TITLE PAGE

Study title: Facilitating access to online NHS primary care services - current experience and future potential

Short study title: Facilitating access to online NHS primary care services

Protocol: Facilitating access to online NHS primary care services - current experience and future potential: Patient survey and qualitative study
Acronym: Di-Facto

Protocol Version Number: 1.3 15-02-2022

Research Reference Numbers:

- **IRAS Project ID:** 289425
- **Lead sponsor number:** L01886
- **Co-Sponsor's number:** 1920/27
- **Research registry unique identifying number:** researchregistry6523

HRA PROTOCOL COMPLIANCE DECLARATION:

This protocol has utilised the HRA protocol template Version 1.1 March 2016 - Qualitative Protocol Tool

FUNDED BY NIHR | National Institute for Health Research

This study is funded by the National Institute for Health Research (NIHR) [Health Services and Delivery Research Programme 128268]. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

SIGNATURE PAGE

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 agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

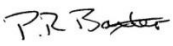
I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol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

For and on behalf of the Study Sponsors:

Signature: Date: 17/03/2022

Name (please print): **Vivienne Shaw**
Position: **Head of Research & Development**
Cambridgeshire and Peterborough
Clinical Commissioning Group

Signature: Date: 17/03/2022



Name (please print): **Pam Baxter**
Position: **Research Governance Manager**
Research Ethics and Governance Office
University of Exeter

Signature: Date: 17/03/2022

Name: **Professor John Campbell**
Position: **Chief Investigator**

LIST OF CONTENTS

KEY STUDY CONTACTS

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Project Manager	Ms Rachel Winder (RW) Research fellow University of Exeter Primary Care Research Group Smeall Building, Magdalen Road Exeter EX1 2LU 01392 726095
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Funder(s)	National Institute of Health Research
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	Dr Jenny Newbould Research Leader Health and Wellbeing RAND Europe Westbrook Centre, Milton Road Cambridge CB4 1YGnewbould@randeurope.org Tel number: 01223 353329, Ext 2536
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	Dr Emma Cockcroft Research Fellow in Patient and Public Involvement University of Exeter Medical School PenARC E.J.Cockcroft@exeter.ac.uk 01392 722764

KEY STUDY CONTACTS (continued)

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	Mrs Christine Marriott Patient representative Patient and Public Involvement University of Exeter Medical School PenARC cmarriott1@sky.com
	Dr Caroline Jenkinson Research Fellow University of Exeter Primary Care Research Group Smeall Building, Magdalen Road Exeter EX1 2LU C.Jenkinson@exeter.ac.uk
	Dr Jo Parsons Research Fellow Unit of Academic Primary Care University of Warwick Gibbet Hill Coventry CV4 7AL Jo.Parsons@warwick.ac.uk
Committees	**Steering group Committee:** Dr Amrit Takhar amrit.takhar@nhs.net Rev David Parkes revdavid.parkes@googlemail.com ; Dr Jeremy Horwood j.horwood@bristol.ac.uk Associate Professor Gary Abel (as statistician) (details as above)

STUDY SUMMARY

Study Title	Facilitating access to online NHS primary care services - current experience and future potential: patient survey and qualitative study
Short title/	Facilitating access to online NHS primary care services/Di-Facto
Study Design	A mixed methods approach is being employed consisting of interlinked work packages: 1) A scoping review will characterise the different approaches to digital facilitation and establish the current evidence base about the effectiveness and cost-effectiveness of different approaches to digital facilitation. 2) A survey of 500 practices with analysis of the responses, linking to data from the national GP Patient Survey. 3) Surveys of 12,000 patients from 60 practices with analysis of the responses, linking to findings from the practice survey. Additional surveys of 3000 patients living with mental health conditions from 15 practices. 4) Qualitative research exploring the potential benefits and challenges associated with different models of digital facilitation, comprising of focused ethnographic case studies in general practice and interviews with wider stakeholders. Additional interviews with 16-20 patients living with mental health conditions. 5) A synthesis of learning from other elements of the study and development of a framework to inform future evaluations. 6) Patients and the public will be involved throughout. **This protocol concerns the elements 3 and 4 of the study, i.e. the patient survey and qualitative exploration as these require HRA regulatory/ethical approval.**
Study Participants	For the patient survey study participants will consist of 12,000 patients randomly selected (up to 320) patients from each practice that participated in the practice survey). A boost sample of 3000 mental health patients who either have a code for anxiety or depression in their medical records or received a recent anxiolytic or antidepressant prescription for anxiety or depression in their medical records, will be randomly selected (up to 220) from 15 practices. The qualitative element will include two components: 1) An interview study with key stakeholders around initiatives to increase the use of online services in general practice. 2) Focused ethnographic case studies in general practices. This will include document review, patient and staff interviews and non-participant observations. Additional interviews with 16-20 patients with mental health conditions will be included at 3-4 practices.
Planned Size of Sample	Patient survey: 12,000 patients invited from approximately 60 practices. 3000 patients living with mental health conditions from 15 practices. Qualitative investigation: 6 to 8 practices will form case studies where we will conduct ethnographic fieldwork. This fieldwork will include interviews (3-4 per practice) with staff (GPs, practice managers and practice staff), the number will vary for each case study, according to size of practice, model of facilitation and who is involved and patients/ carers from each practice. The number of interviews will vary at each case study site, according to size of practice and extent of digital facilitation occurring. Additional interviews with 16-20 patients with mental health conditions will be invited from 3-4 of these practices. We are also conducting a series of interviews with 14-18

	national and regional stakeholders from patient groups and key decision makers in policy and practice.
Follow up	Not applicable
Study Period	01/06/2020 to -31/12/2022
Research Question/ Aims	The overarching aims of this programme of research are to: Identify, characterise and explore the potential benefits and challenges associated with different models of digital facilitation currently in use which are aimed at improving patient access to online services in general practice in England. Use the resulting intelligence to design a framework for future evaluations of the effectiveness and cost-effectiveness of such interventions.

FUNDING AND SUPPORT IN KIND

FUNDER	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre University of Southampton Alpha House, Enterprise Road Southampton SO16 7NS Contact: Donna White Research Manager (Monitoring) Southampton NETSCC NIHR Evaluation Trials and Studies Coordinating Centre (NETSCC) 023 8059 7472 donna.white@nihr.ac.uk	£800,833.40 (plus additional £223,000.00 for 6-month costed extension and additional work focusing on patients with mental health conditions)

ROLES AND RESPONSIBILITIES

Study Sponsor: The study sponsors (Cambridgeshire and Peterborough CCG as lead and University of Exeter as co-sponsor) will ensure that the research team has access to resources and support to deliver the research as proposed and that responsibilities for management, monitoring and reporting of the research are in place prior to the study commencing. The sponsor will ensure that there is agreement on recording, reporting and reviewing significant developments as the research proceeds and approve any modifications to design, obtaining requisite regulatory authority approval.
The sponsor will assume responsibility for operating the management and monitoring systems of the research. Prior to the study commencing the sponsor will be satisfied that:

- The research will respect the dignity, rights, safety and well-being of participants and the relationship with healthcare professionals.
- Where appropriate the research has been reviewed and approved by an NHS Research Ethics Committee and/or the Health Research Authority Approval Programme.
- The Chief Investigator, and other key researchers have the requisite expertise and have access needed to conduct the research successfully.
- The arrangements and resources proposed for the research will allow the collection of high quality, accurate data and the systems and resources will allow appropriate data analysis and data protection.
- Organisations and individuals involved in the research agree the division of responsibilities between them.
- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted to significant developments during the study, whether in relation to the safety of individuals or scientific direction.
- There are arrangements for the conclusion of the study including appropriate plans for the dissemination of findings.

The sponsor plays no role in the design of this study, and will have no role in data analysis or interpretation, or writing up of findings of the study.

Study Funder: The research funder (NIHR) has the responsibility to ensure that there is a proper use of the funds they control. The Funder has reviewed the study plan of the research and established that the research is worthwhile, of high scientific quality and represents good value for money. The research funder has assessed the experience and expertise of the Chief Investigator, other key researchers on the programme and has deemed that there is appropriate infrastructure for the research to be carried out.

The funding review process provided independent peer-reviewed feedback on the design of the programme. The funder plays no further role in the design of this individual study and will have no role in data analysis or interpretation, or writing up of findings of the study. The funder has no role in the decision to submit for publication.

Project Management Group (PMG): A Project Management Group (PMG, Chair John Campbell) is overseeing project delivery, financial oversight and leadership. All co-investigators provide specialist input to the PMG, which includes meeting monthly by video teleconference. Project Manager (Rachel Winder) manages the day-to-day coordination of the programme. Our lead sponsor representative (Vivienne Shaw) provides HRA and project management guidance. The PMG has PPI representation (Christine Marriott), and PPI coordinator (Emma Cockcroft) chairs the PPI Advisory Group and directly reports to and from the PMG. To ensure satisfactory progress/ achievement against milestones, work package leads report to the PMG. Each work package has a named lead senior researcher who oversees all aspects of that work package and report to the PMG.

Di-Facto Steering Group: A steering group will meet on at least four occasions, to coincide and coordinate with whole-team PMG video or face-to-face meetings. The steering group comprises 80% independent members, with the addition of Gary Abel as statistician.

Patient & Public Advisory Group: Public and patient involvement is led by Dr Emma Cockcroft with patient co-applicant, Ms Chris Marriott. We have worked with a core patient and carer advisory group (currently 7 active members) involved in the development of this application. This group meet remotely (since the pandemic restrictions) during the project as well as being involved and updated by email. Active involvement of patients and carers will continue throughout the project, with meetings held at key stages to inform and shape the work. We will also capitalise upon other links and contacts where appropriate. Detailed plans of involvement are outlined in section nine of the main form. PPI input has been included in this application for NHS REC and HRA approvals, for example the PPI group has commented on documents designed for patients.

To date the patient advisory group has had significant input into the content and wording of the patient survey and have been part of early discussions about the case study set up, in terms of how to approach patients and what would be acceptable for observations. They have also help in the development of any patient-facing documents ensuring they make sense and are appropriate.

The patient advisory group will continue to have significant input in a number of key stages, with flexibility to address emerging issues. These include:
1. Survey analysis and interpretation
2. Case study and stakeholder interview analysis - interpretations of the findings, reviewing codes and themes.
3. Synthesis of findings - discussions of the results from the programme of work as a whole, and discussions around approaches to digital facilitation - how such approaches might be implemented in practice and what considerations are important to patients. We will open this meeting up to a larger group, ensuring that we speak to those with low levels of health literacy and digital non-users. Two of the patient advisory group will also attend the planned two-day synthesis workshop, during the final phase of the research.

4. Dissemination – help in ensuring results are disseminated in an understandable and engaging format and to places where relevant people will be able to access them. Here we will also work with the digital-health focused advisory group based at Warwick, and the Society of Academic Primary Care special interest group on health literacy. We have sought input into the final design of the study website.

Chris Marriott (patient, carer, and member of the Peninsula Patient and Public Involvement group) is an integral member of the research team. Chris Marriott will attend all project team meetings, and patient advisory group meetings to ensure there is a patient voice in all discussions and decisions throughout the life of the project.

In addition, PPI facilitator, Emma Cockcroft, is part of the project management group. Emma Cockcroft will work with project lead John Campbell, patient co-applicant Chris Marriott and the wider research team, to ensure full integration of patient involvement throughout the study. Emma Cockcroft will set up and facilitate the involvement of a larger patient advisory group, and plan and deliver meetings at the key stages of the research. Emma Cockcroft will provide support and relevant training for Chris Marriott and the patient advisory group. This will include pre-meetings with Chris Marriott before project team meetings to run through agenda items and explain technical aspects. Emma Cockcroft will ensure that the larger project team follows INVOLVE's values and principles framework for patient involvement in research including respect, support, transparency, responsiveness, fairness of opportunity, and accountability. The planned involvement has been costed in line with INVOLVE and South West Peninsula Applied Research Collaboration (PenARC) guidance.

PROTOCOL CONTRIBUTORS

Two expert academic groups (Exeter and Warwick) will work with the RAND Europe, a not-for-profit research organisation that delivers high quality research and analysis to inform policy and decision making across major areas of public policy. Numerous members of the team have worked together on related successful projects focusing on patient experience of care (NIHR funded IMPROVE programme grant: John Campbell, Gary Abel, Jennifer Newbould) and on alternatives to face-to-face consultations (NIHR-funded Alt-Con project: Helen Atherton John Campbell; and NIHR-funded Telefirst project: Gary Abel, Emma Pitchforth, Jennifer Newbould; CSO Scotland funded ViCo: Helen Atherton, John Campbell) and an ongoing NIHR study on online booking of appointments in primary care (Helen Atherton, Gary Abel, John Campbell). These studies have already resulted in a large number of publications including publications in the Lancet and BMJ.

John Campbell, is a professor of general practice and primary care and a senior academic GP and practising clinician. He has extensive experience of NIHR-funded research (HSDR, HTA), with 380 academic publications. He was a recent adviser to NHSE/DH/CQC/Health Foundation. Previously he was a member on the HSDR panel and board and currently acts as NIHR policy adviser. He is the Chief investigator for Di-Facto and provides overall leadership and oversight of the project. He will ensure

the research is conducted in accordance with the protocol and UK Policy Framework for Health and Social Care Research.

Gary Abel is a statistician and health services researcher bringing a wealth of experience in analysis of patient experience survey data (with over 40 publications) and other routine data. He will provide leadership for the practice and patient surveys and providing oversight for the survey delivery. He will assist John Campbell in overall delivery of the project.

Jon Sussex is an experienced health economist and health policy researcher who has worked on many projects concerning the take-up of innovations in healthcare. He is a Senior Research Leader at RAND Europe and co-directs the Cambridge Centre for Health Services Research (a long-standing collaboration between RAND Europe and the University of Cambridge). Jon leads the RAND Europe Di-Facto team and leads the scoping review and synthesis of learning for the Di-Facto research collaboration as a whole.

Helen Atherton is a primary care health services researcher who brings expertise in digital service delivery in primary care (with over 50 publications). Helen has a particular experience in qualitative research and will lead the qualitative study, providing oversight for the delivery of the qualitative exploration and supervising the wider qualitative team.

Emma Pitchforth is a health services researcher bringing a wealth of understanding of health service organisation and delivery across diverse healthcare settings, including in relation to access and inequalities. She brings methodological experience in qualitative research and scoping reviews and with particular knowledge of the broader health policy context in the UK. She will assist in the delivery of the qualitative case study and will lead on the stakeholder interviews.

Jennifer Newbould is a research leader at RAND Europe, with substantial experience in qualitative research techniques, and is especially interested in patient experience and primary care. Jennifer has worked on numerous health services research projects in primary care including as project leader on the NIHR project exploring Telephone First approaches in primary care. Jennifer provides inputs and advice across all work packages and will lead the RAND Europe qualitative research.

Jeff Lambert is a psychologist and digital health researcher who recently developed and led a trial of a digitally delivered mental health intervention. He has developed and evaluated several digital interventions targeting physical and mental wellbeing (e.g. NIHR HTA ecoacher). He is a co-applicant, who contributes to the design of the project, and will be involved in the practice and patient surveys.

Christopher Clark is Clinical Senior Lecturer in primary care, former NIHR clinical lecturer, and current Chair of RCGP Rural Forum Steering Group. He is a GP in remote practice setting; research interests include rural practice, allied health professionals, organisation of care in primary care, and cardiovascular disease management. He will advise on remote/rural practice/organisational issues and contribute to all project phases.

Emma Cockcroft is a member of the PenARC Patient and Public Involvement Team at the University of Exeter Medical School. She is skilled in planning and facilitating patient involvement in research. She will support the patient and public involvement, attend research team and project advisory group meetings and work with patients and carers to inform key stages of the project.

Christine Marriott is an active and long-term member of the Peninsula Public Involvement Group (PenPIG). She provides lay expertise, including her own experiences of primary care. She attends research team and project advisory group meetings and work with a larger patient /carer group at key points during the project. Christine works in partnership with patients and carers who form part of the wider patient participation group.

Laura Sheard is an associate professor at the University of York. She is a qualitative researcher and her main research interest focuses on exploring the macro/ system level factors relevant to why interventions or programmes are able or unable to embed themselves within the health service. She has expertise in implementation science and marginalized groups which includes prisoners, IV drug users, homeless people and sex workers.

Carol Bryce is a sociologist and qualitative researcher at the University of Warwick with experience of conducting qualitative case studies in use of digital communication in healthcare (e.g. Digital Access Now (DAN) Survey). Carol will conduct the focused ethnographic fieldwork at the West Midlands sites and will contribute to the patient survey, the qualitative exploration, analysis of the qualitative data, and related publication(s).

Mayam Gomez-Cano is a post-doctoral research associate statistician at the University of Exeter with experience of analysing patient experience data, including GP Patient Survey data and will conduct all analysis of data for the patient survey and contribute to related publication(s).

Rachel Winder is a research fellow and a qualified nurse with many years of experience in primary care studies and working with general practices. She is the project manager for Di-Facto, and is responsible for the day to day conduct of the project. She has contributed to the development and management of the practice and patient surveys, planning and implementing the ethnographic case study, the stakeholder interviews and analyses, related publications and report writing.

Caroline Jenkinson is a research fellow at the University of Exeter, experienced in health services research. Her work includes three clinical trials involving patients with treatment resistant depression. Her role in Di-Facto is to carry out the additional work package which focuses on patients living with mental health conditions. She is responsible for developing and conducting the survey of patients living with mental health conditions and will assist the qualitative aspect of this additional work as required.

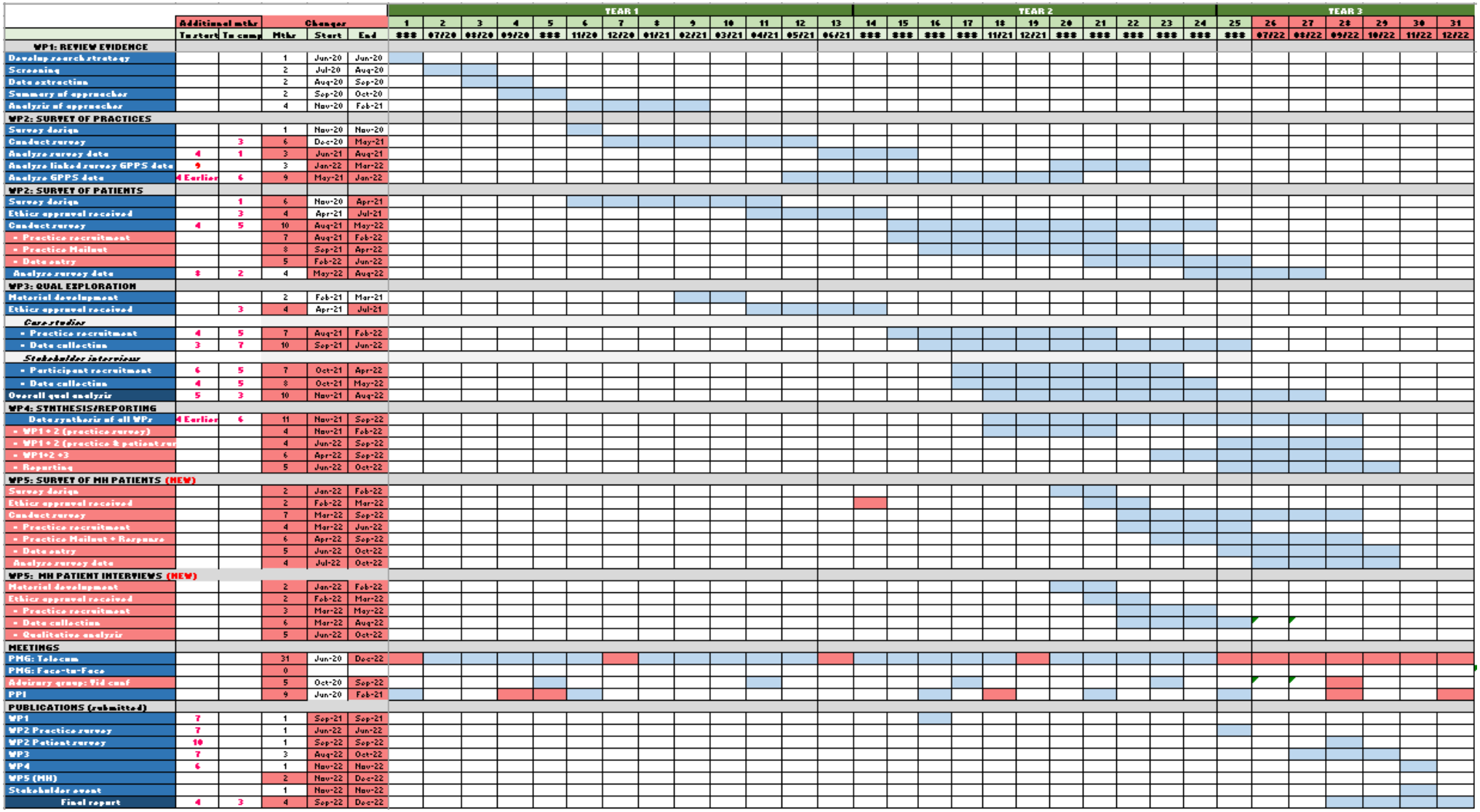
Jo Parsons is a research fellow at the University of Warwick experienced in qualitative health research, and is experienced in digital technology in primary care research. She has experience in conducting interviews on highly sensitive topics, and has experience in service delivery for patients with mental health conditions. Jo is responsible for the data collection and analysis of the qualitative interviews with patients with a mental health condition within this project.
During the conceptualisation of the research idea, three members of the Peninsula patient and public involvement group met with John Campbell and Emma Cockcroft to discuss research objectives and methods. A summary of the meeting was shared with the larger research team and integrated into the research plans. Emma Cockcroft also met with two members of the Peninsula Public Involvement Group (PenPIG) to discuss and plan the patient and public involvement in the project.

KEY WORDS:

- Digital facilitation
- Primary care and access
- General practice
- Online general practice services
- Survey
- Ethnography

GANTT CHART: DI-FACTO

Table 1: Whole study GANTT chart



	Additional mthr		Changes			TEAR 1												TEAR 2												TEAR 3						
	To start	To comp	Mthr	Start	End	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
						###	07/20	08/20	09/20	###	11/20	12/20	01/21	02/21	03/21	04/21	05/21	06/21	###	###	###	###	11/21	12/21	###	###	###	###	###	07/22	08/22	09/22	10/22	11/22	12/22
WP1: REVIEW EVIDENCE																																				
Develop research strategy			1	Jun-20	Jun-20																															
Screening			2	Jul-20	Aug-20																															
Data extraction			2	Aug-20	Sep-20																															
Summary of approaches			2	Sep-20	Oct-20																															
Analysis of approaches			4	Nov-20	Feb-21																															
WP2: SURVEY OF PRACTICES																																				
Survey design			1	Nov-20	Nov-20																															
Conduct survey		3	6	Dec-20	May-21																															
Analyze survey data	4	1	3	Jun-21	Aug-21																															
Analyze linked survey GPPS data	9		3	Jan-22	Mar-22																															
Analyze GPPS data	4 Earlier	6	9	May-21	Jan-22																															
WP2: SURVEY OF PATIENTS																																				
Survey design		1	6	Nov-20	Apr-21																															
Ethics approval received		3	4	Apr-21	Jul-21																															
Conduct survey	4	5	10	Aug-21	May-22																															
- Practice recruitment			7	Aug-21	Feb-22																															
- Practice Mailout			8	Sep-21	Apr-22																															
- Data entry			5	Feb-22	Jun-22																															
Analyze survey data	8	2	4	May-22	Aug-22																															
WP3: QUAL EXPLORATION																																				
Material development			2	Feb-21	Mar-21																															
Ethics approval received		3	4	Apr-21	Jul-21																															
Case studies																																				
- Practice recruitment	4	5	7	Aug-21	Feb-22																															
- Data collection	3	7	10	Sep-21	Jun-22																															
Stakeholder interviews																																				
- Participant recruitment	6	5	7	Oct-21	Apr-22																															
- Data collection	4	5	8	Oct-21	May-22																															
Overall qual analysis	5	3	10	Nov-21	Aug-22																															
WP4: SYNTHESIS/REPORTING																																				
Data synthesis of all WPs	4 Earlier	6	11	Nov-21	Sep-22																															
- WP1 + 2 (practice survey)			4	Nov-21	Feb-22																															
- WP1 + 2 (practice & patient sur			4	Jun-22	Sep-22																															
- WP1+2 +3			6	Apr-22	Sep-22																															
- Reporting			5	Jun-22	Oct-22																															
WP5: SURVEY OF MH PATIENTS (NEW)																																				
Survey design			2	Jan-22	Feb-22																															
Ethics approval received			2	Feb-22	Mar-22																															
Conduct survey			7	Mar-22	Sep-22																															
- Practice recruitment			4	Mar-22	Jun-22																															
- Practice Mailout + Response			6	Apr-22	Sep-22																															
- Data entry			5	Jun-22	Oct-22																															
Analyze survey data			4	Jul-22	Oct-22																															
WP5: MH PATIENT INTERVIEWS (NEW)																																				
Material development			2	Jan-22	Feb-22																															
Ethics approval received			2	Feb-22	Mar-22																															
- Practice recruitment			3	Mar-22	May-22																															
- Data collection			6	Mar-22	Aug-22																															
- Qualitative analysis			5	Jun-22	Oct-22																															
MEETINGS																																				
PMG: Telecon			31	Jun-20	Dec-22																															
PMG: Face-to-Face			0																																	
Advisory group: Vid conf			5	Oct-20	Sep-22																															
PPI			9	Jun-20	Feb-21																															
PUBLICATIONS (submitted)																																				
WP1	7		1	Sep-21	Sep-21																															
WP2 Practice survey	7		1	Jun-22	Jun-22																															
WP2 Patient survey	10		1	Sep-22	Sep-22																															
WP3	7		3	Aug-22	Oct-22																															
WP4	6		1	Nov-22	Nov-22																															
WP5 (MH)			2	Nov-22	Dec-22																															
Stakeholder event			1	Nov-22	Nov-22																															
Final report	4	3	4	Sep-22	Dec-22																															

STUDY PROTOCOL

Facilitating access to online NHS primary care services - current experience and future potential

1. BACKGROUND

Recent years have seen a push by policy makers towards the adoption of online services in primary care in England, ranging from booking appointments, ordering repeat prescriptions and accessing test results and medical records, through to the use of alternatives to face-to-face consultation with a patient (e.g. online messaging and video). Online services, including appointment booking, ordering repeat prescriptions and viewing the patient record have been available to patients in England for over five years(1). In December 2020 32% of registered patients in England had registered to use at least one of these services (2). Prior to the COVID-19 pandemic uptake of alternatives to a face-to-face consultation was already on the increase, but they are far from routine in practice(3). The COVID-19 pandemic has led to an increase in digital routes of contact offered by general practices (for example online triage platforms) and therefore an increased need for patients to be capable of using digital routes to access care(4). During the early stages of the COVID-19 pandemic NHS England encouraged all general practices to move to a 'total triage' model which requires all patients to make an initial contact with their general practice via an online platform (those patients who cannot use online services must use the telephone) so that the information can be used to decide which type of appointment a patient requires (telephone, video, text, online messaging) (5). However, recently published data has shown that even during the pandemic telephone was the most commonly used alternative to a face-to-face consultation, shown to comprise around 90% of all consultations(4, 6), indicating that digital routes of contact are still far from routinely used by patients even though they are more available.

The focus on offering online services raises questions about whether patients are able to engage with these services, realise their benefits and avoid detriments such as precipitating greater inequality. Digital inequalities tend to adversely affect certain groups of people. In this context, individuals from older age groups, non-white ethnicities, those in lower socioeconomic groups, those in poorer health particularly those with mental health conditions, and individuals in rural settings are recognised as vulnerable groups (7-10). It is therefore important to understand how barriers to uptake might be overcome and how patients are best supported in the move to online services of all kinds.

One way to address these potential inequalities is via digital facilitation - actively supporting patients and carers in using practice based online services. In this application we define 'digital facilitation', as 'that range of processes, procedures, and personnel which seeks to support NHS patients in their

uptake and use of online services.' We focus on those processes, procedures and personnel provided by or on behalf of GP practices to support access by their registered patients, and carers of those patients, to NHS online primary care services.

Online services include services accessed via the practice website (e.g. booking appointments, access to records), but also redirection or facilitating access to other on-line information such as self-care resources.

There have been examples of support for using online primary care services previously. 'GP online services' was a nationwide programme introduced by NHS England and the Royal College of General Practitioners (RCGP) in 2013 to encourage practices to offer online services such as online appointment booking, repeat prescriptions and access to their medical record(11, 12). The programme provides support and resource guides to GP surgeries developing their online offer, through a mixture of online and physical promotional materials. The NHS App, introduced in 2019, provides a platform for general practices to offer their online services, which may include online booking, online consultation, secure messaging and access to their GP health record. NHS Digital has provided general practices with advice and guidance on how to promote the app to patients and how to consider digital inclusion(13).

There are specific examples of locally driven digital facilitation. We have had discussions with Lea Valley Health Federation (nine GP practices, 86,000 patients), which has employed a local digital facilitator officer to support patients' and staff engagement with their online services(12). In Lea Valley, implementation was driven by a 'Capacity and Demand audit'(14). The appointment of a digital facilitator was undertaken with the ambition of engaging patients and staff who might otherwise not engage, for personal or economic reasons, or because they lack the digital skills with online services. Appointment of such an individual represents one approach to supporting and facilitating patient and user access.

There is, however, no existing evidence as to the nature and scope, effectiveness, or cost impact of appointing such an individual nor of the various guidance and toolkits mentioned above. This is compounded by the fact that the nature and extent of innovative approaches offered by practices are unknown.

Existing literature

Importance of access to online services: There is evidence to suggest that access to online services may improve outcomes for NHS patients and staff. A systematic review by Mold et al(15) reported that patients accessing online services in primary care had higher levels of satisfaction, improved self-care, and better communication and engagement with clinicians. However, the majority of the studies reviewed were from the US. The same group of authors have also reported that patient access to online services was associated with improved reports of convenience and satisfaction, although staff

were concerned about impact on workload and risk to privacy. A 2019 rapid review(16) focused on 'digital first primary care' reported insufficient evidence to inform policymakers on how best to implement online services, and the potential for inequitable access, and these were factors that healthcare professionals expressed concerned about. These concerns were echoed by our patient/ carer partners during discussions at early stages of developing this proposal. However, the lack of a clear evidence base around digital facilitation and a lack of knowledge about how it is used in practice means an exploratory study is needed.

Challenges to patient engagement with online services: Research shows that medically underserved and vulnerable populations are less likely than other patient groups to engage with digital health technologies(17). The reasons for this lower engagement are complex and include factors that limit access to technologies as well as factors affecting motivations to use the technologies. Specific barriers to engagement with online services for these groups include: a lack of experience with using the internet(17, 18), lower health literacy(17, 19), and a lack of trust towards the information being provided through online interfaces(17, 20). Poor 'usability' can also impede older users from accessing information through patient portals. For example, when older users lost required access codes after registering on patient portals they were discouraged from using the service (17). Research in Scotland has identified further technical and practical considerations (poor connection, 'frozen' images, poor sound quality, slow broadband) in adopting IT innovations(21, 22), including amongst rural populations, who may have limited access to good quality broadband services. In their reviews of the literature, Irizarry et al(19) and others(23) have concluded that the ability of patients to access online health services is strongly influenced by combinations of personal factors such as health literacy, health status, age, ethnicity, education level and whether individuals have caring responsibilities(24). Likewise, in a systematic review of qualitative studies examining the factors affecting patient recruitment to digital health interventions, O'Connor et al(25) concluded that greater investment is required to improve computer literacy to ensure that technologies are accessible and affordable. Even in groups where we might expect higher levels of use of online services, there is evidence that this does not translate into practice. An empirical study examining use of a patient portal offering multiple online services (secure messaging, repeat prescriptions, appointment booking amongst others) identified that patients who might be expected to benefit the most from use of the portal being least likely to use it. In this case younger adults (aged 18-30) were not adopting the services despite them being more likely than older groups to have access to and use the internet(26). Presence or absence of a health condition can also influence engagement with online services(27) for example, UK surveys have found that people with mental health difficulties are more likely to experience digital exclusion(28) and this is especially the case for those with severe mental illness(29).

Cognisant of the complexity of this issue, members of the research team are currently involved in other research examining the unintended consequences of online services in primary care(30, 31) and research investigating patient use and experience of online booking in general practice(32).

Challenges to staff engagement with online services: The digital competence of healthcare professionals and their acceptance of online service provision are also important for successful implementation of online patient services. Konttila et al.(33) argue that healthcare professionals are more accepting of digital technologies when they perceive the technology as helpful for patients and supportive of the practice's workflow, but that factors such as a lack of comfort or perceived issues of competence with using the technology can decrease acceptance and uptake. Healthcare professionals were found to be less accepting of digital technologies when they misunderstood the purpose of the technology, or found it difficult or uncomfortable to use, or when it was not seen as part of their principal work. Konttila and colleagues' systematic review(33) also found that healthcare professionals often experienced information technology education for themselves as pointless, under-resourced, time-consuming, and with poorly understood benefits. However, supportive organisations and managers were found to facilitate support for staff education and acceptance of digital technologies. It thus appears that support for practice staff in using and supporting patients in using digital health technologies is critical, and must be carried out in a sensitive and constructive manner.

Digital facilitation: Although research on the use of digital facilitation is relatively limited to date, there is evidence to support its use and its ability to reduce inequalities in access to digital resources amongst 'harder to reach' and vulnerable groups. One approach to facilitation identified by O'Connor et al involved the use of 'direct engagement', including "consultations with health professionals, employers, personal recommendations from family or friends or being spoken to by research or management staff". Personal recommendations from family or peers, or the endorsement of digital resources by practice staff were found to increase enrolment in digital health technologies. This is further supported by evidence from systematic reviews which find that patients more generally, including comparatively less well served populations, are more likely to engage with digital health resources when they have the encouragement of friends or family members (18, 34, 35). Evidence also suggests that people with lower education levels and older people require more support than other patient groups in order to use digital health applications. We have not identified any evaluations of such engagement approaches in practice although we have identified that poor understanding of service provision may be a barrier to service uptake(36), and that staff have expressed concerns re adverse workload implications which might ensue. There is also evidence showing that introducing the NHS App was associated with improved digital access during its pilot testing phase, with 64% of (3,192) users of the App reporting that they had previously not used online services to access GP services(37). Feedback from practice staff during the pilot testing of the NHS App identified that some practice staff wanted additional training and support in order to effectively communicate with patients about the app and this has recently been provided via online guidance for general practices as a result in the increased use of the app during the pandemic.

Other interventions designed to target direct engagement with digital technologies have been identified, for example the use of 'champions' for GP online services(38), as well as specific interventions to improve people's online health literacy(39). Cowie et al(38) evaluated the implementation of an online tool providing advice to support self-management and the opportunity

to digitally consult with a GP, concluding that the presence of a champion within the practice was a significant factor in ensuring successful integration of the tool. Amongst some patients who had no previous computer experience, training on computer and internet use, effective search skills and interpretation of online information was associated with greater health information seeking and interpretation skills, and with increased self-management.

Facilitation has become more relevant with the move to remote consultation and use of online services by general practice due to the COVID-19 pandemic. The need to generate evidence about how best to deliver digital facilitation is more pressing than ever.

2. RATIONALE

As described in the background, there is a need for digital facilitation to support patients in using online services and there are different examples of what digital facilitation can comprise. It is thus important to understand the extent to which digital facilitators or other approaches to digital facilitation are being used, how they are being used, the impact they are having on uptake of online services, and how such uptake may be impacting patient health and access to healthcare information and services, GP practices, and the wider NHS. For the purposes of the study we define digital facilitation as 'the range of processes, procedures, and personnel put in place within the practice which seeks to support NHS patients in their uptake and use of online services.'

During the Covid-19 pandemic, the prevalence of both mental health conditions and reliance on the digital delivery of healthcare vastly increased. However, patients with mental health conditions may be at greater risk of digital exclusion compared to the general population. We have had the opportunity via additional funding from the NIHR to particularly explore how patients with mental health conditions experience digital facilitation given their high risk of digital exclusion.

3. RESEARCH OBJECTIVES AND AIMS

Objectives

This protocol centres on two key elements of the Di-Facto study: a survey of patients and a focused qualitative exploration comprising ethnographic case studies based within practices, including interviews of practice staff, patients and a stakeholder interview study. Here we outline the aims for the whole study in order to situate these elements in context.

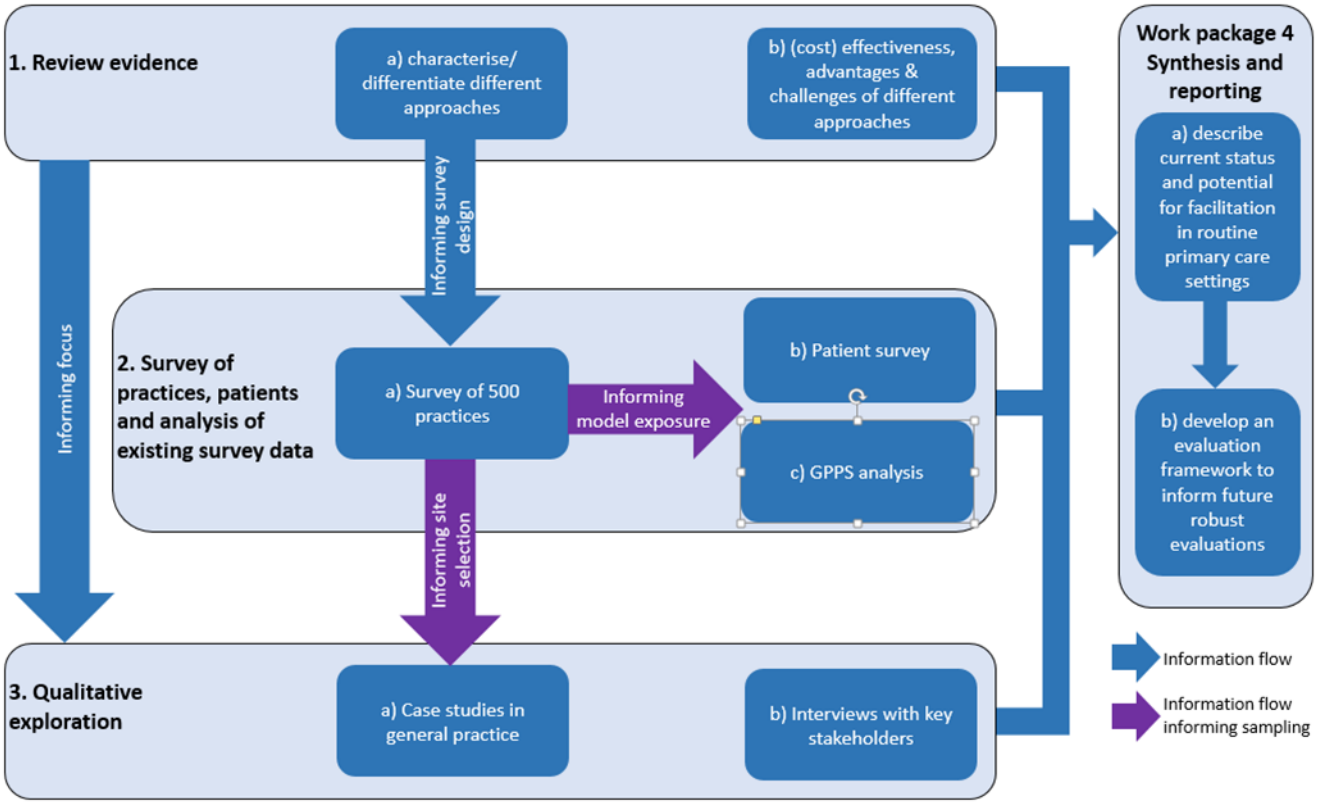
Aims of the Di-Facto study:

- Identify, characterise and explore the potential benefits and challenges associated with different models of digital facilitation currently in use which are aimed at improving patient access to online services in general practice in England.
- Use the resulting data to design a framework for future evaluations of the effectiveness and cost-effectiveness of such interventions.

To address these aims, we are conducting a series of interlinked work packages (Figure 1). The objectives of these work packages are to:

- Review published literature to understand and characterise the range, effectiveness, and cost-effectiveness of models of digital facilitation for improving access to online services within health and other sectors, and to develop a typology of digital facilitation
- Undertake a survey to investigate the range of digital facilitation services currently offered in a sample of English primary care practices, relating this to patient experience of care in those practices as measured by the national GP Patient Survey.
- Undertake a survey to investigate patient views of digital facilitation in a sample of English primary care, relating this to different modes of digital facilitation identified in the practice survey and explore how patient factors predict awareness and uptake of digital facilitation.
- Conduct a qualitative exploration seeking to understand in-depth and from the perspective of practice staff, patients and other stakeholders the potential benefits and challenges associated with different models of digital facilitation.
- Synthesise learning from these elements and develop a framework for future evaluations of effectiveness and cost-effectiveness of models of digital facilitation
- • To explore how patients living with mental health conditions experience digital facilitation (not illustrated in Figure 1).

Figure 1: Flow diagram showing work stage flow



The additional work focusing on patients living with mental health conditions will comprise of a boost sample to the patient survey and additional qualitative interviews. In both cases, findings will be integrated with those from the original patient survey and patient interviews.

The Di-Facto study is focused on staff and patients at general practices across England. The study employs a mixed methods approach and comprises interlinked packages of work:

- A scoping review will characterise the different approaches to digital facilitation and establish the current evidence base about the effectiveness and cost-effectiveness of different approaches to digital facilitation.
- A survey of 500 practices with analysis of the responses, linking to data from the national GP Patient Survey.
- Surveys of 12,000 patients from 60 practices with analysis of the responses, linking to findings from the practice survey. An additional sample of 3000 patients with mental health conditions from 15 practices will be conducted. We will describe the findings from this sample of patients in relation to findings from the more general sample.
- Qualitative research exploring the potential benefits and challenges associated with different models of digital facilitation, comprising of focused ethnographic case studies in general practice and interviews with wider stakeholders. Additional patient interviews will be conducted with 16-20 patients with mental health conditions at 3-4 practices.
- A synthesis of learning from other elements of the study and development of a framework to inform future evaluations. Patients and the public will be involved throughout.

The present ethics application concerns the patient survey and qualitative case studies as these require HRA regulatory/ethical approval. At the study proposal stage, the practice survey was deemed by the Health Research Authority to be service evaluation and not intended to change practice or patient care and thus does not require research related regulatory/ethical approval. This was verified by the lead and co-sponsors in discussions over ethical requirements for the project as a whole. The literature review (nearing completion) and the synthesis of findings from the other elements are desk based activities which do not involve any further data collection and so do not require ethical approval.

This ethics amendment concerns the additional surveys of, and interviews with a boost sample of mental health patients.

Outcome

The ultimate outcome of the project will be a summary of the current status of digital facilitation as presently implemented within primary care. This will include what is known about the likely effectiveness, cost and equity of access implications of the approaches identified, and an indication of the prevalence of various approaches in the three regions of England surveyed (East of England and North London; South-West; West Midlands). We will provide recommendations for future development and implementation of promising approaches to digital facilitation, and provide a

framework for future evaluations to assess the effectiveness, cost-effectiveness and impact on inequalities of access to the online services, of relevant facilitation approaches within primary care settings.

4. THEORETICAL FRAMEWORK

Any exploratory study benefits from the use of a theoretical framework. In this study we are using Weiss' theory based evaluation(40) as our theoretical framework to understand how, and in what ways, different models of digital facilitation bring benefits and challenges to general practice. In our qualitative study theory based evaluation will be used to guide data collection and provide a lens through which data analysis can be conducted. We will then subsequently develop a 'program and implementation theory' informed by the findings of the Di-Facto study as a whole.

Weiss distinguishes between 'program theory', which specifies the mechanism of change, and 'implementation theory' which describes how the intervention is carried out. We will use the theory based evaluation approach to understand how, and in what ways, different models of digital facilitation bring benefits and challenges to general practice and patients. We will do this by drawing on the findings of the evidence synthesis, survey and case studies to develop the program theory and the implementation theory.

To develop the 'program theory' we will use a realist approach to describe provision of digital facilitation in terms of:

- Context (for example characteristics of the general practice, the target patient population, the policy framework, and the IT infrastructure)
- The theory and assumptions underlying the intervention (how and why digital facilitation might lead to benefits)
- The flow of activities that comprise the intervention (the key processes that occur when patients make use of digital facilitation)
- Intended benefits/outcomes (those deemed important to patients and practitioners)

The 'implementation theory' will explore moderating factors which influence the extent to which the process and outcomes are achieved, such as factors acting as barriers and facilitators to practices offering digital facilitation or to different groups of patients using them.

5. PATIENT SURVEY & QUALITATIVE STUDY: DESIGNS, METHODS ANALYSES

PATIENT SURVEY

Study Design

To explore patients' experience of digital facilitation, we will undertake a survey of patients across 60 practices, building on our recent experience of conducting a similar survey in 43 practices in the West

Midlands(27). The survey will focus on patients' perceptions of, and responses to, practices' efforts in respect of digital facilitation. Patients will be recruited from practices who have responded to a survey of 500 practices, currently underway as part of the funded project. The practice survey questionnaire enquires about digital facilitation including whether any such initiatives are targeted at particular patient groups and whether traditional access to services has been withdrawn and replaced entirely by online services. The responses to the survey will allow us to characterise practices in respect of their status vis-a-vis digital facilitation – what arrangements they have implemented, what modes of facilitation they are using, and other relevant characteristics. It will provide a sample from which to select practices to participate in the qualitative exploration. We then intend to conduct a patient survey in the subset of responding practices, allowing us to relate patients' observations and attitudes towards digital facilitation and online services to what their practice has reported.

For the current practice survey sample we will approach 500 practices, each with a minimum of 1,000 registered patients on their list, selected at random from practices in the following CCGs (or former CCGs in the case of Enfield and Haringey, which have recently merged with other CCGs):

- NHS Devon CCG (CCG code: 15N)
- NHS Birmingham and Solihull CCG (CCG code: 15E)
- NHS South Warwickshire CCG (CCG code : 05R)
- NHS Coventry and Rugby CCG (CCG code: 05A)
- NHS Cambridgeshire and Peterborough CCG (CCG code: 06H)
- NHS East and North Hertfordshire CCG (CCG code: 06K)
- NHS North Central London CCG (CCG code 93C) (formerly NHS Enfield CCG, (CCG code: 07X) and NHS Haringey CCG (CCG code: 08D), which have now merged).

We will invite up to 154 practices who responded to the practice survey within the regions outlined above responding to our initial practice survey request (after reminders and telephone follow-up), expecting that around 39% of those 154 practices (i.e. 60 practices) might be prepared to participate and support the patient survey. In each of the practices we will undertake a survey of up to 285 randomly selected adult patients (aged 16 years or over). Random sampling of all adult patients will be used to provide a broadly representative sample of the practice population. Practices will be provided with instructions to produce a random sample of up to 320 adult patients (to allow for exclusion by GPs on screening) and GPs will be requested to screen the patient list for eligibility and suitability.

Sample

The total sampling frame in participating practices is expected to be around 12,000 patients (an average of 200 patients in 60 practices). In order to ensure that there is fair representation across areas reflecting all deprivation quintiles, practices will be categorised in to three groups, based on their deprivation quintile in their area with more patients invited from practices in deprivation groups underrepresented in the practice survey. We anticipate a response rate of 35% resulting in 4,200 completed responses – an average of 70 respondents per practice. Whilst this sample is unlikely to provide statistically reliable scoring of patient experiences at the level of each practice, we will be

able to make comparisons across groups of practices employing different methods of digital facilitation. For example, with this sample size we would have 90% power to see a difference between 30% of patients being aware of digital facilitation in 20 practices employing one mode of digital facilitation, and a rate of 34% in 20 practices employing another model.

Eligibility Criteria

The patient survey will include adult patients (aged 16 and over), registered with a participating general practice. Staff at the general practices will assist us in screening the list of any potential participants to ensure that we exclude those who are receiving end of life care, suffering from a severe mental illness, recently bereaved, below the age range, or otherwise incapable of giving informed consent to participate.

Questionnaire

The brief four-page patient questionnaire mirrors questions in the practice survey and which allow us to compare and contrast responses and incorporates sections on:

- Respondents' familiarity with computers and the internet
- Awareness and uptake of NHS online services
- Support provided by the practice to use online services

The patient questionnaire was developed with the aid of focused research meetings and discussions, drawing upon broad literature review findings, clinical and patient experience, and the experience of the researchers in this field. Development included an initial brain storming event with the projects patient advisory group, as well as follow up feedback on an initial draft. This was to ensure we were asking pertinent questions from the perspective of patients, as well as ensuring it was written appropriately.

Respondents will be asked to provide basic sociodemographic information along with a note of carer status (including parents of children, those who have other caring responsibility, as well as carers of patients who live with mental health disorders, learning disabilities, dementia or other longstanding conditions), working status and health status.

In developing the questionnaire we started with an initial scoping exercise with our study PPI group, followed by a series of workshops with the patient survey study team. Where possible we have drawn on standard question items, some wording from the GP Patient Survey(41) and the Get Digital basic skills assessment questions(42). The wording and/or response options have been adapted where necessary. The draft questionnaire and other patient-facing documents were then reviewed by the PPI group and the entire Di-Facto project team and piloted with a number of volunteers to check clarity and ease of use.

Patients will be invited to include a name and either a postal address or email address if they would like to be entered into a prize draw to win one of ten £25 high street vouchers as an incentive to take part.

While the study was not funded to provide language interpretation and other specialist services, participants are invited to seek support from a trusted friend or relative to help them access the information sheet and complete the questionnaire; in addition, we have set up a dedicated email and phone number (added to the information sent out to patients for those with queries and survey completion'. Large print paper copies of the survey will also be made available on request.

Data collection

General practices will be recruited by study team members in partnership with the Clinical Research Network in the different study areas. We will prioritise practices to give representation across a full range of digital facilitation including a number of practices not doing any. We anticipate that around 60 practices will want to participate. If we find very few of these practices are undertaking digital facilitation we will prioritise those practices that are doing more digital facilitation for inclusion in the patient survey. Being aware of the current situation in primary care (in relation to the COVID-19 pandemic and vaccination programme), we will keep our sample considerations under review.

Once a practice has been recruited as a site we will provide a nominated practice staff member with a structured search in order to extract the names and addresses of up to 320 randomly selected adults from the list of registered patients stored on the practice computer system. This list will be reviewed by the practice to ensure that the survey is not sent to any inappropriate patients (for example, deceased, mentally incapacitated, recently bereaved, under the age range, or otherwise incapable of giving informed consent to participate). The practice will be asked to be as inclusive as possible and reasons for exclusion will be provided to the study team (without patient details) to ensure that exclusions are appropriate. After review the names and addresses of the remaining patients on the list will be imported into a structured Excel file template provided to the practice by the study team (excluding any at the end of the list where they exceed the number required from that practice). In the unlikely event that more than 10% of patients are excluded, we will mail to less than the number of patients required from that practice . This Excel file will be pre-populated with a study ID and password (comprising of four and five alphanumeric characters respectively).

Up to 285 eligible patients will be sent a paper-based invitation from the practice, on behalf of the research team, using the 'Docmail' mailing service. CFH Docmail is an outsourced data processor routinely used by the NHS to deliver bulk mailings to patients. As a consequence the security levels satisfy the necessary GDPR regulations. CFH Docmail provides researchers with a dedicated study account. The study account hosts the patient survey, information sheet and invitation letter. Participating practices will transfer the patients' name, address, study ID and password onto an Excel file which is securely uploaded by the practice to the CFH Docmail account using a unique username and password and choosing the mailing format (e.g. adding a practice letterhead). The practice then reviews and approves the PDF proof. Upon receipt of the files from a practice, CFH Docmail will perform a mail-merge and send automated individual personalised letters, information,

questionnaires and a free post envelope to the selected patients which are usually dispatched to patients the next day.

The research team will not have access to identifiable information on participating patients and GP surgeries cannot access or see each other's data or content.

Information will be provided via a letter of invitation and information sheet about the nature of the survey and how the data will be used and stored. Patients who may have difficulty accessing this information (i.e. due to a physical disability or due to limited literacy in the English language) will be invited to seek support from a trusted friend or relative to help them access the information sheet and complete the questionnaire.

The letters to patients will contain a web-link and QR code to allow the questionnaire to be completed online, if the patient would prefer to do so.

If patients choose to respond using the paper version of the questionnaire they can return it directly to the study team using the included free-post envelope. Paper copies of the questionnaire will include the patient study ID which will allow us to attribute responses to the practice the patient is registered at. As we will not hold any patient details we will not be able to link responses to those. Alternatively patients may complete the questionnaire online, and this would not record their IP address. Details provided by patients who wish to enter the prize draw will be stored separately from the remaining anonymous and unlinkable patient data and in a secure file with access limited to Gary Abel and Rachel Winder. Personal details will be destroyed once the winners have been contacted.

The patient information sheet and the invitation letter will set out how their responses will be used and explain any advantages and disadvantages of taking part. Patients will have been deemed to have consented to participate in the study if they return a questionnaire either by post or online (implied consent).

After two weeks a second letter and questionnaire will be sent to all invited patients via CFH Docmail. The second letter will be amended, thanking the patient if they have already responded. After a further two weeks a reminder postcard will be sent, thanking those who have returned a questionnaire and asking them to take part if they have not already done so. Patients will be invited to include a name and either a postal address or email address if they would like to be entered into a prize draw to win one of ten £25 high street vouchers as an incentive to take part. Any details supplied will only be used for the prize draw.

The questionnaire will be hosted on the JISC Online survey platform(43). Survey data on this platform are secure and strict information security standards are followed (ISO27001 certified) and data is processed in compliance with GDPR. Patients enter the website using the link provided along with the personalised ID and password, or they may scan a QR code which will take them to a personalised

entry into the online questionnaire removing the need to enter the study ID and password. The online questionnaire will record the study ID of the patient, again allowing responses to be linked to the practice but not to patient details. Access to the online survey system will be restricted to those Di-Facto researchers directly managing the Di-Facto patient survey.

Where paper questionnaires are received, study team members will use the JISC Online Survey platform as a means of data entry. If patients have provided names and addresses these will not be entered into the online system. Data will be extracted from the online survey platform in two separate files. The first will contain responses to all questions in the questionnaire as well as the patient study ID, but will not contain any names or addresses supplied for entries into the prize draw. This file will thus be completely anonymous and made available to the study team for analysis. The second file will contain only the names and addresses where provided and will only be made available to the Project Co-ordinator (Gary Abel) and project manager (Rachel Winder) for the purposes of the incentive. All files will be downloaded in CSV format.

The anonymous data from the patient survey will be stored on the University of Exeter computer system in a password protected location which is only accessible to members of the study team. This data will be stored for 10 years before being destroyed. Data on patient name and address will be stored only until the prize draw is performed at the closure of the survey and prizes are distributed. After this point the data will be destroyed.

Data analysis

Data will be analysed using Stata v16(44). Initial descriptive statistics will be calculated in terms of the percentage of patients endorsing different responses for questions concerning:

- Patient characteristics
- Respondents familiarity with computers and the internet
- Awareness and uptake of online services
- Support provided by the practice to use online services

We will then use mixed effects logistic regression models to examine how responses around awareness and uptake of online services, and the support provided by the practice to use online services varies according to a number of factors. Patient factors will be determined from responses to the survey and include age, gender, ethnicity, physical and mental health status, hearing and visual impairment status, carer status, working status. This will allow us to examine questions such as - are older patients less likely to be aware of online services, use online services or make use of support to use online services than younger patients. Practice factors will primarily be focussed on modes of digital facilitation as determined by the Di-Facto practice survey which will allow us to examine questions such as whether patient awareness and engagement with digital facilitation is associated with the mode of digital facilitation employed by a practice. Other practice factors such as patient experience as determined by the national GP Patient Survey and other practice level data that is in the public domain will also be considered.

Separate models will be used for responses to different questions on the questionnaire. Initial univariable models will contain categorical variables representing either patient age, gender, ethnicity, carer status, working status, presence of a physical health condition(s), presence of a mental health conditions, deafness and blindness to allow comparison of experience across different patient groups. All variables will be included in a single model (subject to issues around collinearity) to examine adjusted associations. These models will also include a random intercept for practice to account for the clustering of patients within practice. A second set of models will further include a quantification of respondents' familiarity with computers and the internet to see to what extent this mediates any associations. A final set of models will include classifications of digital facilitation at practices derived from the current practice survey to examine how modes of digital facilitation are associated with patient experiences in those practices.

PATIENT SURVEY – ADDITIONAL SAMPLE OF PATIENTS LIVING WITH MENTAL HEALTH CONDITIONS

Study Design

The Patient Survey will be repeated at 15 GP practices that have already completed the Patient Survey targeting patients living with mental health conditions. We will invite 3000 patients aged 16 years or over who either have a code for anxiety or depression in their medical records or received a recent anxiolytic or antidepressant prescription for anxiety or depression in their medical records. Practices will be provided with information to produce a random sample of up to 220 adult patients and GPs will be requested to screen the patient list for eligibility and suitability. The focus on patients with anxiety and depression is both pragmatic to allow easy identification of potential participants, and focuses on the most common mental health conditions. The sample size would not allow meaningful comparisons between different mental health conditions, and we will therefore consider our findings in respect of the whole sample.

Sample

The total sampling frame in participating practices is expected to be around 3,000 patients (an average of 200 patients in 15 practices). We anticipate a response rate of 20% resulting in 600 completed responses – an average of 40 respondents per practice. This sample is not designed to provide statistically reliable scoring of patient experiences at the level of each practice. Rather we will be able to make comparisons between respondents to this boost sample and those who responded to the original patient survey registered at the same practices (1050 such responses expected). With these responses we expect to have 90% power to see a difference between 30% of patients being aware of digital facilitation in the original sample, and 23% in patients in this boost sample of patients living with mental health conditions.

Eligibility criteria

In addition to that listed in the Patient Survey, patients aged 16 years or over who either have a code for anxiety or depression in their medical records or who have received a recent (less than 12 months) anxiolytic or antidepressant prescription for anxiety or depression in their medical records will be eligible. As before, staff at the general practices will assist us in screening the list of any potential

participants to ensure we exclude those who are: receiving end of life care, suffering severe mental illness, recently bereaved, below the age range, or otherwise incapable of giving informed consent to participate.

Questionnaire

The same questionnaire used in the Patient Survey will be used for the Survey of Patients with Mental Health Conditions. The only difference will be a different QR code so that we can determine whether the completed questionnaires belong to the Patient Survey or the Survey of Patients living with Mental Health Conditions.

Data Collection

Data collection will be the same as the Patient Survey.

Data Analysis

Data analysis will be the same as the Patient Survey. Additional analysis will be undertaken to describe results from the Survey of Patients with Mental Health Conditions and wider Patient Survey.

QUALITATIVE STUDY

Study Design

We will conduct a qualitative study which seeks to understand in-depth and from the perspective of practice staff, patients/carers and other stakeholders the potential benefits and challenges associated with different models of digital facilitation. The study will be informed by the prior research conducted in the wider Di-Facto study; a review and survey of practices which will be used to derive a typology of the different types of digital facilitation. The survey of practices will provide data on the range of digital facilitation services currently offered in a sample of English primary care.
We will conduct a qualitative study comprised of two elements:

1) Focused ethnographic case studies in general practices;

Focused ethnography will be used to explore in-depth the use of digital facilitation in general practices. GP practices will be case studies and through non-participant observation, semi-structured interviews and secondary analysis of documentation, we will build up a detailed picture, exploring what approaches practices have taken to digital facilitation, how they have introduced and/or implemented their approaches, what has made this possible, and what the benefits and challenges have been from the perspective of staff and patients/carers. COVID-19 has led to significant changes in the provision of primary care with an increase in remote consultation and use of online services. The case studies will focus on models of facilitation in place at the time of the research but in addition, will explore changes made in the light of COVID-19. This will include the current services compared to digital facilitation prior to COVID-19 and the anticipated longer-term impact on models of digital facilitation.

2) Interview study with key stakeholders in efforts to increase the use of online services in general practice.

In addition to the in-depth understanding of experiences of digital facilitation within practices, it is important to locate this within a broader context and understanding of the wider drivers of digital facilitation in primary care. We will conduct semi-structured interviews with stakeholders who may have critical oversight at a level beyond individual practices e.g. policymakers and commissioners. The interviews will explore the key drivers of digital facilitation, how stakeholders think digital facilitation works and the intended consequences of its application, both positive and negative. It will also explore issues around digital inclusion and the evolving policy context that the study could help to inform. Through our approach we will understand area-specific context for some case studies and a wider national context.

Setting and participants

The qualitative study will be set in 6-8 general practices selected from four regions of England: South-West England, West Midlands, East of England and North London (assuming a sufficiently wide spread of potential sites are identified in these areas). They will include all types of practice staff, patients and carers as participants within each participating practice.

The stakeholder interview study will be regional and national and will include 14-18 participants, involving those people who may have critical oversight at a level beyond individual practices e.g. GP Federations and CCGs, decision-makers at a national level and patient groups.

Sampling frame: focused ethnographic case studies

Sampling of practices

Our aim is to include a maximally varied sample of 6-8 practices that will provide findings that are widely relevant across a range of primary care settings. Sampling of general practices will focus on seeking variation according to two factors:

a) Experience of and/or delivery of digital facilitation using different approaches. Individual practices will be identified via the practice survey responses and the typology (derived from the literature review and survey) (Figure 2). These will inform the range of approaches studied and may include (but not be limited to) (i) Different approaches to digital facilitation and their delivery (ii) Levels of facilitation use within the practice (iii) Level of digital uptake by patients. Case study sites will necessarily be limited to those practices reporting that they use some form of digital facilitation.

b) Practice characteristics (illustrated in Figure 3) (i) Location (rural/semi-rural/urban) appears to be systematically associated with variation in access to general practice e.g. older people in rural areas have poorer access to general practice services (45) and face digital exclusion due to poor availability of broadband internet(46); (ii) A range of 'Index of Multiple Deprivation'

scores at practice level, as socioeconomic status appears to mediate health disparities via reduced health literacy; (iii) Median age of patients, as although levels of use are increasing, older adults (≥75) are less likely to use the internet, and the 16-34 age group are the highest users of the internet; (iv) List size of the practice (from a range across small (<6,000) to large (>12,000) registered patients).

Figure 2: Flow chart illustrating how the data collected in the practice survey will be used in for ethnographic case studies

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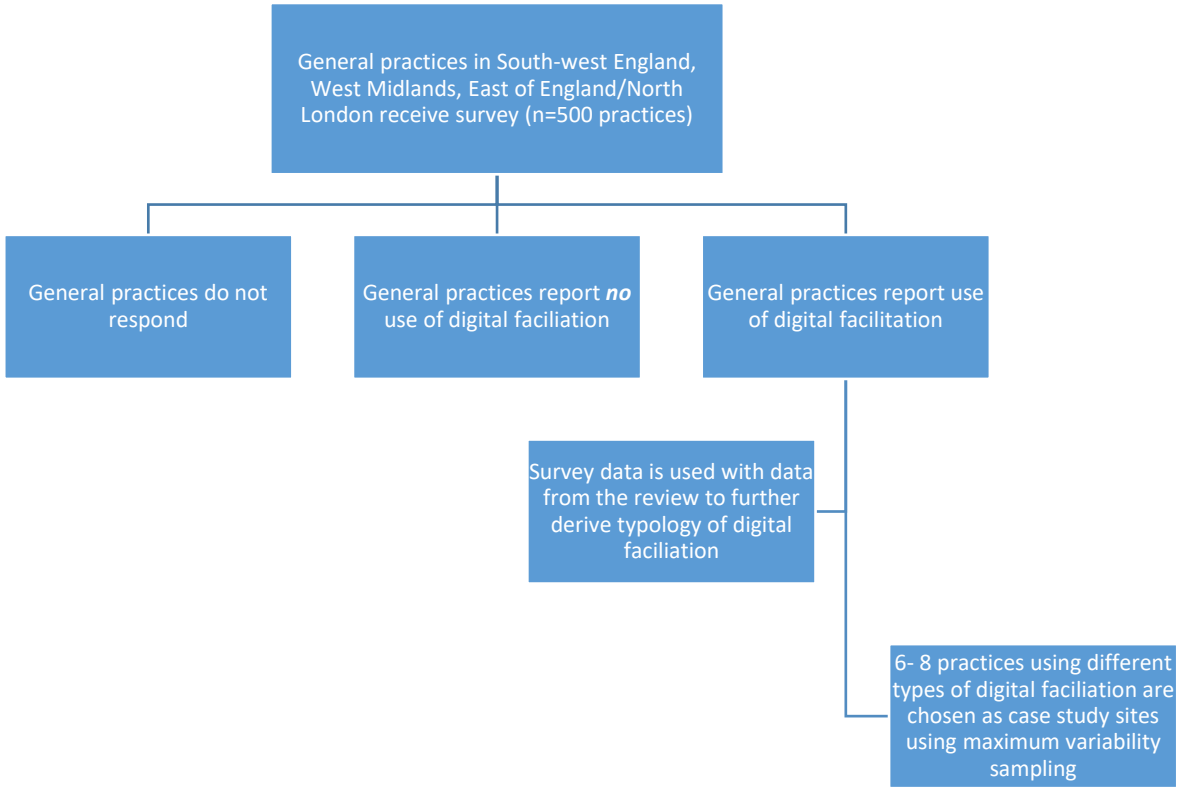
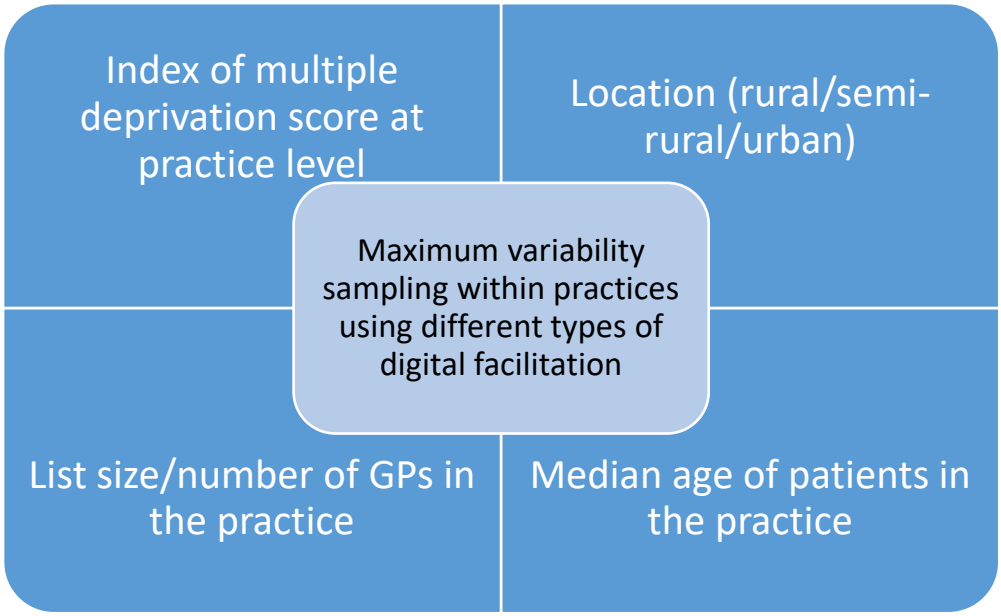


The scoping review and survey may identify additional unanticipated factors that we will consider when sampling. A matrix will be populated with potential practices and used to guide our recruitment, including highlighting gaps in our potential sample.

Figure 3: Illustration of sampling considerations for the selection of case study sites (from the practice survey) and used to guide recruitment, including highlighting gaps in our potential sample



Sampling of staff within practices

One element of the focused ethnography is semi-structured interviews to understand the views and experiences of GPs, practice staff (nurses, nurse practitioners, reception staff, practice manager, administrative staff or any other staff member involved in digital facilitation), patients and carers. We will conduct 3-4 interviews in each practice and we will ensure a diverse sample of participants. The staff we wish to interview will vary by practice, according to the model of facilitation and who is involved and we will be responsive to this.

Sampling of patients within practices

Patients and carers (aged 18 years and over) to be interviewed will be identified in each participating practice during the case study to include those who have been targeted by or participated in efforts to increase uptake of online services. In seeking 3-4 participants per practice, we will look for patients with a mix of characteristics in terms of age, ethnicity, place of residence (e.g. rural/urban, home/care setting) or other characteristics relevant to the model of facilitation.

In addition, we will interview 4-5 patients with mental health conditions in 3-4 of the participating practices. We will focus on patients with anxiety, depression, or severe enduring mental illness identified from diagnoses or from recent prescriptions recorded in the patient record.

Stakeholder interviews

Sampling of participants will be purposive, targeting decision makers known to be engaged on the topic and knowledgeable or regarded as having a key decision-making role. Identification of these stakeholders will be informed by an initial stakeholder analysis, the findings of the review, practice survey, and via existing contacts in patient, policy and professional bodies. Snowball sampling will also be used, as it becomes clear that particular stakeholders may be important to include.

Recruitment

Recruitment of practices

Using the matrix to identify a range of potential sites, we will work with the relevant local Clinical Research Networks in each area to approach practices. Information about the study and what participation will involve will be provided to practices by the CRN. The sampling will be continuously reviewed as practices agree to participate to ensure the intended range.

Interested practices will be provided with written information and a follow-up visit from the research team about the fieldwork. The relevant member of staff at the practice will have an opportunity to ask questions prior to joining the study. They will be expected to share the practice information sheet with staff members informing them about the study. For practices agreeing to participate, a site visit (COVID-19 restriction dependent) will be arranged where the research team will spend time explaining about the study and answering any questions that practice staff have.

Where it is not possible for the CRN to approach a practice (not research active, identified via other connections), we will send an introductory letter inviting the practice to contact the researcher if they are interested in participating, and will follow up with a phone call or email after one week.

Recruitment of practice staff

Within each participating practice all staff members will be informed by a responsible staff member that a researcher will be in the practices conducting non-participation observation. They may at any time decline to be observed and no fieldnotes will be taken about the individual or their work. For semi-structured interviews, GPs, practice managers and practice staff will be approached directly during the fieldwork period and invited to interview by the researcher.

Recruitment of patients

Patients will be identified in accordance with our sampling frame, with the help of practices, either through a person appointed to undertake digital facilitation at the practice or through practice administrators. Practice staff will check the suitability of patients identified as potential participants to ensure that they have capacity to consent or any other reason that they should not be approached. The practice will send patients a postal invitation to participate along with an information sheet about the study. Patients invited to interview because they form part of the sample of patients living with mental health problems will be informed that this is the reason they have been invited within the invitation letter. They will be informed that the invitation has come directly from the general practice and that researchers are not aware of their details and condition and will not be aware unless they choose to respond and take part in an interview. The invitation will be sent on behalf of the research team using the practice letterhead. Recipients will be invited to reply to the study team (using an enclosed reply slip) to indicate that they are willing to participate in the study. Patients may not be aware of the definition or existence of digital facilitation and this will need to be taken into account and explained carefully in the patient information provided. The researcher undertaking the case study will then contact them, answer any questions that they may have about the study and then, if happy to proceed, arrange a time and place for interview.

Recruitment of stakeholders

Individuals will be identified in accordance with the sampling frame and invited to participate by email (or letter). An information leaflet will be included about the study. Recipients will be asked to reply to the email or letter to indicate if they are willing to participate.

Data collection

Focused ethnographic case studies

A researcher will spend up to 8 weeks conducting fieldwork in each practice. One researcher will work in the practice for the duration of each case study although the level of attendance by the researcher will vary according to levels of digital facilitation activities within the practice. In each of the three geographical areas one researcher will conduct fieldwork in 2-3 practices during the study. There will be a lead fieldwork researcher based in Exeter, Warwick and Cambridge (RAND), plus supervision from the study lead in that site. We will develop a case study guide to support the researchers in their fieldwork and ensure consistency across sites and researchers. This will be informed by our theoretical framework; theory based evaluation. We will seek to understand the context, how and why the model of facilitation in use might lead to benefits, the key processes involved, outcomes of importance to patients/carers and staff and factors that may be acting as barriers and facilitators to the practice being able to offer digital facilitation and patients or carers to use online services.

Data collection will include:

i) Non-participant observation to understand how digital facilitation occurs within the practice, with whom, and in what ways

The focus of the non-participant observation will vary according to the mode of digital facilitation in operation within the practice. The observations will not include direct patient care within consultations but be focused on digital facilitation, what is involved and how practice staff and patients/carers interact with different models of facilitation within the context of that practice. The first 1-2 weeks will be spent acquainting themselves with practice staff, familiarising themselves with the practice and understanding the context of digital facilitation, before moving on to focus on digital facilitation. Observations and informal conversations as part of observations will be recorded using field notes. Researchers will take fieldnotes using pen and paper and will not use identifiers or names. Where possible fieldnotes will be made at the time of observation but if not, they will be written up as soon as possible afterwards. A practice code will be allocated to each participating practice so that any information stored about the practice cannot be identified as being from that practice. The key for the practice codes will be stored in a separate online folder from the data and will be password protected, with only the researchers able to access the document.

Individual consent will not be sought for observations. Rather, posters will be put on noticeboards and walls and in both public and staff only areas of the practice, and on the practice website. The poster will include a photograph of the researcher and contact details, along with an explanation

about the study and the dates that the researcher is in the practice. This will allow anyone visiting or working in the practice to contact the researcher should they need or wish to, with questions or concerns about any element of the study process.

The researcher will introduce themselves to staff members, ensuring that anyone present when they are observing is aware of the reason for their presence. Each staff member reserves the right to decline to be observed.

Where researchers are observing interactions around online services and facilitation more closely, they will ask patients or carers verbally whether they are happy to be observed. No identifiable information about patients or carers will be identified through observations.

Working in a general practice requires a high level of agreement between the practice and research team and the acknowledgement that this is a busy environment and that the researchers may be exposed to sensitive issues. The researchers will be aware of and sensitive to situations where their presence could cause issue and will seek guidance from the practice staff as to when it is appropriate to continue or cease data collection.

Researchers will be trained in observation techniques and will have the support of an experienced qualitative researcher who has overseen previous focused ethnographic case studies. Researchers will be aware of the sensitivities of observation and will carefully choose their position and take account of the priority for care and treatment in the settings. Regular research meetings between the fieldworkers and the senior researcher will facilitate reflection on observation processes.

ii) Attending practice meetings

Relevant practice level meetings will be identified through conversations with practice staff and from time spent in the practice. Relevant meetings are likely to be those where online services, the uptake of online services, practice workload or specifically digital facilitation are discussed. The researcher will ensure that all participants at the meeting are aware of who they are and why the researchers are there. The purpose of attendance will be to understand how online services and facilitation fit within the wider work of the practice as well as understand specific issues relating the processes involved in facilitation and any factors that may act as facilitators or barriers to implementation. Field notes will be maintained during and after meetings and, with permission, relevant documentation will be collated. This may include data on uptake of online services or details relating to facilitation (resources, processes, implementation).

iii) Collection of relevant data and documentation, e.g. data on uptake of online services, routine data about practice workload, or documentation relating to the model of facilitation in place

Data or documentation pertaining to online services or facilitation within the practice will be collated and contribute to the richness of data for each case study. Practice staff will be asked to provide these with any identifiable information removed. The researcher will discuss with the practice staff member the relevance of the documents and why they are important in relation to digital facilitation.

iv) 6 – 8 semi-structured interviews with patients, carers, GPs, practice managers and practice staff

Practice staff will be asked if they would be willing to participate in an interview and will be provided with an information sheet about the study. If happy to participate, an interview will be arranged at a convenient time and place. If taking place in the practice, a quiet location will be found to reduce the likelihood of disruption and to provide a confidential setting. Participants will be given the option of a face-to-face or telephone/online interview. Consent will be sought before the interview begins and, with permission, interviews will be audio-recorded. The interviews will seek to explore the drivers for facilitation in the practice, the model of facilitation in use (resources, processes, valued outputs), the perceived success of the facilitation model and factors that may be barriers or facilitators in implementation. Participants will be asked to talk from their perspective and to share their views and experiences. Participants will be free to stop the interview at any time without having to give an explanation should they wish to withdraw.
Where patients and carers have expressed a wish to participate in an interview, they will be provided with an information sheet about the study. A time for an interview will be arranged at a mutually convenient time for researcher and participant. All participants will be offered the option of in-person (at place of convenience, e.g. home or practice) or telephone/online interview. Before commencing the interview, the researcher will again check if the participant has any questions about the study and consent will be taken. Consent will be taken either verbally (if interview takes place over the telephone or online) or as written consent. Interviews will explore the patient/carers use of online services outside of health, their experiences of digital facilitation with the practice and barriers and facilitators to using online GP services. Participants will be given a £10 shopping voucher to thank them for the time taken in participating. Participants will be free to stop the interview at any time without having to give an explanation should they wish to withdraw.

With permission all interviews will be audio recorded. Encrypted recorders will be used for all interviews. Topic guides for staff and patient/carer interviews have been informed by the review, practice survey and theoretical framework. It is anticipated that interviews will last up to one hour.

v) 4-5 semi-structured interviews with patients who have a mental health condition

In three-four practices an additional 4-5 interviews with patients will be conducted, and the procedure will be the same as that described in the previous section (iv).

Stakeholder interviews

Interviews will be arranged at a mutually convenient time for researcher and participant. We anticipate that the majority of interviews will be conducted by phone or Zoom/Teams, according the preference of participants. Consent will be obtained before the interview and with permission, interviews will be audio-recorded. The topic guide explores the key drivers of digital facilitation, how stakeholders think digital facilitation works and the intended consequences of its application, both positive and negative. It will also explore issues around digital inclusion and the evolving policy context that the study could help to inform. Through our approach we will understand area-specific context for some case studies and a wider national context.

Handling of data

Patient survey

CFH Docmail has robust systems in place and all procedures and policies are written within the guidelines of these standards. Security checks are carried out internally by their Process Control Team, departmental manager on a regular basis to ensure continued compliance. Data to and from CFH Docmail is only ever transferred via encrypted channels, e.g. https and SFTP and all data coming into CFH is automatically virus checked by Endpoint Protection. All servers are secured with restricted access both logically and physically. Network layers are protected using firewall rules to restrict the flow of data. All services sit behind dual firewalls and each are from a different manufacturer.

Work email addresses, and general practice names will be retained where practice staff choose to provide this information (i.e. if considering participation in other sections of the study). Patient details will only be stored if provided by the patient for the purpose of contacting them about the prize draw. Their personal data will then be destroyed.

Use of personal addresses, postcodes, faxes, emails or telephone numbers:

Personal details will only be for the above purpose if provided by the participants themselves. Personal data will not be extracted from the practice by the researchers and the practice will make the first contact with patients.

Qualitative study

Patients interested in participating in an interview will return a reply slip to the research team which will include their name and contact details. These details will be kept only until the patient has been contacted and an interview arranged. Only encrypted audio/visual recording devices will be used.

All quotes from surveys and interview or information provided in the survey that could identify a person or the general practice will be anonymised prior to publication.

Consent forms will be completed electronically where possible. If hard copies are used these will be scanned and stored securely and hard copies destroyed.

Audio files of the interviews will be securely sent to, and transcribed by, a professional transcription service (Appen) who have a confidentiality agreement with the University of Warwick where the lead for this qualitative study, Atherton, is based. Whilst the transcription company will be asked not to transcribe identifiable information, each transcript will be checked by the local researcher once returned.

Anonymised transcripts will be stored and managed using the qualitative software package Nvivo. All data will be managed, stored and curated in line with the University of Exeter's Research Data Management Policy and Data Protection (GDPR) Guidance. The data will be in the form of paper (from notes taken during the case study and documents pertaining to models of facilitation) and electronic files (audio recordings, documents and data files). Paper files will be scanned wherever possible so that they can be electronically stored securely and originals securely destroyed. Audio files will be deleted once interviews are fully transcribed and checked. Files (paper and electronic) will be retained for 10 years. The University of Exeter's OneDrive for Business will be used for storing files to which RAND Europe and Warwick researchers are given secure access. Only those researchers working directly on the case studies will have permission to access files. All researchers will work on encrypted laptops and notes from observations or any other parts of data collection will be transferred to the secure shared space at the earliest opportunity.

Data analysis

Data from the focused ethnographic case studies will be analysed with data from the stakeholder interviews. Analysis will be ongoing alongside data collection. All members of the qualitative team at the three research institutions (University of Exeter, University of Warwick, RAND Europe) will contribute to analysis, led by Helen Atherton. Thematic analysis will be applied through the following steps: (i) reading transcripts and developing the coding frame; (ii) agreeing a final coding frame at a team analysis meeting; (iii) gathering related sections of transcripts, fieldnotes and documents under thematic codes, using NVivo to assist in this organisation process (and not for analysis itself); (iv) applying thematic analysis to each line of argument in the text, looking for outliers and negative accounts; (v) sharing findings with the wider research team, participating practices and PPI group to finalise interpretation. The qualitative research team will take part in two analysis workshops, one to agree a coding frame and a second to apply the thematic analysis. The team will engage in fortnightly video meetings during the analysis to ensure consistency of approach and discuss any issues arising. For purposes of this study, analysis of relevant data and documentation obtained from each case study site will be largely descriptive and will provide context.

6. ETHICAL AND REGULATORY CONSIDERATIONS

This is a purely observational study which makes no effort to change practice. As such the consequences of the study for participants are unlikely to arise to harm or disadvantage. The subject of our enquiry i.e. improving access to online primary care services has great potential for good. But we also recognise the potential for inadvertent disadvantage to sections of the population less able to access or use NHS online services – for example to non-English speakers, to socially and economically

vulnerable populations, to individuals with poor IT literacy, or to those living with substantial mental health or learning disorders. Each of our work packages will be alert to, and will aim to address these issues.

This protocol adheres to the UK Framework for Health and Social Care Research and has been approved by North East - Newcastle & North Tyneside 2 Research Ethics Committee (reference number 21/NE/0079).. Before any enrolment of participants into the study, the lead applicant will ensure that appropriate approvals from the HRA and participating organisations are obtained.

Usual informed consent arrangements will be put in place for the involvement of patients and staff. We have worked with the PPI group during this process, particularly when writing patient-facing documents. All data will be stored in an anonymised form on a secure server. Research governance and monitoring will be coordinated by the lead sponsor NHS Cambridgeshire and Peterborough Clinical Commissioning Group.

Assessment and management of risk

Prior to the start of the recruitment, a risk assessment will be conducted to identify any potential risks by the research team. The risk assessment will be completed and any hazards or risks will be identified and managed according to the University of Exeter protocols.

Patient survey

We are aware that occasionally participants can provide information that raises a safeguarding concern. Although we envisage this to be extremely unlikely in this instance (and GPs checked the list before sending out invitations will further minimise any risk), the research team have a duty of care to ensure that safeguarding issues are communicated back to the practice. The research team have put in place a structured guideline for ensuring that any issues of concern identified when analysing the data are managed accordingly. In the first instance, when a researcher identifies an issue of possible concern, the concern will be discussed with the Chief Investigator who will make the decision on whether the concern would be deemed to be in need of safeguarding. In this case, the research team would return to the practice, who would be able to de-anonymise the data. Consideration will need to be given to the timelines of the written responses.

Focused ethnographic study

The ethnographic fieldwork requires both NHS Research Ethics Committee (REC) approval and Health Research Authority (HRA) approval. All researchers conducting the fieldwork will require a research passport in order to conduct this fieldwork within general practices. Each participating practice will have the details of the lead for the qualitative study (Helen Atherton) and will be encouraged to make contact if there are any concerns or questions whilst the researcher is working in the practice. Depending on restrictions relating to the pandemic, researchers will potentially be conducting interviews with patients and/or carers in their homes. Patient and carer participants will be identified

via the general practice (and thus will be known to them) and practices will be informed that researchers may have to attend the homes of potential participants, therefore they will be asked as part of the screening process to ensure that there are no potential safety issues for the researcher. Where researchers are conducting a face-to-face interview they will follow lone working policies (in line with their employing University) and will carry lone working equipment (e.g. alarm, phone).

Research Ethics Committee (REC) and other Regulatory Review and Reports

Before the start of these research activities, a favourable opinion has been gained from the North East - Newcastle & North Tyneside 2 Research Ethics Committee (reference number 21/NE/0079).and Health Research Authority approval (request submitted) for the study protocol, informed consent forms and other relevant documents e.g. posters, topic guides for the ethnographic and interview study. The research team will ensure that:

- Substantial amendments that require review by REC and the Health Research Authority will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC and Health Research Authority will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review and Compliance

The Chief Investigator/Principal Investigator or designee for Di-Facto will ensure that appropriate confirmation from participating organisations are in place before any site enrols patients into the study. Specific arrangements on how to gain confirmation from participating organisations are in place and comply with the relevant guidance for NHS sites.

For any amendment to the study, the Chief Investigator in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

It is the responsibility of the sponsors for the study to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC. Any substantial amendments required for these stages of the study will be made by application to the REC/Health Research Authority, by the sponsor. The sponsor will submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice.

Amendments will also be notified to the R&D NHS Cambridgeshire and Peterborough Clinical Commissioning Group and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS confirmation for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

It is the responsibility of the lead researchers working on the patient survey and qualitative study, along with the project manager to amend the protocol if a decision to amend is made by the study sponsors.

Substantive changes will be communicated to relevant stakeholders (e.g. REC, R&D, regulatory agencies and sites) by the research team on behalf of the lead sponsor using emails and phone calls.

The amendment history will be tracked using electronic files in Teams Di-Facto folder that is shared across research sites. It will also be stored in the Di-Facto folder on the University of Exeter shared drive, which has access restricted to researchers on the Di-Facto Project and at the University of Exeter. Amendments will be tracked with version numbers and dates and recorded at the end of the protocol.

Peer review

This project has been funded by NIHR through the Health Services and Delivery Research panel. During the application process, the proposal was reviewed by seven anonymous independent reviewers (selected by the panel) which included researchers, a statistician, a health economist and patients. The protocol has been reviewed by clinicians, researchers, patient and public advisors. All feedback and comments from the aforementioned reviewers have been addressed and incorporated into this protocol, where appropriate. This protocol has been reviewed and approved by all members of the project management team.

Patient and Public Involvement

To date the patient advisory group has had significant input into the acceptability, design, management of the research. The group have also provided feedback on content and wording of the

patient survey and have been part of early discussions about the case study set up, in terms of how to approach patients and what would be acceptable for observations. They have also helped in the development of any patient-facing documents ensuring they make sense and are appropriate. An additional group comprising of patients with experience of mental health conditions have helped in the development of patient facing documents for the mental health focused aspect of this work.

The patient advisory group will continue to have significant input in a number of key stages, with flexibility to address emerging issues. These include:

1. Survey analysis and interpretation
2. Case study and stakeholder interview analysis.
3. Synthesis of findings - discussions of the results from the programme of work as a whole, and discussions around approaches to digital facilitation - how such approaches might be implemented in practice and what considerations are important to patients. We will open this meeting up to a larger group, ensuring that we speak to those with a range of levels of health literacy and will include digital non-users. Two of the patient advisory group will also attend the planned synthesis workshop.
4. Dissemination – help in ensuring results are disseminated in an understandable and engaging format and to places where relevant people will be able to access them. Here we will also work with the digital-health focused advisory group based in Warwick, and the Society of Academic Primary Care special interest group on health literacy. We have sought input into the final design of the study website.

Chris Marriott (patient, carer, and member of the Peninsula Patient and Public Involvement group) is an integral member of the research team. Chris Marriott will attend all project team meetings, and patient advisory group meetings to ensure there is a patient voice in all discussions and decisions throughout the life of the project.

Protocol compliance

Effective communication between individual members of the project management team and also with the practices who agree to participate in the study will be important to ensure protocol compliance. Protocol compliance will be monitored and managed by the chief investigator (John Campbell) and aided by Gary Abel and project manager Rachel Winder, each of whom will report progress to the project management team.

If accidental protocol deviations occur they will be documented on the relevant forms provided by the co-sponsor and reported to the Chief Investigator and Sponsor as soon as possible and actions taken to prevent their reoccurrence.

Data Protection and Patient Confidentiality

Patient survey:

Each participating practice will be given a practice code and all data relating to that practice will be identified using the code and not the practice name.

The research team do not ask for any personal data from survey participants, although participants can provide their contact details if they wish to take part in the prize draw. Participant details will be kept in a file only containing the names and addresses where provided and will only be made available to the Project Co-ordinator (Gary Abel) and project manager (Rachel Winder) for the purposes of the prize draw. All files will be downloaded in CSV format. The anonymous data from the patient survey will be stored on the University of Exeter computer system in a password protected location which is only accessible to members of the study team.

Due to recent regulatory changes in the way that data is processed (General Data Protection Regulation 2018 and the Data Protection Act 2018) the University of Exeter's lawful basis to process personal data for the purposes of carrying out research is termed as a 'task in the public interest'. Information on processing of personal data on the information sheet to participants provide an explanation of this. If there are any queries about the University's processing of patient survey data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection. If there are any concerns about how the data is controlled and managed for this study then it is also possible to contact the Co-Sponsor Representative, Pam Baxter, Research Governance Manager.

Focused ethnographic case studies:
A practice code will be allocated to each participating practice so that any information stored about the practice cannot be identified as being from that practice. The key for the practice codes will be stored in a separate online folder from the data and will be password protected, with only the researchers able to access the document.

Field notes will not include identifiable information about anyone in the practice. Whilst the researchers are in the practice conducting the observational work it is possible that they will be exposed to information about patients and identifiable information. This is unavoidable, however, none of this information will be recorded and the staff will be reassured that the researchers will not be making notes on any private conversations they may be party to. If the researchers are concerned about anything they see or hear this will be discussed with the CI.

Documents obtained from the practice relating to digital facilitation will be sent to the research team via email and stored securely in a password protected file, separate from information about the participating practices. Field notes will be stored electronically, using the practice code to identify individual practices.

All investigators and study site staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Data will also be kept safe until securely destroyed.

Personal information that is collected will be kept secure in passworded files and on a University of Exeter's One Drive for Business only accessible to the Di-Facto researchers needing access. Where the participants' identifying information is depersonalised and coded, an unrelated sequence of characters will be used. Data will be maintained securely and code linked in separate locations will use encrypted digital files within password protected folders and storage media. Access will be limited to the minimum number of individuals necessary for quality control, audit, and analysis. Personal data only provided to conduct the prize draw and alert the winners will be destroyed following contact with winners. Other personal data will be kept for 6 to 12 months beyond the end of the project and then destroyed. All other data will be kept for 10 years before being securely destroyed. The custodian of the data and data controller is the Chief Investigator at the University of Exeter. A data management plan is being drafted.

Indemnity

The sponsors will ensure appropriate insurance is in place to cover the design, management and conduct of the trial as appropriate. NHS or professional indemnity applies to GP practice staff.

Insurance for the study (Public Liability Insurance Policy and Employers Liability Insurance) is provided by Allianz Insurance Plc
(http://www.exeter.ac.uk/cgr/insuranceauditandrisk/insurancepolicies/public).

No arrangements for payment of compensation have been made in the event of harm to the research participants where no legal liability arises.

Access to the final study dataset

Regarding the patient survey data, individuals involved in the study who have access to the full data set will be limited to the Project Manager (Rachel Winder), Study Coordinator (Gary Abel), and Chief Investigator (John Campbell). An anonymised data file will be produced where patient identifiable information will be securely removed. The file will still contain a practice identifier which will allow the data to be linked at GP practice level to other data sources such as the GP Patient Survey. The anonymised data will be available to study researchers across the sites.

Regarding the qualitative data individuals involved in the study who have access to any identifiable data will be limited to the researchers (Dr Carol Bryce plus two as yet unappointed researchers) on this element of the project, the two local leads (Emma Pitchforth and Jenny Newbould) and the overall lead (Helen Atherton). Anonymised interview transcripts will be accessed by this team and where relevant shared with wider team members for the purposes of analysis.

Data management

The data arising from the study will be controlled by the lead institute (University of Exeter). The team will produce a data management plan describing how the research data will be managed and documented throughout the research project. The data management plan will be regularly updated using a web-based tool (https://dmponline.exeter.ac.uk) provided by the University of Exeter.
The anonymised quantitative patient survey data will be stored in the University of Exeter Repository (ORE): https://ore.exeter.ac.uk/repository/. We do not anticipate the qualitative data being shared. Any external researcher requesting data for secondary analysis would need to approach the team.

On the completion of the study, the data will be summarised from all work packages and a final report prepared for NIHR, according to their guidelines. The full study report will be accessible through NIHR. Participating investigators will be able to publish data according to NIHR guidance and research team publication guide. The NIHR will be acknowledged on all outputs according to their most recent guidance on branding.

Patient participants will have access to the Di-Facto website as written in the information sheets. The Di-Facto website will provide a summary of findings from the study once the Final Report has been written and results have been published in peer-reviewed journals.

7. DISSEMINATION POLICY

The dissemination strategy will be focused on informing NHS patients and carers, policy makers and frontline staff about the current status of digital facilitation, including potential related barriers and benefits. In addition to academic publications we will present our findings at relevant academic, service, and policy conferences, and engage directly with decision-makers and patients through targeted dissemination of a brief research summary. This will be facilitated through the developing project website (accessible at: http://sites.exeter.ac.uk/di-facto/) to support service providers in the use of digital facilitation, and a stakeholder dissemination event held in London (or held virtually if necessary).

The team continue to develop the strategy for dissemination during the monthly Di-Facto project meetings with the wider team.

We will report at the intervals and deadlines stipulated by the NIHR. Our final report to the NIHR will include an analysis of the current status of digital facilitation as presently implemented within primary care. This will include what is known about the likely effectiveness, cost and equity of access implications of the approaches identified, and an indication of the prevalence of various approaches in the four regions of England surveyed (East of England, North London; South-west; West Midlands). The report will provide recommendations for future development and implementation of promising approaches to digital facilitation, and will provide a framework for future evaluations to assess the

effectiveness, cost-effectiveness and impact on inequalities of access to the online services, of relevant facilitation approaches within primary care settings.

We will publish in peer-reviewed journals, present our findings at relevant academic, service, and policy conferences, and engage directly with decision makers (DH, NHSE, NIHR, healthtech bodies, BMA, professional bodies) and patients through targeted dissemination of a brief research summary. We will actively engage with our PPI team during this dissemination and have budgeted to allow our patient Co-applicant (Chris Marriott) and PPI lead (Emma Cockcroft) to attend and present at a national conference and to produce a PPI focused publication. Our dissemination will account for Government healthtech strategy and ambitions(47) which we will keep under constant review, aided by our network of contacts. We have instigated a publication plan which includes instigating and developing suggestions for publication of which is reviewed at monthly meetings.

Towards the end of the study, we will undertake a dissemination event in an accessible location, (e.g. London (or virtually if unable to meet face-to-face). This will involve patients, and practice, policy, and strategic lead personnel; relevant participation and travel costs will be covered. PPI colleagues will have active involvement in the design, and delivery of the event at which we will also secure input from national leads from DH/NHS (advised by collaborator/adviser Hodgson and others). The event will inform the final reporting of our research. In line with our previous approaches(48), we have initiated development of a prototype website to host our findings. We will make this website freely and widely available across the NHS, distributing the link via NHSE NHS Digital and Patient groups to support users and potential users of primary care digital services in their uptake and use of these important services and platforms. The RCGP will provide specific support to dissemination; they offer outstanding experience in this regard through their extensive national and international networks.

The research team will involve the patient representative (Christine Marriott) in dissemination of our findings, in particular, supporting attendance at, and presentation at dissemination events and conferences. The Exeter PPI team (PenARC led) has an outstanding, nationally-leading history in this regarding PPI not just representing input to study design and delivery, but developing scholarly work round PPI. Furthermore, we will seek to disseminate the PPI methodology for this work - what we did in PPI, and the impact of involvement of the research. The PPI group will also be actively involved in helping to ensure results are disseminated in an understandable and engaging format and to places where relevant people will be able to access them.

The research team will work with the digital-health focused advisory group based in Warwick, and the Society of Academic Primary Care special interest group on health literacy. The team will also seek input into the final design of the study website.

Authorship Eligibility Guidelines and any Intended Use of Professional Writers

For authorship eligibility guidelines we will follow The International Committee of Medical Journal Editors (ICMJE) on criteria for named authors i.e. :

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and
- Drafting the work or revising it critically for important intellectual content; and
- Final approval of the version to be published; and
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Participation solely in the acquisition of funding or the collection of data does not justify authorship. Authorship guidelines will be applied as inclusively as possible. When an individual has made a contribution to the manuscript but does not meet these criteria, their contribution should be recognised in the acknowledgements. We will obtain written permission from any individual who is planned to be acknowledged.

No professional writers will be employed for this project, the manuscript and funder report will be written by the project management team, which includes academics, clinicians and patient and public advisors.

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9. APPENDICES

Appendix 1: Required documentation

All local documentation required prior to initiating a participating site (e.g. CVs of the research team, Patient Information Sheet (PIS) on headed paper etc.) are listed here

Document type	Name of file	Dated	
Protocol	Di-Facto Protocol V1.3 15-02-2022	15/02/2022	
Schedule of Events Cost Attribution Template (SoECAT)	DiFacto SoECAT KT Approved March 2021 V1.0	02/03/2021	
Organisation Information Document (OID) - Patient survey	Di-Facto - Qualitative - OID NonCommercial - V1.0 16-03-2021	16/03/2021	
Organisation Information Document (OID) - Qualitative study	Di-Facto - Patient survey - OID NonCommercial - V1.0 16-03-2021	16/03/2021	
Indemnity certificate – Public Liability	UoE Confirmation_of_PL insurance Letter_2021 31-03-2021	01/04/2021	
Indemnity certificate - Professional indemnity	UoE Confirmation_of_prof indemn_Letter_01-04-2021	01/04/2021	
Indemnity - Endorsement inclusion in Biotech and Medical Malpractice Liability	UoE - UK Endt 1 (add Di-Facto trial) 24-03-2021	24/03/2021	
Indemnity - Employers' liability insurance certificate	2021-2022_EL_cert_University of Exeter	01/04/2021	
External peer review	Di-Facto proposal review and rebuttal 13-08-2019	13/08/2019	
CV Chief investigator (John Campbell)	HRA CV JohnCampbell 26-02-21 2 page	26/02/21	
CV Qualitative Lead (Helen Atherton)	HRA CV Helen Atherton 02-03-21	02/03/21	
Patient Survey Materials			
Patient Survey Practice Invitation Letter & Reply	Di-F Patient Survey_Practice Invitation Letter & Reply V1.0 16-03-2021	16/03/2021	
Patient Survey (Mental Health) Practice Invitation Letter and Reply	Di-F Patient Survey B_Practice Invitation Letter & Reply V1.0 14-03-2022	14/03/2022	
Patient Survey Practice Participant Information Sheet	Di-F Patient Survey_Practice PIS V1.1 20-05-2021	20/05/2021	
Patient Survey (Mental Health) Practice Participant Information Sheet	Di-F Patient Survey B_Practice PIS V1.0 14-03-2022	14/03/2022	
Patient Survey Invitation Letter V1.0	Di-F Patient Survey Invitation Letter V1.0 16-03-2021	16/03/2021	
Patient Survey (Mental Health) Invitation Letter V1.0	Di-F Patient Survey B Invitation Letter V1.0 14-03-2022	14/03/2022	
Patient Survey Invite Reminder Letter	Di-F Patient Survey Invite Reminder Letter V1.0 16-03-2021	16/03/2021	
Patient Survey (Mental Health) Invite Reminder Letter	Di-F Patient Survey B Invite Reminder Letter V1.0 14-03-2022	14/03/2022	
Patient Survey Invitation Reminder Card	Di-F Patient Survey Invitation Reminder Card V1.0 16-03-2021	16/03/2021	
Patient Survey (Mental Health) Invitation Reminder Card	Di-F Patient Survey B Invitation Reminder Card V1.0 14-03-2022	14/03/2022	
Patient Survey Patient Participant Information Sheet	Di-F Patient Survey_Patient PIS V1.0 20-05-2021	20/05/2021	

Document type	Name of file	Dated	
Patient Survey (Mental Health) Participant Information Sheet	Di-F Patient Survey B_Patient PIS V1.0 14-03-2022	14/03/2022	
Patient Survey Questionnaire	Di-F Patient Survey_Questionnaire V1.0 16-03-2021	16/03/2021	
Patient Survey (Mental Health) Questionnaire	Di-F Patient Survey B_Questionnaire V1.0 14-03-2022	14/03/2022	
Ethnographic Case Study Materials			
Practice Case Study Invitation Letter	Di-F_Ethnography_Practice Case Study_Invitation Letter_V1.0 160321	16/03/2021	
Practice Case Study Invitation Letter (not via CRNs)	Di-F_Ethnography_Practice Case Study_Invitation Letter_nonCRN_V1.0 160321	16/03/2021	
Practice Case Study Participant Information Sheet	Di-F_Ethnography_Practice Case Study_PIS_V1.1 20-05-2021	20/05/2021	
Practice Case Study Participant Information Sheet	Di-F_Practice Case Study_PIS_B_V1.2 15-02-2022	15/02/2022	
Practice Ethnography Observation Poster	Di-F_Ethnography_Practice Observation Poster_V1.0 160321	16/03/2021	
Patient Interview Invitation Letter and reply Slip	Di-F_Ethnography_Patient Interview_Invitation Letter&reply_V1.0 160321	16/03/2021	
Patient Interview Invitation Letter and reply Slip	Di-F_Patient Interview_Invitation Letter&reply B_V1.0 15-02-2022	15/02/2022	
Patient Interview Participant Information Sheet	Di-F_Ethnography_Patient Interview_PIS_V1.1 20-05-2021	20/05/2021	
Patient Interview Participant Information Sheet	Di-F_Patient Interview_PIS_B V1.0 15-02-2022	15/02/2022	
All Interview Participant Consent Form	Di-F_Ethnography_All Interview Participants Consent Form_V1.1 20-05-2021	20/05/2021	
All Interview Participant Consent Form	Di-F_All Interview Participants Consent Form B_V1.0 15-02-2022	15/02/2022	
Patient Interview Topic Guide	Di-F_Ethnography_Patient Interview_Topic Guide_V1.0 160321	16/03/2021	
Patient Interview Topic Guide	Di-F_Patient Interview_Topic Guide_B_V1.0 15-02-2022	15/02/2022	
Staff Interview Participant Information Sheet	Di-F_Ethnography_Staff Interview_PIS_V1.1 20-05-2021	20/05/2021	
Staff Interview Topic Guide	Di-F_Ethnography_Staff Interview_Topic Guide_V1.0 160321	16/03/2021	
Stakeholder Interview Materials			
Stakeholder Interview Email Invitation	Di-F_Qualitative_Stakeholder Interview_Email Invitation_V1.0 160321	16/03/2021	
Stakeholder Interview Participant Information Sheet	Di-F_Qualitative_Stakeholder Interviews_PIS_V1.1 20-05-2021	20/05/2021	
Stakeholder Interview Participant Consent Form	Di-F_Qualitative_Stakeholder Interview_Participant Consent Form_V1.1 20-05-2021	20/05/2021	
Stakeholder Interview Topic Guide	Di-F_Qualitative_Stakeholder Interviews_Topic Guide_V1.0 160321	16/03/2021	
Data protection entry details	ICO Data Protection register UoE 02-11-2001	02-11-2001	

Appendix 2: Amendment History

All protocol amendments will be listed here whenever a new version of the protocol is produced. Protocol amendments will be submitted to the Sponsor(s) for approval prior to submission to the REC.

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
0	1.1	08/07/2021	N/A	First fully approved version (V1.0 was only approved by ethics but not by HRA/CAG)
1.1	1.2	20/07/2021	J Campbell G Abel R Winder	Patient Survey: Minor protocol change arising from COVID-related challenges in practice recruitment necessitating an increase in the number of patient questionnaires distributed per practice and the NIHR requesting varying the number or patients selected depending on the practices' deprivation quintile in their area
1.2	1.3	15/02/2022	J Campbell H Atherton G Abel R Winder C Jenkinson J Parsons	i) Funding amount increased by 6-month cost extension and the additional work focusing on patients with mental health conditions ii) Study end date now 31.12.2022 iii) Additional work focusing on patients living with mental health conditions iv) Updated Gantt Chart v) Addition of Survey of Patients Living with Mental Health Conditions section vi) Inclusion of interviews with patients with mental health conditions in Qualitative Study section vii) Addition of C Jenkinson and J Parson to Study Contacts

Appendix 3: Co-applicants and key contributors

Chief Investigator	Professor John Campbell
Study Co-ordinator	Associate Professor Gary Abel
Lead: Qualitative exploration	Associate Professor Helen Atherton (HA)
Project Manager	Ms Rachel Winder
Ethnographic case study	Dr Jenny Newbould
Ethnographic case study	Dr Emma Pitchforth
Chief Economist	Mr Jon Sussex
Research Fellow	Dr Carol Bryce
Co-Applicant	Dr Jeffrey Lambert
Postdoctoral Research Associate	Dr Mayam Gomez Cano
Co-Applicant	Dr Christopher Clark
Co-Applicant	Associate Professor Laura Sheard
PPI lead	Dr Emma Cockcroft
Research Fellow	Dr Caroline Jenkinson
Research Fellow	Dr Jo Parsons