Accessible Results: enabling patients with diverse needs to access and understand their blood test results online

IRAS ID: 349062

Sponsor's No: 2024 - 5829

Funder's number: NIHR159467

Protocol Version 1.3: 09/12/2024

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Funder(s)	National Institute for Health Research (NIHR)- Health and Social Care Delivery Research (HSDR) Programme. NIHR159467

Committees	Project management group Study steering committee

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Summary of research

Study Title	Accessible Results: enabling patients with diverse needs to access and understand their blood test results online
Internal ref. no. (or short title)	Accessible results study
Study Design	We will use the person-based approach to develop the intervention through the following work packages: WP1: qualitative interviews with patients and staff WP2: co-production workshops to develop draft tools and guidance WP3: web-based user-testing and refinement of the tools and guidance
Study Participants	Patients and staff from GP practices in recruited in the South-West (Bristol) and North-West (Manchester) of England
Planned Size of Sample (if applicable)	Estimated sample size. WP1 (60) WP2 (100) WP3 (300) TOTAL: 460
Follow up duration	Not applicable
Planned Study Period	Two years
Research Question/Aim(s)	To develop tools and guidance to assist all patients, including those with diverse needs, to access and understand online test results.

Funding

FUNDER(S)	**FINANCIAL SUPPORT**
National Institute for Health and Care Research (NIHR)	£639,391

Role of study sponsor and funder

The sponsor will ensure that the necessary arrangements are in place to facilitate the set-up, running and reporting of the study.

The funder will provide the financial support required to deliver the study.

Roles and responsibilities of the management groups

The study will have a project management group (PMG) and a study steering committee (SSC). The PMG will be responsible for the design, delivery and management of the study. The PMG consists of the study CI, co-investigators including patient and public involvement (PPIE) co-investigators, and the study research team. PMG will have monthly meetings throughout the study.

The SSC will provide independent oversight for the study. They will receive and review progress and accruing data from the study, providing advice on its conduct. The SSC comprises of an independent chair, an independent statistician, an independent academic, an independent clinician, and two PPIE who have not had any prior involvement in the study. It is planned that the SSC will meet four times throughout the course of the study.

PPIE collaborators have been involved in the study from the pre-award development of the proposal and will continue to be involved until the completion of the study. Two PPIE have been involved as co-investigators in the study giving valuable feedback on proposed study plans. Two independent PPIE will be a part of the SSC. An advisory panel consisting of a diverse group of PPIE will be convened to co-produce the study intervention; they will meet regularly throughout the study. Further co-production will be undertaken by conducting workshops among various groups who have experienced online blood results accessibility challenges.

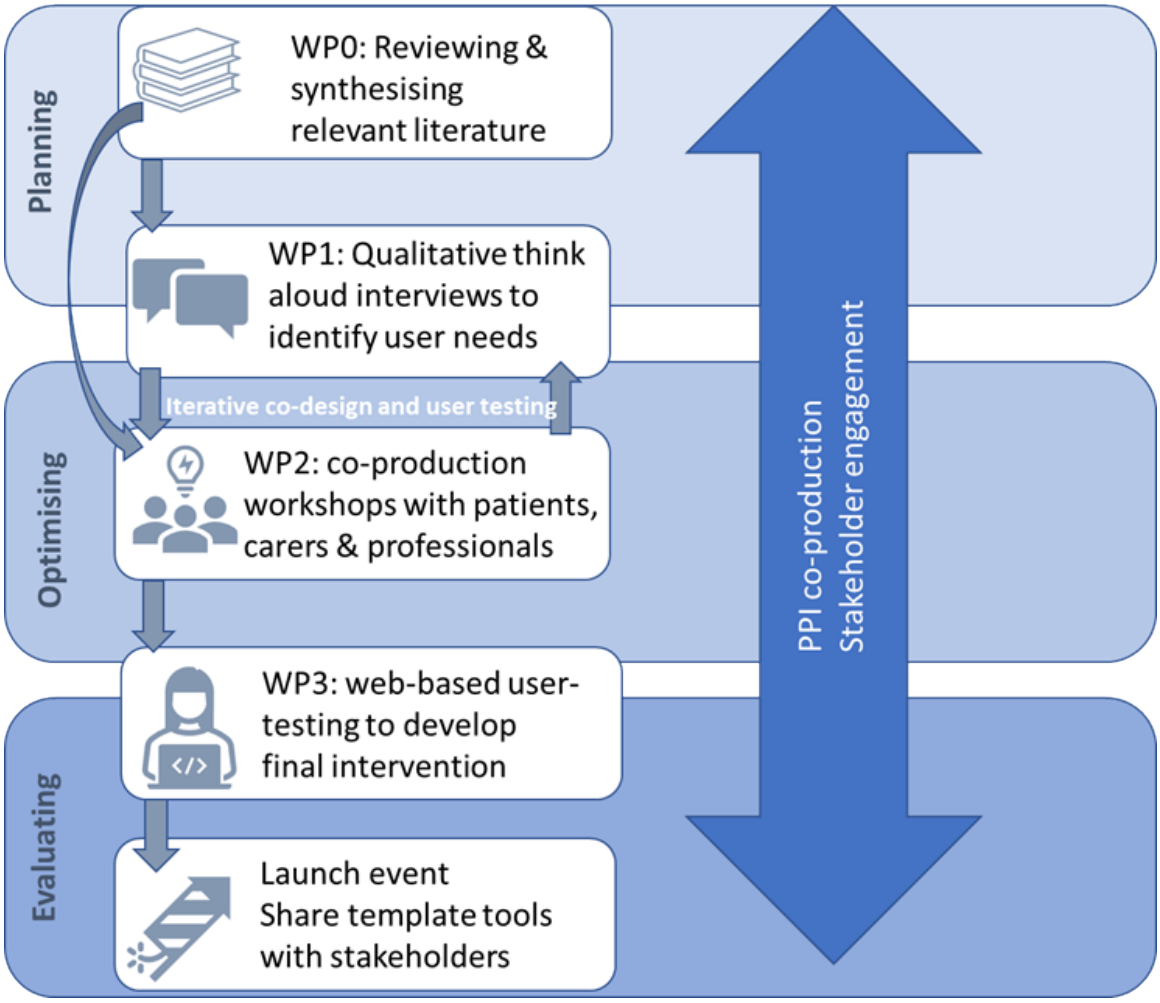
KEY WORDS: Accessible results, blood results, digital health, health informatics, patient communication, EHR, electronic health records, decision-making, patient engagement, digital health literacy, primary care, patient online access

Abbreviations

CI	Chief Investigator
GCP	Good Clinical Practice
NHS	National Health Service
NIHR	National Institute for Health Research
PI	Principal Investigator
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
GP	General Practitioner
NICE	National Institute of Health and Clinical Excellence
PPIE	Patient and Public Involvement and Engagement
PMG	Project Management Group
SSC	Study Steering Committee

Study flow chart

Below is a representation of the study design.



1. Background

"I've been in limbo for quite a few days, is he going to ring me today, has he had them back?"

Patient quotes from our research illustrate some of the challenges, anxieties and frustrations experienced by patients and carers trying to access test results.[1-3] Analyses of indemnity organisation complaints has shown that failure to communicate test results can have important patient safety implications.[4 5] With an estimated 50 million pathology test reports sent to GPs every year in England,[6] communicating blood test results to patients is also an important workload challenge for overstretched primary care teams.

NHS England has rolled out online access to test results to patients via the NHS App and other online services, as a potential solution to this problem.[7 8] However, the NHS App currently provides test results in a format primarily designed to serve the needs of clinicians. Patients or carers need to receive the results of a test, understand what this means to them, and know what the next steps in their care should be. If patients are not provided with this information in a patient-centred way, online access to test results may increase patient anxiety and uncertainty. The James' Lind alliance identified as a priority the need to provide information in patient medical records in a way that improves safety and quality of care.[9]

Research to improve online access to test results is also highly topical in the context of the current workforce crisis and rising workload facing primary care. Improving online access has the potential to reduce telephone calls to GP surgeries to discuss test results,[10] however the opposite is also true, with primary care staff reporting concerns that viewing results online could lead to an increase in patient queries.[11] Ensuring test results are provided to patients in a way that is meaningful to them is important to reduce the need for patients to contact their GP surgery for further information.

Moving to online methods of viewing test results could also disadvantage patients at risk of digital exclusion, as highlighted by a recent House of Commons report.[12] A scoping review on digital technology and health inequalities published in 2020 concluded that many groups who are already subject to disadvantage and worse health outcomes are also subject to digital exclusion;[13] without intervention to improve accessibility, moving to online access for test results has potential to exacerbate the inverse care law.[14] Groups at particular risk of being disadvantaged by online access include elderly patients, minority ethnic groups and people with learning disabilities.

We recently completed a mixed-methods systematic review of 71 studies focused on interventions to improve the communication of test results. [15] Our findings suggest that patients want more detailed information about their blood test results, especially regarding next steps, and they prefer

to receive results quickly. While electronic methods, such as online access and text messaging, were generally well-received, they were not suitable for everyone or all types of results. There was a lack of research into the experiences and preferences of people at risk of digital exclusion for example the elderly, minority ethnic groups, people without English as a first language and those with additional needs.

The aim of this research is to address this problem, by developing tools and guidance to assist all patients, including those with diverse needs, to *access* their test results via online portals including the NHS App and to *understand* what these results mean for their health.

2. Theoretical framework

The person-based approach (PBA) to intervention development will be adopted for this study. PBA is particularly suited to this study as it allows for the exploration of the psychosocial context of a diverse group of intended intervention users and utilise this to co-produce pragmatic, appropriate, and engaging interventions. Through PBA, programme theory will be developed and particular principles required for the success of the intervention identified from the data, literature and discussions with PPIE and the stakeholders.

3. Aims and objectives

The aim of this research is to develop tools and guidance to assist all patients, including those with diverse needs, to access their test results online and to understand what these results mean for their health.

Objectives:

1) To explore the current experiences of patients and carers when accessing blood test results online.
2) To explore primary care staff attitudes and experiences of the shift to online test communication.
3) To identify barriers and facilitators to improving online access to test results for patients with diverse needs.
4) To co-produce and test prototype tools and guidance to improve accessibility of online blood test results.

We acknowledge that it will not be possible to address the accessibility needs of all different possible diverse groups at risk of digital exclusion. We will focus on enabling access to a wide range of diverse

patients, and will target groups at risk, such as those with cultural and language barriers, carers of those with additional needs, and older people at risk of digital exclusion.

3.1 Outcome

The study aims to produce tools that can help patients to access and understand their blood test results more easily. To do this we will develop:

a. A detailed understanding of patient and staff experiences of online access to test results (work package 1)
b. Co-produced draft tools and guidance to improve online test communication (work package 2)
c. Final template tools for dissemination to stakeholders at a launch event (work package 3)

The final output will be an implementation intervention to assist patients with diverse needs to access and understand their blood test results online, which will be shared with a variety of stakeholders including the NHS App team to maximise impact. We anticipate that the implementation intervention may include (but not be limited to) components such as:

• Prototype template tools or infographics for presenting blood test results in a more accessible way in online portal such as the NHS App.
• Template wording for clinicians to use when adding comments to test results to ensure accessible language is used.
• eLearning materials or recommendations for clinicians.
• Posters or leaflets for GP practice waiting areas to improve awareness of online methods of test communication.
• Resources for patients with diverse needs to help them to navigate to their test results on online portals such as the NHS App.
• Translated resources for patients with English as a second language.
• 'Easy read' resources for patients with additional needs.

4. Study Methods

This section sets out the study methods for each phase of the research including the theoretical approach we are using, the design and setting, the sampling and recruitment, data collection, data analysis and consent procedures.

We will use the person-based approach,[16] engaging closely with patients and carers throughout. The project will comprise of three work packages (WP), building on a systematic review (WP0) which is already completed.[17] WP1 will be a qualitative interview study with patients and staff using think-

aloud methods to identify user needs. WP2 will be a series of co-production workshops and public engagement events which will be used to develop draft tools and guidance. WP3 will be web-based user-testing and refinement of the tools and guidance.

4.1 WP1: Qualitative interviews to identify user needs

4.1.1 WP1: Setting and design

This is a multi-centre study. Interviews will be undertaken at a primary care surgery, the participant's home, or other location preferred by the participant. Interviews will also be conducted by telephone or online via Zoom or MS Teams (according to participant preference).

We will conduct qualitative interviews with patients who have recently had blood tests in primary care, and primary care staff, to explore their experiences of online test result communication. This will correspond to the 'identifying user needs' component of the person-based approach. We will not limit recruitment to any specific type of blood test as we are interested in the systems and processes of communication. WP1 and WP2 will run in parallel to ensure that the intervention is developed iteratively based on user needs.

4.1.2 WP1: Sampling and recruitment

The aim of the study is to enhance patients' access to blood test results. Our sampling strategy therefore aims to include a breadth of patient populations that also include those most likely to experience barriers to accessing and understanding their test results within the confines of available time and research resource.

We will recruit six GP practices serving diverse communities in the Bristol and Manchester regions, with support of the NIHR Research Delivery Network. This will include the wider NIHR Lancaster University and Partners region including Greater Manchester, Blackpool and Cumbria, as well as Bristol, North Somerset and South Gloucestershire regions. This will allow us to recruit a mix of urban, suburban and rural practices to ensure a diverse sample. Recruitment will be split 50:50 between Bristol and Manchester.

During study set up, researchers will identify key staff members in participating practices who are involved in the different stages of test communication, such as GPs, allied health professionals, nurses, phlebotomists, receptionists, practice managers. Purposive sampling will be used to recruit a wide range of these primary care staff members for qualitative interviews, with a range of years' experience, age and gender.

For patient interviews, we will use purposive sampling to achieve maximum phenomenon variation in terms of age, gender, ethnicity and reason for blood tests. This is because we anticipate that

different types of test (diagnostic, monitoring or screening) may provoke different needs or reactions when looking at results. During study set up we will identify patient groups or populations which clinical staff think are at particular risk of being disadvantaged by the transition to electronic test result communication. These 'at risk' groups may differ slightly depending on the practice population. We will then purposively target to achieve a diverse sample, including these 'at risk' groups. We anticipate that this may include purposive sampling of; minority ethnic groups who may have cultural or language barriers to accessing online test results; people with disabilities which could impact on their abilities to access online test results and their carers (e.g., learning disability or mental health problems); and older people with self-reported low levels of digital literacy.

Final sample size will be contingent on obtaining sufficient information power[18] and on the iterative approach described; based on previous experience we estimate this will involve recruiting around 50-60 participants in total (approximately 40 patients and 20 staff).

Eligibility criteria: Patient and carer interview participants

Inclusion criteria

- Patient aged ≥18 who has had a blood test in the previous month

Or:

- Carer aged ≥18 of a patient who has had a blood test in the previous month

Exclusion criteria

- Clinician feels it would be clinically inappropriate to invite a participant (e.g. patient on palliative care register)
- Person is unable to give informed consent

Eligibility Criteria: Primary Care Staff Interview Participants

Inclusion criteria

- A member of primary care staff involved in systems of blood test communication (to include both clinical and non-clinical staff).
- Employed at a GP practice that has implemented patient online access to test results.

Exclusion criteria

- Locum staff or staff members working less than one day per week in a practice

Patients will be invited to participate in the study by GP practice staff at the time of blood testing, or as soon as possible thereafter. Methods of recruitment will be flexible to accommodate different

practices patterns and routines for blood testing. Options for recruitment include: text message invitations at the time of testing or when appointment reminders are sent by text; targeted text messages using searches of the electronic health records to target specific 'at risk' groups; posters in phlebotomy clinics; researchers sitting in a spare room at the time of phlebotomy clinics to discuss the study with patients; or leaflets issued via phlebotomists to patients. Leaflets will be translated into up to five different languages; the choice of languages will be based on the advice of clinicians in recruited practices. We have previous successful experience of recruiting patients and clinicians for qualitative interviews about blood testing using similar methods.[1 2] Patients will receive £25 vouchers to recompense their time in participating in the study, primary care staff will be paid in accordance with NIHR Research Delivery Network agreed rates. Reasonable travel expenses for any visits in addition to normal care will be paid in full for all participants.

Interested participants will be asked to complete an expression of interest form including basic demographic data to enable purposive sampling. These will be made available in paper or digital format. Expressions of interest will then be followed up by a member of the research team via the participant's preferred channel of communication and time. Any expressions of interest from participants that are not included in the purposive sample will be contacted by the study team to thank them for their interest and to invite them to join a reserve list in case of dropouts.

Invitations to participate in the study will be managed collaboratively between the research team and participating practices, with practices being encouraged to invite specific sociodemographic groups of interest as the study progresses. This iterative process will ensure that the sample is purposive and aligns with the study's broader aims of achieving maximum variation and inclusivity, particularly for patients likely to face additional barriers to research participation and accessing their results.

4.1.3 WP1: Consent

Participants will receive study information tailored to their communication needs and preferences as part of the recruitment process . Practice staff will not be required to consent patients, only to issue patient information to eligible participants. Informed consent will be obtained at the start of the interview. Consent forms will include an optional expression of interest for participating in WP2 workshops. For telephone and online interviews, consent will be taken verbally, but will be recorded and will replicate the consenting text used on the written consent forms.

Consent will be obtained by a member of the research team by asking participants to sign a hard copy or email a digital copy of the consent form . Where a participant is unable to sign or mark a document to indicate their consent, arrangements will be made for their consent to be witnessed

and documented. Those involved in obtaining consent will be trained in assessing capacity, having completed Good Clinical Practice Training. If a participant is deemed to lack capacity to consent they will be thanked for their time and reimbursed for their expenses but will not be included in the study.

Withdrawal from the study

Participants will be informed they can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected.

As part of the consent process, participants will also be reminded that it will not be possible to remove their data from the project once it has been anonymised and forms part of the data set.

4.1.4 WP1: Data collection - Patient interviews

Semi-structured qualitative interviews will be conducted either online (via Microsoft Teams or Zoom) or face-to-face, depending on patient and staff preference. University approved interpreters will be used to enable non-English speaking participants to take part in the study. Patients will be encouraged to obtain their results prior to the interview if possible. This will allow patients time to digest and reflect on the results before interviews are conducted. If patients have not been able to access their test results due to barriers to communication, or where a follow up consultation to discuss results is still pending, then the interview will explore their experience of waiting for or trying to access online test results. Where possible we will then aim to conduct a second follow up interview in order to track their experiences and gain a better understanding of the patient journey between testing and receiving their results.

Patient interviews will be broken down into two sections. The first section will explore participants' experience of receiving their test results. Initial questions will cover patient understanding of the reasons for testing, and systems of test result communication. Patients who have accessed their test results online will be asked to review their test results during the interview and think-aloud techniques will be used to explore: usability and experience of navigating their online test results; what the test results show; what this means to the patient; what happens next; what they think about the way the results are presented; and what information could help them to better understand their tests. It is possible that some participants may not have the chance to look at their results before the interview, to mitigate for this we will incorporate some buffer time at the start of the interview schedule in case a participant needs time to access their records.

We will explore potential workload implications associated with communication by exploring with patients whether they plan to book any follow up telephone or face-to-face consultations with a

clinician to discuss their results or if they might respond in other ways such as asking a family member or undertaking their own online research. We will also explore any unanticipated consequences of the move to online test result communication, for example wider issues relating to loneliness and the wellbeing of older and socially excluded people.

For the second part of the interview participants who have not been able to view their own online test results will be shown prototype test results, as they are currently presented in the NHS App. The NHS App team have offered to provide these as interactive prototypes for this research , we will have static mock-up test results available as a backup in case of technical problems. This is important as we anticipate that participants with barriers to accessibility are less likely to have viewed their results online. By sharing mock-up test results they will be able to get an idea of what their results *would* look like if they were viewed on the NHS App. This will allow us to use think-aloud methods to explore how current methods of online test communication would be perceived by those with accessibility barriers, and how these could be made more inclusive. WP1 and WP2 will run in parallel, allowing us to share mock-ups of hypothetical test results using our draft template tools in later WP1 interviews for user-testing and iterative feedback.

4.1.5 WP1: Data collection - Primary care staff interviews

Interviews will aim to explore staff attitudes and experiences of the shift to online test communication. The topic guide will include questions about staff members experience of patient online access to blood test results; their perception of the impact of the shift to online test communication on primary care workload; discussion of practice protocols for online test communication. We will also discuss with staff which patient groups are perceived to have accessibility barriers to online test communication and why. During later WP1 interviews we will share mock-ups of hypothetical results using our draft WP2 template tools, for iterative feedback from primary care staff members as part of the person-based approach.

Additionally, during interviews with clinical staff who regularly review and comment on patient blood test results, participants will be asked to review recently filed test results from their pathology inbox. This will help ensure that their insights are grounded in real-life clinical practice. For these clinician interviews additional topic guide questions will explore what these test results show; what patient comments the clinician will add to the results; how any actions will be communicated to the patient; and any potential barriers the patient might face in accessing or understanding their test results online. We will also conduct interviews with staff members who do not typically comment on patient results but are involved in other areas, such as booking or performing tests and supporting patients with retrieving and understanding their results. The topic guide for these interviews will be

adapted to explore how staff in these roles experience supporting patients with test result communication.

With the respondents' permission, telephone/ video call and in-person interviews will be digitally audio-recorded on a university provided encrypted audio device, or via Zoom/MS Team recording platforms as appropriate.

4.1.6 Data analysis

Recordings will be transcribed verbatim using a University of Bristol approved transcription service, and stored securely on a controlled departmental file storage location on the University servers. Transcripts will be anonymised by members of the research team, uploaded into NVivo data management software, and analysed using thematic analysis.[19] Categories of data and thematic relationships will be identified and written up as descriptive and interpretive accounts.

4.2 WP2: Co-production workshops with stakeholders

Co-production workshops with stakeholders will be used to iteratively develop template tools and guidance for online blood test result communication.

We will conduct 8-10 workshops in total, with separate workshops for patient groups and staff. Workshops with community groups will be conducted in community settings to help engage people from diverse communities. Workshops with staff will be conducted online to facilitate attendance. We anticipate that the workshops will last around an hour and a half.

Workshops will be co-facilitated by a research team member and either a PPIE co-applicant, a community support worker or community group organiser, depending on the needs of the group. A second member of the research team will attend to observe and take notes. With the participants' permission, workshops will be audio-recorded via encrypted audio-recorders or via Zoom/MS Teams recording platforms.

Due to the dynamic nature of the co-production process, we may need to conduct additional workshops or engage in other forms of co-production activities such as email communication to elicit additional comments on the iterative development of prototype tools and guidance. Additional public engagement activities will also be conducted to enable wider engagement (see PPIE section).

4.2.1 WP2: Setting and design

Co-production workshops will be held with participants recruited through general practice, clinical networks and community organisations within Bristol and Greater Manchester. It is anticipated that

the workshops with the clinicians and the patients will be conducted either face-to face or remotely if the target group are better accessed that way.

4.2.2 WP2: Sampling and Recruitment

We will conduct 8-10 workshops in total, each comprising 6-10 participants, we anticipate approximately 100 workshop participants. A subgroup of patients and clinicians from the six GP practices in WP1 will be invited to participate in co-production workshops. Recruitment will be supplemented via local community groups in Bristol and Manchester (see below) in order to achieve a diverse sample of participants including a range of ages, genders and ethnicities. Priority patient groups will be determined based on primary care staff responses in WP1 and findings from the literature. Activities that concern publicising the study to identify and recruit potential participants will take place at a primary care site or via community organisations serving potential participants. For example, we will ask community organisations to promote the study via recruitment posters at meeting venues or via other communication channels such as newsletters and social media. Primary care staff recruitment may also include snowball sampling or advertising the study within the research teams' professional networks.

Patient and carer participants will be compensated for their time, receiving a £35 voucher in accordance with NIHR RDN guidance. Practices will also be compensated for staff time with per-person rates calculated and agreed by the NIHR RDN team. Reasonable travel expenses will be paid in full for all participants.

WP2: Inclusion criteria

Patient workshops:

- Participant aged ≥18

Or:

- Carer aged ≥18 of a patient

Exclusion criteria

Person is unable to give informed consent

Clinician workshops:

People aged ≥18 employed in a role that involves communicating test results to patients. For example, GPs, nurses, receptionists, practice managers, healthcare assistants, laboratory staff, clinical biochemists or haematologists.

4.2.3 WP2: Consent

Patients recruited through GP practices (in WS1), will receive study information from practice staff. The consent forms will include an optional expression of interest for participating in WP2 workshops. Consent will be obtained by a member of the research team by asking participants to sign a hard copy or email a digital copy of the consent form . Where a participant is unable to sign or mark a document to indicate their consent, arrangements will be made for their consent to be witnessed and documented.

Patients recruited through community organisations will receive a study invitation through their community group coordinator/lead. The study information will then be shared with them ahead of the workshop. At the workshops, hard copies of the consent forms will distributed. Time will be allocated at the start of the workshop to allow completion of the informed consent process.

Clinicians will be recruited via clinical networks including through GP practices. Interested clinicians from the GP practices will be able to contact the research team via email. The research team will then email them the study information sheet and consent forms for their consideration and completion. For clinicians recruited through snowball sampling, the research team will contact them with study information inviting them to the study. The clinicians will then have the opportunity to read the information and either complete the consent form and share with the study team, or decline participation. Clinicians who do not respond to the first email will be re-contacted a couple of weeks later. If they still do not respond they will not be contacted further.

Withdrawal from the study

Participants will be informed they can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected.

As part of the consent process, participants will also be reminded that it will not be possible to remove their data from the project once it has been anonymised and forms part of the data set.

4.2.4 WP2: Data collection - co-production workshops

During the initial workshops we will share examples of patient-centred methods of online test result display identified by WP0, and compare these with methods of communication currently used by the online portals such as the NHS app. The topic guide will explore: what they liked and disliked about these different test result displays; how these test result displays could be made more accessible for patients; what other support is needed to help patients and clinicians shift to online methods of test communication; what information is needed to help patients to understand and interpret their online test results; and how online test results communication could be made more acceptable and accessible to all. The topic guide will be developed with our PPIE panel to ensure that questions are worded sensitively for patient and public participants. Workshop participants who are interested in

contributing further will be invited to join the PPIE advisory panel responsible for iterative development of the intervention.

Feedback from the workshops will be used to develop the draft template tools and guidance, which will then be shared in subsequent workshops and iteratively adapted. We will also share the draft template tools during the ongoing WP1 qualitative interviews which will be run in parallel with WP2, to gain in-depth feedback on the draft intervention using think-aloud techniques.

4.2.5 Data analysis and intervention development

Analysis of WP1 and WP2 will run in parallel with data collection. Interviews and workshops will be audio-recorded using an encrypted digital recorder or via Zoom/MS Team recording platforms. Recordings will be transcribed verbatim using a University of Bristol approved transcription service, and stored securely on a controlled departmental file storage location on the University servers. Transcripts will be anonymised by members of the research team, uploaded into NVivo data management software, and analysed using thematic analysis.[19] Categories of data and thematic relationships will be identified and written up as descriptive and interpretive accounts. Patient and public co-applicants will be involved looking at and interpreting the emerging data and will work with the research team to co-produce a list of 'guiding principles' which will shape the development of the intervention. These guiding principles are defined by the person-based approach as broad over-arching principles that can inspire and inform the intervention development by highlighting the distinctive ways that the intervention will address key context-specific behavioral issues.

Findings from WP1 and WP2 and views and suggestions of the PPIE panel will be continuously summarised into an intervention planning table. This will bring together all the available evidence about what elements are needed in the intervention and why. For example, if we identify that a barrier to test communication is a lack of understanding of the meaning of test results then our resources could include suggested template wording for clinicians to use when filing different types of blood test results. We anticipate the intervention will include a range of template tools for displaying blood test results in an accessible way, as well as guidelines and resources for improving accessibility of online systems of test communication. The PPIE advisory panel will meet regularly during the development and iteration of the intervention. Feedback from later co-production workshops and user-testing will be collated into a table of changes, which will be used to iteratively amend the initial template tools.

During the intervention development phase, we will also collaborate with the NHS App team to support their work on test result communication, ensuring that any tools we design complement existing resources rather than duplicate them.

4.3 WP3: Web based user-testing of prototype tools

This work package will use a web-based questionnaire to gain feedback on the draft prototype tools from a wider pool of users in order to iteratively develop the final tools.

4.3.1 WP3: Setting and design

A postal questionnaire or a link to an online version of a vignette-based questionnaire will be distributed to patients aged ≥18 who had recent blood tests in the six GP practices recruited in WP1 as well as patients and carers from the community groups involved in WP2.

4.3.2 WP3: Sampling and recruitment

Non-probability sampling will identify patients (and carers of patients) aged ≥18 who had recent blood tests. Sample size will be contingent on our primary outcome; however, we estimate that ≥3,000 eligible patients could be invited from the six GP practices recruited (assuming 500 blood tests per month per average practice). This will ensure that participants are broadly representative of the population receiving primary care blood tests and have recent lived experience of receiving blood test results to inform their views on our prototype tools.

Previous similar questionnaires achieved adequate power with 200-300 participants:[20 21] comfortably achievable with our proposed methods. If required, we will also recruit additional participants via the NHS App as discussed below.

We will offer practices a range of options to maximise recruitment and to ensure patients with accessibility needs are not excluded. Firstly, we will encourage phlebotomists to invite eligible participants at the time of blood testing; with the option of sending a text message link to the online version of the survey, or providing a printed copy with a pre-paid return envelope to mitigate against digital exclusion. This will be supplemented by using automated searches of the electronic health records to identify patients aged over 18 years who had recent blood tests. Practices will be given the option to exclude any participants where the clinician feels it would be clinically inappropriate to invite them to participate (e.g. those on the palliative care register). Eligible patients will then be invited to participate in the questionnaire by batch text message. In order to boost recruitment amongst specific disadvantaged groups we will also disseminate the questionnaire via the community groups involved in WP2. Participation will be voluntary, and responses will be fully anonymous.

As part of our collaboration with the NHS App team, we have been offered the option of additionally recruiting participants directly from the NHS App using Qualtrix software. Recent similar surveys which have been disseminated via the NHS App received over 1000 responses in 24 hours. We

anticipate that it is unlikely to be possible to implement our full questionnaire via the app, as the app is limited to a small number of questions. However, if it would benefit our intervention development to disseminate a subset of questions to a wider pool of users using the app, we will consider using this method to boost recruitment and increase the power and generalizability of our findings.

Eligibility criteria
Inclusion criteria:

- Patient (or carer of a patient) aged ≥18 who has had a blood test in the past 1 month

OR

- Patient (or carer of a patient) aged ≥18 who has been involved in the WP2 workshops who has had a blood test within the past 12 months

Exclusion criteria:

- Clinician feels it would be clinically inappropriate to invite a participant (e.g. patient on palliative care register)

4.3.3 WP3: Consent

The front page of the questionnaire will explain that by completing the questionnaire they are consenting for their responses to be used as part of the study.

4.3.4 WP3: Data collection

The first section of the questionnaire will collect demographic data on participants including age, gender and self-reported ethnicity. Identifiable data such as patient's name, postcode and contact details will not be collected. Participants will then complete questions to explore test understanding and satisfaction using a range of experimental vignettes. We anticipate the vignette cases could include: a patient having routine monitoring blood tests for chronic conditions; a patient with non-specific symptoms; and a patient with significant symptoms which might indicate cancer. Mockup test results will be presented with each scenario, including normal, borderline and abnormal test results. For each scenario we will compare current methods of test communication, with our template tools for test communication. We will compare patient understanding, patient anxiety and patient satisfaction with communication developed using our implementation intervention, versus current practice for test communication. We will also include a behavioural outcome to explore the likelihood of seeking further medical advice, in order to gain insights into the potential workload implications of our intervention. The questionnaire will be developed based on pre-existing validated instruments and previous questionnaires.[20 22 23] We will work with our PPIE advisory panel to finalise

outcome measures which are important to patients, and will test the questions with the community groups in WP2 as part of the iterative development of the intervention.

As well as template tools we anticipate our intervention will include a range of additional recommendations to help patients access their test results online and to understand what these results mean for their health. This could include recommendations for GP practices or for primary care clinicians to help patients to access and understand their online test results. We will ask participants to indicate to what extent they agree with these recommendations, and which recommendations they would rank as most important and why.

4.3.5 WP3: Data analysis and development of final implementation intervention

The questionnaire will be analysed using descriptive statistics (percentages, medians, inter quartile ranges) to describe and quantify the findings. Questionnaire findings will be collated into the table of changes, referring back to the guiding principles. The study team and PPIE advisory panel will use the table of changes to develop a final version of the intervention for dissemination.

5. Ethical and regulatory considerations

The study will be conducted in full conformance with General Data Protection Regulation (GDPR), Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research.

The study documentation adheres to the Health Research Authority (HRA)'s participant information quality standards and their participant information design and review principles. The voluntary nature of participation in each work package (1-3) will be made clear in information given to participants. Participants will be informed they can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected. As part of the consent process, participants will also be reminded that it will not be possible to remove their data from the project once it has been anonymised and forms part of the data set. Participants will be asked to provide their written or audio recorded verbal, informed consent to take part prior to all interviews and workshops commencing. All participants will be assured of the confidentiality of the data collected, and will be asked for permission to publish anonymised quotations from research activities.

The Chief Investigator and research team will preserve the confidentiality of participants in accordance with the Data Protection Act and GDPR. The presentation and reporting of data will remove any information that may lead, directly or indirectly, to the identification of individuals. Confidentiality of qualitative data will be maintained by anonymising the interview transcript as soon as is practicable, providing participants with a study number and ensuring that any identifiable

individuals or institutions discussed during interviews are anonymised sufficiently to ensure they cannot be readily identifiable. The study numbers will be linked to the participants in a database, which will be password−protected and stored on a Bristol University computer, accessible only by the core research team.

5.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a REC for the study protocol, informed consent forms and other relevant documents. Substantial amendments that require review by NHS REC 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 will be retained.

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.

Before any site can enrol patients into the study, the Chief Investigator or Principal Investigator will ensure that appropriate approvals from participating organisations are in place. For any amendment to the study, the Chief Investigator or designee, 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.

5.2.1 End of study

The study is planned to end on 31/08/2026. The Chief Investigator will notify the REC of the end of the study. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications to the REC.

5.3 Peer review

We received funding for this study as part of a competitive application process. The grant was agreed by the National Institute for Health and Care Research (Grant reference: NIHR159467) and approval was subject to a robust peer-review process. At stage 1 the grant application was reviewed by the funding committee which comprises ‘senior, experienced clinicians, senior NHS Managers, methodologists (including triallists, statisticians and health economists) and public contributors, who are all active in their field’. At stage 2 the grant application was also reviewed by four independent experts.

The protocol and other documents will be reviewed by North West – Greater Manchester (GM) East REC.

5.4 Patient & Public Involvement

Patient and Public Involvement and Engagement (PPIE) is a core feature of the person-based approach and is central to our research plans. Our research plans involve three levels of Patient and Public Involvement to ensure both breadth and depth of engagement. Firstly, we have two PPIE co-applicants who are fully involved as members of the project team, attending monthly PGM meetings and 6 monthly stakeholder meetings. Secondly, we will recruit a diverse PPIE advisory panel of 6-10 members, who will work closely with the research team to develop the implementation intervention.

A particular strength of our PPIE plan is the partnership between the two Universities. This means that we can draw upon a breadth of contributors; drawing on the expertise of Professor Sanders (co-applicant) who Chairs the Greater Manchester Public and Community Involvement and Engagement forum and has extensive experience of participatory research and strong links with voluntary, community and social enterprises. We will also benefit from the expertise of Alisha Newman, a specialist PPIE lead for Bristol Centre for Academic Primary Care. PPIE will be planned and tracked using the PIRIT tool (developed by Newman),[24] will be evaluated using the CUBE framework,[25] and will be reported following the GRIPP2 reporting guidelines.[26]

5.4.1 PPIE co-applicants

Our two PPIE co-applicants have helped contribute to this bid, including the Plain English summary. They are integral to the development and delivery of each WP and will be involved in every stage of the project from conception to completion. Jane Sprackman is an experienced PPIE contributor who has over 20 years' experience as a GP deputy practice manager, and prior to that as a GP receptionist, giving her valuable insights into test communication in primary care. Anna Ferguson Montague is an experienced PPEI contributor who has been involved in several projects on test communication. Jane Sprackman and Anna Ferguson Montague both have lived experience of test communication both as patients and as carers for elderly relatives and are working with Dr Watson as co-applicants on the systematic review which forms WP0 of this project. They will be involved in monthly PMG meetings and will also take part in the 6 monthly stakeholder meetings, to ensure the patient voice is represented in these meetings.

5.4.2 PPIE advisory panel

Our PPIE advisory panel of 6-10 members will meet at least every 4 months during the project, and more frequently during co-production phase when they will be involved in iterative development of

the intervention. They will contribute to planning recruitment, producing patient information leaflets, developing and piloting the interview and workshop topic guides, co-producing the intervention and contributing to dissemination and outputs such as patient accessible animations and infographics. We will use an impact log to record the outcomes of our PPIE work and will use the CUBE framework to allow our public contributors to reflect on their involvement and experiences and to help evaluate and improve our public engagement throughout the project. The PPIE lead from the Centre for Academic Primary Care Research (Newman) will ensure PPIE participants are supported throughout the project and provided with relevant training opportunities.

5.4.3 Wider public engagement activities

We recognise that traditional research practices, such as completing forms, or sharing personal information, may create barriers for some community groups and members of the public we aim to include in our study as part of the co-production process. To address these challenges, we plan to offer additional opportunities for public engagement through more informal activities. These public involvement initiatives will be designed and coordinated in collaboration with community organisation gatekeepers to ensure they are inclusive and culturally sensitive to each group's specific needs. For instance, it may be more effective to attend existing group meetings and set up a 'drop-in' area where researchers and members of the community can have discussions on accessibility of online blood test results. These insights would contribute to the iterative co-production of the tools, and ensure anonymity.

5.5 Protocol compliance

Protocol compliance will be managed by the entire research team. Any deviations non-compliances, or breaches of the protocol will be documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

5.6 Data protection and patient confidentiality

Interviews and workshop discussions will be recorded using University approved encrypted digital audio recorders or via MS Teams/Zoom recording platforms. Audio recordings will be transcribed by a University of Bristol approved Transcription service and a confidentiality agreement will be signed prior to this work commencing. The digital data collected will be stored on secure University of Bristol password protected computers. Researchers based at the University of Manchester will be provided with honorary contracts to facilitate direct access to secure servers at the University of

Bristol. Data in written form, such as written consent forms, will be stored in locked filing cabinets in secure University of Bristol or University of Manchester offices.

Access to the full study data set will be limited to members of the immediate research team (JW, CO, EK, BM, GD) and authorised individuals necessary for quality control, audit and analysis. Interview and workshop discussion transcripts will be edited to remove identifying details, and participants will be allocated a unique study ID to prevent linkage of data to participant details except by members of the immediate research team (JW, CO, EK, BM, GD). Participant identifiable information will be replaced by general descriptions of those characteristics. Data will be encrypted in accordance with the University of Bristol Information Security Policies whenever it is transmitted electronically or otherwise conveyed.

Personal data including age, ethnicity, gender, education qualification, employment status, self-reported disability and first language along with the unique study identifier, will be stored on a secure password protected University network filestore space.

A file that links study ID to participants' names and contact details will be stored in a separate password protected location to avoid someone without authorisation being able to link names to anonymised data files. No personal identifiable information will be collected for the WP3 questionnaire.

Storage of all data will comply with the Data Protection Act 2018, the General Data Protection Regulation (GDPR) 2016 and University of Bristol's data protection policies. All members of the research team will comply with the terms of the study DPIA. Storage will be on secure University computer systems.

5.6.1 Archiving

Electronic audio recordings and consent forms will be held for 3 years or until the study is finished, whichever occurs sooner. After this period electronic audio recordings will be deleted and consent forms will be disposed of using the University of Bristol's or University of Manchester's offices confidential waste service. In accordance with the University of Bristol's 'Guidance on the Retention of Research Records and Data For studies involving human participants, their tissue and/or human data' (Research Governance Team, Research Data Service, v.4.1, April 2024), anonymised, analysed data e.g. NVIVO database and summaries of data – will be retained for a minimum of ten years.

Study data will be securely archived for a minimum of 10 years on University of Bristol premises, with the Chief Investigator as data custodian.

5.7 Indemnity

The University of Bristol has arranged insurance to cover the legal liability of the University as research sponsor in the possibility of harm to a research participant arising from the management of the research by the University and as protocol authors for harm to participants as a result of the design of the research.

The University of Bristol holds Professional Negligence insurance to cover the legal liability of the University, for harm to participants arising from the design of the research, where the research protocol was designed by the University.

5.8 Access to the final study dataset

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

Access to the full anonymised study data set will be limited to members of the immediate research team (JW, CO, EK, BM,GD), the study steering group and other authorised individuals necessary for quality control, audit and analysis as outlined above.

5.9 Safety considerations and adverse events

Safety considerations in this study are minimal as it will consist of participation in interviews, co-production workshop and/or a survey. We do not expect any adverse events. See section 10 below for further consideration of risks.

6. Dissemination plan

The host institution, University of Bristol own all foreground IP and research data. All arising Know How will be owned by whichever party(ies) that creates it.

6.1 Launch Event

We will present the final template tools and guidance at a launch event, and will invite stakeholders including commissioners, commercial and non-profit companies, disability charities, patient groups and healthcare professionals in order to share our findings with a diverse group of stakeholders. We will make our template tools and guidance freely available so that they can be used by the NHS App team and other commercial and non-profit companies involved in online blood test communication.

We will work in close collaboration with the implementation team of the BNSSG Impact Accelerator Unit (IAU). The IAU is overseen by a Professor of Knowledge Mobilisation and is recognised by the NIHR Engagement and Dissemination Centre as a case study in how an Integrated Care Board (ICB) can support evidence use.

6.2 Stakeholder engagement and knowledge mobilisation

We will make full use of established relationships with stakeholders from conception to completion of the project to ensure dissemination is an iterative and ongoing process. We are already collaborating with the NHS App team who are keen to support our work and have expressed an interest in implementing our template tools and guidance . As well as the NHS App team, our stakeholder group will include representatives from LabTestsOnline (who provide resources to help patients understand laboratory tests), Patient Knows Best and Evergreen Life (technology platforms which integrate with the NHS App to provide online access to test results), EMIS and TPP (the two main providers of GP electronic health records), as well as patient representatives. This stakeholder group will meet 6 monthly by teleconference throughout the project, with additional email communication on an as required basis. This will allow the research team to share interim findings with key stakeholders including the NHS App team to maximise impact. Stakeholder group meetings will also be important to ensure that the final intervention is developed in line with stakeholder needs and is informed by ongoing developments in this rapidly changing field. We already have strong links with key stakeholders: Watson (PI) and McMillan (co-app) have ongoing advisory roles with the NHS App team. McMillan had an honorary contract with NHSE and was a research advisor on the ‘accelerating citizen access to primary care records’ programme. McMillan also works with Evergreen Life on a number of projects including the CHARIOT Project.[27] Watson is a member of the LabTestsOnline editorial board.

6.3 Dissemination outputs

Results will be presented at national and international conferences (targets: Society for Academic Primary Care, Royal College of General Practitioners, Society for Improved Diagnosis in Medicine). Academic papers from all three WP will be submitted to high impact factor journals for open access publication (targets: the BMJ, British Journal of General Practice). We will work with our PPIE co-production panel to produce patient-relevant and accessible research summaries (such as animations, infographics or digital case stories). Dissemination will be supported by a specialist Communications Officer. We will also work with the University of Bristol’s Policy Bristol unit, which specialises in enhancing the influence and impact of research on policy and practice. We will collaborate with them to produce and disseminate a policy briefing to summarise the policy

implications of our research. If our findings support the need for eLearning modules for clinicians to improve online test communication, we could produce these as part of a suite of eLearning which McMillan (co-app) is already working on, as part of his role for NHSE (see https://learninghub.nhs.uk/catalogue/gpdata/about#catalogue-details).

6.4 Impact

We are working in close collaboration with the NHS App team who have stated in their letter of support that they "*look forward to incorporating insights generated by the work into future App developments*." The findings of this research will therefore have direct impact on patients using the NHS App, and the insights from our research also have potential to influence other patient portals for accessing test results such as Patient Knows Best. These changes have the potential to impact patients, clinicians and policymakers. For patients, improving the accessibility of online blood tests is important patient empowerment, and patient-centred care. It is also important for patient safety, as failure to communicate test results effectively could lead to delays in diagnosis and treatments. For clinicians, improving accessibility of online blood test results could improve efficiency and reduce the number of patients requiring follow up appointments to discuss test results, with important implications for workload. For policymakers our findings could have implications beyond primary care, with relevance to secondary care blood test communication. With over a billion pathology tests per year in the NHS[6] this research has potential to have major strategic importance for the NHS.

6.5 Authorship eligibility guidelines and any intended use of professional writers

The Chief Investigator (JW) will coordinate the first publication. All publications arising from the Research shall give due credit to the Parties involved (including authorship where appropriate) as determined in compliance with International Committee of Medical Journal Editors (ICMJE) guidelines.

7. Equity, diversity and inclusion

This research will follow guidance from the NIHR Equity, Diversity and Inclusion (EDI) toolkit to ensure that EDI principles are embedded into the design and conduct of the research.

7.1 Research team

All members of the research team will complete cultural competency training, to ensure that the team have the necessary self-awareness, knowledge and skills to ensure EDI principles are appropriately integrated into all aspects of the research. Training will be done as a team and will include discussion and reflection as a team to ensure that we create an inclusive culture and avoid tokenism.

7.2 Wider Public Engagement and Public involvement

We have already held two workshops with diverse participants from predominantly Somali and Caribbean heritage in inner city Bristol in preparation for this bid. They shared their lived experiences of the challenges and frustrations of attempting to access test results. Ms Baptiste, a public contributor of Caribbean heritage co-facilitated the most recent workshop and has agreed to be a member of our PPIE advisory panel. We will conduct further workshops to recruit a diverse group of participants with lived experiences of medical testing onto our PPIE co-production panel. This will help ensure that we incorporate diverse perspectives and lived experiences into the planning of our research. Our PPIE panel will be involved in planning recruitment to minimize barriers to participation and developing patient materials for WP1-3 to ensure they are accessible.

7.3 Work package 1: qualitative interviews

Patient information leaflets and consent forms will be translated into up to five different languages to allow a diverse range of participants to be recruited into WP1. The choice of languages will be tailored to the local populations, following consultation with the recruited practices and local community groups. Qualitative interviews will be conducted either online or face to face depending on patient preference, to accommodate accessibility needs. Translators will be available (either online or face to face) for those who prefer to conduct their interview in a different language.

7.4 Work package 2: co-production workshops

We will build on our extensive experience of participatory research and strong links with voluntary, community and social enterprises to facilitate meaningful engagement and co-production with diverse communities. Where possible we will invite community group leaders to co-facilitate workshops with members of the research team. We will involve a translator (ideally from within the community groups) to overcome language barriers to participation. We are aware that there are broader programmes[28] being actioned by the voluntary sector aiming to combat digital inclusion by helping people to access the internet; whilst gaining access to the internet would be beyond the scope of this project we will collaborate with existing community programmes where possible.

7.5 Work package 3: questionnaire

Whilst the main method for disseminating the questionnaire will be online, we will also offer the option of a paper version of the questionnaire which can be handed out by phlebotomists at the time of blood testing in participating practices. We will also disseminate the questionnaire via the community groups which were involved in WP2, to maximise diversity in recruitment and minimize barriers to participation amongst disadvantaged groups.

8. Study Management

8.1 Project Management Group (PMG)

The project management group (PMG) will comprise of the co-applicant team, PPIE co-applicants and the project research staff. The PMG will meet monthly by teleconference, with face-to-face meetings every six months throughout the project. Agendas and relevant meeting documents will be sent to the PMG for review prior to each meeting. Minutes will be taken, and actions documented and reviewed.

8.2 Contracting organisation

The PI will be provided with an Honorary Contract with BNSSG ICB. The ICB is the research office for all community-based health & care research within BNSSG, including primary care projects led by local clinical academics, and has a portfolio of 40+ NIHR grants managed using this model. The ICB is an experienced host of research, and its model has been used as an exemplar by NHS England, the R&D Forum and shared as best practice by the colleagues at DH&SC and the NIHR. The ICB research team employs a Joint Office model, in conjunction with the CRN, with staff employed across the ICB, University of Bristol and UWE, covering Research Management, Research Governance, Research Finance, Research Contracts and Research Sponsorship.

Further, the ICB has an Impact Accelerator Unit (IAU) which delivers enhanced dissemination of research evidence to the staff delivering health and care services. The IAU is a joint venture in partnership with the Universities of Bristol and UWE and applies knowledge mobilisation theory to deliver meaningful and lasting impacts for the health of the population. The IAU is ICB led, and utilises and enhances existing ICB resources (such as Medicines Optimisation, Primary Care Delivery, Digital Transformation, Clinical Effectiveness etc) to maximise the impact of research. The ICB's IAU model has been discussed with and endorsed by Senior members of NIHR.

The ICB is an active member of many national networks (research, clinical and professional groups) with ICBs across the country, spreading learning and supporting dissemination of research and findings. The ICB is therefore best placed to support spread and adoption of IP, but because of the Partnership working of the Bristol Health Partners Academic Health Science Centre, does not do this in isolation. The AHSC IP Policy (agreed by both the ICB Host and University Sponsor) provides sharing of expertise between the ICB and Sponsor TTO for maximising benefits of our collaborative research.

9. Project timetable

	Year 1												Year 2											
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Date	Sep	Oct	Nov	Dec	J25	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec	J26	Feb	Mar	Apr	May	Jun	Jul	Aug
Work package 0																								
Development of conceptual framework																								
Publication of systematic review																								
Work package 1																								
Protocol development																								
Ethics and R&D																								
Recruitment and site set up																								
Interviews																								
Analysis																								
Write up																								
Work package 2																								
Protocol development																								
Ethics and R&D																								
Recruitment																								
Co-production workshops																								
Analysis																								
Write up																								
Work package 3																								
Protocol development																								
Ethics and R&D																								
Questionnaire development & piloting																								
Recruitment and data collection																								
Analysis																								
Project oversight																								
PMG meetings																								
Stakeholder meetings																								
PPIE advisory panel meetings																								
Dissemination																								
Final report writing																								
Launch event																								
Conferences																								

10. Risk Assessment

10.1 Assessment and management of risk

This study requires research activities that require participants to share and discuss information about recent test result communications. This process carries some risks that need to be effectively managed to reduce the risk of potential harms to the participant and researcher. Potential risks and mitigations to overcome these are outlined below.

For patients:

1) Inconvenience of involvement in the study.

Mitigation: Participation will be entirely voluntary, and interviews will be scheduled at a time and location most convenient for the patient. Participants will be offered the option of either attending the interview in-person at their surgery or participating online. Patients will receive a voucher in accordance with NIHR RDN agreed rates to recompense them for their time. Reasonable travel expenses for any visits in addition to normal care will be paid in full for all participants.

2) Some participants may not fully understand the information presented within our standard participant information sheet or consent form which will impact on their capacity to provide informed consent.

Mitigation 1: The participant information sheet and consent form will be made available in range of different formats such as another language or an easy access format.

Mitigation 2: We will provide the option of including an interpreter to accompany participants to any research activities, including ascertaining eligibility and obtaining consent, as well as participating in interviews or co-production workshops. We will also provide the option of enabling participants to bring a support worker, carer or family member to help the participant feel more comfortable taking part in the research and fully understand what is being asked of them.

3) Some participants may have other accessibility requirements which make it difficult for them to provide written consent.

Mitigation: The option to provide verbal recorded consent as opposed to written consent will be offered to participants who may experience difficulties with writing.

4) There is a potential risk that patient interviews could cause anxiety and/or distress; thinking and talking about blood tests may raise questions or worries patients might not otherwise have considered, or test results may have identified a serious illness, such as cancer.

Mitigation: We acknowledge the potential ethical challenges of this approach, however we have experience of successfully conducting similar interviews with patients who received test results by text message or via receptionists. To minimise the chance of causing patient anxiety the research team will co-design the topic guide with our PPIE co-applicants, then pilot it with our wider PPIE advisory panel and amend it based on their feedback. All test results released to patients online will first have been viewed and filed by a primary care clinician with clinical responsibility for ensuring that the test results are suitable to be viewed by the patient. Participants will be encouraged to review their results before the interview, to ensure they are able to navigate the online systems and to allow patients time to digest and reflect on the results before interviews are conducted. A distress protocol will be put in place in case a participant becomes distressed during an interview, including clear guidelines for pausing or terminating an interview, providing follow-up, and debriefing.

5) Risk: Although interviews (WP1) and workshop discussions (WP2) will not discuss the patient's medical history, there is a risk that patients could make medical disclosures to the interviewer or the rest of the workshop group.

Mitigation 1: Prior to interviews, it will be emphasised that the interviewer is not clinically trained and cannot provide medical advice. If medical questions or concerns arise during the interviews, participants will be encouraged to contact their GP practice for clinical advice. It will be explained that although interviews are confidential this is not absolute and disclosure would be necessary if safeguarding concerns were disclosed, and a protocol will be put in place to manage these circumstances including a pathway to report significant safety concerns to back to a senior clinician at the GP practice if required.

Mitigation 2: Interviews will be conducted by experienced qualitative researchers (Davidge and Ochieng); they will be supported by Watson (PI) and McMillan (co-app) experienced GPs, who will provide support and debriefing in case medical or safeguarding concerns arise during interviews. Researchers will receive debriefings on a weekly basis or as needed in situations where safeguarding concerns are raised regarding a participant.

For Primary Care staff the main risks are:

1) Inconvenience of supporting patient involvement in the study.

Recruitment of patient participants may cause inconvenience for members of staff involved in the study. We will minimise this by making recruitment as simple as possible and by ensuring that methods of recruitment are flexible so that different practice procedures for blood testing can be accommodated. Practice staff will not be required to consent patients, only to issue patient information leaflets to eligible participants. Research costs concerning staff time to set up and recruit for the study will be reimbursed in accordance with the NIHR RDN principles.

2) Inconvenience of Primary care staff involvement in interviews (WP1) and workshops (WP2).

Interviews will be done flexibly, by telephone or face to face at a time convenient to the members of staff taking part to minimise inconvenience. Similarly, workshops will be scheduled according to staff availability and convenience. Payment for staff participant time will be reimbursed at agreed NIHR RDN rates.

3) Clinicians may feel defensive about their medical decisions when discussing recent blood tests performed with researchers.

Mitigation: To prevent this, it will be emphasised within the study information provided, and at the beginning of interviews, that the purpose is not to make any judgements but instead we are interested in exploring GPs understanding and communication around testing with an overall aim of trying to help more patients to be able to understand their results.

4) As a result of engaging patients in discussions about their recent test results, there is a potential risk of increasing the primary care workload, as patients may make additional enquiries about their results they might not otherwise have made.

Mitigation: All patient materials and the interview topic guide will be piloted and discussed with our PPI group to reduce the likelihood that this results in additional anxiety. However, there remains the possibility that a patient may still contact their practice for further explanation or reassurance. We aim to recruit 6-10 patients per practice so this is not likely to have a significant impact on practice workload.

For researchers:

This study requires researchers to undertake fieldwork interviews with patients and health professionals online, at a primary care practice, the University, their place of residence or any other mutually agreed location. Risks of undertaking research with close social interaction with the research participants can include:

1) Risk of physical threat or abuse toward the researcher
2) Risk of psychological trauma, as a result of actual or threatened violence or the nature of what is disclosed during the interaction
3) Risk of causing psychological harm to others.

All study risk assessments will adhere to the University of Bristol Health and safety guidance for research undertaken in the community.

Mitigation 1: Prior to undertaking fieldwork, research activities will be subject to a risk assessment which will outline appropriate measures to ensure that both participants and researchers have a full understanding of the intent of the research, the participant has properly consented to the research, the researcher is as fully briefed as possible about a research participant, expectations of the researcher and the participant are properly managed, and the researcher has had appropriate training and experience for the nature of the research.

Mitigation 2: Research activities that involve researchers working directly with research participants outside of University premises in community settings, participants' homes or environments unfamiliar to the researcher, will also be subject to risk assessment to ensure compliance with the Health and Safety at Work Act 1974. These risk assessments will identify potential hazards, assess risks and put appropriate control measures in place to mitigate those risks before the research activity commences.

Mitigation 3: Researchers CO and GD have experience of undertaking research interviews with participants in their homes. University of Bristol Lone worker Guidance will be incorporated into the planning of any research activities that involve lone working and unsupervised contact with participants away from university premises.

Mitigation 4: Additionally, the Chief Investigator and any researcher undertaking fieldwork will ensure that there is a designated person who is fully briefed on planned research activities that are undertaken away from University premises. As per the lone working policy, an action plan will be agreed between the Chief Investigator and Researcher to include specific visit details, schedules, prearranged call times, names and addresses of research participants, phone numbers, overnight accommodation details, what to do in the event of a change in plan and anything else relevant to the nature of the research. This information will be kept in a sealed envelope and treated as confidential.

References

1. Watson J, Salisbury C, Whiting PF, et al. 'I guess I'll wait to hear'— communication of blood test results in primary care a qualitative study. *Br J Gen Pract* 2022:BJGP.2022.0069. doi: 10.3399/bjgp.2022.0069
2. Watson J, Whiting PF, Salisbury C, et al. Blood tests in primary care: A qualitative study of communication and decision-making between doctors and patients. *Health Expectations* 2022;n/a(n/a) doi: https://doi.org/10.1111/hex.13564
3. McMillan B, Davidge G, Brown L, et al. A qualitative exploration of patients' experiences, needs and expectations regarding online access to their primary care record. *BMJ open* 2021;11(3):e044221. doi: 10.1136/bmjopen-2020-044221
4. Bowie P, Price J, Hepworth N, et al. System hazards in managing laboratory test requests and results in primary care: medical protection database analysis and conceptual model. *BMJ open* 2015;5(11):e008968. doi: 10.1136/bmjopen-2015-008968
5. Baylis D, Price J, Bowie P. Content analysis of 50 clinical negligence claims involving test results management systems in general practice. *BMJ Open Quality* 2018;7(4):e000463. doi: 10.1136/bmjoq-2018-000463
6. RCPath. Pathology Facts and Figures [Available from: https://www.rcpath.org/discover-pathology/news/fact-sheets/pathology-facts-and-figures-.html accessed 11/07/2023.
7. Digital N. Access to patient records through the NHS App 2022 [Available from: https://digital.nhs.uk/services/nhs-app/nhs-app-guidance-for-gp-practices/guidance-on-nhs-app-features/accelerating-patient-access-to-their-record accessed 11/10/2022.
8. McMillan B, Davidge G, Blease C, et al. Implications of the changes to patient online records access in English primary care. *Br J Gen Pract* 2022;72(725):558-59. doi: 10.3399/bjgp22X721205
9. Lind J. Patient Safety in Primary Care Top 10 https://www.jla.nihr.ac.uk/priority-setting-partnerships/patient-safety-in-primary-care/top-10-priorities.htm2017 [Available from: https://www.jla.nihr.ac.uk/priority-setting-partnerships/patient-safety-in-primary-care/top-10-priorities.htm.
10. Fitton C, Fitton R, Hannan A, et al. The impact of patient record access on appointments and telephone calls in two English general practices: a population-based study. *London J Prim Care (Abingdon)* 2014;6(1):8-15. doi: 10.1080/17571472.2014.11493405
11. Davidge G, Brown L, Lyons M, et al. Primary care staff's views and experience of patients' online access to their electronic health record: a qualitative exploration. *Br J Gen Pract* 2023;73(731):e418-e26. doi: 10.3399/bjgp.2022.0436
12. Peckham S. Evaluation of Government Commitments made on the digitisation of the NHS. 2023
13. Honeyman M, Maguire D, Evans H, et al. Digital technology and health inequalities: a scoping review. *Cardiff: Public Health Wales NHS Trust* 2020
14. Tudor Hart J. THE INVERSE CARE LAW. *The Lancet* 1971;297(7696):405-12. doi: https://doi.org/10.1016/S0140-6736(71)92410-X
15. Nankervis H, Huntley A, Whiting P, et al. Blood test result communication in primary care: mixed methods systematic review protocol. *BJGP Open* 2023:BJGPO.2023.0105. doi: 10.3399/bjgpo.2023.0105
16. Yardley L, Morrison L, Bradbury K, et al. The person-based approach to intervention development: application to digital health-related behavior change interventions. *Journal of medical Internet research* 2015;17(1):e4055.
17. Nankervis H, Huntley A, Whiting P, et al. Communicating blood test results in primary care: a mixed methods systematic review. *Br J Gen Pract* 2024:BJGP.2024.0338. doi: 10.3399/bjgp.2024.0338
18. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies:Guided by Information Power. *Qualitative Health Research* 2016;26(13):1753-60. doi: 10.1177/1049732315617444

19. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology* 2006;3(2):77-101.
20. Zikmund-Fisher BJ, Scherer AM, Witteman HO, et al. Graphics help patients distinguish between urgent and non-urgent deviations in laboratory test results. *Journal of the American Medical Informatics Association : JAMIA* 2017;24(3):520-28. doi: 10.1093/jamia/ocw169
21. Bar-Lev S, Beimel D. Numbers, graphs and words – do we really understand the lab test results accessible via the patient portals? *Israel Journal of Health Policy Research* 2020;9(1):58. doi: 10.1186/s13584-020-00415-z
22. Zhang Z, Citardi D, Xing A, et al. Patient Challenges and Needs in Comprehending Laboratory Test Results: Mixed Methods Study. *J Med Internet Res* 2020;22(12):e18725. doi: 10.2196/18725 [published Online First: 2020/12/08]
23. Giardina TD, Baldwin J, Nystrom DT, et al. Patient perceptions of receiving test results via online portals: a mixed-methods study. *Journal of the American Medical Informatics Association* 2017;25(4):440-46. doi: 10.1093/jamia/ocx140
24. Newman A, Baddeley E, Seddon K, et al. 19 Launch of the public involvement in research impact toolkit. *BMJ Supportive & Palliative Care* 2023;13(Suppl 1):A7-A8. doi: 10.1136/spcare-2023-MCRC.18
25. Gibson A, Welsman J, Britten N. Evaluating patient and public involvement in health research: from theoretical model to practical workshop. *Health Expectations* 2017;20(5):826-35. doi: https://doi.org/10.1111/hex.12486
26. Staniszewska S, Brett J, Simera I, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *BMJ* 2017;358:j3453. doi: 10.1136/bmj.j3453
27. McMillan B. **CHARIOT: A Cardiovascular Health Assessment and Risk-based Intervention Optimisation Tool embedded within the patient-facing health record** [Available from: https://www.spcr.nihr.ac.uk/research/projects/chariot-a-cardiovascular-health-assessment-and-risk-based-intervention-optimisation-tool-embedded-within-the-patient-facing-health-record.
28. Brunt S. Implications of the changes to patient online records access in English primary care (letter). *BJGP* 2023 doi: https://bjgp.org/content/72/725/558/tab-e-letters#implications-of-the-changes-to-patient-online-records-access-in-english-primary-care