

SUMU-Endo

Single-use versus Multiple-use Endoscopes in Gastroenterology:

Multi methods analysis to balancing infection control and environmental impact

PROTOCOL

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research, the ICH Good Clinical Practice guidelines and the Sponsor’s SOPs.

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

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

For and on behalf of the Study Sponsor:

Signature:

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Date:

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Name (please print):

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Position:

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Chief Investigator:

Signature:

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Date:

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Name: (please print):

.....

Position:

.....

KEY STUDY CONTACTS

Chief Investigator	<p>Professor Ramesh P Arasaradnam, OBE Professor of Gastroenterology University Hospitals Coventry & Warwickshire (UHCW) NHS Trust Clifford Bridge Road Coventry CV2 2DX Ramesh.arasaradnam@uhcw.nhs.uk</p>
Co-investigators	<p>Professor Norman Waugh University of Warwick N.r.Waugh@abdn.ac.uk</p> <p>Associate Professor Yen-Fu Chen University of Warwick/University of Birmingham Y-f.chen@warwick.ac.uk/y.chen.25@bham.ac.uk</p> <p>Professor Amy Grove University of Warwick/University of Birmingham A.l.grove@warwick.ac.uk/a.l.grove@bham.ac.uk</p> <p>Dr Stuart Coles University of Warwick Stuart.coles@uhcw.nhs.uk</p> <p>Dr Lazaros Andronis University of Warwick L.Andronis@warwick.ac.uk</p> <p>Dr Mandana Zanganeh University of Warwick Mandana.zanganeh@warwick.ac.uk</p> <p>Dr Bu'Hussain Hayee Kings College Hospital NHS Foundation Trust b.hayee@nhs.net</p> <p>Professor Shaji Sebastian Hull University Teaching Hospitals NHS Trust shaji.sebastian4@nhs.net</p> <p>Dr Anjan Dhar County Durham and Darlington NHS Foundation Trust adhar@nhs.net</p> <p>Dr Anant Sudarshan University of Warwick</p>

	<p>Anant.sudarshan@warwick.ac.uk</p> <p>Dr Julia Gauly University of Warwick/University of Birmingham Julia.Gauly@warwick.ac.uk/j.t.gaully@bham.ac.uk</p> <p>Ms Poonam Parmar PPI Representative</p> <p>Mr Peter Wheatstone PPI Representative</p> <p>Ms Caitlin Woodman PPI Representative</p>
Sponsor	<p>Sonia Kandola Research and Development Department UHCW NHS Trust Clifford Bridge Road Coventry CV2 2DX ResearchSponsorship@uhcw.nhs.uk Tel: 02476 966195</p>
Funder	<p>National Institute for Health Research (NIHR) Fairbairn House 71-75 Clarendon Road Leeds LS2 9PH Tel: 0113 343 2314</p>
Trial Co-ordination Centre	<p>Violet Matthews Trial Manager UHCW NHS Trust Clifford Bridge Road Coventry CV2 2DX SumuEndostudyoffice@uhcw.nhs.uk Tel: 02476 966907</p>

STUDY SUMMARY

Full study title	SUMU-Endo: Single-use versus Multiple-use Endoscopes in Gastroenterology: Multi methods analysis to balancing infection control and environmental impact
Short study title	SUMU-Endo
Study aim	To explore the views and experiences of patients receiving endoscopy and staff involved in procuring, using, cleaning and decontaminating endoscopes.
Study design	A multi-centre mixed-methods qualitative study using interviews and focus groups.
Study participants	Patients who have had an endoscopy in the NHS. NHS staff involved in supply chain, decontamination of endoscopes.
Planned Size of Sample	30 NHS Patients 30 NHS Staff
Planned Study period	18 months
Planned recruitment start date	01 Aug 2024
Planned recruitment end date	30 September 2025
Planned study end date	31 December 2025
Objectives	<p><u>Patient interviews</u></p> <p>1. To explore the views and experiences of patients receiving endoscopy in the NHS</p> <p><u>Staff focus groups/interviews</u></p> <p>1. To explore the views and experiences of staff involved in procuring, using, cleaning and decontaminating endoscopes in the NHS.</p>

STUDY FLOW CHART

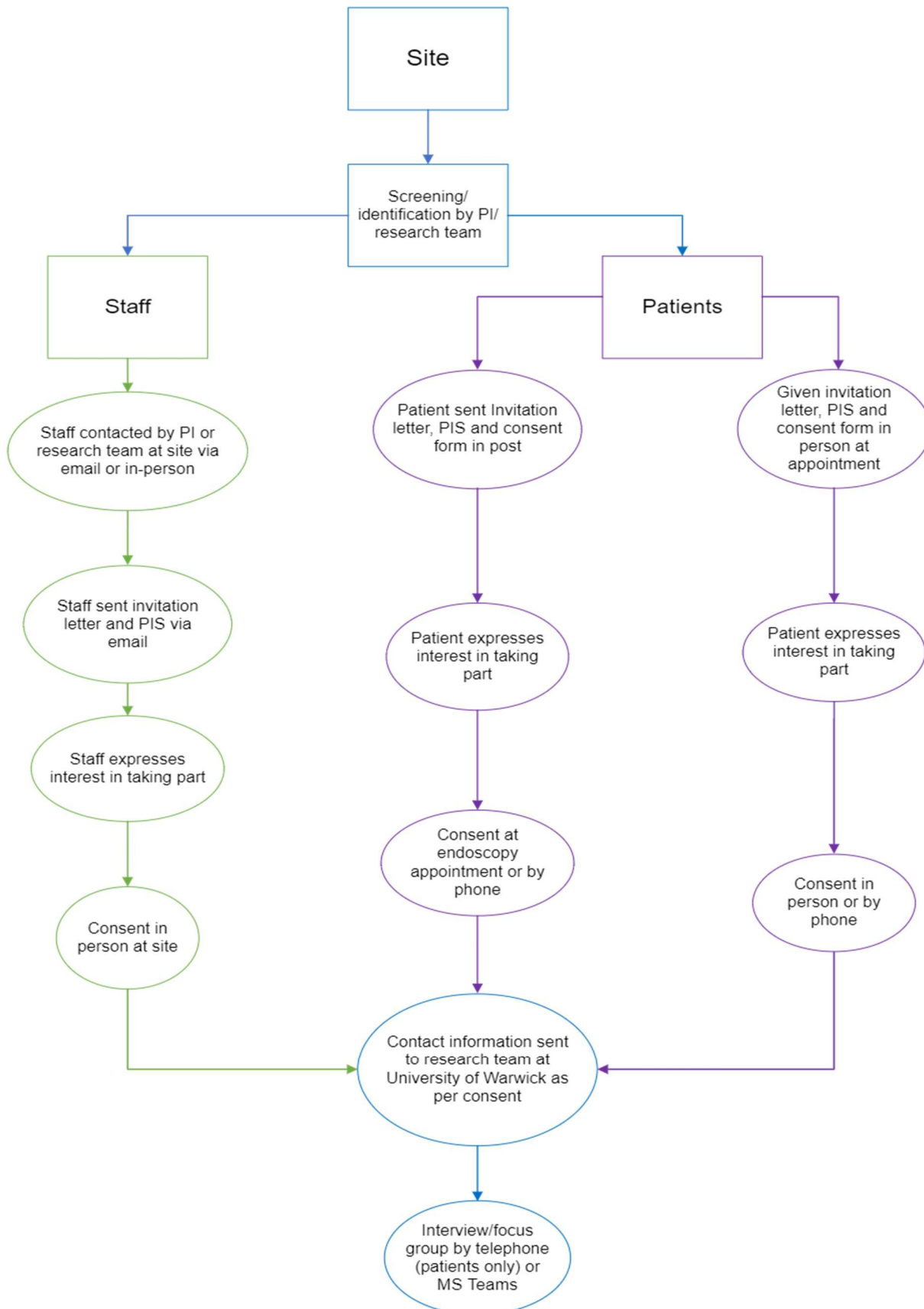


Figure 1: Flow of participants through the study

SCHEDULE OF EVENTS

Table 1: Schedule of Events

Procedure	Screening	Visit 1 – in person	Visit 1 – remotely
Eligibility assessment	X		
Informed consent		X	X*
Type of endoscopy procedure and type of endoscope	X*		
Demographic data	X	X	X
Participate in Focus Group/Interview		X	X

*patients only.

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LIST OF ABBREVIATIONS

CI	Chief Investigator
CRF	Case Report Form
ED&I	Equality, Diversity & Inclusion
EU	European Union
GCP	Good Clinical Practice
GI	Gastrointestinal
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ISF	Investigator Site File
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OSOP	One Sheet of Paper
PI	Principal Investigator
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PPRAG	Patient and Public Research Advisory Group
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
UoB	University of Birmingham
UHCW	University Hospitals Coventry & Warwickshire
UoW	University of Warwick
WP	Work Package

1. INTRODUCTION

1.1 Background

The scientific community, including healthcare professionals, has called for action to tackle the harm to health from climate change and to aid transition to a sustainable and healthier world ^[1]. The UK is one of the top 20 nations of highest carbon dioxide (CO₂) emissions globally (314 million tonnes of CO₂ equivalent) ^[2]. The National Health Service (NHS) contributes up to 5% of the total UK CO₂ emissions and the NHS Greener plan ^[3] aims to reach net zero carbon emissions by 2040. As Hensher (2020) noted: *“Health care has become an enthusiastic consumer and discarder of plastics, especially since the advent of disposable plastic items as an adjunct for hygiene and infection control”* ^[4]. The COVID-19 pandemic adversely affected NHS emissions due to increased use of personal protective equipment (PPE) and cleaning products. Single-use devices may seem attractive for infection control ^[5, 6] though we need to balance infection control and environmental impact of single-use versus multiple-use devices and equipment.

Endoscopes are a good example of the issues facing sustainable healthcare. Although they are made mainly from plastic (90%), they are traditionally multiple-use devices that are used repeatedly following decontamination after each use ^[7]. There are comprehensive operational procedures for decontamination of endoscopes, but these are resource intensive and require well-trained personnel. Several commercial companies (Ambu, Boston Scientific, Pentax) now market single-use endoscopes and endoscope accessories. These single-use devices are increasingly marketed on the grounds that they reduce the risk of infection and the need for decontamination, but there are concerns about their clinical performance, costs, and environmental impact ^[8-10]. Thus, there is an urgent need to assess the evidence objectively given enthusiasm by Industry to embed single-use endoscopes in practice. There will also be cost implications for less affluent countries thereby widening inequalities in access to diagnostic tests. Importantly, the impact of CO₂ generation in the manufacturing, use and disposable of both single and multiple-use endoscopes must be considered. The findings from this study will thus have international significance and applicability with a drive towards sustainability in healthcare.

Robust evidence is needed to guide policy makers and practitioners to decide whether and under what circumstances single-use endoscopes may be preferred over multiple-use endoscopes. Such evidence needs to take into account clinical outcomes including infection risk, costs and environmental impact, and consider different perspectives, including those of patients and carers, healthcare staff, manufacturers and policy makers. This project aims to address this urgent need for evidence ^[11]. The work needs to be done soon before single-use endoscopes are widely implemented.

Our primary aim is to provide evidence for NHS decision makers on the use of single-use vs. multiple-use endoscopes in gastroenterology, with the following objectives and work packages (WPs):

Work package 1: Review of evidence on technical performance, test accuracy and infection risk of single-use vs multiple-use gastrointestinal (GI) endoscopes, and of literature for other work packages.

Work package 2: Assess costs and consequences arising from use of single-use endoscopes compared to multiple-use ones. It will include specific patient groups (e.g., immunocompromised, those with severe infections) and settings (e.g., intensive care unit) taking into account all factors - costs of purchase, decontamination, consequences of infections and so on.

Work package 3: Assess the wider environmental consequences of a shift to single-use endoscopes including impact on scarce resources for their production and effect of disposal, including landfill and incineration, and the greenhouse gases and waste generated (including transport and storage).

Work package 4: Explore the views of patients receiving endoscopy and staff involved in using, cleaning and decontaminating endoscopes.

Work package 5: Provide evidence for patients, health professionals, service commissioners, manufacturers, environmental management and policy makers to make decisions on single-use and multiple-use endoscopes.

The figure below explains how the WP's come together to form the mixed methods study:

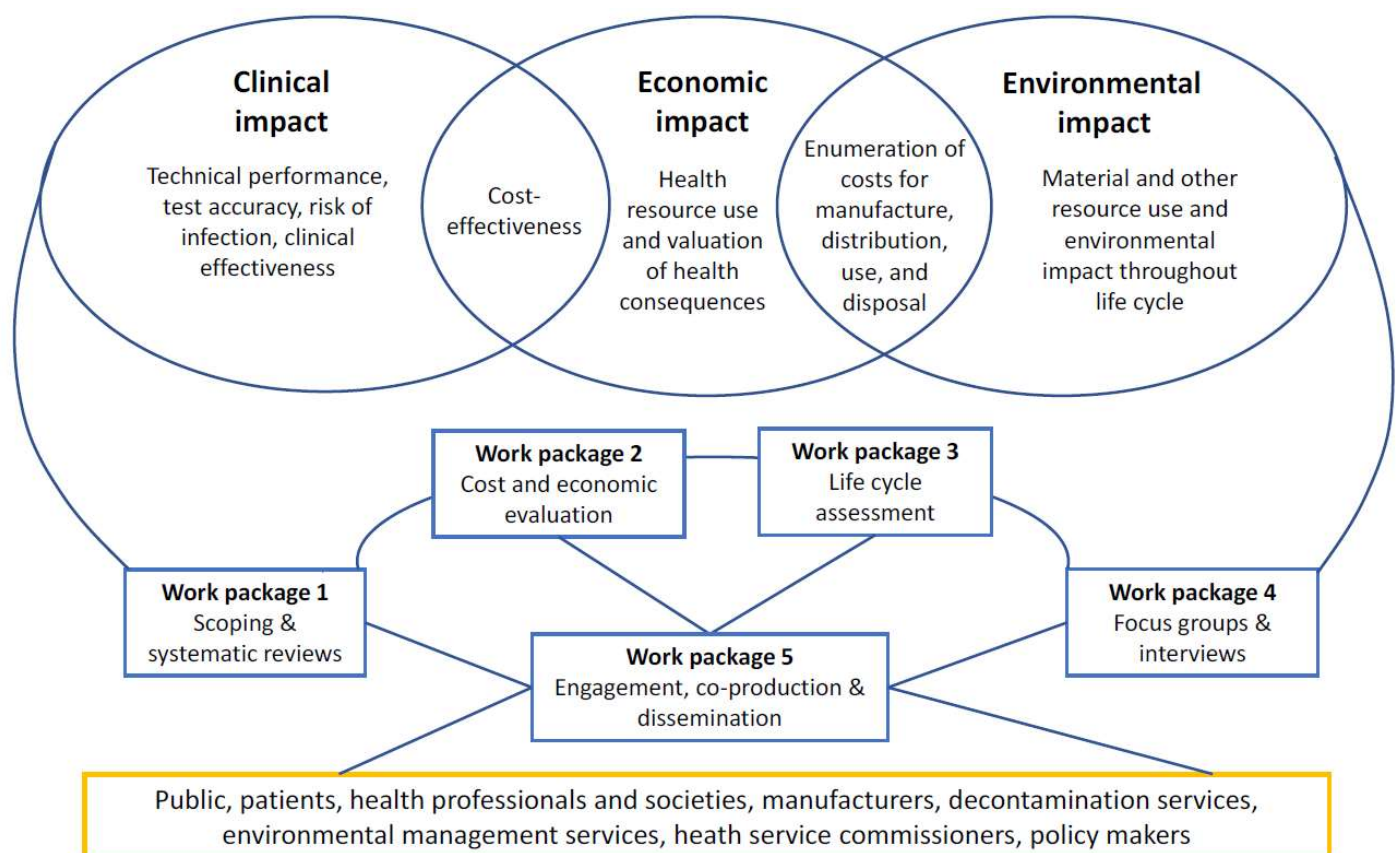


Figure 1: Overview of SUMU Endo project structure

1.2 Justification

Research on the environmental impact of various medical devices and procedures is growing ^[12]. Evidence has emerged most notably in surgery and anaesthesia ^[13-15]. A recently published systematic review examined the cost-effectiveness of single versus multiple-use bronchoscopes but did not consider environmental impact ^[16], which was addressed by another study ^[17]. The latter study found that the comparative environmental impact between single-use and reusable bronchoscopes is highly dependent on the cleaning procedures and the use of protective equipment during the disinfection of multiple-use bronchoscopes. A small number of reviews have also examined clinical performance of flexible ureteropyeloscopes ^[18] and endoscopes used in urological procedures. Research on the environmental impacts of single-use versus multiple-use endoscopes remains very limited. The NHS needs high quality evidence on the cost-effectiveness of disposable endoscopes compared to multiple-use ones. Gastroenterology is the largest user of endoscopes with approximately 1.5 million procedures annually in the UK ^[19], and therefore, decisions concerning single-use versus multiple-use endoscopes used in GI tracts could have major clinical, economic and environmental impacts. While evidence is also emerging in this field, we are not aware of any comprehensive evaluation of evidence related to GI endoscopes that cover all these important aspects ^[7]. This proposed research will fill in this important evidence gap.

While the scope of this study is limited to the endoscopes used in gastroenterology, the target is that the methods used to incorporate the views and experiences of patients and staff will be transferable, e.g. to other types of endoscopes and surgical equipment. Similarly, the systematic review (WP1) will search and synthesise literature to identify key considerations and the underlying mechanisms through which various factors may influence the choice between single-use and multiple-use devices, and how these vary by contextual characteristics of person and place. An important output of the project will be a novel system-based logic model ^[20] which depicts the extended endoscope life cycle in the broad ecosystem beyond clinical care pathways. This logic model will be informed by outputs from this study (as well as the other WPs) and will show the mechanisms by which single-use or multiple-use endoscopes influence effectiveness, cost-effectiveness, and environment, and will provide an evidence-based foundation to build on and promote sustainability and the transferability of research findings to other surgical equipment and areas of practice.

Endoscopy is a relatively invasive intervention from the perspective of patients. Patients know they are receiving endoscopy, and often know what the procedure involves and who might do it. However, little information is shared regarding the medical device (the scope) which the clinician uses to perform the intervention. Patients may not be aware that different types of endoscopes are available, with varying environmental profiles. This study is important to understand and work with the degree of risk people having endoscopy are willing to accept, and to understand what additional information people would like, in order

to feel satisfied with different endoscope options. It will be important to determine how the balance between infection control and environmental impact should best be communicated to people in accessible formats.

1.3 Proposed study

This project is taking place as part of Work Package 4 (WP4, see Figure 1). A range of data collection methods will be used to discern the attitudes and experiences of NHS patients receiving endoscopy, and staff working in the NHS who handle colonoscopes and other GI endoscopes before and after use (e.g., selection, procurement, disinfection, and disposal of endoscopes).

1.4 Study population

Patients who have had or are awaiting an endoscope in the NHS will be approached for this study, as well as staff working in the NHS involved in the life cycle of endoscopes.

2 OBJECTIVES

2.1 Primary objective

To explore the views and experiences of patients receiving endoscopy and staff involved in procuring, performing endoscopies, cleaning and decontaminating endoscopes.

2.2 Primary outcome measures

As this is a qualitative study, there is no primary outcome measure. However, the aim is to present the experience, attitudes and values of staff and patients in narrative form (final report and publication) and in visual summary formats (infographics), to be shared across the relevant networks and contribute to the overall study aim of providing evidence for NHS decision makers on the use of single-use vs. multiple-use endoscopes in gastroenterology.

3 STUDY DESIGN AND METHODS OF DATA COLLECTION AND ANALYSIS

3.1 Study Design and Data Collection

This is a cross sectional qualitative study involving two methods of data collection. Data collection using both methods will be conducted in parallel.

Method 1: Semi-structured interviews with NHS patients.

NHS patients will be purposefully sampled to take part in semi-structured interviews. Screening will be done at site by the PI and/or research team. Patients will be approached either at their endoscopy appointment, where the study will be explained and documents shared with them, or by being sent the study information and documents in the post. They will be given at least 24 hours to decide if they'd like to participate.

Patients interested in taking part can contact the research team and express their interest via details provided on the PIS. Alternatively, they may be contacted by the research team after a reasonable amount of time has passed, to see if they have received and read the PIS and are interested in taking part.

Consent to participate will be obtained either in-person at an appointment or remotely by telephone by the PI or an appropriately qualified member of the research team at the site, before the interview is performed. An interview date will be arranged with the participant at a time and date that is acceptable to them. The interviews will be conducted by an experienced qualitative research team member, using a topic guide developed for this study, and last approximately 30-60 minutes.

Patients can choose whether they want to be interviewed via Microsoft Teams or by telephone. Participants will be made aware that the interviews will be recorded and professionally transcribed, and will be anonymised. Once the interview is complete the research team member will transfer the interview file to the secure university cloud storage. Interviews and demographic data will be pseudonymised prior to transcription and anonymised following the transcription.

Analysis will be conducted in parallel to data collection to allow for progressive focusing as the data collection progresses. Analysis will follow the steps of thematic analysis. Each file will be transcribed and checked for accuracy against the original file. Once accuracy is assured the audio/video files will be deleted.

Once analysis is complete, the transcripts containing raw data will be archived and stored on University secure storage. Aggregate anonymised data will be made available to the wider research team for report writing.

Translation and interpretation will be available for all persons who might not adequately understand verbal explanations. Translation and interpreters will be provided from across a network of support at UHCW and academic partners.

Method 2: Focus groups/Interviews with NHS staff.

NHS staff will be identified by the PI, or research team at each site and invited to take part via email or verbally in-person. They will be given the PIS and will have at least 24 hours to decide if they'd like to take part. A follow up email will be sent by the PI or research team after a reasonable amount of time has passed with no contact.

Consent to participate will be obtained in-person by the PI or an appropriately qualified member of the research team at site before the focus group. Focus groups of 2-5 people will be conducted virtually via Microsoft Teams by an experienced qualitative research team member. However, if this is not feasible due to time constraints, a one-on-one interview may be scheduled instead. Participants will be made aware that the focus groups/interviews will be recorded, anonymised and professionally transcribed.

Each focus group or interview may take 30-60 minutes to complete, during which participants will be asked questions according to a topic guide. Data handling, storage and analysis will follow the same procedure as for the interview data.

The topic guides for both interviews and focus groups will be used flexibly rather than tightly scripted. However, pre-work and discussion with patient contributors suggests that key questions will aim to understand staff and patients' perception of risk from reuse or disposal of equipment, and views about environmental impact of medical procedures.

The topic guide for both the interviews and focus groups will be informed by discussion with the patient contributor group, research team, and data collected in work packages 1-3.

3.2 Data Analysis

Qualitative data will be analysed in offices located at the University of Warwick (UoW) and University of Birmingham (UoB), using university computers. Both institutions will be used due to researchers changing affiliation during this project. Analysis will be supported using both Microsoft Excel and NVivo. Pseudonymised recordings will be sent to a transcription company who are preferred suppliers of our academic partners. Pseudonymised transcripts will be stored electronically on UoW and UoB servers on password protected files. Analysis will be conducted by a member of the research team, with support from the study collaborators.

Analysis will follow the steps of thematic analysis outlined by Braun and Clarke (2021) ^[44]. Analysis will begin with reading and rereading the data contained in the pseudonymised and transcribed interviews and focus groups. Transcripts will be cross-checked with the original recordings to ensure accuracy of the transcription. Transcripts will then be line-by-line coded by an experienced qualitative researcher and 10% will be independently coded by the Work Package lead. An initial coding frame (after 3-5 transcriptions) will be shared with the wider research team for feedback and cross checking of codes and meaning. Codes will be assembled into categories and themes using the One Sheet of Paper (OSOP) technique ^[45]. OSOP can be used when presenting stages of qualitative analysis back to the research team and stakeholder groups, who may not be experienced qualitative researchers.

Data from staff focus groups/interviews and patient interviews will be analysed separately, first by centre and then, by participant group. It is recognised that abstract lessons may be learnt from exploring the entirety of the data. Therefore, if appropriate, the patient and staff qualitative data will be compared, contrasted and combined, looking for consistencies and inconsistencies in the data and for deviant cases which require further investigation.

Initial findings will be shared in stakeholder consultation workshops with the Patient and Public Research Advisory Group (PPRAG) to capture the views of people who are invited to receive endoscopy, and second with the Green Endoscopy Network (which has international membership) and the British Society of Gastroenterology Endoscopy Committee. Where appropriate, the consultation feedback will be incorporated into our final qualitative findings (e.g., to help expand, or interpret themes) and subsequent recommendations, exploring how information provision for endoscopy could be better provided to people invited for endoscopy.

Findings will be reviewed in the context of equality, diversity and inclusion (ED&I) to investigate the impact of the work on different groups of people, for example, could the

results generate or contribute to inequalities in accessing procedures. Input from patient contributors to this study suggested that consideration could be given to the application of this work in resource poor settings. For example, it was asked “would single-use scopes prove more difficult to dispose of if the appropriate infrastructure were not in place?” Patient contributors were also interested in the usefulness of this work for other medical procedures - such as surgical instruments.

4. STUDY SETTING

This study will be multi-centre, across 6 sites in England, Scotland and Wales. The only requirement for entry into the study is that the hospital site deliver endoscopy services.

Using professional networks and links with The British Society of Gastroenterology, gastroenterology units have been identified to participate in the study. Participants (staff and patients) will be sampled from those people who work in or access endoscopy services at these sites.

Some sites will be large tertiary centres which do complex endoscopic procedures, others will be District General Hospitals who do the vast majority of diagnostic endoscopies and the less complex therapeutic endoscopy. It is essential that ED&I is attended to in the selection of sites and participants to ensure a representative sample is obtained, and conclusions and recommendations can be drawn that are appropriate to the population in the UK. The aim will be for maximal variation in the sample, both in terms of the hospitals recruited (local population and geography) and the NHS staff and patients who are invited to participate (e.g., age, gender, ethnicity). The local population of the centres will include rural and urban areas with residents of mixed socioeconomic status.

5. ELIGIBILITY CRITERIA

5.1 Inclusion criteria

Patients

- Over the age of 18
- Patient has been invited to an NHS endoscopic clinic to undertake an upper GI endoscope procedure, including diagnostic endoscopies and the less complex therapeutic endoscopy.
- Patient is able to read and understand information provided
- Patient has capacity to provide consent
- Patient is able to participate in an interview.

Staff

- Over the age of 18
- Employed by the NHS
- Working in relevant endoscopy unit - primary work involves the conduct of endoscopy and/or waste disposal services (decontamination or disposal).

5.2 Exclusion criteria

- Patient has received a lower GI endoscopy, e.g. colonoscopy or sigmoidoscopy
- Non-NHS service providers and receivers. (e.g., private diagnostic clinics)

6. STUDY PROCEDURES

6.1 Sampling

6.1.1 Size of sample

No sample size calculation was derived as this is a qualitative study where we aim to maximally sample participants across the units (not depth of investigation at each unit). We will use maximum variation sampling based on the following parameters: age, ethnicity, gender for all participants, and years of experience for NHS staff.

Patients

We plan to interview 5 patients from 6 sites but recognise that flexibility needs to be maintained to ensure diversity in the participant sample.

Staff

The planned number of staff participants is 30 (5 staff from 6 sites) but we will allow flexibility within units, for example if one participant performs both selection and procurement.

6.2 Recruitment

Patients

We will conduct interviews with patients from 6 hospitals. The PI and research team at each site will identify potential participants through the clinic list. Potential participants who require an endoscopy will be asked if they are interested in the study and given study documentation in person. Alternatively, patients can be sent an invitation letter, PIS and consent form via post and be given at least 24 hours to decide if they would like to take part.

Interested patients can contact the research team using the details provided in the study documents. Alternatively, they will be contacted after a reasonable amount of time has passed with no response to see if they are interested. If they agree to take part, consent will be obtained either in-person at attendance of the clinic, or via the telephone if necessary.

Staff

The PI and research team at each site will generate a list of all staff who work across the endoscopy pathway and identify potential study participants. Participants will be invited to take part in the study via email invitation along with the PIS from the site PI, or informed about the study in person and given a PIS.

Staff will have at least 24 hours to decide if they'd like to take part. If they agree, the PI and research team at site will then contact the member of staff to consent them in-person. Their contact details will be provided to the experienced qualitative researcher after consent who will then organise a focus group consisting of 2-5 members of staff on Microsoft Teams. However if this is not possible, an individual interview will be scheduled. Staff recruitment will continue until all segments of the extended endoscopy care pathway are accounted for, or when saturation is reached in the data collection.

6.3 Consent

Patients

Written consent will be obtained prior to interview by an appropriately trained and delegated member of the research team at each site. Telephone consent will only be obtained if the patient has already attended an endoscopy appointment and has no further appointments scheduled.

In person consent: If the patient has expressed an interest to take part in the study, consent will be obtained in person at the next clinic appointment.

Telephone consent: For patients who have already had their endoscopy, consent will be obtained via telephone. A member of the research team will confirm with the patient that they have read the PIS and consent form, and answer any questions. They will go through each clause of the consent form and document on the ICF by initialling each relevant box. They will then sign the consent form in place of the participant. The process must also be documented in the patient's medical notes including the study name, start and end time of the conversation, and specify which clauses of the consent they agree/disagree to.

Staff

If they have agreed to take part, staff will be consented in person at the site by the PI or member of the research team.

It will be explained to both sets that entry into the study is entirely voluntary and the right of a participant to refuse participation without giving reasons will be respected and recorded on the screening log. Participants can withdraw prior to, during or after the interview/focus group. They will have 7 days post-interview/focus group to withdraw their data from the study, before it is anonymised. Participants may be withdrawn from the study at the discretion of the investigator and/or co-investigators due to safety concerns. However, this is not anticipated to be an issue.

6.4 Site Staff Training

The research team will provide training for all site members who will be responsible for conducting study related procedures. This will include information on confirming eligibility and obtaining consent. Training logs and the delegation log will be used to document who has received training; research staff taking part in the study will sign the site delegation log and update the study team when a new member joins the research team or the local PI changes.

6.5 End of study

The study will end after data saturation has been achieved.

The study will be stopped early if:

- Mandated by the Ethics Committee
- Funding for the study ceases

Given this study is low risk it is highly unlikely that a safety concern would emerge that would result in early termination of the study.

The REC will be notified in writing within 90 days when the study has been concluded or within 15 days if terminated early.

7. DATA MANAGEMENT

Personal data collected during the study will be handled and stored in accordance with the 2018 Data Protection Act and General Data Protection Regulation. UoW and UoB will be the data processors for this study and will store and analyse all data on secure university computers.

Personal identifying information will be held securely in password protected files on site servers. Personal data (participants name and telephone number) will be made available to members of the research team who will be responsible for undertaking the interviews/focus groups. Handling of personal data will be clearly documented in the patient information sheet and consent obtained. Personal data will be kept for up to 12 months after the study has ended.

Study data will be securely stored for up to 10 years after the study ends. Following the interviews/focus groups, data will be pseudonymised and a unique study number designated to each participant. After 7 days after the interviews/focus groups, the interview data will be anonymised.

Disclosure of confidential information will only be considered if there is an issue, which may jeopardise the safety of the participant or another person, according to UHCW SOP and the UK regulatory framework.

7.1 Data collection and management

Telephone interviews will be audio recorded using encrypted devices from University of Warwick or University of Birmingham. Interviews and focus groups conducted virtually will be audio/video recorded using MS Teams or audio recorded using encrypted devices – participants can choose to turn off their camera if they wish. If not, the audio recording and transcript will be separated from the video, which will subsequently be deleted. Following the data collection, data will be pseudonymised and sent to an approved UoW/UoB supplier for transcription services, after which it will be anonymised.

Demographic data will be collected for each participant, including the age group, sex, ethnicity for all participants. For NHS patients, the type of endoscopy procedure will be

collected as well as the type of endoscope. Years of experience will be collected for NHS staff. This will be stored in a secure password protected file and kept separately to any identifiable information, identified only by unique study ID. This data will be shared with university researchers according to the terms of the Data Sharing Agreement.

7.2 Data storage

The pseudonymised research data will be stored on secure university servers in password protected files until analysis is completed. Once complete, aggregate data will be available to write the final study reports. Identifiable participant data (email addresses and phone numbers) will be kept on a password protected file on secure university computers. This will be stored separately to raw pseudonymised research data.

7.3 Data access

All data collected will be pseudonymised after the collection of data for each participant. Confidentiality will be strictly maintained, and names or addresses will not be disclosed to anyone other than the staff involved in running the study.

Direct access to source data/documents will be available for study-related monitoring or audit by UHCW for internal audit, regulatory authorities or ethics committees.

The PI must arrange for retention of study records on site in accordance with GCP and local Trust's policies.

The CI and study team will have access to the final study data set. Contractual agreements will be in place to limit access of the final data set.

7.4 Archiving

Research data will be stored for up to 10 years after the study commences. After this, all research data will be destroyed.

The data will be included in a final study report which will be submitted to the research funder, but also as peer reviewed journal publications. As the latter is unpredictable in terms of time and content of publications, raw pseudonymised data will be kept beyond the date of the project close.

8. STUDY OVERSIGHT

8.1 Role and responsibilities of the Sponsor

UHCW has agreed to act as sponsor for this study and will undertake the responsibilities of sponsor as defined by the UK Policy Framework for Health and Social Care Research and ICH Good Clinical Practice. An authorised representative of the Sponsor has approved the final version of this protocol with respect to the study design, conduct, data analysis and interpretation and plans for publication and dissemination of results. As sponsor, UHCW provides indemnity for this study and, as such, will be responsible for claims for any negligent harm suffered by anyone as a result of participating in this study. The indemnity is renewed on an annual basis and will continue for the duration of the study.

8.2 Role and responsibilities of the Funder

Funding for this study is provided by the National Institute for Health and Care Research (NIHR). The design and management of this study are entirely independent of the funder.

8.3 Trial Management Arrangements

8.3.1 Trial Coordination

The study will be coordinated by the Trial Management Unit at UHCW. The Trial Manager will have responsibility for overseeing day to day coordination of the study and reporting regularly via study meetings. The Trial Manager's responsibilities include, but are not limited to:

- Coordinating protocol development, patient and trial management documents
- Correspondence with study funder and tracking of progress against agreed milestones;
- Setting up and maintaining the Trial Master File
- Ensuring necessary approvals are in place before the start of the trial at each site
- Producing trial progress reports and coordinating study meetings and minutes;
- Ensuring data security and quality and ensuring data protection laws are adhered to;
- Ensuring complete records are in place for audit and monitoring purposes;
- Ensuring the trial is conducted in accordance with the ICH GCP;
- Archiving all original trial documents including the data forms in line with UHCW NHS Trust policy

8.3.2 Principal Investigators

Site Principal Investigator responsibilities include, but are not limited to:

- Ensuring that the trial is conducted as set out in the protocol and supporting documents;
- Delegating trial related responsibilities only to suitably trained and qualified personnel and ensuring that those with delegated responsibilities fully understand and agree to the duties being delegated to them;
- Ensuring that CVs and evidence of appropriate training for all Site staff are available in the Trial Site File;
- Ensuring that all delegated duties are captured in the study Delegation Log;
- Ensuring the trial is conducted in accordance with ICH GCP principles;
- Allowing access to source data for monitoring, audit and inspection;
- Ensuring that all source data is complete and provided to the Trial Manager at regular intervals.

9. MONITORING, AUDIT & INSPECTION

The study may be monitored by the study management group to ensure that the study is being conducted as per protocol, adhering to Research Governance and GCP. Central

monitoring activities may be performed. The approach to, and extent of, monitoring will be specified in a study monitoring plan determined by the risk assessment undertaken prior to the start of the study.

The recruiting site is obliged to assist the sponsor in monitoring the study. These may include hosting site visits, providing information for remote monitoring, or putting procedures in place to monitor the study internally.

10. ETHICAL AND REGULATORY CONSIDERATIONS

10.1 Ethical approval and research governance

The study will be conducted in compliance with the principles of the ICH GCP guidelines and in accordance with all applicable regulatory guidance, including, but not limited to, the UK policy framework for health and social care research. Ethical approval for this study will be sought from the Research Ethics Committee combined with Health Research Authority (HRA) approval.

No study activities will commence until favourable ethical opinion and HRA approval has been obtained. Progress reports and a final report at the conclusion of the study will be submitted to the approving REC within the timelines defined by the committee.

Before enrolling patients into the study, the study site will ensure that the local conduct of the study has the agreement of the relevant NHS Trust Research & Development (R&D) department. Confirmation of capacity and capability will be obtained from both R&D departments prior to commencement of the study at all participating sites.

Substantial protocol amendments (e.g., changes to eligibility criteria, outcomes, analyses) will be communicated by the study team to relevant parties i.e., investigators, RECs, participants, NHS Trusts, study registries, journals, as appropriate.

10.2 Peer review

This proposed study and methods were peer reviewed by the NIHR HS&DR independent funding Committee as part of the funding application. Feedback was given and changes suggested after stage 1, with amendments and recommendations taken on board for stage 2. After this, the project was successfully awarded funding.

10.3 Public and Patient Involvement

Patients with personal experience of endoscopy have been involved throughout the shaping and design of the study. A group of public and patient contributors at UHCW, part of the PPRAG, have been vital in shaping ideas. Contributors provided feedback on the initial research ideas and together, the face validity of the study was assessed, and if the research aims were relevant to patients and addressed the patient needs and the delivery of the endoscopy service in the NHS.

Discussion of research project design helped to plan a project that is relevant to patients, and whether the methods are acceptable and ethical in the NHS. The research team hopes

to have enough PPI representatives to enable flexible regional and national involvement at project meetings and advisory group reviews.

The PPI members named as co-applicants on this protocol have experience of endoscopy, and have reviewed and fed back on the study documentation enabling us to create a useable document set.

10.4 Assessment and management of risk

This is a non-interventional, qualitative study and no changes will be made to participant's ongoing or routine care because of participation. Risks are therefore minimal, aside from the usual risks associated with a endoscopy procedure as per Standard of Care. We will undertake a study specific risk assessment and develop a monitoring plan to ensure any risks identified are dealt with appropriately. It is therefore unlikely that any adverse events will occur because of participation in this study. Any adverse events that do occur will be managed according to local sites Standard Operating Procedures as appropriate.

11. DISSEMINATION POLICY

The results of this research are intended to be disseminated in various formats including but not limited to dissertations, conference presentations, and publications. No participant-identifiable information will be included in any method for dissemination of the study results. Use of quotations/extracts from interviews may be used as part of the results dissemination however the anonymity of the participant will be ensured. This will be made explicitly clear on the patient information sheet and consent form.

Participants will be informed of the lay summary of the results depending on their preference. If willing, this will be distributed to participants via email. This document will be checked by the PPRAG prior to its distribution.

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