Study Title: Remote by Default 2 – the new normal?

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Chief Investigator Signature:

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained

All researchers declare that they have no conflicts of interest.

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, HRA (where required) unless authorised to do so.

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1. KEY STUDY CONTACTS

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2. LAY SUMMARY

AIM

To inform high-quality, safe and equitable care in UK general practice in the context of policies which require phone, video or e-consultation by default.

BACKGROUND

When COVID-19 struck, general practice shifted to predominantly phone, video or e-consultations instead of face-to-face. Remote had benefits (e.g. reducing spread of COVID-19), but also downsides (technical glitches; inequalities of access; missed diagnoses; reduced continuity of care; and patients simply not seeking care at all). Despite this, the Secretary of State for Health of the UK, Matt Hancock declared on 30th July 2020 that remote-by-default is here to stay.

RESEARCH QUESTION

To what extent is remote-by-default, introduced for infection control during the pandemic, fit for purpose for the long term – and how can we make remote care better and safer?

DESIGN AND METHODS

Mixed-method case study with co-design workshops and cross-sector stakeholder events.

OBJECTIVES AND METHODS

1. GP PRACTICES
We will support up to 11 GP practices to develop effective remote services and alternatives where needed. We'll help them collect data and use their findings to inform improvement efforts.

2. PATIENTS
We will interview up to 100 patients in total (including sub-study, Appendix A) selected for diversity (age, ethnicity, locality, socio-economic status, condition[s], digital literacy), and hold two workshops (one remotely and one in person, Covid allowing) where patients help co-design ways to combine remote and face-to-face models.

3. WIDER SYSTEM
We will engage stakeholders – including policymakers, local government, professional bodies, industry, civil society and patient groups – in ongoing dialogue about how to deliver and support a more equitable, less risky remote-by-default service. We'll interview them and hold cross-sector stakeholder events (big Zoom meetings), working both before and after the events to build relationships and action ideas.

KEY THEMES TO STUDY

1. QUALITY AND SAFETY OF CARE, illustrated by 4 kinds of consultation:
    a. long-term conditions e.g. diabetes;
    b. continuity of care (being able to see one's own doctor or nurse);
    c. early detection of cancer (e.g. how easy it is to get seen for a new breast lump);
    d. multiple complex conditions (including patients in care homes);

2. INEQUALITIES OF ACCESS relating to (e.g.) health or digital literacy, language barriers, financial hardship, or nature of disability or illness;

3. WORKFORCE, including staff well-being, training and supervision as well as mismatch between staff capacity and demand;

4. INFRASTRUCTURE, including technical (hard/software, interoperability) and regulatory (e.g. information governance, quality inspections) challenges.

PATIENT AND PUBLIC INVOLVEMENT

We have an established external advisory group with extensive lay representation including a lay chair (AAN, co-applicant). We have strong links to local PPI groups in our study sites, and will establish a PPI

virtual group with buddying of others not fully online. Patients and lay people have been formatively and iteratively involved throughout the current project; their input has been crucial to shaping this bid (especially the kinds of remote consultations they're most concerned about). They will continue to be actively involved in all aspects of the study.

DELIVERABLES

Range of patient/carer experience of remote, 4 digital inclusion workshops, support for change in 10 GP practices, cross-case learning, 4 cross-sector stakeholder events with follow-on support for policy action, academic papers and policy briefings, lay summaries and resources.

1. SYNOPSIS

Study Title	Remote by Default 2: The New Normal?
Internal ref. no. / short title	Remote by Default 2 (RBD2)
Sponsor	University of Oxford
Study Design, including methodology	Mixed-method, multi-site case study with co-design workshops and cross-sector stakeholder events.
Study Participants, including sampling strategy	PRACTICE LEVEL: Staff from up to 11 GP practices, including clinicians, managers support staff and social care providers who support patients to access remote care PATIENT LEVEL: NHS patients registered at these practices, sampled for diversity in socio-economic status, illness/conditions, age, gender, ethnicity and digital literacy SYSTEM LEVEL: National policymakers and other key stakeholders, selected for their involvement in remote GP services in some way
Sample Size	up to 125 practice staff up to 100 total patients (~90 for RBD2, and 9 for sub- study, Appendix A) up to 8 social prescribers up to 36 national stakeholders
Planned Study Period	1.9.21-30.11.23
Planned Recruitment period	1.10.21-30.11.23
Aim	To inform a more fit-for-purpose remote-by-default model in general practice which takes account of a) quality and safety of care, b) equity and inclusivity, c) staff wellbeing and training, and d) the wider technical and regulatory infrastructure.
Research Questions	1. How can we ensure that the remote-by-default model supports high-quality, safe care to all patients (including those at risk of digital exclusion)? 2. How can we balance a remote-by-default model with the provision of traditional face-to-face consultations where appropriate?

	3. How can we meet the wellbeing and training needs of general practice staff as remote-by-default becomes business as usual? 4. What are the infrastructural challenges of remote-by-default and how can they be overcome?
Objectives	1. PRACTICE LEVEL Objective: Follow a maximum-variety sample of up to 11 GP practices for up to 2 years as they seek to introduce, improve and sustain remote-by-default consultations, supporting them in developing effective remote services and equitable alternatives where needed. Methods: Build mixed-methods longitudinal case studies via staff interviews, document analysis, ethnography (adapted to virtual if necessary). Support practices through action research and 3 co-design workshops covering digital inclusion and those delivering social care 2. PATIENT LEVEL Objective: Capture the patient experience of remote-by-default consultations and ensure this perspective is incorporated in practice- and system-level efforts to improve and augment remote-by-default services. Methods: up to 100 interviews and 2 digital inclusion co-design workshops with patients and carers. 3. SYSTEM LEVEL Objective: Engage stakeholders – including policymakers, professional bodies, industry, local governments, national care forum, civil society and patient groups – in an ongoing dialogue about how to deliver and support a more equitable, less risky remote-by-default service. Methods: 36 elite interviews plus 4 stakeholder events (described below)
Committees	Information Governance Committee at the Nuffield Department of Primary Care Health Sciences. Reviews and approves Information Governance policies around data management of the research, and makes sure that research complies with regulations around good practice.

2. ABBREVIATIONS

AAN	Anica Alvarez Nishio
CI	Chief Investigator
CRF	Case Report Form
EAG	External Advisory Group
ESRC	Economic and Social Research Council

GMC	General Medical Council
GP	General practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
ID	Identification document
IRAS	Integrated Research Assessment System
MHRA	Medicines and Healthcare Devices Regulatory Agency
MRC	Medical Research Council
MSDIT	Medical Sciences Division Information Technology
NASSS	Non-adoption, Abandonment and challenges to Scale-up, Spread and Sustainability
NDPCHS	Nuffield Department of Primary Care Health Sciences
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
PERCS	Planning and Evaluating Remote Consultation Services
PI	Principal Investigator
PIS	Participant/ Patient Information Sheet
PPI	Patient and Public Involvement
PPI[E]	Patient and Public Involvement [and Engagement]
R&D	NHS Trust R&D Department
RBD1	Remote by Default 1
RBD2	Remote by Default 2
REC	Research Ethics Committee
RGEA	Research Governance, Ethics & Assurance team, University of Oxford
RES	Research Ethics Service
SOP	Standard Operating Procedure
SS	Sara Shaw
TEC	Technology Enabled Care
TG	Trisha Greenhalgh

3. BACKGROUND AND RATIONALE

The remote-by-default policy in UK general practice, introduced for infection control during the acute phase of the pandemic, seems likely to be continued long term. There are unanswered questions about how to optimise this service model. We build on a previous mixed-method study by our team—Remote by Default—which was set up and conducted at speed in the early months of the pandemic to look at the pandemic response. The research questions of that previous study relevant to this application included:

1. *What is the new and emerging organisational, regional and national level context for video consulting in the Covid-19 pandemic?*
2. *How can general practice best support and manage 'long Covid' in a remote-by-default context?*
3. *How can action research, informed by complexity principles, support the rapid implementation, spread and scale-up of remote-by-default models of primary care in the Covid-19 crisis?*
4. *How do health care professionals assess symptoms associated with COVID-19 by phone/video?*

That study, which we are now calling Remote by Default 1 (RBD1), was funded by ESRC, sponsored by the University of Oxford, and received ethics approval from East Midlands (Leicester Central) NHS Research Ethics Committee on 20th June 2020 (IRAS 283196), REC reference 20/EM/0128. Various subsequent amendments have also been approved, and some practices who are part of RBD1 will go forward with RBD2, though we have also recruited some new practices. RBD1 is ongoing and due to finish on 30th November 2021. We have already produced a wealth of publications from that study [1-22] and further data analysis and writing up is ongoing.

On 30th July 2020, two months after we officially commenced the RBD1 study (though in practice some of the work and funding was backdated), the Secretary of State for Health and Social Care, Matt Hancock, announced that "all consultations should be remote by default", not just during the pandemic but indefinitely. The ability to walk into (or phone) a GP surgery and request an appointment is something we have taken for granted since 1948 – but which we may now have lost. Instead, patients now face the hurdle of "total triage"[23] (the requirement to access care by electronic form or telephone in the first instance) before they can access a clinician. Most commonly, as our RBD1 research has found, they will be offered a phone call.

Thus, it became clear early in our RBD1 research that a) remote by default care even beyond the pandemic had—suddenly and unexpectedly—become a *political* priority and b) there was a need urgent research into when, why and in what circumstances the benefits of this model outweighed its disadvantages. It was also clear to us that if the model is here to stay, we need to make it more equitable and less risky (in terms of both managing clinical risk and uncertainty and managing wider risks such as safeguarding of the vulnerable).

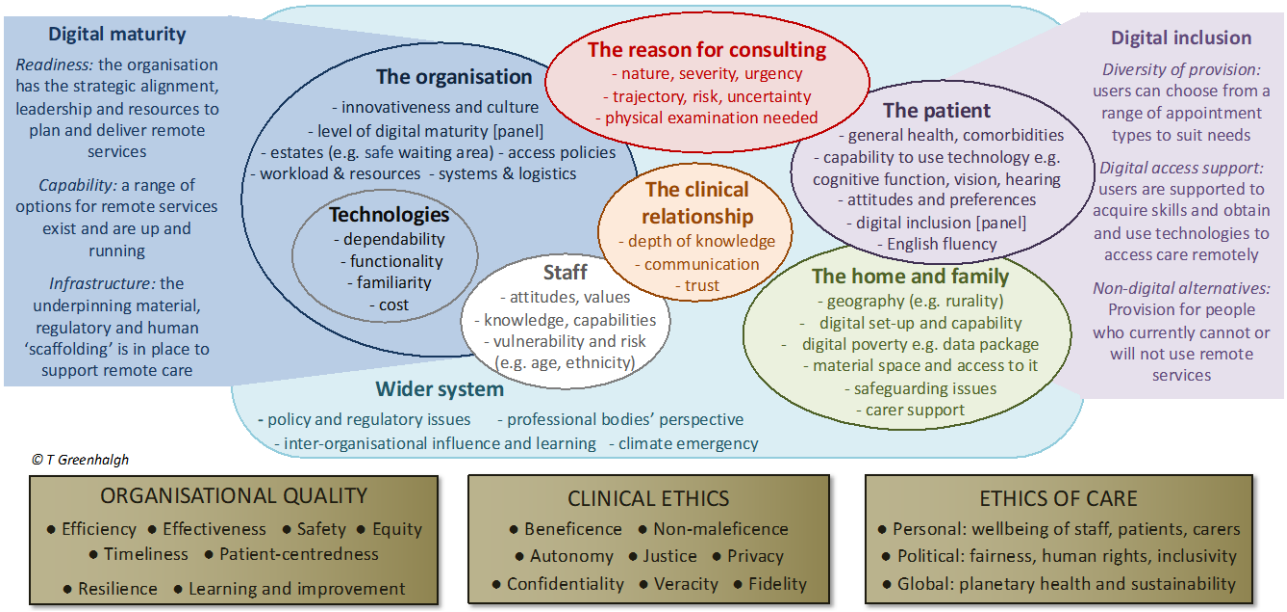
The impetus for the present study is partly our concern that policy enthusiasm for remote-by-default as a long-term option may be premature. In RBD1, we have found that whilst remote assessment of general practice patients by online symptom triage, telephone and video has benefits (not least, in the current context, infection control), the downsides are many and include digital exclusion (some people are unable or unwilling to access general practice remotely), various kinds of technical failure (sometimes with underlying infrastructure such as bandwidth), missed 'doorknob encounters' (where a patient mentions an important problem just as they are leaving), difficulty maintaining a personal clinician-patient relationship, and threats to confidence (leading to overprescribing, over-referral and over-

investigation) and to wellbeing, training and supervision in health professionals. Our current RBD1 study is documenting the benefits, risks and unintended consequences of remote-by-default during the pandemic. In this new study, we seek to extend that work to study what some policymakers call the "new normal" – a time when the risk-benefit balance for a remote-by-default service may have changed.

To sum up both the published literature and our own unpublished findings, the quality and safety of clinical care – notably in relation to long-term condition management, relational continuity of care, early detection of cancer, and complex multimorbidity – may be at risk in a remote-by-default model, and these threats to quality are likely to have a disproportionate effect on key vulnerable groups. The wellbeing and training of staff has not yet adapted to the new model, and there are unanswered questions about technical infrastructure and also regulation and governance of GP services going forward. However, there already exist rare examples where remote-by-default appears to be working well and is valued by patients and staff, which may provide important lessons for the NHS and more widely.

A particularly relevant output of the RBD1 study is the PERCS (Planning and Evaluating Remote Consultation Services) [1], which was adapted from the NASSS framework previously developed by our team [24], to take account of new data derived from our case studies conducted during the pandemic. PERCS, shown in Figure 1, illustrates our finding that the decision to offer a remote consultation (as opposed to a face-to-face consultation or other action) involves multiple interacting influences. Fundamentally it is a practical, ethical judgement which draws on the principles of both professional ethics and organisational quality. We plan to apply and develop the PERCS framework further in RBD2.

Figure 1: PERCS (Planning and Evaluating Remote Consultation Services) model of multiple interacting influences on the success of remote consulting



4. AIM / RESEARCH QUESTIONS / OBJECTIVES

Aim / Research Questions / Objectives

AIM: To inform a more fit-for-purpose remote-by-default model in UK general practice which takes account of a) quality and safety of care, b) equity and inclusivity, c) staff wellbeing and training, and d) the wider technical and regulatory infrastructure.

STRATEGIC OBJECTIVES

1. PRACTICE LEVEL: Follow a sample of up to11 GP practices for two years as they seek to introduce, improve and sustain remote-by-default consultations, supporting them in developing effective remote services and equitable alternatives to remote where needed.
2. PATIENT LEVEL: Capture the patient experience of remote-by-default consultations and ensure that this perspective is incorporated in practice- and system-level efforts to improve and augment remote-by-default services.
3. SYSTEM LEVEL: Engage a wide range of stakeholders – including policymakers, NHS, professional bodies, industry, civil society and patient groups – in an ongoing dialogue about how to deliver and support a more equitable, less risky remote-by-default service.

OPERATIONAL OBJECTIVES

1. PRACTICE LEVEL:
    a. Using an embedded researcher-in-residence model, build relationships with up to 11 GP practices selected for maximum variety in digital maturity, geographic location (e.g. urban/rural/remote) and population demographics. Support PPI reps in those practices.
    b. Undertake interviews (up to 30 per practice) and collect documentary data (e.g. protocols, patient leaflets, workload data) from each practice to build a case study.
    c. Follow practice case studies longitudinally over time, supporting them to a) optimise quality and safety of care; b) ensure digital inclusion and provide equitable alternatives for the digitally excluded; c) maintain wellbeing and train and support their staff; d) overcome infrastructural hurdles (both technical and regulatory).
    d. Run two online co-design workshops for up to 40 people each (with hands-on activities in small groups), incorporating insights from patient/carer workshops (see below).

2. PATIENT LEVEL:
    a. Recruit a diverse sample of up to 100 service users (patients and carers), most of whom will be registered with participating GP practices, with some identified through patient groups or snowballing, ensuring that we include a range of people at risk of digital exclusion.
    b. Through narrative interviews (by phone, video or face to face as preferred), capture the patient/carer experience of remote-by-default consultations across four key quality and

safety areas (long term condition monitoring, getting an appointment with own clinician, symptoms that could indicate early cancer, and complex multimorbidity).

c. Hold two co-design workshops (one remote and one face to face), each with up to 20 patients and carers, to generate insights about how digital inclusion impacts on access and quality and safety of care, and generate a range of 'digital inclusion personas'. Hold a third co-design workshop to gain insight into those that provide social care navigation

3. SYSTEM LEVEL:
   a. Build relationships with key stakeholders (listed under strategic objective 3) through up to 36 elite interviews and extending our ongoing stakeholder map and up-to 8 interviews with those that offer or commission social care provision.
   b. Hold four large, cross-sector stakeholder events, including preparatory and follow-up activities, focused respectively on quality and safety of care; digital inclusion (informed by digital inclusion personas); staff wellbeing, training and supervision; and technical and regulatory infrastructure.

5. STUDY DESIGN

a) Methodology

Mixed-method, multi-site case study with co-design workshops and cross-sector stakeholder events. By 'mixed methods', we mean "*research in which … researchers combine elements of qualitative and quantitative approaches … for the broad purposes of breadth and depth of understanding and corroboration*".[25]

b) Sampling Strategy

Sampling for geographical and sociodemographic variation of practices

We will build on our ongoing 'Remote by Default 1' (RBD1) study, where we have working relationships and ethical approvals for 4 localities in diverse settings (Greenwich, Oxfordshire, Plymouth and South Wales). We will add practices in other localities (notably Scotland, including both inner-city and remote), and we will maintain links with national policymakers, professional bodies and patient groups. Whereas in RBD1 we sampled by locality (e.g. Greenwich), gained an understanding of locality-wide issues (e.g. Clinical Commissioning Group) and then honed in on two or three practices in each locality, in RBD2 we will take the individual GP practice as our main unit of analysis, and 'zoom out' from there to study locality-wide context. Many but not all of the practices we recruit for RBD2 will be in localities whose history, geography and demographics we are now very familiar with.

Sampling for digital maturity of practices

In sampling the 11 practices for full case study analysis (and additional 2 practices for a 'deep dive' of our cross cutting themes), we have sought maximum variety in practices' **readiness** (the extent to which the

practice has the strategic alignment, leadership and resources needed to plan and deliver a range of remote services), **capability** (the extent to which different aspects of remote services are technically present and up and running) and **infrastructure** (the extent to which the underpinning material, regulatory and human resource infrastructure is in place to support remote care). Drawing on previous models and frameworks (including a 136-item digital maturity self-assessment survey[26] which informed the NHS Five-year Forward View[27] but was abandoned soon after; a digital maturity matrix for electronic records;[28] and McCulloch et al's IDEAL framework for surgical innovations, many of which are technologies or technology-supported processes[29]), we have developed a simple and pragmatic maturity scale for general practice remote care (Table 1). The 13 practices on our shortlist (of which up to 11 will go forward for full case study analysis, and an additional 2 practices will be involved in enhanced learning through a 'deep dive' into our cross-cutting themes of digital exclusion and staff wellbeing and workflows at those sites) range from Traditional (low maturity) to System-oriented (high maturity) on our scale. The Traditional practice claims to have good reasons for resisting the move to remote (i.e. a desire to serve a deprived and digitally excluded population). The Digitally Embedded and System-oriented practices are keen to spread their ideas to other practices.

TABLE 1: MATURITY SCALE FOR GENERAL PRACTICES IN RELATION TO REMOTE CARE

Practice descriptor (use of technology)	**How the practice currently uses traditional technology (e.g. phone, online access) and new technology (e.g. video, telehealth apps) for remote care**
● TRADITIONAL (reactive)	Limited leadership or vision for remote services (there may be a strategic decision and rationale to resist these). Phone is used for triage and call-backs e.g. for demand management and as a response to the pandemic. Patient online access is mostly disabled. Video and telehealth are rarely if ever used and may be actively discouraged. Key infrastructure may not be in place. Digital inequalities either not addressed or addressed by focusing on face to face services.
●● TRADITIONAL WITH LONE INNOVATOR (ad hoc, demonstration)	Within a traditional practice, one staff member is enthusiastic about remote care, s/he attempts to use novel technologies and engage others in doing so, but has not yet succeeded in getting others to share the vision, influencing practice strategy or changing practice routines or policies. Infrastructure may be inadequate. Digital inclusion not yet a priority issue.
●●● DIGITALLY CURIOUS (experimenting)	The practice has a vision and plans for providing remote care. Traditional and new technologies are used creatively, and adjusted iteratively, to try to improve an aspect of care within the practice. These creative efforts may include measures to overcome digital inequalities. Focus is on technical details and feasibility (i.e. making something work). Infrastructure is adequate but may have limitations.
●●●● DIGITALLY EMBEDDED (learning and improving)	Both traditional and new technologies are used creatively and strategically, and benefits and disbenefits are evaluated, with the aim of improving remote care in all relevant areas across the practice, including efforts to meet the needs of digitally excluded groups. Digital capability is high (i.e. many services are successfully delivered remotely). Focus is on quality improvement and organisational learning. Work practices and routines are continuously adapted. Technical infrastructure is good as a result of strategic investment.
●●●●● SYSTEM-ORIENTED (extending and spreading)	Strategy and vision for remote services are strong and extend beyond the practice itself. Reducing digital inequalities is one aspect of a wider vision for an effective, efficient, equitable remote service. Digital capability is high. Staff are actively involved in

	developing and evaluating remote services beyond the practice – e.g. through inter-organisational benchmarking, quality improvement collaboratives, CCG-wide planning, research, national guidelines.

DESCRIPTION OF PRACTICES WHO HAVE SIGNED UP

We have gained commitment from 13 GP practices, of which 10 or 11 will become cases in the study (Table 2).

TABLE 2: THE GENERAL PRACTICES WHO HAVE SIGNED UP

Level of maturity with remote care (more dots = more mature)	Practice code	Features	Index of multiple deprivation (more dots = more deprived)	Ethnic mix (more dots = more diverse)	Demographic and employment profile
●●●●●	Camden 1	Inner city, national digital innovator, keen to spread novel models of care	●●	●●●●●	High proportion of professional, managerial, students and retired
●●●●●	Oxfordshire 2	Rural, teaching practice, national digital innovator, national test site for GP digital innovations	●●	●●	Mixed population with high proportion of elderly living alone but also farmers, refugees and a traveller site
●●●●	South Wales 2	Suburban and semi-rural; local digital innovator	●●●●	●	High proportion of retired and chronically sick
●●●●	Greenwich 1	Urban, serving very socially and ethnically diverse population	●●●●	●●●●●	High proportion of young families and those in manual or unskilled jobs
●●●●	Plymouth 1	Urban but remote from tertiary care; high % of homeless; GPs keen on face-to-face	●●●●	●	Very high proportion in semi-skilled and unskilled jobs
●●●	West Wales 2*	Rural and extremely remote; has one main and two very remote branch surgeries open part-time; keen user of video technology	●●	●	Similar demographics to South Wales 1 but slightly less deprived
●●●	Glasgow 1	'Deep End' inner-city practice	●●●●●	●●	High proportion in unskilled or semi-skilled jobs or unemployed

●●●	Glasgow 2	Urban but remote from tertiary care	●●●●	●●●	Wide range of backgrounds and occupations
●●	Oxfordshire 1	Suburban, teaching	●	●●●	Serves mixed population including many low-paid hospital staff
●●	Watford 1	Urban digital leaders	●●●●	●●●●●	Wide range of backgrounds, affluent
●	Plymouth 2	'Deep End' inner-city practice, keen to prioritise care of those not digitally connected	●●●●●	●●	Much of population in semi-skilled jobs; high proportion of students
●●●	Oxfordshire 3	Urban; high proportion of patients with English as a second language; practice covers areas with high rates of deprivation. Staff wellbeing has suffered here particularly. Training practice. Has close links with district nursing and health visiting service.	●●●●	●●●●	Ethnically diverse practice; serves areas with high rates of deprivation; serves a mix of patients including those with chronic conditions who require home visits and learning disabilities. Staff are a mix of clinical, non-clinical, administrative and reception.
●●●●	North East London	Urban; high proportion of patients with English as a second language; practice covers areas with high rates of deprivation. Keen users of telephone consultations with a few services regularly using video consultations. Motivated to practice digital inclusion	●●	●●●●	Ethnically diverse practice; serves a mix of areas - some with high rates of deprivation across London; serves a mix of patients including those with chronic conditions and mental health issues. Staff are a mix of clinical, non-clinical, administrative and reception.

Sampling of patients for interviews and co-design workshops

In sampling patient participants, we will seek maximum variety in age, socio-demographic background, ethnicity and housing status (e.g. homeless or 'sofa-surfing', privately rented, owner-occupied) as well as digital literacy/confidence and type of illness/condition.

We will use three complementary approaches to recruiting patient participants: practice staff, social media groups, and snowballing. We will ask practice staff to invite patients to join the study. We anticipate that on average 7-8 per practice will join, including some with long-term conditions, identified as having complex needs, some who are keen to ensure continuity of care for themselves or a relative,

some with experience of possible early cancer symptoms (e.g. breast lump, rectal bleeding, persistent cough), and some with multimorbidity (perhaps in a care home). We will also recruit some additional participants via social media groups (e.g. diabetes patient groups, mental health groups, minority ethnic advocacy groups), by using Twitter and Facebook accounts, though this method will have less emphasis than practice recruiting. Finally, we will use targeted snowballing to extend our reach (e.g. a young and digitally confident person who is a second- or third-generation immigrant from a minority ethnic group may be able to connect us to a grandparent who speaks limited English and has few or no digital devices themselves). In the past, we have connected well with such people using the telephone, and also by making selected use of local face to face visits. Note also that whilst patient and advocacy groups undertake a lot of activity online, they have well-established ways of reaching digitally less connected members, including via local reps, telephone and post.

This approach will allow us to include a perspective on what it is like accessing and being cared for in participating practices as well as a more generic patient voice, including those who are keen on advocacy for particular condition or identity. We will ask practices, patient groups and snowball contacts to identify people whom they think may have found it challenging to consult remotely (including the mode of consultation), as well as those who are keen and confident and able to help advise and support others. Two of the participating practices (with whom we are already working) have already been able to find us homeless people to interview. Carers of people unable to give a full account of their own experience (e.g. those with cognitive impairment) will also be included in the sample. We will note advice given by one of our current PPI reps, that people being very digitally literate in certain respects (e.g. navigating Facebook or Twitter) but less digitally literate in others (e.g. navigating NHS advice sites or answering the questions on an e-consultation form).

Sampling of practice staff

Generally, staff to be interviewed or observed from each site will be identified *ad hoc* from informal conversations with practice managers or day to day interactions. Site staff will also help identify social care providers (care homes, domiciliary care agencies, housing/homelessness services) who support patients to access remote care.

Sampling of national-level stakeholders

During the current RBD1 study, we have been developing and maintaining a stakeholder map of key players in different sectors including national policymakers (e.g. NHS England and Improvement, Health Education England, Scottish and Welsh governments), NHS (including clinical directors, chief clinical information officers and informal digital champions), local government associations, industry (both large tech providers and start-ups, many of whom developed new products during the pandemic and made these available free or at low cost to the NHS), professional bodies (including Royal Colleges) and advisors (e.g. defence societies), regulators (such as National Institute for Health and Clinical Excellence [NICE], General Medical Council [GMC], National Care Forum, Medicines and Healthcare Devices Regulatory Agency [MHRA]), and third-sector groups including patient advocacy groups and shelters (e.g. MIND, Diabetes UK, Alzheimer's Society). This stakeholder map will continue from RBD1 to the proposed RBD2 study, and we anticipate it will grow as new partners come on board. All stakeholder

representatives are in email contact and have given informal interviews to explain their perspective and hear about the study.

c) Methods of Data Collection

HOW WE WILL WORK WITH PRACTICES TO BUILD RICH ETHNOGRAPHIC CASE STUDIES AND DO ACTION RESEARCH

We will assign a postdoctoral researcher-in-residence[30 31] to each practice. Each postdoc will be responsible for building a relationship with 2-4 practices and following those practices over the two years of the study, keeping in close touch with other postdocs and joining in monthly research meetings to compare evolving case studies and undertake cross-case analysis. In some cases, a doctoral student may be the researcher in- residence. In both cases junior researchers will be allocated and supported by at least one senior researcher and/or clinical academic. The practice case studies will be built iteratively and adaptively, depending on experiences and priorities that are salient locally. Broadly speaking, we will begin with an informal interview with a lead clinician or practice manager and then arrange interviews periodically with key practice staff, asking them to send us documents to build the case study (e.g. practice leaflets, annual reports, audits). In some cases, ethnographic participant observation of practice staff and patients will be used to better understand staff wellbeing and working conditions, and the clinical and administrative work involved, the role of the therapeutic relationship between patient and GP, and experiences of different modes of consulting.

The function of participant observation as a method is to embed the researcher within the community of study, through the mechanism of performing the same (or similar) daily activities as them (in this case, supporting some minor admin tasks). If required by the practise, in some instances an honorary contract for the assigned researcher-in residence will be used. By organising an NHS email and smart card, the researcher will be able to receive staff circulars and notifications of team meetings in real time, meaning they will be completely embedded into the practice and need not rely on staff recollections of what information or meetings might be relevant. The postdoc assigned to the practice will be their single point of contact with the research team, will work with a named contact in the practice and with their practice PPI rep (see PPI section), and will keep the practice informed of activities (such as virtual workshops) and new resources (e.g. guidance) as these appear. Where appropriate, postdocs will attend meetings via video link and undertake virtual ethnography.

Staff interviews will be a mix of semi-structured (with a list of question prompts) narrative (more conversational in format, encouraging the interviewee to talk about things that are relevant and high-priority for the practice). A key aspect of the narrative interview is seeking context and descriptive richness, often using case examples. Prompts for narrative interviews take the form of (e.g.) “can you tell me more about that?” or “what happened next and how did everyone react?”. In some instances, ‘Go-along’ interviews with be used. These may be synchronous; Researchers may observe a patient receiving care navigation support followed by a semi-structured interview with the care navigator, or asynchronous; This entails care navigators elucidating on the environmental, patient and service contexts through taking a series of photographs, notes and voice memos over the course of a month – such as showing the room or equipment used to connect a patient to a remote consultation. See below for detailed data management plan.

In some cases, staff will also be invited to share photos and pictures of their experiences of the pandemic and shift in working styles (photo elicitation), to help facilitate the interviews and enhance analysis. These will be photographs that the participant feels are particularly representative of their working experiences during the pandemic and will not include any personal information. This may include exclusively their working environment (i.e. their desk or workroom) and purposefully not include any persons, or it may include some public spaces that may include other persons. Should participants choose to share images with the researcher for research or dissemination purposes, this will be done securely and anything identifiable in the images will be blurred (including facial features, documents, or visible logos). We anticipate formally interviewing on average 10-15 staff per practice, on up to three occasions over the two years.

The researchers-in-residence will work ethnographically, building on our team's experience in both face-to-face and virtual ethnography (e.g. our MRC-funded work on methodology and theory of organisational case study research[32]). We have a particular interest in what Star called the ethnography of infrastructure.[33] We will use strategic ethnography: a focused and historically-informed approach to data collection and analysis that considers the biography of artefacts in organisations – that is, how they emerged, their inter-relationships and inter-dependencies, and what they are becoming.[34] These authors emphasise the potential of *"multi-sited ethnography to provide more robust, contexted understandings of complex objects"*. Artefacts (in this case, the hardware and software for phone, video and e-consultations and triage) are considered as evolving components of a complex, dynamic system. Our new digital maturity scale (described above) to guide purposive sampling of a wide range of contexts was the first step in this theoretically-driven ethnography.

In an additional work package (part of a DPhil program- EL) we will also explore how the inclusion of such 'technological artefacts' and the introduction of processes to implement their use has impacted on the relationship between GPs and their patients. Historically this has been a grounding principle of general practice, however there is evidence that declining rates of continuity combined with changing roles and use of digital approaches may be affecting this interaction. In three of the 11 practices one researcher-in-residence will purposively select, with the help of the practice team, a maximum of three patients in each site. Patients will be selected to ensure a range of demographic backgrounds, levels of digital literacy, and medical backgrounds are represented. These patients will be asked to keep an audio diary over a 18-24-month period. Such diaries can facilitate an exploration of participants' lived experiences in action and in situ, within a specific environment, and as such can capture rich, intimate qualitative data through participants' paralinguistic interaction with them.

The nine patients recruited specifically to explore the changing therapeutic relationship with GPs will be invited to take part in up to six individual interviews over the 18-24 month period(or until saturation), which may be narrative or semi-structured in design and may take place remotely or in-person as the patient prefers. For each of these nine patients we will also conduct up to six interviews over 18-24months with GPs or other members of staff with whom these patients interact. Additionally, will observe (and audio/video record where possible) up to three consultations for each patient with a GP. Swinglehurst et al. have shown the additional value video recordings can bring to an analysis of the patient-doctor interaction beyond direct observation, thus it is hoped this approach will add a richness to the patient-GP case studies (see Appendix C for details of additional work package)

Our study is mixed-method but primarily qualitative. Quantitative data will be used to support the qualitative analysis. Specifically, our analytic approach is to generate narrative longitudinal case studies of up to11 GP practices (the practice is our main unit of analysis). Quantitative data will be *part of the story* in each case study (and also part of an over-arching story of national context). This is likely to include: staffing levels, training audits, uptake data for face to face and remote analysed by demographics (e.g. age, gender, deprivation derived from postcode) and condition (e.g. proportion of asthma consultations undertaken by phone / video / face to face), aggregated patient survey data, at the practice level patterns of consultation activity recorded on the electronic booking systems (i.e. aggregated data will include frequency of appointment types (e.g. telephone, video, in person) and proportion of appointment types according to demographic categories (e.g. age, gender, ethnicity)), and at the level of the patient an examination of patient record data (with consent, working in situ at each practice), to retrospectively chart care trajectories and use of different modalities in the previous 24 months. These will be used both to build the case studies and inform the action research.

As well as collecting ethnographic data, we will apply the principles of action research[35] (for example, agreeing twin goals of local action and wider learning; taking an iterative and collaborative approach *with* practice members; establishing locally-appropriate ways to rapidly evaluate and feed into learning; and seeking participation and buy-in from staff and patients) to support each practice in its efforts to learn and develop around four goals (identified in our RBD1 study as high-priority for practices, patients and policymakers): a) optimising quality and safety of care; b) ensuring digital inclusion and providing equitable alternatives for the digitally excluded; c) maintaining staff wellbeing and training and supporting their staff; and d) overcoming infrastructural hurdles (both technical and regulatory). The action research component has two goals: local change and generalisable learning. The local change is a driver for deeper engagement and better data. The generalisable learning occurs through the generation of rich, case-based understanding which supports theorising; it also generates learning about the change process itself and what might help other (non-research) practices going forward.

As part of a package of wider support for practices, and given the value of inter-organisational networking and support in complex change,[36] we will offer a series of webinars, link them to a range of resources (e.g. clinical standards and guidance, patient resources) as we develop these, and set up an e-mail discussion list for key practice contacts. We will also, through our partner Thrive by Design, run two online co-design digital inclusion workshops for up to 40 people each; these are described below in a separate section. Data analysis methods are described below.

PATIENT INTERVIEWS

Depending on their choice, patient interviews will be undertaken by video, telephone or face to face (using approved infection control precautions as appropriate); based on our current experience in RBD1, we anticipate that the vast majority will be via video or phone but for example interviews of homeless people have been done at lunch clubs for the homeless in a private room. As with practice staff interviews (see above), patient interviews will be undertaken using a combination of semi-structured (list of questions) and narrative (conversational, seeking stories) format.

The aim of interviews (100 in all, repeated once during the study if patients are comfortable with that) is to capture the patient and carer experience of remote-by-default consultations across four key quality and safety areas (long term condition monitoring, getting an appointment with own clinician and maintaining continuity of a therapeutic relationship over time, presenting with symptoms that could

indicate early cancer, and care for complex multimorbidity). Two digital exclusion co-design workshops with patients and carers, described in a separate section below.

In some cases patients will also be asked to keep an audio diary over a 18-24-month period. They will be given a Dictaphone to record their experiences of the therapeutic relationship (see Appendix C for details)..

STAFF INTERVIEWS

Generally, staff interviews with be undertaken by video, telephone or face to face as required. They will follow a combination of semi-structured (list of questions) and narrative (conversational, seeking stories) format or 'Go-along' interviews (Synchronous: observation followed by a semi-structured interview or Asynchronous: using photographs, notes and voice memos to help explain the experiences of delivering social care provision).

FOCUS GROUPS

Social prescribers will be recruited through local Community Development trusts linked within two geographically and socio-economically disparate study sites (Plymouth and Oxford). The focus group will capture experiences and perspectives of offering digital support since the rapid shift to digitalised health and social care services. We will explore perspectives on whether digital support is integral to the social prescribing role and what infrastructural supports might be needed to embed this work into existing roles and responsibilities. We intend to conduct one focus group with up to 8 social prescribers online and one co-design workshop (online) on processes of care navigation aimed at people working in, or commissioning, social care settings (up to 15 people).

DIGITAL INCLUSION CO-DESIGN WORKSHOPS RUN BY THRIVE BY DESIGN

In our current study (RBD1), we have developed a good working partnership with a non-profit digital co-design agency called Thrive by Design (formerly mHabitat), who have taken on several new staff with a background in digital inclusion. Two Thrive by Design staff were involved in preparing the report *'Digital Inclusion in Health and Care'* from the Good Things Foundation.[37] Combining their longstanding expertise in digital codesign with their growing expertise in digital inclusion, Thrive by Design have developed a workshop-based methodology for designing for digital inclusion. The standard format they have been using during the pandemic is to run workshops in a virtual setting, using creative online design techniques and making use of virtual breakout groups and retuning to virtual plenaries. However, the methodology is not dependent on video conferencing. Other formats which can be used include individual telephone calls followed by a group telephone call, in which participants simply receive a phone call or dial a freephone number.

The detail of the Thrive by Design workshops will be worked out with our PPI group and practice contacts once the study starts, but provisionally we plan the following:

Two patient and carer co-design workshops, each up to 20 people, to address the design question: *"How can we best provide safe and effective care through remote consultations, and what measures do we need to put in place for people for whom remote consultations are unsuitable or unacceptable?".* One will be held virtually (Zoom). The other will include people less comfortable with Zoom, probably using

telephone in an asynchronous format (i.e. building a picture over several days/weeks). Insights from the workshops will be used by Thrive by Design to create a set of digital personas – a widely-used tool in the design of technology-aided workflows and practices.[38 39] A persona is a fictional character who encompasses features we need to think about when selecting technologies and designing and embedding technology-aided services. A digital inclusion persona embodies the needs of a group at risk of exclusion (e.g. Fred is a 35-yr-old heroin addict living in cardboard city who gets his methadone from an NHS clinic).

The personas and wider insights from the patient and carer workshops will be used to inform and enliven two additional digital inclusion workshops for practice staff. Both these will be held virtually and involve up to 40 people each (including clinicians, managers, administrators and PPI reps). Preparatory briefing materials will be sent out beforehand. Participants will work partly in small breakout rooms to think creatively about meeting the needs of the different digital inclusion personas. The outputs of these workshops are unlikely to be simple or universal solutions; we anticipate however that they will generate a) ideas for how (and for whom) to deploy existing remote technologies, b) ideas for additional off-the-shelf products which could enhance provision; c) ideas to inform design of new technologies. These workshops will be written up in a formal report to inform the system-level (cross-sector stakeholder) events and activities described below. A third multistakeholder workshop will involve those delivering social care.

ELITE INTERVIEWS

Elite interviews are crucial for fleshing out the macro level context of policy, regulation, public-private partnerships, financing and reimbursement, and more. We use elite interviews both to gather such data and to build strategic links for future dissemination (plus feed preliminary findings back to them). This is has worked well in the current RBD1 study e.g. our strong links with Digital First Primary Care Team at NHS England and TEC (Technology Enabled Care) teams in Scottish and Welsh governments, who periodically contact us about specific implementation challenges.

We will use a methodology developed and refined by Sara Shaw for interviewing national policymakers and other busy senior people. The sampling frame for these interviews will include all the groups set out in the previous paragraph.

We use a combination of about 10 initial quick, informal interviews (often very helpful to glean over-arching themes and issues) and 20 more formal semi-structured and narrative interviews. The former will not be audiotaped (and hence may provide opportunity for candid insights) but we will take contemporaneous notes. The latter will be taped and professionally transcribed. Notes and transcripts will be added to our dataset on NVIVO and used to provide wider context for the patient interviews and the practice case studies and help with cross-case interpretation and synthesis. These elite interviews serve a dual purpose – capturing multi-sector, senior-level perspectives but also oiling the wheels for subsequent dissemination and take up of findings.

CROSS-SECTOR STAKEHOLDER EVENTS

During RBD1 we have held four virtual cross-sector stakeholder events using a method developed by our partner The Nuffield Trust. Prior to the pandemic, these were generally held in person – for example in a half-day networking and briefing event in London. We have found that these events work well in a virtual

format which allow a wider range of people to attend. However, depending on how the pandemic plays out, we may revert to a face-to-face format for some of these workshops.

The format includes identifying a wide mix of stakeholders (including patient groups) whose perspectives are relevant to the chosen theme, making personal contact to invite and engage them, and preparing and circulating a preliminary resource pack (with key materials such as an agenda and objectives, a lay summary of our research, digital inclusion personas, an anonymised and fictionalised significant event). At the event, a short plenary is held to introduce the event, and then participants move into breakout groups to discuss an aspect of the issue. There may be one long breakout or two short ones. A final plenary brings groups together to report back, continue discussion and identify specific steps which need to be taken. Follow-up activities include meetings with particular stakeholders, convening smaller task and finish groups (e.g. to prepare a policy briefing), or planning a new stream of research. The stakeholder events will on the following topics which were highlighted in RBD1 as high-priority issues for practices: • Event 1 (month 7): Quality and safety of care • Event 2 (month 11): Overcoming digital inequalities. • Event 3 (month 16): Wellbeing, training and support of practice staff • Event 4 (month 20): Improving the infrastructure for a remote-by-default service.

Note: the above events start in month 7 because they build on the interviews and case study analyses we'll be doing in the first six months and on the digital inclusion co-design workshops in months 1-6.

d) Methods of Data Analysis

All formal interviews and ethnographic field notes will be transcribed and anonymised. These will be stored on an encrypted server at the University of Oxford which meets the highest standards of data security and information governance, along with other data including research diary notes from team members, key emails and correspondence, patient-facing materials such as websites and leaflets, facilitator notes and chat comments made during the digital inclusion co-design workshops, digital personas and workshop reports from Thrive by Design (formerly mHabitat), practice annual reports and audits, including quantitative data on uptake of different kinds of consultation, and material shared in the course of the action research (e.g. staff training plans, anonymised significant events). The national-level interviews and documents described in the next section will also be added.

We will enter our qualitative data onto NVIVO, which allows for easy storage, indexing, categorising and coding of qualitative data. As an initial step for familiarisation and data categorisation, we will develop and use a broad coding framework. This framework will allow us to easily identify sections of text on each of the core issues we are seeking to study (e.g. management of symptoms that could reveal early cancer; staff wellbeing); sub-codes will be created within this framework as needed. In addition, we will also consider each interview (and any subsequent interviews with the same person) in a more holistic way to identify key narratives or storylines (something that can be missed if the focus is exclusively on line-by-line coding of text). When studying stories, we ask questions such as "who are the characters?" (including who is being depicted as heroes, villains and victims), "what is the plot?" (what actions and events are significant, in what way are they surprising or unexpected, and what is the chain of causality), "who is the intended audience for the story?", "who is absent from the story?" and so on. Stories can, of course, include quantitative data (e.g. in a story of how uptake of video consultations in a particular practice first rose and then fell).

To initiate and build on practice-based case studies and cross-case comparisons, will use hermeneutic methods, in particular the constant comparative method described by Glaser,[40 41] where each new data item is added to a progressively richer picture of the whole. It tends to work particularly well when following a complex phenomenon over time. For each of the11 full case studies, we will combine the various data sources (interviews, ethnographic observations, documents, quantitative data) to build a rich narrative of the local emergence, current use and intended evolution (or replacement) of these artefacts over both short and long temporal scales, using our four marker conditions as windows to reveal the details of organisational processes and systems.

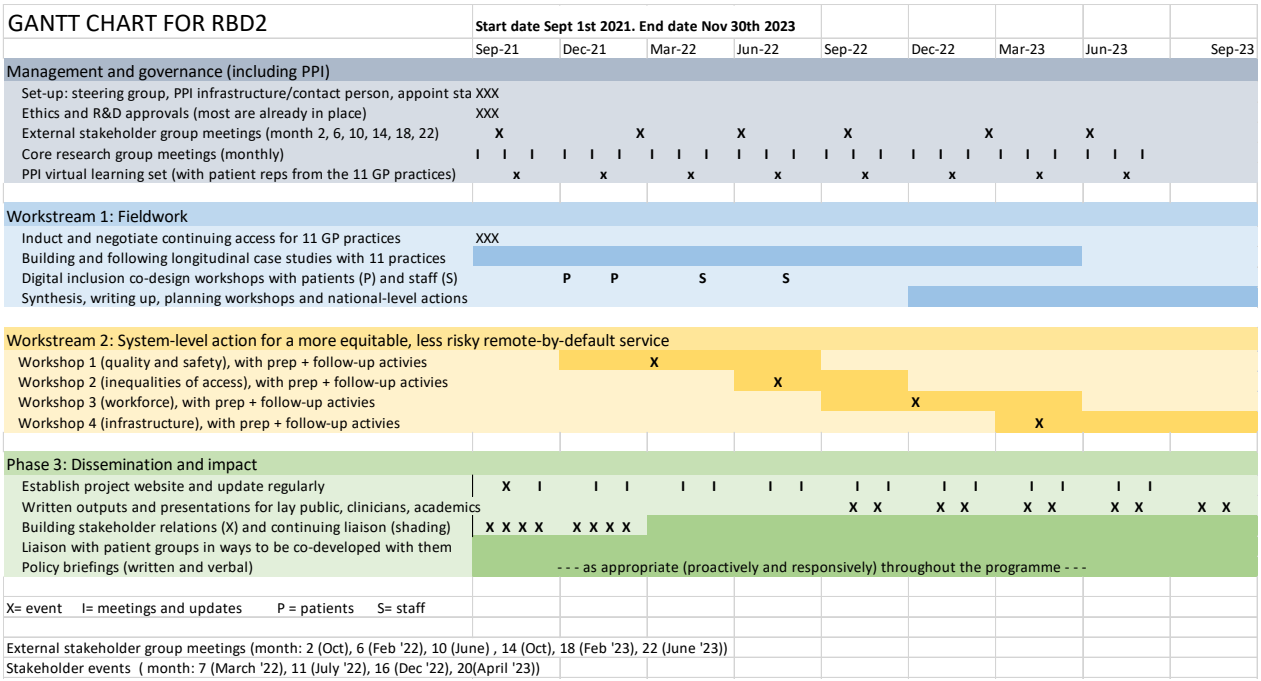
Six weeks into the study, the postdoc leading each case study will draw all the practice-specific data sources together to prepare an initial 'familiarisation document' to share with the research team (and with the practice itself). These will summarise the background and context for the 11 participating practices in full case studies and the issues and challenges each faces. These interim summaries will be discussed among the team in our monthly review meetings, leading to an emerging set of cross-case themes to explore. Narrative methods will be crucial for drawing out understanding of micro-level causal pathways which explain (e.g.) why something that 'succeeded' in one setting 'failed' in another. Narrative richness will also allow us to identify and test demi-regularities (things that tend to be the case in particular circumstances) and candidate theories which explain these. Key to cross-case analysis is reflection and discussion among the embedded researchers, and also among PPI representatives in the different practice settings. As the study progresses, we will add detail to both the individual practice summaries and also to the over-arching summary of the cross-case themes. Following the principles of the constant comparative method, we will seek disconfirming data (qualitative or quantitative data which would lead us to question our current understanding) and use these data to amend or refine our understanding. Additional participating sites will follow a similar approach, focusing on a 'deep dive' into cross cutting themes of digital exclusion and staff wellbeing and workflows, which will feed into the broader findings from other sites. These 'deep dive' elements form the basis of interlinked DPhil programmes of work.

The same approach will be taken for patient interviews and material from patient workshops. An initial summary document will be prepared through thematic and narrative analysis of the first few interviews, and this summary will be progressively refined as each additional interview is added.[41]

With both the practice- and patient-level analyses and also for the system-level interviews, a key step will be member checking. This will happen at two levels. Firstly, if an interview needs clarifying (e.g. if there are contradictory statements), we will send the interviewee a summary and illustrate this with quotes from the transcript, asking them to confirm or refine. Second, we will share an overall summary with all interviewees and invite comments which we'll discuss and use to refine or clarify our synthesis. In the PPI section, we described how we did this in RBD1 using two options: a Zoom webinar inviting participatory discussion and/or anonymous comments in the chat, and an offer to send a printed written summary.

e) Study Sequence and Duration

As per Gantt chart:



8. PARTICIPANT IDENTIFICATION

a) Study Participants

Study participants can be divided into three groups: patients, practice staff, national stakeholders. We consider each group below.

IDENTIFICATION OF PATIENT PARTICIPANTS

Patient participants from will be identified in three ways: by practice staff in participating practices; by snowballing from another patient who is already doing the study; and via patient organisations.

IDENTIFICATION OF PRACTICE STAFF PARTICIPANTS

Any and all staff working in a participating practice will be eligible to be interviewed if they wish.

IDENTIFICATION OF SOCIAL PRESCRIBERS

Community Development Trusts and other networks linked to our participating practices in Oxford and Plymouth will support the recruitment of social prescribers. Social prescribers will be eligible to take part in a focus group if they wish.

IDENTIFICATION OF NATIONAL STAKEHOLDER PARTICIPANTS

Any national stakeholder who is involved in remote care in general practice is eligible to be interviewed. In practice, because this study follows on from RBD1, we already have a large database of such stakeholders and will work from that.

b) Inclusion Criteria

INCLUSION CRITERIA FOR PATIENT PARTICIPANTS

Inclusion criteria for patient participants are as follows:

- over 18
- willing and able to provide informed consent
- diagnosed with any relevant condition (inc those considered to have complex needs), receiving care from participating services

- INCLUSION CRITERIA FOR PATIENT PARTICIPANTS who are specifically 'Underserved Patients' (low-income, elderly, limited English speakers who are more likely to be digitally excluded)
- over 18
- willing and able to provide informed consent
- diagnosed with any relevant condition, receiving care from participating services

And any two from the following:

- Low socioeconomic status (SES),
- limited English-speaker,
- >65 years old

INCLUSION CRITERIA FOR STAFF PARTICIPANTS

Staff will be included if:

- their job description (formal or informal) includes an aspect of implementing or using the technologies and/or services being investigated;
- they are willing and able to provide informed consent

INCLUSION CRITERIA FOR NATIONAL STAKEHOLDERS

National stakeholders will be included if:

- their job description (formal or informal) includes an aspect of planning or implementing the technologies and/or services being investigated;
- they are willing and able to provide informed consent

c) Exclusion Criteria

EXCLUSION CRITERIA FOR PATIENT PARTICIPANTS

- inability to read or speak English unless a relevant translator is available
- co-morbidity preventing participation

EXCLUSION CRITERIA FOR STAFF PARTICIPANTS

- No specific exclusions.

EXCLUSION CRITERIA FOR NATIONAL STAKEHOLDER PARTICIPANTS

- No specific exclusions.

9. STUDY ACTIVITIES

a) Recruitment

RECRUITMENT OF PATIENT PARTICIPANTS

Patient participants will first be approached by someone outside the research team (usually, a member of practice staff, but occasionally a member of a patient support group or a personal contact such as a friend or relative who has already done an interview with us). We will follow the standard conventions for ensuring that the person understands that participation is voluntary, they can withdraw at any time and personal details will be anonymised.

RECRUITMENT OF PRACTICE STAFF PARTICIPANTS

No staff member will be required to give an interview. Each practice will have an assigned researcher-in-residence and be asked to assign a practice named contact (e.g. lead GP, practice manager) to liaise with them. We will work through the practice named contact to ask who would like to give an interview about their experience of, and perspective on, remote by default services. We will aim to interview 10-15 practice staff including doctors, nurses, advanced nurse practitioners, managers, receptionists, pharmacists and so on. We will follow the same methodology as our ongoing RBD1 study where we 'snowball' from one interviewee to another by asking them to nominate someone else in the practice who they think would provide a contrasting perspective.

For observation of group meetings in the practices, the researcher will share the participant information sheet with members of the group well in advance of the first meeting and collect verbal consent from the group before taking de-identified notes. The agreement of the group to be observed for the study will be recorded in minutes of the meeting. For observations taking place in public areas of the building, for example, the waiting room, reception area, staff break room or corridors, a senior member of the practice will have already agreed for the practice to participate. Posters, giving advanced warning of observation will be on display in advance to the practice site. No action is required to opt-in to observations in public spaces. There is a robust opt-out policy should individuals wish not to participate (see Section b).

For observations taking place in consultation rooms consent will be sought directly from each individual in the room (member of staff and patient).
For 'Go along' interviews regarding social care provision we are not recruiting patients, but patients may be present in synchronous go-along interviews. While our focus is on the delivery of digital care navigation work,

we will be sensitive to the need for patient privacy and will ask care navigators to avoid revealing any patient identifiable details (e.g. not showing patient's records, or revealing their full name). Care navigators will inform patients/people they are supporting that they have a researcher present either in-person or virtually.

RECRUITMENT OF NATIONAL STAKEHOLDER PARTICIPANTS

We already have strong links to national stakeholder organisations (e.g. a number of representatives from NHS England, Scottish Government and various Clinical Commissioning Groups sit on our RBD1 External Advisory Group), and a spreadsheet of stakeholders. Commencing with these people, we will continue to sample interviewees to build our understanding of the national picture. Where appropriate we will use snowballing (i.e. ask interviewees to nominate another senior stakeholder and introduce us by email). We will also use 'cold' approaches (e.g. emailing the person) but in our experience a personal introduction is usually more effective at this level. No stakeholder will be put under pressure to do an interview.

RECRUITMENT OF SOCIAL PRESCRIBERS

Community Development Trusts and other social prescribing networks linked to two of our participating practices (Oxford and Plymouth) will support the recruitment of social prescribers. Social prescribers will be eligible to take part in a focus group if they wish.

b) Informed Consent

Where face-to-face meetings are appropriate and safe (e.g., considering the situation around the COVID-19 pandemic) and a researcher will be present: 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 no less than: 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. The researcher will clearly state that participation is voluntary, and that the participant is free to withdraw from the study at any time for any reason without prejudice to future care or affecting their legal rights, and with no obligation to give the reason for withdrawal.

Where face-to-face meetings are not appropriate, patients, staff or stakeholders who have communicated that they are willing to participate in the study will be contacted by a member of the research team by telephone or video call as per their choice. Participants will have the opportunity to ask any questions. After a suitably in-depth explanation, the researcher will clearly state that participation is voluntary, and that the participant is free to withdraw from the study at any time for any reason without prejudice to future care or affecting their legal rights, and with no obligation to give the reason for withdrawal. The researcher will then read aloud the consent form and ask the participant to provide verbal consent for each point on the form, which the researcher will record. The researcher will record their own name and the participant's name on the consent form, and then sign and date the form. A copy of the consent form will be sent to the participant by secure post with recorded delivery in a sealed envelope marked as "confidential", or as a password encrypted attachment by Oxford University email with subject mentioning "confidential"; the password will be emailed separately from the attachment.

For patient participants, a copy will be added to their medical notes. The original signed form will be retained by the research team.

In observing group meetings, it is technically difficult to provide written or verbal consent forms to all participants, therefore, verbal consent will instead be taken from the group as a whole before taking notes. Some groups may decide to take a vote. With others, the chair/facilitator may ask members of the group if they have any objections. We will respect the overall decision of the group however it is made. The observations will not begin until the meeting after the decision has been made to allow us to do so. The research will collect verbal consent from the group before taking notes. The agreement of the group to participate in the study will be recorded in minutes of the meeting. The name on the verbal consent form will likely be the chair/facilitator of the group or other senior staff member who the group are happy to nominate. For group meeting observations, the researcher will seek verbal permission at the start of each new meeting, so as new members of the team are able to be informed and opt-out should they wish. There is a robust opt-out policy should individuals wish not to participate.

In observing in common areas of a practice, it is technically difficult to provide written or verbal consent forms. A senior member of staff will have already agreed for observations to occur on a given day. Advance notice posters will be put up throughout the practice in the two weeks before, and for the duration of, data collection at a given site. Copies of the participant information sheet will also be available from reception and deposit boxes in the waiting room and staff break room. If anyone is not happy to be observed, they will inform the researcher verbally or by using provided visual identifiers, and they will be excluded from analysis.

For observations of staff and patients in a consultation room (i.e. in person, over video, or phone consultation), verbal consent will be sought from all participants. Anywhere where verbal consent is taken the consent form will be read out loud. The participant consented will have their name on the form, they will verbally indicate consent to each tick box, which will be initialled by the person taking consent. The verbal ICF will only signed by the person taking consent (not the participant). A copy of the consent form will be sent to the participants by secure mail or electronic transfer.

For group meeting observations and consultation observations, if after reading the participant information sheet and further discussions at the start of the meeting, a particular individual is not happy to be observed, we will offer to ensure that no quotes from that individual are written down. If an individual is not satisfied with this solution, then the researcher will agree, for the person, to exit the meeting.

For Go-along' interviews care navigators will consent to be observed and/or interviewed. Whilst it is the care navigator who will be the research participant, we want to ensure that patients/people being supported by the care navigator are treated with consideration and respect and given the opportunity to decline to be involved in the study if they chose. To enable this, care navigators will inform patients/people they are supporting that they have a researcher present either in-person or virtually. Patients/people being supported will be 18 years old or older and will be assumed to have capacity. Researchers will wait outside or will not be admitted to an online meeting until the patient has agreed to the researcher accompanying the care navigator. Care navigators will seek permissions from informal carers where available and will also seek an indication that the carer is comfortable for the researcher to accompany the care navigator where despondency, disengagement or signs of distress will interpreted

as a withdrawal from participation. Trained researchers will be sensitive to their presence in the room and will remove themselves at any point if the patient appears or if asked to by the care navigator.

The person who obtained the consent must be suitably qualified and experienced and have been authorised to do so by the Chief/Principal Investigator.

c) Screening and Eligibility Assessment

Initial eligibility will be decided using the Inclusion and Exclusion criteria. Each participant must satisfy all criteria stated (see Inclusion Criteria and Exclusion Criteria). As cases accumulate, the research will seek out patients, staff and other stakeholders whose circumstances and perspectives provide a contrast to those already included to achieve maximum variety in clinical, social, ethnic and personal circumstances and health/digital literacy.

d) Data Collection

In most cases, interviews will be conducted by a secure video connection (e.g. Zoom or Microsoft Teams) and audio-recorded by the researcher. Those who prefer a telephone interview will be accommodated, using an additional recording device. Where face-to-face contact is possible and safe, and where this is preferred, members of the research team will use an audio recorder in the GP surgery or the patient's home. We will use the recording option in Zoom or Teams and transfer the data (if necessary) to the University of Oxford using FILR, the cloud-based management system.

Documentary material for asynchronous 'Go Along' Interviews (photographs, voice memos or notes) will not be collected or stored by researchers. Photographs will not involve persons in view but will for example, show the room or equipment used to connect a patient to a remote consultation. These documents and recordings will be presented by the care navigator during a virtual research interview and will serve as prompts for discussion. This documentary evidence will not be transferred onto the research team as data it will only be shown during an interview as a cultural probe for semi-structured interviews.

Observed consultations will be video-recorded using a digital recording device and the recording will be transferred directly to the University of Oxford as above. Similarly, participant audio-diaries will be collected by the patient on an individual hand-held, password-protected digital voice recorder and transferred as soon as is practically possible to the research team during site visits to be stored as above at the University of Oxford.

At the practice level aggregated data will be collected on the mode of consultation. This includes frequency of appointment types (e.g., telephone, video, in person) and proportion of appointment types according to demographic categories (e.g. age, gender, ethnicity). This data will not include patient level information. This data will be provided by the GP practice team and securely sent to the research team in accordance with Oxford University data security policy.

Data collection at the patient level will include an examination of patient record data (with consent, working in situ at each practice), to retrospectively chart care trajectories and use of different modalities in the previous 24 months. We will extract minimum data from patient records, focusing on type of

consultation over time and recording relevant diagnostic and therapeutic information to aid understanding about how complexity shapes decision making about modality. The medical information will be provided to the research team by the GP practice team once informed consent from the patient has been provided. This will include the clinician's written notes taken during the patient's consultation. The data will be securely sent to the research team in accordance with Oxford University data security policy.

e) Discontinuation/Withdrawal of Participants from Study

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 interview, but choose for their consultation to still be used in analysis. Participants may also withdraw their consent, meaning that they wish to withdraw from the study completely.

According to the design of the study, participants may have the following two options for withdrawal;

1) 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. Their data will be anonymised and no further data would be collected after withdrawal.

2) 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 addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including, but not limited to:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with study requirements (e.g., the patient decides that they do not want parts of the consultation recorded, such as the physical examination)

In cases where participants are withdrawn from the study, all data from that participant collected up to that point will be deleted and excluded from the study if requested. Additional participants will be recruited to meet the sample size requirements set for the study.

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

f) Definition of End of Study

The end of the study is the point at which all study data has been collected by the University researcher.

g) Description of Analytical Methods

This is a mixed-methods study, combining several methodologies (qualitative interviews, document analysis, synthesis of quantitative data on practice performance and mode of consultation) but oriented to producing rich longitudinal case studies of GP practices introducing remote care, contextualised in a national narrative of relevant policy and wider issues. Using the PERCS framework (Figure 1) as a guide, qualitative data will be analysed thematically and quantitative data summarised descriptively before using narrative as a summarising and synthesising tool. Cross-case analysis will pick up the key cross-cutting themes of quality and safety of care, inequalities of access, workforce (including wellbeing, training, and mismatch between capacity and demand), and infrastructure (technical, regulatory, human). Further details can be supplied.

10. DATA MANAGEMENT

a) 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.

b) Data Recording and Record Keeping

We will follow participant wishes on whether or when to anonymise data as recorded in the informed consent form (see 9.b. *Informed Consent*). If necessary, video-recordings will be pseudonymised using video editing software (Adobe Premiere Pro CC, Adobe Inc.) as soon as either (a) recordings are downloaded from the camcorder or (b) recordings are downloaded from FILR, the cloud-based data management service (see. We will apply a visual filter and remove any names and mask voices from the audio track. Where photographs are taken or shared and intended to be used as part of the public research findings, verbal permission will be sought from any subject(s) in the photograph. Where permission is not given, or it is not possible to obtain permission from subjects in the photographs, then those photographs will be redacted from public use or subjects within photographs will be anonymised using blurring software upon secure receipt of them. Aggregate data received from GP site (i.e., on mode of consultation) will not include patient level data. Patient level data (with consent) will be recorded either by i) researcher is given access to records and takes notes, or ii) GP site sends summary data (minimally required) securely to Oxford and stored as described below.

Any ambiguous or difficult cases will be referred to the NDPCHS Information Governance Committee.

The data will be retained by the CI at the NDPCHS, University of Oxford, and onto password protected storage on University computers/MSDIT servers, where personal details will be stored securely, separately from the research data. ID numbers will be stored in separate password protected digital folders (not linked to the study data files).

Personal data such as contact details that could identify a participant, will be destroyed as soon as it is practical to do so and no later than 12 months after the end of the study.

Pseudonymised transcripts of interviews and consultations may be kept for up to 15 years. If patients provided informed consent for their data to be used for re-analysis/teaching (see Informed Consent), we will keep video-recordings of their consultations for up to 15 years to write additional papers, reports, and support teaching courses. Once these are completed, video and audio data will be destroyed.

11. QUALITY ASSURANCE PROCEDURES

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

12. ETHICAL AND REGULATORY CONSIDERATIONS

a) Declaration of Helsinki

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

b) Approvals

Following Sponsor approval the protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), 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.

c) Other Ethical Considerations

The answers participants provide during the interview or information revealed during the observation of a consultation or audio diary may lead to disclosure of information that raises concern about a person's wellbeing or care. If this happens, the researcher will raise this with one of the chief investigators who will use professional judgement on a case by case basis but would normally contact the participant for further discussion and suggest the patient contact their GP. Where this concerns a staff member, the CI may suggest they contact their occupational health services department. However, each case will be dealt with on its particular merits.

It is possible that the staff might disclose evidence of dangerously poor practice (either their own or colleague/ institution's) during interview. Should we suspect or detect poor practices we will immediately discuss this within our core team (which includes practising clinicians) and if necessary communicate straight away with the relevant regulatory authority.

The involvement of practices in the RBD2 study will require some time input (for which practices are being paid). It is possible that heavy workload may make their participation stressful, but we anticipate

that the collaborative learning and webinars will help make the remote by default experience *less* stressful.

There are risks to objectivity by granting honorary NHS status to researchers. While relationships between the researcher and practice staff is enhanced, the interpretation of events may be affected and result in biased reporting. However, this risk can be minimised by the researcher regularly discussing findings with independent academic colleagues in the study who can challenge the researcher to think through alternative perspectives.

d) Reporting

The CIs 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.

e) Participant Confidentiality

The research team will safeguard the privacy of participants' personal data. This dataset, especially the audio and video files, raises confidentiality issues. The processing of the personal data of participants will be minimised by making use of a unique participant ID number on all study documents and any electronic database, with the exception of the consent form and CRF, where participant initials may be added. All documents and electronic files will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the UK General Data Protection Regulations (UK GDPR) and Data Protection Act 2018, which requires data to be anonymised as soon as it is practical to do so.

f) Expenses and Benefits

In general participants (staff and cross- stakeholder) will not be paid for time or inconvenience for participating in the research, and there are no expenses anticipated as there is no travel for participants. Patients who participate in interviews will be offered a voucher to the amount of £10 per completed interview. The NIHR's (2020) guidance on improving the inclusion of underserved in clinical research cites that lack of effective incentives is a key barrier to research participation. As the inclusion of underserved patients is of key interest to the research. The rights and dignity of the participant will remain intact, and the consent process will ensure participants understand their rights to withdraw their participation during and after the interview. Reference to the incentive in the information will make clear that it is just a small compensation for the inconvenience of taking part. Separately, we will pay INVOLVE rates (£150 per day) honorarium for patient participation in the PPI groups.

13. FINANCE AND INSURANCE

a) Funding

The study is funded by National Institute for Health Research as part of its Health Service and Delivery Research stream, awarded to Prof Trisha Greenhalgh (CI).

b) Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment that is provided.

c) Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

14. 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 National Institute for Health Research. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

15. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Not applicable

16. ARCHIVING

At the end of the study, electronic files containing the pseudonymised data will be transferred to an encrypted hard drive and will be stored securely in the Nuffield Department of Primary Care Health Sciences (NDPCHS), University of Oxford for up to 15 years. This will be in line with local SOPs. Access to this will be limited to members of the research team.

After the archiving period has ended, the paper documents and electronic files will be confidentially and securely destroyed in line with the Data Retention and Deletion Policy at NDPCHS.

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APPENDIX A: STUDY FLOW CHART

REMOTE-BY-DEFAULT 2: THE NEW NORMAL?

AIM: To inform a more fit-for-purpose remote-by-default model which takes account of a) quality and safety, b) equity and inclusivity, c) staff wellbeing and training, d) technical and regulatory infrastructure

RESEARCH QUESTIONS:

1. How can we make remote care better and safer (including designing for digital inclusivity)?
2. How can we balance remote options with traditional face-to-face care for those who need it?
3. How can we optimise workload and meet the training and wellbeing needs of general practice staff?
4. What are the infrastructural challenges of remote services and how might they be overcome?

STUDY DESIGN: Mixed-method, multi-site case study in diverse localities across UK, with co-design workshops and engagement activities at patient, practice and system level

Governance and groundwork

Governance
- Ethics / R&D
- Intersectoral advisory group
- Patient / lay advisory panel

11 general practices
- Gain access
- Build working relationships
- Identify and pilot data sources

National stakeholders
- Elite interviews
- Maintain links

DATA SOURCES & METHODS *Adapted to virtual as needed*

PRACTICE LEVEL
Longitudinal case studies of 11 practices using interviews, documents (e.g. policies, protocols, workload), and strategic ethnography.

PATIENT LEVEL
100 narrative interviews, incl. care navigators
Engagement via local and online patient / lay groups
4 digital inclusion co-design workshops

SYSTEM LEVEL
36 elite interviews
8 social prescribers
National-level documents

ANALYSIS, focusing on key cross-cutting themes

- Access & triage
- Digital & wider inequalities
- Quality & safety of care:
  - Continuity of care
  - Timely diagnosis of serious illness
  - Long-term conditions
  - Multi-morbidity and complex needs
- Workforce: workload, wellbeing & training
- Technologies & their associated infrastructure
- Planetary health

DELIVERABLES


Local learning and change, driven by patient experience


Resources (e.g. digital personas) to support inclusive service redesign


Input to policy via in-reach, outreach and ongoing links


Guidance for staff, patients and social care providers


Publications for a range of audiences

DISSEMINATION: System-level action for a high-quality, equitable and safe remote genera practice service

4 cross-sector stakeholder events (each involving ~50 people) to further explore key themes in emerging data → Follow-on activities with macro actors (e.g. policy, regulators, industry, patient / user groups) → Collaborative input to the complex, multifaceted challenge of delivering digital services and mitigating inequality

APPENDIX B: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	1.1		Stuart Faulkner	Administrative changes and changes to reimbursement for patient interviews and possibility of honorary contract status use for researchers
2	2.0		Stuart Faulkner	Addition of study sites. Addition of study participants Addition of methods: photo elicitation, additional ethnographic observation Changes to study documents
3	3.0		Stuart Faulkner	Addition of study participants Addition of methods: Focus group, 'Go-along' interviews, quantitative data collection at practice and patient level, Changes to study documents, new study documents added, changes to inclusion criteria, modified end of study date.
4	4.0		Stuart Faulkner	Addition of study participants Addition of methods: Audio diary New study documents added, modified end of recruitment date. Addition of investigator to protocol.

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee, and HRA (where required).

Appendix C

Additional work package for related DPhil program of work (Emma Ladds), funded separately by a Wellcome grant.

'What is the role of the therapeutic relationship in 'modern' General Practice'

Background: The relationship between patient and doctor has long been an important part of medicine (Balint 1956, McWhinney 1998). Such interactions have been celebrated for their richness, humanity and therapeutic potential. High-quality relationships can lead to greater patient and professional satisfaction, concordance and efficiency (Greenhalgh and Heath 2010), and continuity of care is associated with improved health outcomes (Pereira Gray 2017).

Recent years have seen great changes in UK primary care, with rapid incorporation of digital, remote, and asynchronous patient interactions within increasingly multidisciplinary, strained systems. The demands of these changes on patients, clinicians, and teams have been exacerbated by the global pandemic, declining levels of GPs, rising patient demand, and an ageing, complex patient population. Preliminary data collected through the Remote-by-Default 2 (RbD2) study suggests these changes have impacted the interactions between patients and primary care teams and their relationships.

Aim: To explore the therapeutic relationship at a time of rapid change and system stress in general practice, with particular emphasis on the shift to remote models of care.

Research questions: 1. How have changes in UK general practice, including digital, remote, and asynchronous patient encounters, system pressures and workforce alterations affected the therapeutic relationship? 2. What are the implications for how we might best support patients, clinicians and practices, given the current constraints?

Method:

Practice selection: Three diverse general practices from those in main the RbD2 study have been selected: one in rural Oxfordshire (relatively affluent and digitally progressive); one in inner city Plymouth (with high levels of deprivation and associated challenges); and one in South Wales (where a high proportion of the practice population are Welsh speakers).

Participant selection: From each participating practice, 3 patients who represent a range of contexts and likely different experiences will be selected. We aim to capture a range of ages, demographic characteristics, medical conditions, and specific needs and will include those with 'routine' primary care issues e.g.: chronic diseases alongside those with additional complexities or vulnerabilities e.g.: mental health problems, complex psychosocial factors, or multimorbidity. It is expected that patients will be recruited separately from the main RBD2 study. However, should an appropriate patient be willing to be involved in the main study and this sub-study, they will be consented separately for both studies.

Data collection: We will use an ethnographic approach to follow participants through encounters with their primary care team over 24 months (or earlier if data saturation is achieved). We will use pre-existing observation data from the main RbD2 study to provide context and will undertake further observation during site visits, including sketches of the practice(s) and setting(s). We will also:

- Invite each patient to keep an audio diary (with prompts to encourage reflections) about their encounters with their primary care team using an individual dictaphone.
- Invite each patient (and the relevant GP or staff member) to participate in up to 3 observed and/or video recorded consultations over the 2-year period.
- Invite each patient to take part in up to 6 individual interviews over the 2-year period, which may take place remotely or in-person as the patient prefers
- Invite GPs or other staff members with which each patient interacts to take part in up to 6 individual interviews over the 2-year period, which again may be remote or in-person.

Additionally, patients will be asked to allow the research team to review their electronic patient record over the 2-year period to allow an understanding of the practice processes and communications, which have resulted in encounters and contacts.

Analysis: We will build a case of each patient, looking at a) intersubjectivity and therapeutic dialogue, narrative medicine, therapeutic 'emplotment' (becoming trapped in one's story), and 'presence'— a concept that considers how well interactions are achieved in the virtual environment. To study the wider practice and system context, theories from social science of healthcare organisations (e.g., hidden work or task shifting) will be used. If there is a therapeutic relationship with one or more clinicians, this/these will be explored as they unfold over time. If there is not, we will explore how this absence impacts the patient's care over time. The technique of 'zooming out' from the individual case to consider how the practice- and system-level contexts have enabled or constrained the provision of relationship-based care and how this may have resulted in generating failed demand or other inefficiencies will help in analysis. Synthesise across cases will draw lessons about what the modern therapeutic relationship is, how it can be supported, and what the implications are for patients, primary care clinicians, practices and the healthcare system.

Dissemination: Findings will be shared with patient and practice participants and take account of their responses when finalising my interpretation and writing up. We will then disseminate the results through academic papers, conference presentations and more innovative ways to get a wider and deeper engagement with GPs, GP trainees, GP practices and the wider patient population. These methods will be developed in collaboration with the RCGP's Patients and Carers Partnership Groups (PCPG) and representatives from the GP trainees' Associates in Training (AiT) Group e.g.: blogs, webinars, or cartoon stories.

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