I4F: Isla for Frailty Feasibility Study

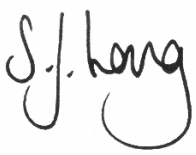
Acceptability, feasibility, and potential effectiveness of video-based patient records for supporting care delivery for older people with frailty.

Version 6: 17/04/2024

MAIN SPONSOR: Imperial College Healthcare NHS Trust
FUNDERS: NIHR; HEE

IRAS Project ID: 313814
Sponsor reference: 23SM8192
REC reference: 313814

Protocol authorised by:

Name & Role	Date	Signature
Phoebe Averill (CI)	17/04/2024	
Susannah Long (Clinical Lead for the study)	23/01/2024	

Study Management Group

Chief Investigator:

- Dr Phoebe Averill: Research Associate – Imperial College London

Co-investigators:

- Mr Erik Mayer: Transformation Chief Clinical Information Officer - Imperial College Healthcare NHS Trust (ICHT); Clinical Reader (ICL)
- Dr Susannah Long: Clinical Lead for the study; Consultant Physician & Geriatrician - ICHT
- Alex Taylor: lay partner with lived experience of caring for a frail, older relative
- Tiffany Ollivierre-Harris: Team Lead Occupational Therapist in Elderly and Specialist Medicine - ICHT
- Dr. Sophia Ellis: Internal Medicine Trainee
- Pete Hansell: Cofounder – Isla
- Dr Rachael Lear: Honorary Research Fellow – Imperial College London (ICL) & Imperial College Healthcare NHS Trust (ICHT); Advanced Nurse Practitioner in General Practice

Clinical Queries

Clinical queries should be directed to Dr Susannah Long who will direct the query to the appropriate person.

Sponsor

Imperial College Healthcare NHS Trust is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Research Governance and Integrity Team
Imperial College London and Imperial College Healthcare NHS Trust
Room 215, Level 2, Medical School Building
Norfolk Place
London, W2 1PG
Tel: **0207 594 1862**
Imperial College - Research Governance and Integrity Team (RGIT) Website

Funders

NIHR & HEE

This protocol describes the I4F study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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GLOSSARY OF ABBREVIATIONS

I4F	Isla for Frailty Feasibility study
ICHT	Imperial College Healthcare NHS Trust
ICL	Imperial College London

KEYWORDS

Frailty
Video-recording
Communication
Patient assessment
Care transitions
Care continuity

STUDY SUMMARY

TITLE	**Isla for Frailty feasibility study (I4F)** Acceptability, feasibility, and potential effectiveness of video-based patient records for supporting care delivery for older people with frailty.
DESIGN	Single-centre, non-randomised, mixed-methods feasibility study with embedded process evaluation
INTERVENTION	Video-based patient records (3-month pilot) alongside usual care
OBJECTIVES	*Primary objective:* Determine the **acceptability** of using video-recordings to capture the functional abilities, support needs, and care preferences of older inpatients with frailty *Secondary objectives:* (a) determine the **feasibility** of implementing a visual medical record platform (Isla) in the acute Medicine for the Elderly setting (b) explore the **potential effectiveness** of patient videos for supporting elderly inpatient care
OUTCOME MEASURES	Acceptability of the intervention among patients & care-providers Recruitment & retention rates Intervention barriers & facilitators Video view metrics Perceived impacts on: i) inpatient assessment & clinical decision-making; ii) multi-disciplinary team communication; iii) care continuity during a hospital stay; iv) person-centred care during a hospital stay
POPULATION	Older people with frailty and their care-providers
ELIGIBILITY	Inpatients aged ≥65 years with or without capacity to consent. Patients lacking capacity to consent but otherwise meeting inclusion criteria will be eligible for study participation on the condition that a 'consultee' is available to advise on the patient's likely wishes and feelings about taking part.
DURATION	17 months

1. INTRODUCTION

BACKGROUND

People living with frailty represent a complex and growing challenge for health and social care providers. Around 10% of people aged over 65 years have frailty, rising to nearly 50% of those aged over 85 years, and frailty prevalence is expected to increase alongside the growth of the aging population. Older people with frailty commonly require input from multiple professionals in several organisations across primary, secondary, and social care. Professional bodies such as the British Geriatrics Society have advocated for responsible information sharing to ensure that older people with frailty are supported to age well. Yet, as patients move between different parts of the health and care service, communication between providers is frequently ineffective, assessments are duplicated, and carers are repeatedly asked to provide the same information. Poorly coordinated care is linked to avoidable complications, accelerated deconditioning, and loss of independence, as well as greater carer burden and increased costs to health and social care.

Much communication across organisational boundaries takes place through written referrals and (increasingly) through shared electronic patient records. Communication is therefore predominantly text-based, which is apposite for key clinical details (e.g. diagnosis/past medical history/medications/allergies). Comprehensive geriatric assessment and documentation standards such as those produced by the Professional Record Standards Body are known to support information exchange between professionals. However, text-based information often fails to convey the individual complexities and nuances of an older person's functional capabilities and support needs: receiving professionals may be left wondering 'Is this normal for this patient?' It is vital that health and care professionals can recognise and track subtle changes to proactively manage avoidable deconditioning and deliver individualised, person-centred care. More sophisticated modes of documentation and communication are needed to improve patient assessment and care continuity across transitions of care.

In an age of smartphones, people are increasingly telling their stories using photographs and video recordings. During the Covid-19 pandemic, remote clinical consultations using videoconferencing became routine practice. However, a clear advantage of video recording is the creation of a permanent visual record that can be reviewed by different professionals involved in a patient's care.

Previous research

A recent Cochrane review evidenced patient and health service benefits of using mobile technologies to enhance communication between healthcare providers across care settings (Gonçalves-Bradley et al 2020). In ten trials, a portable device was used to obtain clinical images (ultrasound scans, retinal images, photographs of skin conditions), which were then transmitted for further assessment. While there was some evidence that sharing still images between providers improved the timeliness of specialist assessment and treatment, none of the trials examined the application of video-recordings to enhance provider-provider communication.

We have conducted a systematic review to synthesis the academic literature and professional and regulatory guidance on video-recording patients for direct care purposes. Our review (manuscript in progress) identified 27 studies in which patients were videorecorded to support diagnosis, care, or treatment. Studies suggest that video recording patients for direct care purposes is acceptable to

most people – providing that the benefits to patients are clear and risks (privacy/ data protection) are properly mitigated.

RATIONALE FOR CURRENT STUDY

Video recording could enhance the safety and quality of care transitions for older people with frailty through providing objective and richly detailed visual information about their functional capabilities, support needs, and care preferences. Making and sharing patient video recordings raises important ethical and legal considerations that would need to be addressed to enable the practical application of video for direct care purposes. There is a need to explore the acceptability, feasibility, and potential value of embedding in the electronic patient record video recordings captured during routine care, towards improving the safety and quality of care transitions for older people living with frailty.

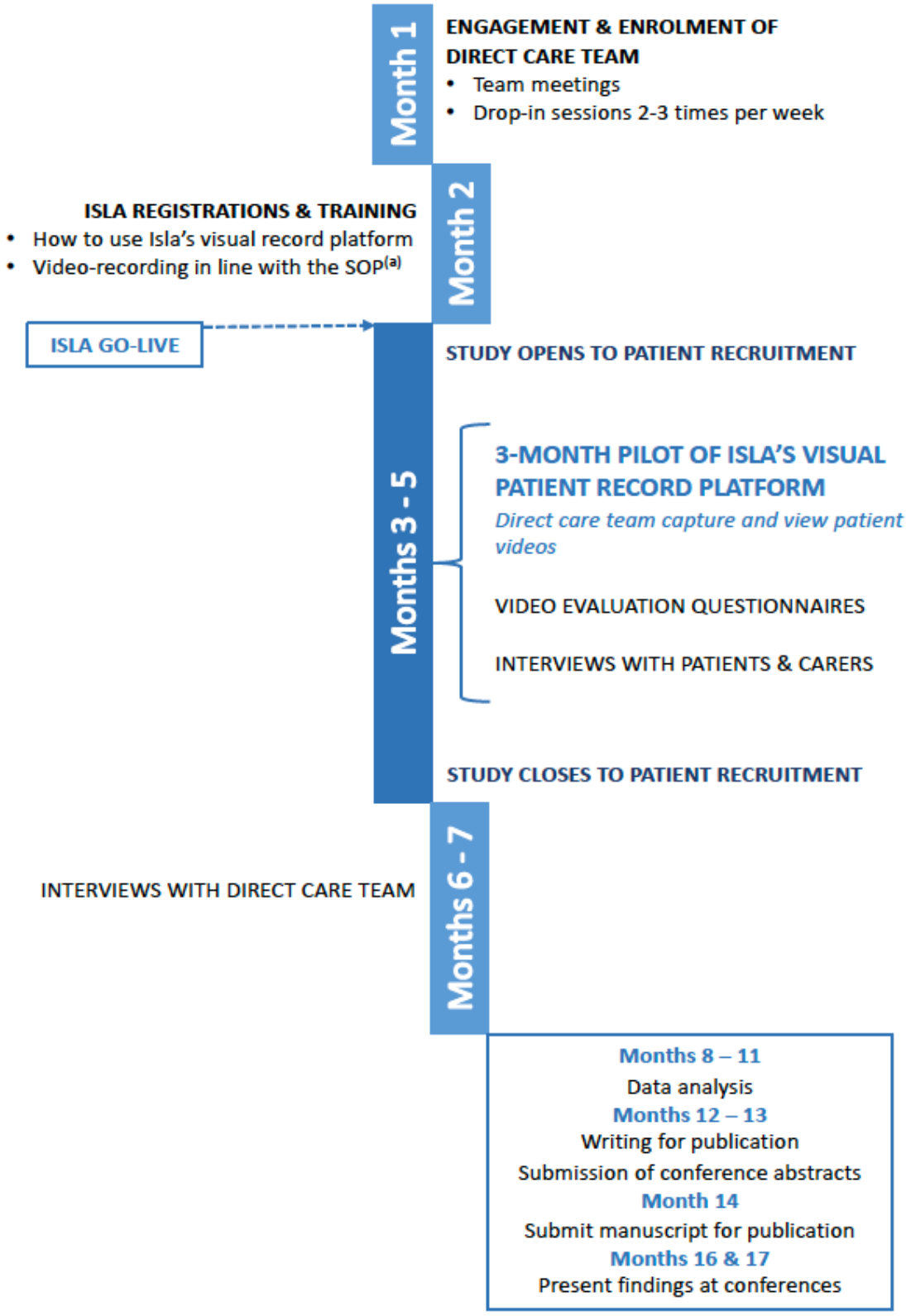
2. STUDY OBJECTIVES

Primary objective:
Determine the **acceptability** of using video-recordings to capture the functional abilities, support needs, and preferences of older inpatients with frailty, to support clinical assessment and care delivery

Secondary objectives:
(a) determine the **feasibility** of implementing a visual medical record platform (Isla) in the acute Medicine for the Elderly setting
(b) explore the **potential effectiveness** of patient videos for supporting elderly inpatient care

Findings from this feasibility study will be used to refine our video-recording procedures and inform the design of a larger trial in which the effectiveness of patient video-recordings for improving the quality and safety of care transitions will be examined.

3. STUDY OVERVIEW & TIMELINES



(a) Standard Operating Procedure for video-recording and consent.

4. STUDY DESIGN

This protocol describes a single-centre, non-randomised, mixed-methods pilot study with embedded process evaluation. The revised UK Medical Research Council (MRC) framework for developing and evaluating complex interventions emphasises that feasibility assessment is essential to reduce key uncertainties around i) evaluation design (e.g. recruitment rate, outcomes), and ii) the intervention itself (e.g. acceptability, capacity of care team to deliver the intervention) (10). This current study will address key uncertainties relating to both the evaluation design and the visual patient record platform intervention to inform decisions around progression to a definitive trial.

5. STUDY SETTING

The setting for the study is an acute Medicine for the Elderly ward at St. Mary's Hospital, Imperial College Healthcare NHS Trust (ICHT).

6. PARTICIPANT ELIGIBILITY

We aim to recruit 95 participants, including patients (n=30), their carers (n=30), and ward staff (n=35).

PATIENTS

We aim to recruit 30 patients during a 3-month pilot.

Inclusion Criteria:

- Admitted as an inpatient to the acute Medicine for the Elderly ward during a 3-month pilot phase of Isla's visual record platform
- Aged ≥65 years old
- Are considered to be frail or pre-frail by the direct care team
- Have capacity to consent to study participation OR lack capacity to consent on the condition that a 'personal consultee' is available to advise on the patient's likely wishes and feelings about taking part.

Exclusion criteria:

Patients who lack capacity to consent will be excluded if a personal consultee is not available to advise on the patients' likely wishes or feelings about taking part.

Reasonable attempts will be made to include patients who do not speak or understand English, by involving the patient's next-of-kin in interpreting, or by using local professional interpreting services (e.g. LanguageLine).

CARERS

Patient-carer dyads will be recruited, where possible.

Inclusion Criteria:

- Aged ≥18 years
- Provide the patient/care-recipient with assistance in their daily activities and are unpaid for these caring activities
- Are willing to participate in an interview as part of the study

A carer may be a member of the patient's family, a friend, or other person who provides the patient with unpaid care.

Exclusion Criteria:

- Carers will be excluded if the patient/care-recipient declined to participate in the study.

WARD TEAM

Inclusion Criteria:

- Clinical staff working on the Medicine for the Elderly ward at St Mary's Hospital.
- Staff must be working regular shifts on the ward during study initiation and pilot phases
- Staff must have an active nhs.net account.

Exclusion Criteria:

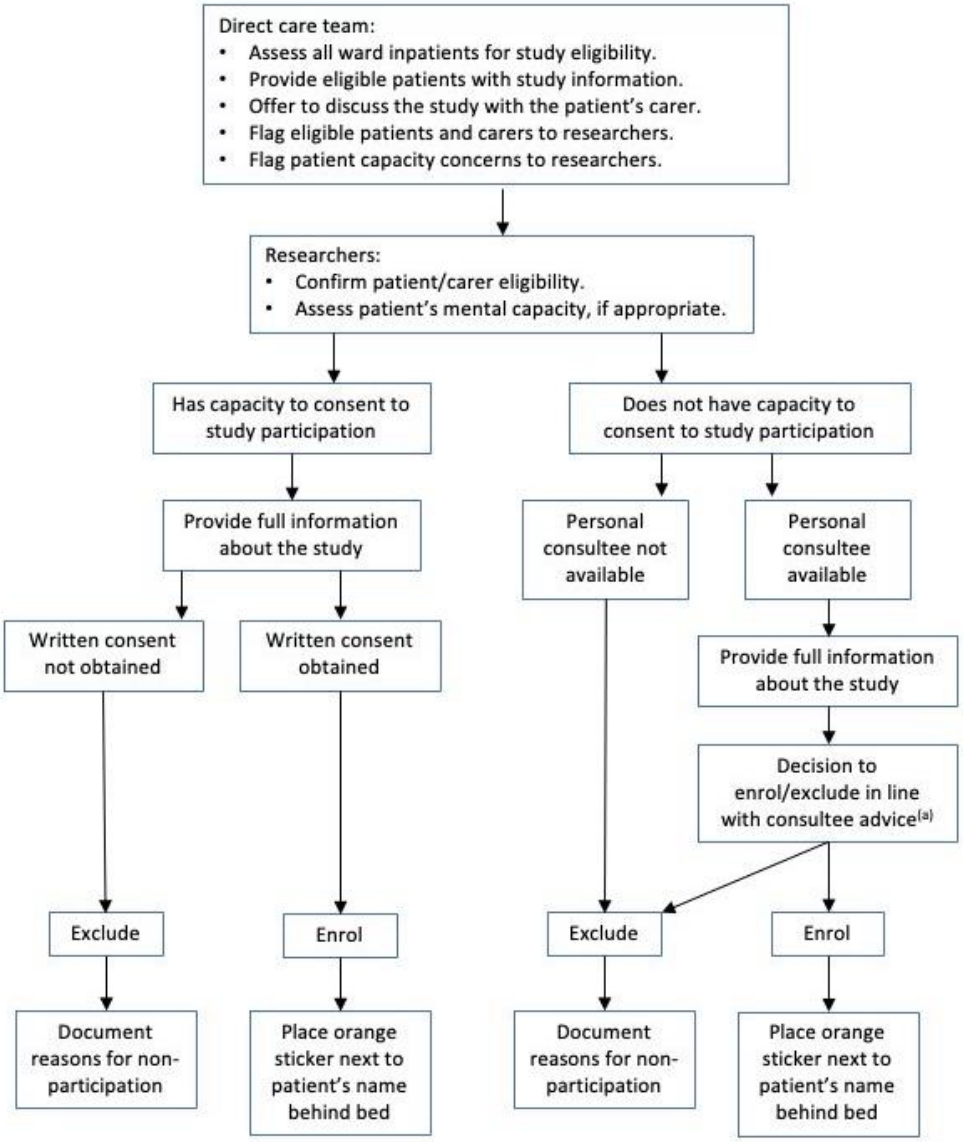
- Ad-hoc bank/agency staff
- Permanent staff on long-term leave (e.g. sick/maternity) during the pilot

7. PARTICIPANT ENROLMENT

PATIENTS & CARERS

Figure 1 summarises the procedures for patient screening and enrolment. Screening and enrolment of patients and carers into the study will take place during a 3-month pilot phase of Isla's visual record platform on the Medicine for the Elderly ward. Screening and enrolment outcomes will be documented on the **screening/ enrolment log.** Potential participants (patients and carers) will be screened for eligibility by the patient's direct care team. Patients and their carers will be approached initially by members of the patient's direct care team; a team member will explain the purpose of the study and will provide a **patient and carer participant information sheets.**

Figure 1: patient screening and enrolment procedures



The first approach will take place following admission to Medicine for the Elderly ward when the patient is clinically stable. The direct care team will check whether the carer is happy to be contacted by the researcher, either by email or telephone, and will take the carer's contact details. The direct care team will flag all potential participants (patients and carers) to the researcher (an Imperial College Research Associate who holds a Licence to Attend with ICHT).

At least 24 hours after the first approach by the direct care team, the researcher will visit the patient on the ward to confirm study eligibility and to complete enrolment procedures. The researcher will approach the patient and ask them if they have any questions about the study and whether might be interested in participating. The researcher will offer to discuss the study with the patient, either at that time or another date/ time during the admission, until the patient is satisfied that all his/her questions have been answered fully. The participant information sheet contains visual aids to support the patient's understanding of what will happen to them during the study; the researcher will refer to these as needed. The researcher will offer the patient and the carer additional time to consider whether to participate.

If the direct care team have any concerns that a patient may lack capacity to consent to study participation, Dr Susannah Long or Dr Phoebe Averill will undertake and document a **Mental Capacity Assessment** before proceeding to enrolment.

Enrolment of patients with capacity to consent

If, after consideration of information about the study, the patient wishes to participate and has capacity to make that decision, the researcher will ask the patient to sign the **consent form for patients with capacity.** As part of the consent process, the patient will be asked to consider their ongoing study participation in the eventuality that they lose capacity to consent during the study (e.g. the develop confusion/delirium); the researcher will ask whether they would like to remain in the study, and whether they would still like their data to be used in the study.

Enrolment of carers

Patients' family members/ informal carers will be invited to participate as interviewees. The patient will be asked to identify a family member/ informal carer (unpaid) who provides the patient with assistance in their daily activities. If the patient's family member/ carer is available at the time the researcher visits the ward, they can be included in the discussions about the study and consent to will be sought at the same time as the patient. If the carer is not available on the ward at the time of the researcher's visit, the researcher will contact the carer by telephone. The researcher will offer to discuss the study with the family member/ carer, either at that time or another date/ time, until the family member/ carer is satisfied that all his/her questions have been answered fully. The researcher will offer the family member/ carer additional time to consider whether to participate. If the family member/ carer wishes to participate, they will be asked to provide consent, by signing a printed carer consent form or by completing the electronic carer consent form; a link to this will be sent to the carer via email or SMS.

Enrolment of patients lacking capacity to consent

If, prior to enrolment, a potential participant is assessed as not having capacity to make the decision about taking part in the study, the researcher will still provide the potential participant with study information according to their capacity of understanding and using the photographs in the information sheet as visual aids, if needed.

Reasonable steps will be taken to identify a personal consultee, in line with the requirements of section 32(3) of the *Mental Capacity Act 2005* and the Department of Health's *Guidance on nominating a consultee for research involving adults who lack capacity to consent* (2008). A personal consultee will be identified by the patient's direct care team. The personal consultee could be a family member, carer (unpaid) or friend, who knows the patient well and assists them with their daily activities, including making decisions about their welfare; this person may already be acting under a Lasting Power of Attorney, but this is not a pre-requisite.

If no appropriate person can be identified who is willing to act as a personal consultee, the patient will be excluded from the study. Note: *nominated* consultees will not be appointed for the purposes of this study; members of the patient's direct care team on the Medicine for the Elderly ward cannot be nominated as consultees because the direct care team are involved with the study.

The initial contact with the potential consultee will be made by the patient's direct care team. The direct care team will outline the purpose of the study and the role of a consultee, emphasising to the potential consultee that he/she is not obliged to undertake this role. The direct care team will ask the potential consultee if the researcher may contact them directly to provide further information about the study; this could be over the telephone or face-to-face on the ward. The researcher will provide full verbal and written information about the study (**consultee information sheet)**. The consultee will be asked to consider the patient's likely wishes and feelings about taking part. The researcher will offer the consultee additional time to consider this before communicating the patient's likely wishes and feelings about study participation to the researcher. The researcher will make it clear to the consultee that they are not being asked to provide their personal views on study participation, nor are they being asked to consent to the study on the patient's behalf. A decision to recruit or exclude the patient will be made by the researcher in line with the consultee's advice and any previous relevant statements or wishes communicated by the patient, whether verbal or non-verbal. Consultee advice will be recorded on a **printed consultee declaration form** or a**n electronic consultee declaration form.** If the consultee advises that the patient would not have wanted to take part, the researcher will abide by this. If a consultee is not available or declines to offer advice about the patient's wishes, the patient will be excluded from the study.

Patients who lose capacity during the study

During the initial consent process, patients will be asked to consider whether they would want data already collected about them that is in an identifiable form (e.g. video-recordings) to be used in the study in the event that they lose capacity (e.g. if they develop confusion/delirium as a result of their illness). The research team will act in accordance with the patient's wishes. The Study Information Sheet includes a clear statement regarding retention and use of identifiable data following loss of capacity.

During the initial consent process the patient will also be asked to consider whether they would want to continue to be included in the study in the event that they lose capacity. During the study, capacity of participants will be monitored by the direct care team. During the study, capacity of participants will be monitored by the direct care team and there will be regular communication between the clinical lead and the researchers about capacity concerns. If loss of capacity occurs a personal consultee would be sought to advise on whether the patient should continue to be included in the study. The consultees' advice will be documented on a **consultee declaration form**.

Patients who regain capacity during the study

If a patient who lacked capacity to consent to study participation subsequently regains capacity during the study, the researcher will approach the participant to explain what has happened to the participant as part of the study so far, and to seek ongoing consent. The researcher will provide the participant with a **recovered capacity participant information sheet.** The researcher will also provide the patient with verbal information about the study, including what has already happened to the patient as part of the study. Consent for continued participation will be documented on the **recovered capacity consent form.** Should the participant wish to withdraw from the study, the researcher will inform the patient about how their data will be handled depending on the stage at which the patient withdraws from the study:

- If no video-recordings have been taken, the researcher will communicate to the direct care team that the patient has withdrawn consent for study participation and no recordings should be taken. The patient's data will not be included in the study.
- If video-recordings have already been taken, the patient will be advised that these recordings will continue to form part of the patient's electronic health record and they will be available for review by the direct care team only for the purposes of patient care. However, the patient can request that their data remains in the study or is removed. The patient's wishes regarding the handling of their study data will be documented on the recovered capacity consent form.

WARD TEAM

There will be a 4-week staff engagement and enrolment phase for the direct care team on the Medicine for the Elderly ward at the beginning of the study. All clinical staff working on the Medicine for the Elderly ward will receive verbal and written information about the study from the research team during twice-weekly drop-in sessions and routinely scheduled team meetings (**staff study information sheet**). Staff will be informed about:

- the aims of the study
- study eligibility for patients and their family members/carers
- the purpose of the video-recordings
- permitted uses of the video-recordings
- access to the video footage
- governance measures and mechanisms for ensuring patient and staff privacy and confidentiality
- what staff can expect should they choose to participate in the evaluation of the video-recording pilot.

Staff will be reassured that they can choose not to be involved in recording or appearing in patient videos. They can also choose not to participate in the evaluation of the video-recording pilot. Staff will have the opportunity to ask questions and have them answered fully by the clinical lead for the study and/or the researcher. Staff who are willing to participate in the evaluation of the video-recording initiative will be asked to sign a **ward staff consent form.**

WITHDRAWAL CRITERIA

Participants can request to be withdrawn from the study at any time.

If a patient who lacks capacity gives any indication that he/she objects to study participation (whether verbally or non-verbally), the researcher and the personal consultee will discuss whether it would be in the patient's best interests to withdraw them from the study.

Participant withdrawal should be documented in the Screening/Enrolment Log.

SAMPLE SIZE

The aim is to recruit 95 participants, including patients (n=30), their carers (n=30), and ward staff (n=35). No power calculation has been undertaken since this feasibility study will evaluate acceptability/feasibility in principle rather than obtaining statistically significant results and will assess progression criteria in a pragmatic but purposively diverse sample of patients/carers/healthcare professionals.

INCENTIVES AND PAYMENTS

Participants will not receive any payments or incentives for study participation.
Individual researchers will not receive any personal payment over and above normal salary, or any other benefits or incentives.

8. DESCRIPTION OF THE INTERVENTION

A detailed description of the intervention is provided below, in accordance with TIDieR guidelines (Template for Intervention Description & Replication).

Brief name

Isla for Frailty

Why: rationale for the intervention

The lack of secure and efficient ways to acquire, store and share photographs and videos may partly explain why visual data have not been fully exploited in healthcare to date. Yet, visual information

can be very helpful when assessing patients and communicating information about a patient's condition to other healthcare professionals. Video-recordings could support existing verbal and written handovers between care-providers enabling objective and accurate assessments of the frail older person's condition and support needs.

What: materials

Isla is a technology company providing a visual patient record platform. The platform allows anyone involved in a patient's care to capture and review visual data (photographs, videos) relating to a patient's health. The platform is web-based (a "progressive web application") and supports secure capture of visual data with encrypted storage in the cloud.

To capture visual data using Isla, the user must be logged into the platform on a smartphone/ mobile device with an in-built camera with WiFi connection. Isla's application can be added to the device's homescreen; registered users enter their NHS.net credentials to log in. The device should be connected to the 'eduroam' WiFi network, which is available in the study setting and accessible by all clinical staff with an NHS.net account.

Isla interfaces with Electronic Health Record (EHR) systems including Cerner, enabling health professionals to view data held on Isla's servers from within the electronic patient record, via the 'Cerner Red Button'. Health professionals can also view a patient's visual record through a secure weblink requiring an NHS email address and password.

The Isla visual patient record platform is approved by NHS Digital and satisfies all NHS and ICHT data security and protection requirements (See **Imperial College Healthcare NHS Trust's Data Protection Impact Assessment for Isla**).

What: procedure

There will be a 3-month pilot of ISLA's visual record platform in the study setting. Isla will be used by the Medicine for the Elderly team to record, store and review video-recordings of patient participants. The videos will capture aspects of the patient's condition/functional ability that the team believes could usefully support care-provider communications and ongoing patient assessment, including:

- Mobility
- Transfers
- Eating and drinking
- Alertness
- Cognitive function (e.g. 4AT assessment or instructional tasks)
- Behaviour
- Communication
- Clinical examinations
- Patient preferences

Note, personal care or toileting will *not* be recorded.

Video views by the direct care team
Patient videos will be available for view by the direct care team during the patient's inpatient stay. The study protocol does not dictate when the videos will be reviewed by members of the direct care team; rather, the study will explore the real-world use of patient videos within the setting. The direct care team will be encouraged to view the videos and to use them in a way that they feel is useful to support patient care – for example, the videos could be used to support communication about a patient's condition/support needs during shift handovers, during ward rounds and MDT meetings, to inform discharge planning, or in discussions with the patients' family members/informal carers.

Who

Videos will be recorded by members of the patient's direct care team (doctors/ nurses/ healthcare assistants/ therapists) in accordance with the **Patient video-recording and Consent Standard Operating Procedure (SOP).** All clinical staff will have received training on Data Security Awareness as part of their statutory and mandatory training in the Trust. Additionally, they will receive training on how to use Isla's visual patient record platform and on the video-recording SOP, at the beginning of the study (see 'Staff engagement & preparation for the pilot' below).

How

Staff engagement & preparation for the pilot

Extensive staff engagement activities will be undertaken prior to the 3-month pilot of Isla's visual patient record platform in the study setting. The clinical lead for the study and the researcher will present the video-recording initiative to all medical, nursing and allied health professional staff during routine clinical team meetings and during drop-in sessions held by the clinical lead and the researcher on the ward. These engagement activities will take place 2-3 times per week over the course of four weeks to ensure coverage of the full staffing rota. During the staff engagement phase, staff will be provided with information about:

- the aims of the study
- the purpose of the video-recordings
- what staff can expect should they choose to participate in the evaluation of the Isla for Frailty intervention

Further information about staff enrolment procedures and consent are provided in section 7.2.

All permanent clinical staff members who work in the study setting will be registered with Isla prior to the pilot, providing they have consented to this. ICHT healthcare professionals participating in the care transitions review of patient videos will also be registered with Isla.

All healthcare professionals participating in the study will receive training on how to use Isla's platform and how to record patient videos according to the **Video-recording SOP** prior to platform's 'go live' date in the study setting.

The research team will place **study signage** around the ward to indicate to other patients and visitors that eligible patients and staff are participating in a research study involving video-recordings.

During the pilot

Patient enrolment will commence on the go-live date for the Isla platform in the study setting. On completion of enrolment procedures, the researcher will add the patient participants to the patient list in Isla and will flag new study participants to the direct care team at the time of enrolment.

Study participants will be highlighted on the direct care team's handover documentation (iWard or patient jobs list). The following abbreviations will indicate whether or not a patient has video submission available for view from within the electronic patient record in Cerner:

- I4F-0: patient is enrolled in the I4F study, no video submissions
- I4F-V: patient is enrolled in the I4F study, videos available for view

Study participants will be reviewed during daily ward rounds and multidisciplinary team (MDT) meetings; the direct care team will discuss which aspects of the patient's condition/support needs (if any) should be video recorded. The team will agree who among the team has accountability for ensuring the chosen video recording is taken on a case-by-case basis. The decision to record a video will be documented as part of the daily plan in the patient's record on Cerner, on the junior doctors' jobs list, and on the **Video Tracker.**

All patient videos will be recorded in accordance with the video-recording standard operating procedure. Once a video-recording has been taken and submitted to the patient's record, signage will be placed on the wall at the back of the patient's bed **(Signage B)**

Where

Patient videos will be recorded on the Medicine for the Elderly ward or in other areas within St. Mary's hospital where patients' functional abilities are assessed (e.g. hospital staircase, therapy kitchen; therapy gym).

Patient videos will be viewed on an ICHT password-protected computer on Trust premises.

When & how much

There will be no fixed schedule of video-recordings. The frequency of recordings will be at the discretion of the consultant in charge of the direct care team considering the patient's condition. However, as a minimum, video-recordings will be captured when the patient is assessed as 'medically optimised' prior to hospital discharge. The duration of video-recordings will be no longer than five minutes per recording.

There will be no fixed schedule of video viewings by the direct care team. The direct care team will be encouraged to view the videos and to use them in a way that they feel is useful to support patient care – for example, the videos could be used to support communication about a patient's condition/support needs during shift handovers, during ward rounds and MDT meetings, to inform discharge planning, or in discussions with the patients' family members/informal carers.

Tailoring

The content and number of video-recordings will differ between patients due to the heterogeneity of medical conditions, functional abilities, and support needs.

How well
Each video-recording request/ attempt/ submission will be documented on the **Video Tracker.** Issues relating to the video-recording process will also be documented on the tracker.

9. OUTCOME MEASURES

Primary outcome measure:

- Patient, carer and staff perspectives on the acceptability of video-based records

Secondary outcome measures:

- Recruitment and retention rates
- % of patient participants with videos linked to the electronic patient record
- Video view metrics
- Intervention barriers & facilitators
- Perceived impacts of video-based records on:
    - inpatient assessment & clinical decision-making
    - multi-disciplinary team communication
    - care continuity during a hospital stay
    - person-centred care during a hospital stay
- No. of videos raising cause for concern reported to the clinical lead

Table 1 (see overleaf) provides a summary of outcomes, measures/ approaches for obtaining data, and analyses (qualitative and quantitative), corresponding to the primary and secondary study objectives. In line with standard feasibility study objectives, clinical outcomes are not examined at this early investigative phase of the project.

Table 1: Summary of outcomes, measures/approaches, and methods of analysis

Objective	Outcomes	Measures/data collection	Methods of analysis
Acceptability	Patient/carer acceptability	- % of eligible participants declining enrolment & reasons for non-participation (screening/enrolment log)	Descriptive statistics
		- % of enrolled patients with ≥ 1 video linked to the EPR	Descriptive statistics
		- Semi-structured interview at or within 2 weeks of discharge	Framework analysis
		- Video evaluation questionnaire	Descriptive statistics & Framework analysis
	Direct care team acceptability	- Semi-structured interview after the 3-month pilot	Framework analysis
		- No. of videos requested, attempted & submitted (video tracker)	Descriptive statistics
Feasibility	Patient enrolment	-% of eligible participants who were enrolled into the study (screening/enrolment log)	Descriptive statistics
		- diversity of study sample (screening/enrolment log)	Descriptive statistics
	Intervention barriers & facilitators	- Semi-structured interviews with patients/carers	Framework analysis
		- Semi-structured interviews with direct care team	Framework analysis
	Use of the Isla platform	- % of participants with videos linked to the EPR	Descriptive statistics
		- Video view metrics	Descriptive statistics
	Privacy & security concerns	- No. of videos raising cause for concern reported to the clinical lead	Descriptive statistics
			Descriptive statistics
Perceived effectiveness	Perceived impacts on: i) inpatient assessment & clinical decision-making ii) multi-disciplinary team communication iii) care continuity during a hospital stay iv) person-centred care during a hospital stay	- Video evaluation questionnaires	Descriptive statistics & Framework analysis
		- Semi-structured interviews with direct care team after the pilot	Framework analysis
		- Semi-structured interviews with patients/patient-carer dyads at or within 2 weeks of discharge	Framework analysis

EPR = electronic patient record; ICHT = Imperial College Healthcare NHS Trust

10. DATA COLLECTION

Screening/Enrolment Log
The eligibility and enrolment status of all patients screened for the study will be documented on the **Screening/Enrolment Log;** this includes reasons for non-enrolment. This log will be kept in the study file in the Doctor's Office on the Medicine for the Elderly ward. It will be reviewed by and completed by the direct care team and the researcher during the 3-month pilot of Isla's platform.

Video Tracker
Patient video requests, attempts, submissions, and any issues associated with taking the recordings will be documented on the **Video Tracker.** The Video Tracker will be kept in the study file in the Doctor's Office on the Medicine for the Elderly ward. It will be used during ward rounds to document team decisions about which aspects of a patient participant's condition/functional ability are to be video-recorded. The Video Tracker will also be used to document 'Videos attempted'; 'Videos submitted' and any issues related to video-recording that the team experienced. At the end of the 3-month pilot, the paper records will be scanned and transferred to, and stored in, Imperial College Healthcare NHS Trust's Clinical, Analytics, Research and Evaluation (iCARE) informatics environment.

Video Evaluation Questionnaires
Staff experiences with viewing patient videos will be captured using a short **video evaluation questionnaire.** The direct care team will be encouraged to complete a video evaluation questionnaire for each video they have viewed. The questionnaire consists of seven closed-ended, multiple-choice questions with space for free-text comments. The questionnaire is anonymous and takes less than five minutes to complete. The questionnaire will be administered using a combination of methods to encourage a good response rate among busy clinical professionals. The questionnaire will be available to complete electronically, via Isla's platform, each time a member of staff views a patient video. Paper-based copies of the questionnaire will also be distributed to the direct care team to complete during 'downtime' periods – e.g. whilst awaiting handover or whilst awaiting meetings/ward round to begin. The paper-based video evaluation questionnaires will be administered by the researcher or by the clinical lead. Completed paper-based questionnaires will be placed in an envelope to preserve respondents' anonymity. At the end of the 3-month pilot, all questionnaire data will be transferred to an Excel file and stored in Imperial College Healthcare NHS Trust's Clinical, Analytics, Research and Evaluation (iCARE) informatics environment.

Interviews with patients & carers
The researcher will conduct semi-structured interviews with patients/ patients-carer dyads at or within two weeks of hospital discharge, or within 2 weeks of the end of the Isla pilot, whichever is sooner. The main aim of these interviews is to understand patients' experiences of being video recorded. Interviews will take place on the ward if the patient is still an inpatient, or over the telephone/Microsoft Teams/Zoom, according to the patient/carer's preferences if the patient has already been discharged. Written consent for interview will have been taken during the enrolment phase. However, due to the potential for fluctuating capacity in this patient group, the researcher will review the patient's capacity before the interview and conduct a further MCA, if appropriate. The patient and the carer will be asked to verbally confirm their consent, and this will be audio-recorded at the start of the interview. If the patient lacks capacity to consent, the researcher will

seek advice from the carer (as consultee) about whether the patient would want to go ahead with the interview; the carer/consultee's advice will be respected.

Interviews will follow the **patient/carer interview topic guide** and will last approximately 30 minutes. The researcher will adapt her language and use visual aids appropriate to the patient's level of understanding to enable patients with cognitive impairment to participate. Interviews will be audio-recorded and professionally transcribed. Any names/identifiers will be replaced with pseudonyms during the transcription process. Transcripts will be transferred to, and stored in, Imperial College Healthcare NHS Trust's Clinical, Analytics, Research and Evaluation (iCARE) informatics environment.

Interviews with ward staff
The researcher will undertake semi-structured interviews with consenting members of the patient's direct care team during a 2-month period following the pilot of Isla's platform in the Medicine for the Elderly ward. The interviews will explore staff experiences with Isla's visual patient record platform and impacts of the platform on patient assessment & clinical decision-making, team communication, and care delivery. Permission will be sought from the ward manager/Consultant in charge to release individual staff members for interview. Interviews will take place in a meeting room on or near to the ward, or over the telephone/ Microsoft Teams/ Zoom according to the interviewee's preference. Written consent for the interviews will be taken and a study identifier will be assigned. Interviews will follow the **interview topic guide for ward staff** and will last approximately 30 minutes. Interviews will be audio-recorded and professionally transcribed. Any names/identifiers will be replaced with pseudonyms during the transcription process. Transcripts will be transferred to, and stored in, Imperial College Healthcare NHS Trust's Clinical, Analytics, Research and Evaluation (iCARE) informatics environment.

Video View Metrics
At the end of the 3-month pilot of Isla's platform, video view metrics will be exported from Isla's audit log. Prior to storing the spreadsheet for descriptive analysis, the audit log will be pseudonymised by replacing the patient's name with their study ID and the names of the clinical staff who viewed the videos will be removed. The video view metrics spreadsheet will be transferred to, and stored in, Imperial College Healthcare NHS Trust's Clinical, Analytics, Research and Evaluation (iCARE) informatics environment.

11. END OF STUDY

The end of study will be the last date of data collection – i.e. the date of the last interview with a study participant; this will take place within two months of the end of the pilot of Isla's visual patient record platform in the study setting. Thereafter, the research team will undertake data analysis and dissemination of the study findings (months 8 – 17). There will be no patient/participant follow up.

CRITERIA FOR ELECTIVELY STOPPING THE STUDY PREMATURELY:

In the unlikely event that there is a security incident (data leak, cyber security incident) that impacts on Isla's visual record platform, the study will be stopped pending investigation of the incident and return to normal operations.

12. DATA ANALYSIS

Table 1 (pages 19-20) summarises the outcomes of interest, measures/approaches, and methods of data analysis.

As this is a feasibility study, quantitative analyses will be primarily descriptive. Counts and percentages will be calculated for categorical variables; means and standard deviations (SD) will be calculated for continuous variables.

Analyses of qualitative data (Video Evaluation Questionnaire - free-text responses; interview transcripts) will be undertaken using the Framework method developed by Ritchie & Spencer. Sekhon's *Theoretical Framework of Acceptability of Healthcare Interventions* will provide *a priori* themes as part of the framework for analysis of direct care team interview transcripts; themes emerging from the data itself will be added to the framework during the analytical process.

The theoretical framework of acceptability consists of seven component constructs: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy. These are defined further below:

- Affective Attitude: How an individual feels about the intervention
- Burden: The amount of effort required to participate in the intervention
- Ethicality: The extent to which the intervention has a good fit with an individual's value system
- Intervention Coherence: The extent to which the participant understands the intervention and how it works
- Opportunity Costs: The extent to which benefits, profits, or values must be given up to engage in the intervention
- Perceived Effectiveness: The extent to which the intervention is perceived to achieve its purpose
- Self-efficacy: The participant's confidence that they can perform the behaviour(s) required to participate in the intervention

13. ADVERSE EVENTS

Staff witnessing any behaviour on a patient videorecording that is cause for concern should report their concerns immediately to the clinical lead Dr Susannah Long, either in person or via email Susannah.long2@nhs.net. Alternatively, Jessica Fernandes (Matron – Medicine for the Elderly) jessica.fernandes@nhs.net, or Selam Delaportas (Ward Manager – Medicine for the Elderly) selam.delaportas@nhs.net, may be contacted.

A **Security Incident** is any incident that occurs by accident or deliberately that impacts Isla's users or the patient data on the system. This could be anything that threatens the confidentiality, integrity or availability of information, data or services delivered by Isla. This includes unauthorised access to, use, disclosure, modification, or destruction of data or services used or provided by Isla. In the unlikely event that there is a security incident, the study will be stopped pending investigation of the incident and return to normal operations.

DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*

- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

5.3.1 Non serious AEs

All such events, whether expected or not, should be recorded.

5.3.2 Serious AEs

An SAE form should be completed and emailed to the Chief Investigator within 24 hours. However, relapse and death due to frailty, and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the South Central - Oxford C Research Ethics Committee where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all related and unexpected SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs
RGIT@imperial.ac.uk
CI email (and contact details below)

phoebe.averill@nhs.net Please send SAE forms to: phoebe.averill@nhs.net
Tel: 07391 003330 **(Mon to Fri 09.00 – 17.00)**

14. REGULATORY ISSUES

ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the South Central - Oxford C Research Ethics Committee (23/SC/0167) (REC) and Health Research Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

CONSENT

Consent to enter the study, including enrolment procedures for adults lacking capacity to consent, is outlined in section 7 of this protocol. Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent or a signed consultee declaration form will be obtained. The right of the participant to refuse to participate without giving reasons will be respected. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

CONFIDENTIALITY

Isla's privacy notice outlines how Isla protects patients' privacy in their role as data processor, on behalf of Imperial College Healthcare NHS Trust as data controller.

Research data will be anonymous or pseudonymised, as per section 10 of this protocol.

All research data will be transferred to, and stored in, Imperial College Healthcare NHS Trust's Clinical, Analytics, Research and Evaluation (iCARE) informatics environment. iCARE is a secure NHS

based platform. The research team will access the data in the NHS platform, meaning the data does not leave the NHS. All access to the data is audited and controlled within the NHS. Data and all appropriate documentation will be stored for a minimum of 5 years after the completion of the study.

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

INDEMNITY

Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Resolution for NHS Trusts in England, which apply to this study.

SPONSOR

Imperial College Healthcare NHS trust will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trust taking part in this study.

FUNDING

NIHR and HEE are funding this study. NHS support costs are covered; however, study participants will not receive payment.

AUDITS

The study may be subject to audit by Imperial College Healthcare NHS Trust under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research.

15. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated by Dr. Phoebe Averill (Chief Investigator), Mr. Erik Mayer (ICHT Transformation Chief Clinical Information Officer) and Dr. Susy Long (Clinical Lead), working closely with the direct care team on the Medicine for the Elderly ward.

Phoebe Averill will be responsible for liaising with Isla (named contact: Zawadi Shongwe – Technical Programme Manager), the ICHT IT Project Manager for Isla (Emily Chan), and with the study sponsor (Imperial College Healthcare NHS Trust).

16. PUBLICATION POLICY

Key audiences likely to benefit from hearing about our findings are:

A. Professionals involved in assessing/caring for older people with frailty

B. Patients and carers
C. Academia

We will use multiple vehicles for dissemination, including:

- Presentations at the British Geriatrics Society Autumn meeting (Nov-2024) and the International Society for Quality in Healthcare conference (Oct-2024) (A).
- Peer-reviewed publications – target journal: *Age & Ageing* (A&C).
- Visual/lay summaries for patient/carer participants, disseminated to the public via local NHS newsletters and national patient-facing organisations (Carers UK/National Voices) (B).
- An internal report and workshops/meetings with Imperial College Healthcare NHS Trust staff
- Online press releases/social media, using existing networks/NIHR infrastructure to broaden dissemination and increase awareness (A-C).

17. REFERENCES

Gonçalves-Bradley DC, Maria ARJ, Ricci-Cabello I, Villanueva G, Fønhus MS, Glenton C, et al. Mobile technologies to support healthcare provider to healthcare provider communication and management of care (Review). Cochrane Database of Systematic Reviews. 2020;1–102.

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