experiences and issues of importance to our participants, while we recognize that there will also be a deductive element to the analysis driven by the domains of the theoretical framework employed for our analysis (NASSS framework) and by other theoretical insights that become relevant during the analytical process (e.g. how health informatics interventions may produce 'intervention-generated inequalities' drawing on the framework by Veinot et al) (16). Our PPI group will be involved in the process of data analysis and sense-making. Analysis will take place in parallel to data collection until data saturation is reached, to account for the widest range of experiences. Videos will be destroyed after analysis.

The aim of the qualitative analysis will be to develop transferable learning on how large-scale digital transformation works in healthcare, using the NHS App as an exemplar of technology-supported patient access to primary care.

These findings will be presented as narrative case studies and will feed into the development of a consolidated theory of change, i.e. set of assumptions about how this (and other similar) complex digital health programmes would be expected to lead to intended outcomes, including unanticipated implications in practice, following discussions with delivery teams and review of published reports). Meetings between the evaluation team, delivery team and patient representatives will contribute to the refinement of the theory of change by identifying areas where it does not adequately explain the observed findings, or where there are competing assumptions that may hinder progress with implementation.

A strong theoretical basis will also be built for the analysis of findings, prospectively drawing on the NASSS framework (non-adoption, abandonment, scale-up, spread, sustainability), an evidence-based, framework developed to illuminate and theorise the implementation, and roll out of the NHS App (8) - Figure 2. Technology failures, partial successes and unanticipated problems will be explained by teasing out the multiple aspects of complexity across interacting domains, including the clinical condition, technology, value proposition, adopter system, organisation, context and temporal change. CP is one of the co-authors of this framework (and has previously authored other articles on complexity-informed approaches to researching, implementing and spreading innovations).



Figure 2: THE NASSS FRAMEWORK: explaining non-adoption, abandonment and challenges to scale-up, spread and sustainability of technological innovations in a health/care setting (11).

By drawing on the NASSS framework we will be able to study multiple interacting influences across a number of domains: differences in engagement with the NHS App depending on the nature of different health conditions, the complexity of the technology itself and its modifications over time in the context of an established base (e.g. other patient portals), the value generated for different stakeholders, as well as the emergent role of NHS staff in its introduction, organisational structures and the complexity of wider service provision in the NHS. Using a longitudinal, adaptive approach we will collect and theoretically analyse data across these domains to better understand how to manage complexity in different contexts, both in this technological project but also in terms of transferring lessons for future digital initiatives.

5.5 Study Sequenfce and Duration

The study commenced on 1st October 2020 and will continue for a period of 24 months.

NHS App	Evaluation	project	plan	outline
		p. 0,000	P	044

	2020 2021						2022																	
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
Qualitative Workstream																								



6. PARTICIPANT IDENTIFICATION

6.1 Study Participants

6.1.1 NHS patients, carers and members of the public

We will carry out semi-structured, qualitative interviews with 25-30 patients, carers and members of the public. A subset of participants will be invited to a follow-up interview 12 months.

A sub-set of those interviewed (n=10-12) will be observed, with ethnographic observation (spending time with the participant in their day-to-day activities, especially in terms of their health behaviours and interactions with wider technology, in general). Where Covid-19 restrictions are still in place, we will ask a small sample of these interviewees (up to 5) to develop video diaries of their self-management practices and healthcare access to share with the research team.

A sub-set of those interviewed (n=10-12) will also take part in think aloud interviews where we undertake interactive methods to observe participants using the app (such as booking appointments on the app or looking at their GP records).

We will provide options to participants to decide if they only want to participate in an interview or if they would also like to participate in observation and/or think aloud methods.

We anticipate conducting 4 focus groups, each involving 6-8 patients and carers (n=24-32) who have not already participated in interviews.

6.1.2 NHS Staff

Recruitment will primarily focus on the 5 GP practice case studies, where we expect to engage between 4-6 NHS staff per practice in semi-structured interviews (n=20-30). A subset of these participants will be interviewed twice over 12 months, to be able to follow up on growing familiarity with the new processes and any impacts on the service.

Observations will be carried out periodically (where feasible, at least 2 in-person visits, per GP practice over 12 months).

6.1.3 Stakeholders

6.1.3.1 Local Commissioners

We will carry out semi-structured interviews with 5-7 commissioners at different levels of seniority from the localities of the case studies, as well as additional areas where significant insights can be gained. These will last approximately 45-60 minutes.

6.1.3.2 Delivery teams

We will hold semi-structured interviews with 5-10 key members of the development and delivery teams at NHS Digital, NHS England and other organisations as relevant and observe 5-10 key delivery meetings, workshops, 'app clinics' and other interactions. Interviews will last approximately 45-60 minutes.

By working collaboratively with the delivery teams at NHS Digital, NHS England and other agencies (e.g. NHSX), we will be able to a) track technology upgrades and other developments that may have an impact on functionality and uptake, b) ensure that our work compliments rather than overlaps with work carried out by NHS agencies, while retaining critical distance, c) feedback our findings in real time to contribute to the agile delivery process, strengthen organisational learning and contribute to sustainable solutions, d) adjust our research plan in a timely way to take account of unanticipated changes in the development or delivery process, and d) draw maximum learning from this wider process of digital transformation in primary care.

6.2 Inclusion Criteria

6.2.1 All participants

- Participants must be 18 years or older
- Willing and able to give informed consent for participation

6.2.2 NHS Staff

• NHS professionals from different areas of NHS General Practice such as doctors, receptionists, and practice managers

6.2.3 Stakeholders

6.2.3.1 Local Commissioners

• Professionals involved in the commissioning of NHS services

6.2.3.2 Delivery teams

• Professionals involved in the planning, development, roll out, policy making or communication of the NHS App

6.3 Exclusion Criteria

6.3.1 All participants

• Not willing or able to give informed consent for participation

6.3.2 Stakeholders

6.3.2.1 Local Commissioners

• Not involved in the commissioning of NHS services

6.3.2.2 Delivery teams

• Lack of involvement in strategic planning, development, roll out, policy making or communication of the NHS App

6.4 Recruitment

6.4.1 NHS patients, carers and members of the public

Participants will be primarily recruited from our 5 GP practice case studies (supported by their LCRN) and through the list of interested patients (and practices) that NHS Digital holds.. We will also recruit people (NHS App users and non-users) through advertising the study online (e.g. social media) and in professional networks, either using an open call or through targeted invites to participate in the study (e.g. if someone is using the NHS App hashtag on social media). It is very important that our sample is inclusive and captures diversity. To achieve this we will work with voluntary and community organisations to ensure that the views from a wide range of patient groups are represented within the constraints of the total number of our sample (e.g. non-users, patients with rare or potentially stigmatising conditions, patients dealing with new diagnoses or ongoing health changes, specific ethnic groups). This maximum variation approach to sampling will aim to recruit patients across age groups, health needs and conditions, different ethnic and socioeconomic backgrounds, and with different levels of self-assessed health and IT literacy. Groups with significantly higher primary care consultation rates will be particularly targeted, including parents with young children, older people (and their carers), those with multimorbidities and people from deprived communities

6.4.2 NHS Staff

The recruitment strategy will include working with the NIHR LCRNs in Oxfordshire, Northwest London (where part of the study team is based), but also with LCRNS in the Midlands, North East and North West. Recruitment will be facilitated by NIHR LCRN primary care networks and the NHS Digital delivery team. We will also recruit people through advertising the study on online (e.g. social media) and in professional networks, and through targeted invites to participate in the study. We will follow a staged approach in the recruitment of GP practices to ensure we cover a wide range of characteristics and fully explore emerging themes.

6.4.3 Local Commissioners

Recruitment will primarily focus on the 5 GP practice case studies using purposive sampling. We will engage our wider networks to reach out to local commissioners and with direct contact with local commissioning groups to invite them to take part in the study. Local commissioners may also be purposively sampled and contacted directly through publicly available email addresses.

6.4.4 Delivery teams

Our project team have good working relationships with key individuals in NHS agencies that will be able to facilitate close collaboration. We have planned formal and informal opportunities for dialogue and knowledge exchange throughout the project.

6.5 Informed Consent

We have engaged our PPI group in developing our participant information and consent materials. Participants must provide informed verbal consent before any study specific activities are undertaken.

Study participants will receive a participant information leaflet (PIL) by email prior to the interview/focus group/observation and will be asked by a University researcher to provide oral consent at the start of the interview. The PIL will detail: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; 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 (for patient participants), and with no obligation to give the reason for withdrawal. The researcher will record the consent on a "record of verbal consent form". A copy of the form will be forwarded to the participant by post or email at the completion of the interview/focus group/observation. The original signed form will be retained at the study site.

The participant will be allowed as much time as wished to consider the information (at least 72 hours), and the opportunity to question the researcher or other independent parties to decide whether they will participate in the study. Participants will have opportunities to ask questions during the interview and afterwards via email or phone to the researcher.

The researcher who obtains the consent will be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator.

6.6 Subsequent Visits

Most participants will have one study visit/engagement, while a sub-set of patient/carer participants will receive between two and three engagements if they take part in a semi-structured interview, a think aloud interview or observation (if the additional think aloud interview/observation are part of a separate interview or on a different day/time) as well as a follow up semi-structured interview approximately 12 months on from the original semi-structured interview. NHS staff will be involved in between one and four study visits/engagements but which could include an original interview, follow-up interview 12 months on and up to two observations. Stakeholders (Commissioners or Development team) participants will have one study visit/engagement in the form of a semi-structured interview.

6.7 Discontinuation/Withdrawal of Participants from Study

V1.8 22/12/2020 Page 21 of 32 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

Participants may choose to stop their active involvement in the research but choose to remain on passive study follow-up (i.e. those wanting to receive a summary of findings from the study). Participants may also withdraw their consent, meaning that they wish to withdraw from the study completely. 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.

Withdrawn participants will be replaced if there is capacity and time left to recruit more participants.

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

7. DATA MANAGEMENT

7.1 Access to Data

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

7.2 Data Recording and Record Keeping

All study data will be entered on NVivo.

The participants will be identified by a unique study specific number in any database. The name and any other identifying detail will NOT be included in any study data electronic file. All data from the study (audio recordings, transcripts, field notes, photographs and videos) will be password-protected and kept on an encrypted, non-networked computer at the University of Oxford. In those stored data, participants will be referred to only by pseudonym. We will keep a separate, password-protected record of participants' real names and corresponding pseudonyms (accessed by members of the team only). Any personal identifiers relating to individual participants will be held for less than six months after the end of this 24 month study.

Interviews and focus groups will be recorded onto an encrypted local University of Oxford laptop and downloaded straight away into a protected folder on the H drive (a secure university drive which only approved members of the research team have access to). Audio-recordings will be transcribed by a professional transcriber under a non-disclosure confidentiality agreement and destroyed after the transcripts have been checked for accuracy. De-identified study data transcripts of interviews will be kept for 10 years, but these will not be used for secondary analysis. Quotes or photo/video extracts used in publications will be in pseudonymised or pixelated format that does not identify participants. De-identified research data will be stored for 10 years after the end of data collection.

Data will be stored and managed according to the University of Oxford data management and security policies and in accordance with the Data Protection Act, General Data Protection Regulation (GDPR) and other relevant legislation. All investigators, research staff, and steering group members will comply with the requirements of the Data Protection Act 2018 and GDPR 2016/679 with regards to the collection, storage, processing and disclosure of data including any personal information. Both the Principal Investigators are the data custodians. University of Oxford is the data controller.

8. DEFINITION OF END OF STUDY

The end of the study is the point at which the last focus group or interview (whichever is later) of the last participant has occurred.

9. QUALITY ASSURANCE PROCEDURES

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

10. ETHICAL AND REGULATORY CONSIDERATIONS

10.1 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

10.2 Approvals

Following Sponsor approval of the protocol, informed consent form, participant information sheet (and any other participant documents) will be submitted to an appropriate Research Ethics Committee (REC), HRA (where required), and host institution(s) for written approval.

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

10.3 Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

10.4 Indemnity

Insurance and indemnity arrangements lie with the sponsor (University of Oxford). The University of Oxford maintains Public Liability and Professional Liability insurance, which will operate in this respect.

10.5 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.

10.6 Expenses and Benefits

As a token of appreciation, we will offer each patient or carer participant a £25 voucher to cover their time and travel expenses (if any). All other participants will be participating as part of their professional role and in their professional capacity, and so in these cases would not expect to be reimbursed.

Practices will be offered £1000 each to take part, assuming around 11 hours of GP time in each.

11. QUANTITATIVE WORKSTREAM

12. STUDY OBJECTIVES

This study aims to evaluate the effectiveness of the NHS App in meeting its goals by looking at early patterns of uptake and adoption. We will use observational data from the NHS App to assess use and acceptability by looking at total app downloads and registrations, total number of appointments bookings, total number of medical records viewed, and the number of prescriptions ordered. We will look at overall patterns, regional variations, and variation with various demographic factors and patient survey scores.

13. STUDY DESIGN

The study period for this analysis will be from January 2019 to end 2022.

13.1 Descriptive analysis of NHS App adoption

Descriptive statistics will be used to summarize monthly NHS App metrics at a national, regional and GP practice level. The data will be described using summary statistics. The number of patients who have used the NHS App each month will be reported on a monthly basis, at the individual and GP practice level as well as usage rates for its core functions – appointment booking, record access, prescription ordering, recording organ donation status and setting data sharing preference. These data will be reported over the NHS App rollout period (January 2019 to July 2019) and for 24 months post rollout period (to January 2021).

We will use our privileged access to the NHS App analytic data to compare the adoption and usage rate of those who use different routes for onboarding and proving their identity and for access to their account (e.g. those choosing biometric ID vs those using password and SMS).

We will also report overall monthly usage of online patient services (whether through the NHS App or other systems), including online record access, online appointment booking and online prescribing for the 24 months before the NHS App rollout period, over the rollout period, and for the 24 months post rollout. Summary measures and associated measures of variation will be presented to capture the variation in the various datasets.

A heat map extracted from the NHS App dashboard will display the total percentage of the GP patient population aged 13+ registered for the App across the whole country. Lowest and highest App registrations by CCG will also be presented for the UK population. All data will be taken from the anonymized NHS App dashboard.

13.2 Time Series Analysis

An ecological time series and an interrupted time series (ITS) analysis will be used to analyze the impact of the first UK national lockdown due to COVID-19 that occurred on March 26, 2020. The time series analysis will evaluate changes in uptake and the longitudinal impact of the pandemic on different functionalities of the App.7 An interruption will be added to the time series on April 1, 2020, to estimate changes in uptake before and after announcement of the first lockdown. The ITS will explore changes in level and trend for national App logins, appointment bookings, medical records viewed, and prescriptions ordered between January 2019 and May 2021.

The ITS model will then assess if there was a change in App usage immediately after the first lockdown (the level) and if a change in trend occurred over the whole study period.

13.3 Cross-sectional analysis

A cross-sectional analysis of the differences in NHS App registration and other rates by age, sex, ethnicity, Index of Multiple Deprivation (IMD), size of the GP practice and long-term physical or mental health conditions, disabilities or illness will be done. This will use a negative binomial regression model to calculate incidence rate rations (IRR) across the different groups.

13.4 Associations with General Practice Patient Survey

We will compare NHS app usage against general practice patient survey scores from the GPPS. GPPS data will be linked to the NHS App data using GP practice code as an identifier.

The main outcome variables will be weekly rates of each NHS App function used (e.g. registrations, logins, prescriptions ordered, medical record views and appointments booked) per 1,000 registered GP practice population. These will be compared against the following GPPS patient experience metrics:

- <u>Ease of phone access</u>: "Generally, how easy is it to get through to someone at your GP practice on the phone?" [GPPS Question Q1]
- <u>Ease of web access/use</u>: "How easy is it to use your GP practice's website to look for information or access services?" [GPPS Question Q4]
- <u>Overall GP practice experience</u>: "Overall, how would you describe your experience of your GP practice?" [GPPS Question Q30]

compare Negative binomial regression models will be used to calculate incidence rate ratios to explore differences in the use of the various NHS App features for each GPPS variable.

14. DATA SOURCES

Data on usage of the NHS App at national and local level will be taken from a dashboard developed by NHS England and NHS Digital. The NHS App dashboard displays the number of users who have downloaded and registered for the App, as well as which features patients are using through the App. This dashboard is open to all academics and NHS workers. We have obtained permission from NHS Digital.

Metrics currently available through the dashboard include App registrations, App downloads, appointment bookings and cancellations, medical record views, prescription requests, visits to NHS 111

online, organ donation registrations and withdrawals, users visiting the health A-Z, and users visiting the national data opt-out site.

Data metrics can be viewed on a weekly or monthly level and be broken down by regions, sustainability and transformation partnerships (STP) (planning framework for NHS services), clinical commissioning groups (CCG) (groups of general practices (GPs) set up by the Health and Social Care Act 2012 that deliver NHS services in England), and GP practice. The research team did not have access to personalidentifiable information. All NHS App metrics and descriptions are included in the Appendix.

Covariates data mapping socio-demographic profile of patients at the GP practice level will be obtained from a number of verifiable public health data sources. Socio-demographic data on the age and gender of all GP registered population were obtained from the NHS digital website. Data on ethnic composition and deprivation will be obtained from Fingertips public health profiles, and data on long-term health conditions was extracted from the GP Patient Survey (GPPS) database.

Data on patient experience of care and care access will be extracted from the GP Patient Survey (GPPS) database. GPPS is a survey of approximately 2.4 million adult GP registered patients in the UK and is currently conducted annually.

15. Quantitative work [planned - but not attempted]

The following components of the quantitative analysis were intended to be completed – but following the inability to link data through CPRD at the practice level due to the COVID pandemic – were not attempted.

15.1 Practice level analysis

- 15.1.2 We will use practice level data on NHS App usage, linked to data on use of patient online services (the Patient Online Management Information (POMI) dataset described below) and practice level CPRD data to examine the impact of the introduction of the NHS App on usage of the three patient online services 1) the proportion of patients accessing their medical record, 2) the proportion of repeat prescriptions obtained digitally, and 3) the proportion of GP appointments booked online. In this analysis, we will be able to include practice CPRD data on demographic characteristics, including age, gender, deprivation, ethnicity and urban/rural status. Poisson multivariable regression will be used to examine the association between NHS App usage and the use of patient online services at practice level.
- 15.1.3 We will use practice level data on NHS App usage, linked to CPRD, to examine the impact of the introduction of the NHS App on the practice consultation rate, and the type of consultation (e.g. in person or by phone). Poisson multivariable regression will be used to examine associations between NHS App usage and consultation rate.
- 15.1.4 We will use GP practice level POMI data to investigate if usage of the three patient online services -1) the proportion of patients accessing their medical record, 2) the proportion of repeat prescriptions obtained digitally, 3) and the proportion of GP appointments booked online changed following the NHS App rollout period. We will also investigate changes in organ donation rates and national data opt out rates over this period. Data will be aggregated by month to impute into an interrupted time series analysis (ARIMA model). The size of the effect of the intervention and

changes in the trend of the effect over time will be assessed using this segmented regression analysis. This method will estimate changes in the mean, level and slope between the pre- and post-implementation arms and will account for a lag/step-wise change in the assumed linear trends.

15.1.5 Patient satisfaction with GP services and any changes in satisfaction pre/post NHS App implementation will be assessed using the General Practice Patient Survey using an interrupted time series analysis - although this will only have annual data points. This will use questions from the survey: 1) Overall, how would you describe your experience of making an appointment? 2) Overall, how would you describe your experience of your GP practice?

16. REGULATORY ISSUES

16.1 Ethics approval

The Principal Investigator has obtained approval from the Head of Department and approval from the Research Governance Integrity Team (RGIT)/ favourable opinion from Imperial College Research Ethics Committee (ICREC). ICREC reference: 21IC7292

16.2 Consent

Consent was not required due to the aggregated nature of all the statistics used in the study – all of which were at practice level or above.

16.3 Confidentiality

The Principal Investigator will preserve the confidentiality of participants and fulfil transparency requirements under the General Data Protection Regulation. Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

16.4 Funding

National Institute for Health Research - Health Services and Delivery Research (HSDR) programme, project number: NIHR128285

16.5 Audits

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies.

16. OVERALL COMPONENTS

17. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through a regular weekly study management group, chaired by the study principal investigators. Meetings occur on a weekly basis with all members of the core study team.

18. PATIENT AND PUBLIC INVOLVEMENT

18.1Building PPI into the study

18.1.1 What we have done so far

Our experienced PPI contributor Bernard Gudgin has been involved in our methodological discussion and made comments and suggestions on this protocol. Working with patient involvement centres and long-term condition support groups, we have created a project-specific PPI group to inform the design, interpretation and dissemination of the study, including co-writing public facing information, creating qualitative discussion guides, and co-authoring publications. The group is made up of 4 PPI representatives. We actively recruited from PPI networks in Oxford, Wessex and London, asking potentially interested participants to send in a short description of why they would like to take part and sharing an outline of the study and expectations of PPI involvement (See Appendix A).

In addition to looking for participants with specific knowledge and enthusiasm for technology, we sought some who have different views – both for and against new technology - and try to balance the group members. We paid particular attention to inclusivity and diversity in age, gender, ethnicity, caring responsibilities and health experience, and tried to ensure that we covered all aspects of the 'digital divide'.

18.1.2 What we are planning to do

Specific tasks for the PPI group to engage in include 1) choice of case study sites, 2) developing the IG approvals, 3) developing participant information and consent material, 4) engagement in synthesis of qualitative findings, 5) engagement in analysis of quantitative findings, 6) co-authoring papers and 7) engagement with public, practitioners and policymakers. These have all been costed against the INVOLVE criteria, including travel, carer and childcare costs so that we can obtain a diverse set of views into the PPI process.

In particular, PPI involvement so far has informed the research questions in our qualitative work (including how to ask about acceptability). It has also helped inform our recruitment strategy, and what sort of patients we will try to include to get a balanced set of views (including people with both positive and negative views on technology).

19. DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

The approach to the study has been designed to inform improvement and further development of the app and to inform future commissioning decisions. We anticipate that the findings of this work (regardless of the nature and direction of the findings) will be of interest to both the wider public and NHS staff working in primary care. Consequently, we intend to be active in communicating our findings to both audiences, as well as contributing to normal academic dissemination.

This work will further the science of the measurement of the adoption of digital technologies in the NHS. Our approach presents a useful demonstration of methods that could potentially be used for evaluation of further digital transformational work in the NHS and other health systems.

Anticipated outputs include:

- Regular briefing on emerging findings to NHSX
- A final evaluation report for the delivery team and policymakers
- Academic papers and the final academic report/monograph for the NIHR Journals Library.
- Conference outputs at events for the HSR, digital health and primary care communities
- Public information material for GP practice patient groups, social media and the NHS website

20. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the National Institute of Health Research. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

CI	Chief Investigator
CTRG	Clinical Trials & Research Governance, University of Oxford
CUREC	Central University Research Ethics Committee
GDPR	General Data Protection Regulation
GP	General Practitioner
HRA	Health Research Authority
LCRN	Local Clinical Research Network
NASSS	Non-adoption, Abandonment, and challenges to Scale-Up, Spread, and Sustainability framework
NHS	National Health Service
PI	Principal Investigator
PIL	Participant Information Leaflet
PPI	Patient and Public Involvement
REC	Research Ethics Committee

21. ABBREVIATIONS

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