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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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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	Primary: To provide evidence for NHS decision makers on the use of single-use vs. multiple-use endoscopes in gastroenterology. Secondary: To explore how sustainability issues might be considered in future technology assessment by policy-makers such as NICE.
Study design	Multi-methods analysis
Planned study start date	01 Jun 2023
Planned study end date	31 May 2025
	Objectives
Primary	WP1: 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. WP2: Assess costs and consequences arising from use of single-use endoscopes compared to multiple-use ones. We 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 etc. WP3: 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). WP4: Explore the views of patients receiving endoscopy and staff involved in using, cleaning and decontaminating endoscopes. WP5: Provide evidence for patients, health professionals, service commissioners, manufacturers, environmental management and policy makers to make decisions on single-use and multiple-use endoscopes.

STUDY FLOW CHART

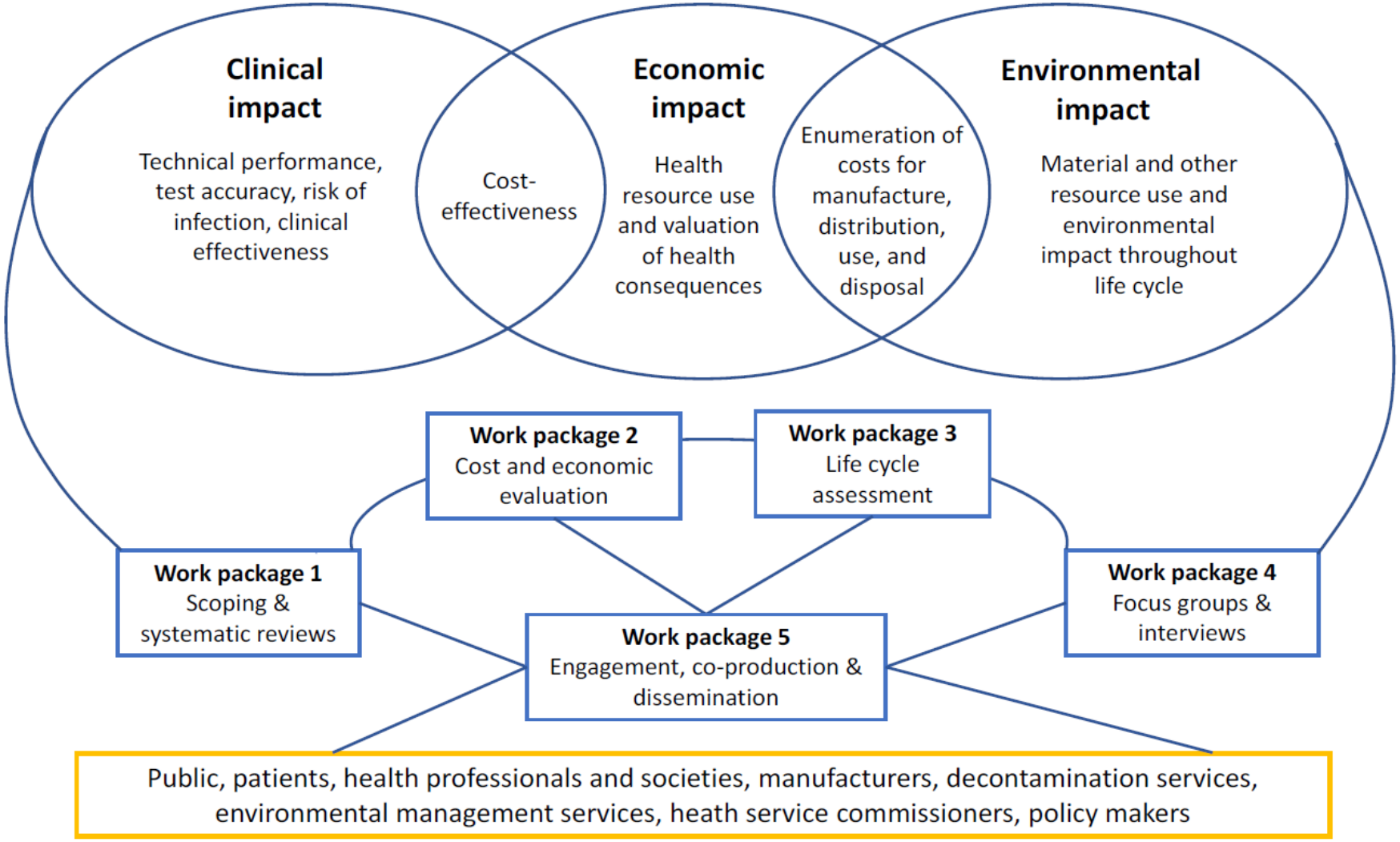

Figure 1: Overview of SUMU Endo project structure

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GANNT CHART

Project year	Year 1						Year 2					
Activity in months	1-2	3-4	5-6	7-8	9-10	11-12	13-14	15-16	17-18	19-20	21-22	23-24
WP1. Literature search and synthesis of clinical evidence												
Task 1.1 Broad search of relevant clinical, economic and environmental literature	■	■					■					
Task 1.2 Systematic review of clinical evidence: technical performance, infection risk, diagnostic accuracy		■	■	■	■	■	■	■	■			
Task 1.3 Rapid synthesis of key factors influencing single-use vs reusable decisions across endoscopy, anaesthesia and surgery										■	■	■
WP2. Assessment of costs and consequences from the health care system viewpoint												
Task 2.1. Review of existing economic literature	■	■	■									
Task 2.2. Economic analysis plan			■	■								
Task 2.3. Analysis and preparation of findings					■	■	■	■	■			
Task 2.4. Development of framework and Expert Advisory Group meeting										■	■	■
WP3. Assessment of environmental impacts using life cycle assessment												
Task 3.1. Goal and scope				■								
Task 3.2. Inventory analysis					■	■	■					
Task 3.3. Impact assessment							■	■				
Task 3.4. Interpretation								■	■			
Task 3.5. Development of multi-criteria decision aiding framework										■	■	■
WP4. Views and experiences of patients and staff												
Task 4.1. Ethical approval				■								
Task 4.2. Site selection and recruitment			■	■								
Task 4.3. Primary data collection: patients and staff					■	■	■					
Task 4.1. Qualitative data anlaysis						■	■	■	■			
Task 4.5. Work package report writing										■	■	■
WP5. Patient and stakeholder engagement, collaboration and decision aid development												
Task 5.1. Patient and stakeholder engagement will be ongoing throughout the project	■	■	■	■	■	■	■	■	■	■	■	■

Notes: ■ indicates work to be undertaken in the first 18 months of project ■ indicates work to be undertaken in the extended 6 months of project

Figure 2: GANTT chart indicating the approximate timeline of work to be undertaken across the project lifespan.

Contents

STUDY PROTOCOL

1. INTRODUCTION

1.1 Background and rationale

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, as stated in the Commissioning Brief, 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, we need to consider the impact of CO2 generation in the manufacturing, use and disposable of both single and multiple-use endoscopes. Our findings 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.

1.2 Why is this research important?

1.2.1 Clinical importance

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. We will develop optimal models of carbon reduction and identify the issues around reusable devices.

While we limit the scope of our proposed study to the endoscopes used in gastroenterology, we believe that the methods used to synthesise evidence, examine economic and environmental consequences, and incorporate the views / experiences of patients and staff (see work packages 1-5) will be transferable e.g., to other types of endoscopes and surgical equipment. Similarly, in our systematic review (see WP1) we 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 our study 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, to be informed by outputs from all work packages, 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.

1.2.2 Importance to patients

Endoscopy is a relatively invasive intervention from the perspective of patients. Patients know they are receiving endoscopy, and often 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, and that the clinician has a choice in what type is used. Consultation with our local gastroenterology patient group (Patient and Public Research Advisory Group – PPRAG) revealed that people often assume that each endoscope is "new" and they said they "would be concerned" about reusing endoscopes that had been used for other patients. This concern appeared to stem from a lack of awareness of the decontamination process for endoscopes rather than a concern about which type of scope is used. Our study is important to understand and work with the overall degree of risk people having endoscopy are willing to accept, and to understand what additional information people would like to feel satisfied with different endoscope options. We will work alongside PPRAG and our public and patient co-applicants to understand risk acceptance and how it may change if more information about infection control processes is available. We will also determine how the balance between infection control and environmental impact should best be communicated to people in accessible formats.

1.2.3 Environmental importance

Sir Simon Stevens (NHS Chief Medical Officer) in "Delivering a 'Net Zero' National Health Service" [3] advocated a broader analysis than is provided by traditional health economics. Economic evaluations carried out as part of health technology assessments include costs to NHS and social care, with some consideration of costs to patients and carers, but very rarely include environmental costs and benefits, such as pollution and conservation of scarce resources. We will use innovative methods including life cycle assessment in this proposed research to address the crucial gap in knowledge. In addition to examining the specific topic of single-use versus multiple-use endoscopes in gastroenterology, we will use this example to explore how environmental/sustainability issues could be considered in future technology appraisals. We will do this in consultation with NICE and Health Technology Board for Scotland (Health Technology Wales declined to take part).
The NHS needs high quality evidence on the value of single-use endoscopes compared to multiple-use ones.

1.3 Review of existing research

Previous studies have compared single-use and multiple-use medical devices and equipment. For example, McGain et al. (2017) compared resource use and consequences of anaesthesia in two hospitals, one which re-uses anaesthetic equipment (face masks, airways, laryngoscope blades) and the other using single-use disposables [15]. They concluded that re-use may reduce CO2 emissions but could treble water use and that, "comparisons between the environmental effects of reusables and single-use equipment were more complex and depended particularly upon the source of energy to manufacture or clean the equipment". They used life cycle inventory assessment (LCIA) methodology [21] to assess environmental impacts. Guidelines produced by SETAC (Society for Environmental Toxicology and Chemistry) cover what should be included in a life cycle assessment including [22]:

- raw material acquisition,
- processing and manufacturing,
- distribution and transportation,
- use/reuse and maintenance,
- recycling and waste management.

McGain et al. assessed impact on climate change, water depletion, eutrophication, solid waste, human toxicity, terrestrial ecotoxicity; freshwater ecotoxicity and marine ecotoxicity [15]. Bang et al. report a randomised controlled trial (RCT) of single-use (EXALT Model D, Boston Scientific) versus multiple-use duodenoscopes (Olympus TJF 180) [23]. The cost of a single-use duodenoscope is US$2500–2900 (additional cost for the procedure). The cost per procedure for a reusable duodenoscope was US$612 at their centre, assuming an infection rate of 0.4%. They did not consider costs of disposal. They argue that duodenoscopes used for endoscopic retrograde cholangiopancreatography (ERCP) are more complex than colonoscopes and more difficult to clean and disinfect. They cite an FDA report of 3-4% bacterial contamination and a requirement to stop using fixed endcap duodenoscopes. The BSG Green Gastroenterology Group (Dhar et al 2021) [24] noted that reports of a high proportion of contamination in reusable duodenoscopes [25] probably reflected inadequate decontamination, and that contamination should be very low if the British Society of Gastroenterology (BSG) cleaning and disinfection guidance is followed [26]. They comment: *"A significant amount of waste is already generated from an endoscopic procedure (up to 1.5kg) of which only a fraction is recyclable with the rest going to landfill or being incinerated"*[24].

Sørensen et al. (2018) compared the environmental impacts of single-use and multiple-use bronchoscopes with two main outcomes: gas emissions and loss of scarce resources [17]. They assumed recycling of materials where possible and incineration of the rest. They assumed that only one device could be cleaned at a time which affects the amount of PPE used. They provide good detail of the complexities involved in re-use, transportation, handling and PPE, chemicals used, labour and re-packaging. They include the impact of material production

for the disposable scopes, but not materials for reusable ones. They do not account for how often a reusable scope could be used. More recently Nguyen et al. (2022) suggest that carbon generation with single-use duodenoscopes is higher compared to multiple-use scopes applying several assumptions in their model [27].
Our scoping review shows a lack of comprehensive, high-quality research of economic and environmental impacts of single-use versus multiple-use GI endoscopes. However, the field is moving rapidly [27-29].

1.4 Cleaning and disinfection

Concerns about re-use of endoscopes may stem from fear of infection transmission but the true risk remains unclear [5, 6]. One issue is how the effect of any contamination is assessed. A key question is not whether organisms can be detected by swabbing endoscopes but whether their presence leads to clinically significant infection. That may depend on the destination of the endoscope. For example, a colonoscope enters a rich microbiome of gut organisms. A study of endoscope cleaning and sterilisation is provided by Lichtenstein and Alfa, who also review infection risks from inadequately cleaned scopes [30]. The BSG working party report on decontamination of equipment for GI endoscopy described procedures which should be followed [26]. Very detailed costing was provided by Ofstead et al [31]. But these studies do not cover environmental costs. We need to consider costs of sterilisation but also of materials and chemicals used, recycling and waste. However, we feel that there is no need to review methods of disinfection – we will simply refer to existing guidance, and then do a costing and consequences study.

1.5 Disposal and environmental impact

Endoscopes are usually made of plastic polymer with some latex at the distal end, plus fibreoptic light transmission cables. Disposal or recycling may be complex. Most endoscopes consist of 90% plastic, 4% steel, 4% electronic chips and 2% rubber [32]. Previous estimates suggest that each endoscopic procedure produced an average of 2.1kg of waste [7]. When disposable endoscopes were used, reprocessing (which caused 13% of waste mass) was not required but nevertheless overall waste increased by 24% [7].

2 OBJECTIVES AND OUTCOMES

Our study adopts mixed methods to achieve the following two aims across five work packages (WP).

2.1 Primary aim

To provide evidence for NHS decision makers on the use of single-use vs. multiple-use endoscopes in gastroenterology.

2.2 Secondary aim

To explore how sustainability issues might be considered in future technology assessment by policy-makers such as NICE.

2.3 Study objectives

The study objectives will be delivered through the specific work packages outlined below:

- WP1: To conduct a systematic search of literature covering all work packages, to review the best available evidence on technical performance, test accuracy and infection risk of single-use versus multiple-use GI endoscopes, and to identify key considerations, mechanisms and context affecting choices.
- WP2: To assess costs and consequences arising from use of single-use endoscopes compared to multiple-use ones in relevant patient groups (e.g., immunocompromised, those with severe infections) and settings (e.g., intensive care unit), by considering different factors (e.g., costs of purchase, decontamination, consequences of infections etc.).
- WP3. To assess the wider environmental consequences of a shift to disposable endoscopes including impact on scarce resources for their production and effect of disposal, including landfill and incineration, and the greenhouse gases and waste generated (transportation and storage).
- WP4. To explore the views and experiences of patients receiving endoscopy and staff involved in using, cleaning and decontaminating endoscopes.
- WP5. To engage with patients and stakeholders including health professionals, service commissioners, manufacturers, environmental management, and policy makers to coproduce evidence and formulate recommendations.

The first two objectives (WP1&2) replicate traditional health technology assessment methods.

For the third objective (WP3), we will quantify resources used for production and disposal and wider environmental impact, even if it is not possible to put monetary values on all of these. The clinical infection risk, costs and environmental impact may vary by type of endoscope and patient groups, and the case for single-use may vary. We will assess the case for single-use endoscopes separately for upper GI endoscopy, colonoscopy, endoscopic ultrasound (EUS) and endoscopic retrograde cholagio-pancreatography (ERCP). There may be other possibilities. It may be environmentally more beneficial but clinically as good to use newer technologies such as capsule endoscopy (camera on a pill to image the large bowel), Cytosponge (string test to look for cells that may harbour cancer in the gullet) or CT colon for diagnosis, with endoscopy being used more for treatment.

Objectives four and five (WP 4&5) are exploratory and seek to understand the views of patients and staff to co-produce recommendations.

3 STUDY PLAN

Design: multi-method study comprised of a systematic review, cost-consequence analysis, life cycle assessment, focus groups and interviews and patient and stakeholder engagement, coproduction, and dissemination (Figure 1: Overview of SUMU Endo project structure).

3.1 WP1: Literature search and synthesis of clinical evidence

WP1 consists of:

1. A comprehensive search and mapping of relevant studies concerning single-use versus reusable GI endoscopes, covering clinical, economic and environmental literature;
2. A systematic review of best available clinical evidence on technical performance, test accuracy and clinical effectiveness and safety on single-use versus multiple-use GI endoscopes;

and potentially:

3. A rapid synthesis of recent systematic reviews and key studies addressing the issues of comparisons and trade-off between single-use versus reusable endoscopes, surgical and anaesthesia equipment.

Task 1.1. Broad search and mapping of relevant literature on GI endoscopes

Literature search strategy

We will undertake a broad search to identify relevant literature to inform the three systematic reviews planned within various work packages of the project: WP1 - review of effectiveness; WP2 - review of economic impact; WP3: review of environmental impact. We will search the Cochrane Library, MEDLINE, EMBASE and trial registries using indexed terms and text words related GI endoscopes/endoscopy, combined with terms related single-use/disposable/reusable, multiple-use infection, sustainability, economic and environmental impact. Reference lists of key papers identified from the search will be examined, and relevant stakeholders may be contacted to locate further studies.

Study screening, mapping and routing

Records retrieved from literature searches will be imported into EndNote. The following inclusion criteria will be applied to titles and abstracts during the initial study screening:

Populations: patients undergoing endoscopy of the GI tract; health care staff who may be at risk of infection during these procedures or reprocessing or disposal of equipment.

Interventions: single-use GI endoscopes and accessories for diagnostic or interventional procedures.

Comparators: multiple-use GI endoscopes and accessories. Studies with no comparator will also be considered.

Outcomes: technical performance (including procedure completion rate), diagnostic test accuracy, infection risk (defined as clinically important infection), clinical effectiveness, adverse events, resource use, cost-effectiveness, environmental impact (e.g., carbon dioxide [CO2]-equivalent emissions). The importance of measuring accuracy and completion rates is in case success in visualising organs varies between disposable and reusable scopes. We will exclude studies based only on isolation of contaminating organisms by swabbing devices, but will record a table of such exclusions.

Full-text articles will be retrieved for studies potentially meeting the above criteria. They will be mapped/coded according to study design and outcomes evaluated and routed into relevant systematic reviews as described below.

Clinical review (WP1) will include systematic reviews, randomised controlled trials, nonrandomised controlled studies or diagnostic test accuracy studies that compared single-use versus multiple-use GI endoscopes and accessories with regard to technical performance, test accuracy, procedure completion rates and procedure-related infections. Studies without a comparator group will be considered only if they provide clinically important evidence (e.g., large case series estimating infection risk for single-use or reusable endoscopes or cost data) or where they provide evidence that can be compared with similar series.

Economic review (WP2) will include economic evaluations that compared single-use versus multiple-use GI endoscopes and accessories; costing studies of single-use and/or multiple-use GI endoscopes that are applicable to UK settings.

Environmental review (WP3) will include life cycle assessment and other forms of environmental impact assessment for single-use and/or reusable GI endoscopes.

The volume and nature (including study design and outcomes evaluated) of relevant studies will be provided as summary tables (evidence maps). An article can be included in more than one review if it reports outcomes relevant to different reviews. Final inclusion decisions will be made within individual reviews based on full text. Study screening, coding and selection will be undertaken by two reviewers independently, with discrepancies resolved by discussion or referring to the wider project team for arbitration. Data extraction, risk of bias assessment and data synthesis for each of the reviews will be undertaken within the respective work packages. The methods for effectiveness review are described below.

Task 1.2. Systematic review of clinical evidence

Studies routed to the clinical review during the mapping process described above will be evaluated using standard systematic review methods based on the Cochrane Handbook. Key steps are briefly summarised below.

Data extraction and risk of bias assessment

Data will be extracted from the included studies using data extraction forms designed and piloted for the review. Data items to be extracted include citation details, study design features, characteristics of study participants/samples/endoscopes, setting, outcomes, funding sources and conflict of interests.

We expect a potentially wide range of study designs among relevant studies. Suitable quality assessment or critical appraisal tools (e.g. AMSTAR 2 for systematic reviews [33]; the Cochrane Risk of Bias 2.0 Tool for randomised control trials; NIH checklists and Joanna Briggs Institute Critical Appraisal Checklists for other study designs) will be used to quality assess the included studies. Findings of quality assessment will inform sensitivity analyses (e.g., by excluding studies with high risk of bias) and interpretation of the evidence.

Data synthesis

Considering the potential diversity in the design and perspective of included studies, and in endoscopic procedures, equipment, decontamination process, patient population and outcomes evaluated, quantitative meta-analysis is unlikely to be feasible but will be considered if suitable data are found. If meta-analysis is performed, a random effects model will be used for primary analysis with a fixed effect model used as a sensitivity analysis. Where applicable, the overall certainty of evidence will be assessed using the GRADE framework [34].

Task 1.3. Rapid synthesis of key factors influencing comparison and choice between single-use versus multiple-use endoscopic, surgical and anaesthesia devices

We have planned a rapid synthesis of evidence which will draw upon recent systematic reviews, clinical guidelines and other seminal papers concerning the comparison and choice between single-use and reusable devices in the broad field of endoscopy, surgical and anaesthesia procedures. A separate broad search within these fields, which may be followed by further iterative searches, will be undertaken. Starting with the most recent systematic reviews and clinical guidelines, we will identify key factors that have been considered or examined when decisions are made in relation to the adoption of single-use versus multiple-use devices using thematic analysis. The findings will be considered alongside emerging findings from other work packages to inform the development of a logic model illustrating common issues and factors that may be applicable across different clinical areas and shed light on unique features that need to be considered in each field.

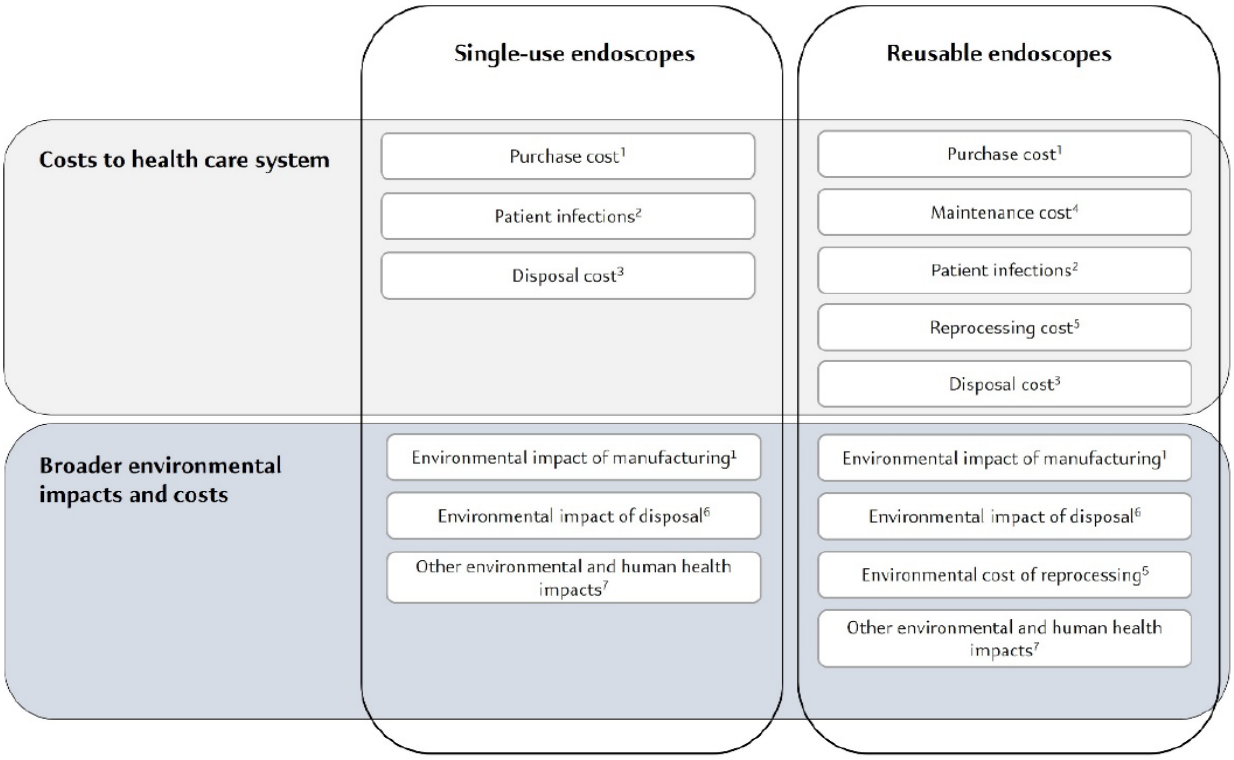
3.2 WP2: Assessment of costs and consequences from the health care system viewpoint

The primary aim of WP2 is to identify, quantify and compare the broader costs and consequences associated with single-use and reusable endoscopes. As an additional aim, we will use this work as a vehicle to develop a framework for incorporating broader impacts and considerations in health economic evaluations. Both aims will be pursued through a series of interrelated tasks.

Task 2.1. Review of existing economic literature

The first task will involve understanding the available literature and evidence. As a first step, we will review all full and partial economic evaluations of single-use and multiple-use GI endoscopes planned in WP1. In addition, we will review the available literature to understand and summarise the range of methods employed in existing economic evaluations concerned more broadly with environmental impact of health technologies. Studies we have identified through preliminary searches point to diversity in employed methods, inputs included and ways of converting inputs into monetary terms (e.g. Sherman et al. 2018 [35]; Mouritsen et al., 2020 [16] ; Le et al., 2022 [27]). We will conduct this review following well-established guidance[36, 37]: we will search key bibliographic databases and grey literature depositories, select studies using pre-specified criteria and extract relevant information using tailored extraction forms. We will then summarise and present findings according to key study characteristics (e.g., scope and perspective, inputs (costs) included, monetary valuation of inputs and outputs, main findings, whether/how findings vary by setting/condition etc.).

Task 2.2. Economic analysis plan



Notes: [1] cost/impact due to raw material extraction, manufacturing, packaging and distribution; [2]cost arising from risk of patient infection [3]cost of recycling borne by NHS; [4]cost of regular maintenance and repair; [5]cost/impacts due mechanical cleaning, disinfection, rinsing, drying and repackaging. [6] environmental impact of incineration and landfill disposal; [7] contribution to global warming, human toxicity and other midpoint impact categories (Cinelli et al, 2016; J Clean Prod 126:277).

Findings from Task 2.1 will inform the next task, which will involve designing the economic evaluation and laying out its key features in an economic analysis plan. As part of the plan, we will draw suitable boundaries, flesh out the methods to be used and establish the scope of the analysis, which will help delineate the series of inputs, impacts and considerations to be accounted for and avoid inclusion of irrelevant factors or double-counting. For example, in relation to endoscopes, we have identified costs incurred by the NHS (e.g., acquisition costs, maintenance cost, disinfection and repackaging costs, expected cost of dealing with clinical infection, cost of waste disposal) as well as broader environmental costs (e.g., environmental cost of manufacturing, cost of disposal and disinfection, environmental and human health impact) (see Figure 3) which will be, where possible, given in monetary terms. The plan will be presented at an Expert Advisory Group meeting, which will bring together representatives of 'producers' and 'users' of economic evaluations (e.g., health economists, environmental economists, local and national decision makers) to discuss and debate the scope and key design characteristics of the analysis.

Figure 3: Categories of costs and impacts related to single-use and multiple-use GI endoscopes.

Task 2.3. Analysis and presentation of findings.

The analysis plan will use principles of economic evaluation [4, 38, 39] to compare the two options of interest: single-use versus reusable endoscopes. Evidence on relevant parameters for each option (e.g., cost of disposal, infection risk

associated with different types of endoscopes) will come from the available literature (i.e., studies identified through the review in WP1 and, where needed, through additional targeted searches aiming to identify values of specific parameters) and other sources (e.g. engagement with manufacturers and waste management bodies). The cost of disinfection will be estimated through a micro-costing study, where the exact processes and resources (personnel, material) will be identified and recorded. This will be facilitated by our collaboration with the Central Sterilising Club (https://centralsterilisingclub.org) and their representative in SUMU-Endo. Costs will be apportioned appropriately to take into account the effective lifetime and maintenance costs of reusable endoscopes.

Analysis will be carried out to synthesise, compare and present key costs (for impacts that can be presented in monetary values) and impacts arising from each of the compared options. Impacts which are difficult to convert into monies will also be listed in a disaggregated form, as consequences [40]. Findings (incremental cost per endoscopy with each option, costs and consequences associated with each option) will be the main output of this work package and will subsequently be combined with findings of the life cycle assessment (WP3).

Task 2.4. Development of framework and Expert Advisory Group meeting.

The analysis completed in WP2 will serve as a case study for the development of a framework for incorporating broader impacts, considerations and objectives in health economic evaluations. The tasks (delineation of boundaries, design of analytic element, consultation with stakeholders, evidence retrieval, analysis and presentation of findings) will be presented as a roadmap and a framework which will be readily available to be adapted in studies seeking to embed broader environmental impacts in economic evaluations. The framework will be presented at a second Expert Advisory Group meeting taking the form of a roundtable discussion, which will draw on this evaluation to provide guidance for conducting economic evaluations that incorporate environmental considerations.

3.3 WP3: Assessment of environmental impacts using life cycle assessment

In order to perform a comprehensive analysis of the environmental impact of single-use versus reusable GI endoscopes, we will undertake a life cycle assessment (LCA), which will be led by Dr Coles from Warwick Manufacturing Group who is an expert in this methodology. WP3 will be conducted following the principles and guidelines outlined in ISO 14040 & ISO 14044.

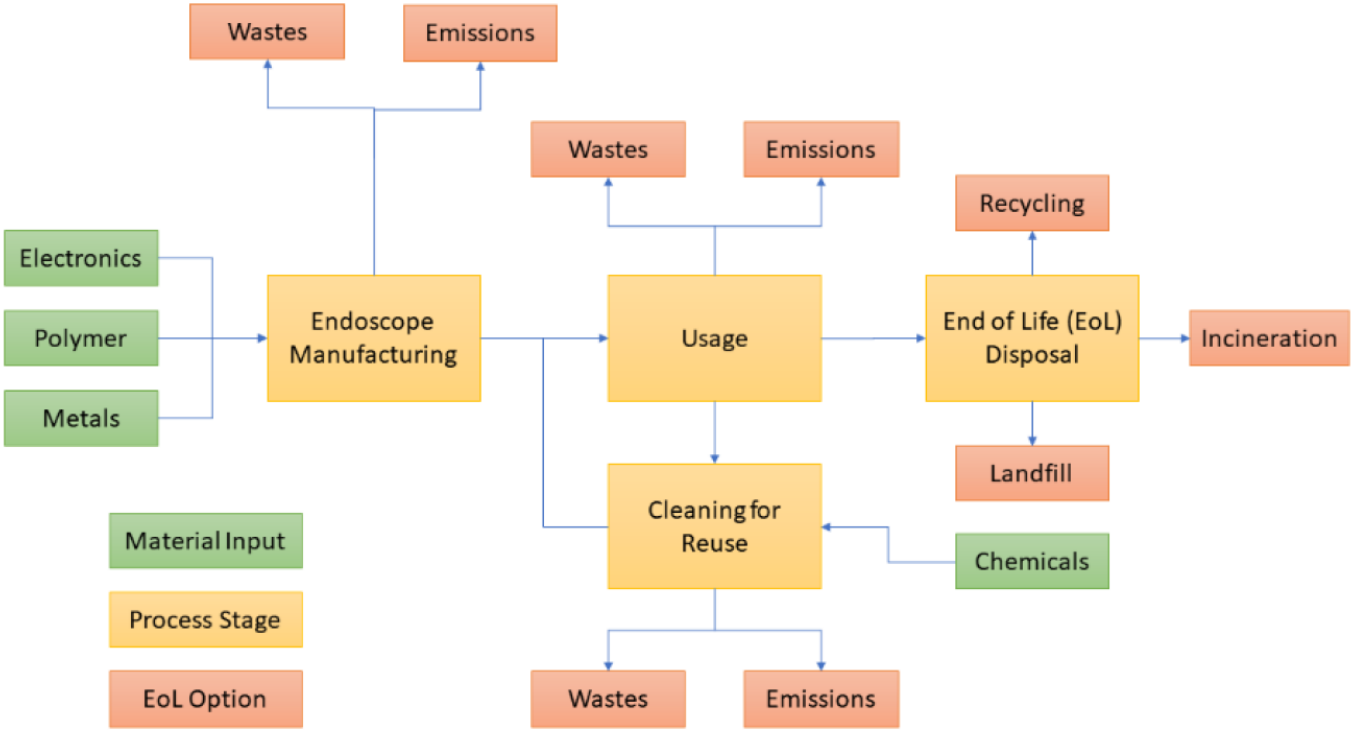
This can be broken down into four tasks that make up the work package as a whole.

Task 3.1. Goal and scope

The first stage is to outline the system boundary that will be covered as part of the LCA study. It is envisaged that the study will take a cradle-to-grave study,

encompassing material sourcing and production, GI endoscope manufacturing, usage and disposal. Previous work from Nguyen et al., (2022) has looked at a similar system of single-use vs. multiple-use duodenoscopes [27], but does not cover the full scope that we intend to cover as it did not look at end-of-life disposal of the single-use duodenoscopes. Additionally, the functional unit of one procedure does not fairly compare the true impact of single-use vs multiple-use duodenoscopes. Our work also plans to engage with manufacturers to get accurate data on endoscope composition to avoid making too many assumptions and invalidating the results of the study.

Figure 4 shows a simplified system boundary for the study which would be the starting point for the goal and scope work. Stages relating to material inputs and



processing would also have ancillary inputs, such as electricity, transportation, and water consumption included, but these are not shown on the diagram for clarity. Each of the process stages are likely to be broken down into a number of sub-stages, allowing for the study to highlight exactly where the environmental burden is on the process, and therefore make suggestions as to how it could be reduced further in the future (Task 3.4).

Figure 4: Simplified System Boundary depicting broadly scope of the work.

Alongside this, a systematic review of the literature on the environmental impacts of disposable and reusable GI endoscopes identified from WP1 will be conducted. Whilst it is unlikely to find work published in the literature with an identical system boundary and geographical / temporal inputs, this study will be

used to inform Task 3.4, as well as being published to inform the wider community on the existing state of the art.

Task 3.2. Inventory analysis

Using the system boundary created in Task 3.1, process steps will be identified, and the material/product flows mapped within the boundary to create a full picture of the life cycle of a GI endoscope for both single-use and multiple-use scenarios. For each process step, an inventory of inputs and outputs (such as materials, energy, wastes, emissions) will be created to complete the life cycle inventory. This will be completed using a combination of data available through Warwick's existing provision, collection of primary data from manufacturers, previous projects with industrial partners (where data can be shared) and interpreting existing publications from the literature. We have agreement in principle from an endoscope manufacturer to share data around use of bio-degradable material and recycling process.

Task 3.3. Impact assessment

LCA Software available at Warwick (such as GaBi & openLCA) will be used to perform the impact assessment. The life cycle inventory from Task 3.2 will be mapped in the software, which calculates the impacts according to a chosen methodology. In this instance, the impact assessment methodology will be ReCiPe 2016 [21], a widely used methodology internationally that is built upon a collaboration between the creators of two previous methodologies (Ecoindicator 99 and CML 2000). It produces information on 18 impact categories such as climate change, human toxicity, resource depletion and water consumption. However, in order to compare against existing studies (in Task 3.4), the software also allows for the recalculation of impacts based on previously used methodologies, allowing for fair comparisons where appropriate.

Task 3.4. Interpretation

The final stage is to interpret the findings. There are three main conclusions that are expected to be drawn from the work. The first is the comparison of impacts between single-use and multiple-use GI endoscopes and a decision as to which appears to be the environmentally most promising approach, taking into account all the resources used in re-use. Secondly, both scenarios will be analysed to find the areas where the most significant environmental burdens lie, and whether there are options for mitigating this. This allows for a sensitivity analysis to be completed, which could potentially show that one approach will be preferred in the future if certain conditions can be met. The final conclusion will be to compare against existing studies where possible (assuming similar functional units, scopes, inputs etc.) and inform future work in this field by the full publication of the LCA datasets.

Task 3.5 Multi-criteria decision aiding framework

In addition, the work will extend to cover the development of a multi criteria decision aiding framework, looking at all of the viable option for single-use or

multiple-use endoscopes. This model would incorporate techno-economic, health outcomes and environmental impacts, creating a more holistic sustainability assessment. The framework for the assessment would follow the same methodology as work previously published by Coles at Warwick in the area of nanoproducts, maximising the output from the wide-ranging interdisciplinary team at Warwick [41, 42].

3.4 WP4: Explore the views and experiences of patients receiving endoscopy and staff and service providers involved in using, cleaning and decontaminating endoscopes.

WP4 will be overseen by Professor Amy Grove who is an expert in qualitative methods with more than 15 years' experience conducting qualitative and mixed methods research in healthcare. This includes 13 years NIHR Fellowship funding to produce cross sectional and longitudinal qualitative studies in the NHS. Prof Grove will oversee all qualitative elements of the study and supervise the qualitative post-doctoral researcher who is also experienced in healthcare research.

We will use a range of data collection methods to elicit the attitudes and experiences of NHS patients receiving endoscopy and NHS staff who handle colonoscopes and other GI endoscopes before and after use (e.g., selection, procurement, disinfection, and disposal of endoscopes).

Site selection

We have used and will continue to use our professional networks and links with The British Society of Gastroenterology who have identified gastroenterology units to participate in our study. Recruitment will be conducted in six centres in the UK. Some are large tertiary centres which do complex endoscopic procedures, others are District General Hospitals who do the vast majority of diagnostic endoscopies and the less complex therapeutic endoscopy. The local population of the six centres will include rural and urban areas with residents of mixed socioeconomic status. It is essential that we attend to equality, diversity and inclusion (EDI) in the selection of sites and participants to ensure we obtain a representative sample. Improved representation will allow us to draw conclusions and recommendations that are appropriate to the population in the UK.

We will aim for maximal variation in our sample, both in terms of the hospitals recruited (local population and geography) and the NHS staff and patients who we invite to participate (e.g., seniority, gender, ethnicity, level of education). The local population of the six centres include rural and urban areas with residents of mixed socioeconomic status.

Participant recruitment and data collection

NHS staff will be purposefully selected from each unit using snowball techniques until we have representation from procurement to disposal, and across seniority,

gender and ethnicity characteristics. Staff recruitment will continue until all segments of the extended endoscope care pathway are accounted for, or when saturation is reached in the data collection. Small focus groups (2-3 people) will be conducted with staff who perform endoscopes, and those who are responsible for procurement, re-use and disposal. Potential participants will be contacted via email and sent the study information sheet and consent form as attachments to the project invitation. The focus groups aim to uncover their views and any aspects of decontamination or disposal not captured in the systematic review (WP1). The planned number of staff participants is 30 (5 staff from 6 units) but we will allow flexibility within units, for example if one participant performs both selection and procurement. Staff recruitment will continue until all segments of the extended endoscope care pathway are accounted for, or when data saturation is reached.

NHS patients will be purposefully sampled to take part in semi-structured interviews. Patients will be identified from each centre through attendance at endoscopy clinics. A study information sheet will be shared with potential participants inviting them to contact the research team if they are interested in the study. We will provide translated study materials to NHS patients upon request (e.g., Welsh, Polish, Punjabi, Urdu, Bengali, Gujarati, Arabic etc).

Potential participants will be contacted by the researcher team via email and/or telephone to assess their suitability for the study (e.g., have received an endoscopy, able to participate in an interview). Consent to participate will be obtained before the interview is performed. We plan to interview five patients from each of our six sites but recognise that flexibility needs to be maintained to ensure diversity in the participant sample. As per the NIHR INCLUDE framework we will provide a translator to conduct the interviews if required or requested by potential participants. Translators will be sourced via the CRN and networks across the University [43].

The staff focus groups and patient interviews will be conducted face to face where possible by an experienced qualitative researcher. Virtual data collection will be facilitated where this is preferred to encourage accessibility to a range of participants. Participants will be made aware that the focus groups and interviews will be recorded and professionally transcribed. Each focus group may take 45-60 minutes to complete, during which participants will be asked questions according to a topic guide. The topic guide for both the interviews and focus groups will be informed by discussion with our patient contributor group, research team, and data collected in workpackages1-3. The topic guide will be used flexibly rather than tightly scripted. However, our pre-work and discussion with patient contributors suggests that key questions will aim to understand staff and patients' perception of and attitude to risk from reuse or disposal or equipment, and views about environmental impact of medical procedures.

Data analysis

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. We will cross check transcripts 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 A. Grove. 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]. We have found OSOP extremely useful when presenting stages of qualitative analysis back to the research team and stakeholder group who may not be experienced qualitative researchers. Data from staff focus groups and patient interviews will be analysed separately, first by centre and then, by participant group. We recognise that abstract lessons may be learnt from exploring the entirety of the data. Therefore, if appropriate, we will compare, contrast and combine the patient and staff qualitative data 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 PPRAG patient contributor group 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, we will incorporate the consultation feedback 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.

We will review our findings in the context of ED&I to investigate the impact of our work on different groups of people, for example, could our results generate or contribute to inequalities in accessing procedures. Input from our patient contributors during preparation for of the protocol suggest that consideration could be given to the application of our work in resource poor settings, for example we were 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 our work for other medical procedures - such as surgical instruments. These are important considerations which we will build on from the findings of WP1.

Ethical considerations

As WP4 includes NHS patient interviews, we will apply for ethical approval for this work package.

We will conduct focus groups with people employed by the NHS and waste disposal services, who will be asked for their informed consent before their interview takes place. For this group, participants will be invited to participate due to their job role. However, we recognise that some potential patient

participants may be invited for endoscopy to undergo clinical investigations. Therefore, they may be worried or uncertain about their health and wellbeing. For this reason, we will work closely with NHS staff in recruiting clinics and deploy trained qualitative researchers who are skilled in recruiting patients sensitively and with compassion. All study participants will retain the right to withdraw from the study up to two weeks after their interview/focus group takes place.

Data protection and security will be addressed by identifying and recruiting participants who are introduced to us by our clinical collaborators. Identifiable information connected to the data we collect will only be available to researchers named on this project who are also employed by the University of Warwick, stored on a password protected secure server and destroyed once the project report is accepted by the funders. Only research services (i.e., transcription) approved by the University of Warwick will be involved in the conduct of this research.

3.5 WP5: Patient and stakeholder engagement, collaboration and decision aid development

In WP5 we will conduct formal data integration to develop an evidence-based decision aid for Gastrointestinal endoscopy. We will adopt a pragmatic approach to mixing methods in our study, which is underpinned by a subtle realist epistemological view [47]. Subtle realism reflects the notion that we can only know reality from our own perspective of it, and therefore, pragmatism will allow us to identify what works best, when trying to find the answers to our pre-specified research question [48].

The findings of the systematic review, economic study and qualitative work will be integrated using data consolidation and merging [48, 49] to develop a GI endoscopy decision aid in collaboration with our patient contributors and stakeholder group.

The methodological underpinning for our complex synthesis, stems from use of the extended Pillar Integration Process (ePIP), developed by A. Grove [50, 51]. This joint display method originates from mixed methods methodological research and is the first data integration method providing explicit steps on how to integrate data from three data sources. Joint displays are one way to integrate and represent integration in mixed methods research, and ePIP, is a highly transparent four-stage method for integrating difference types of data in a matrix. We will follow the stages of ePIP including listing, matching, checking, and pillar building, where the final 'pillar' represents meta-themes, which are akin to meta-inferences. ePIP urges users to identify the synergy that happens through the integration of qualitative and quantitative components of a mixed method study to generate a final synthesis which is 'more' than its component parts (e.g., 1 (QUANT) +1 (QUANT) +1 (QUAL) = 4). The integration will identify the 'key ingredients' that will be incorporated into a decision aid which will be

developed in collaboration with our project stakeholder group via scope definition, content requirements, prototyping, and assessing feasibility of the decision aid [52].

The aim of this decision aid is to provide people with sufficient appropriately accessible information to feel confident in the type of endoscope they may receive, thereby balancing the degree of risk they are willing to accept with the economic and environmental impact of their treatment. We envisage this decision aid could be used to facilitate conversations between patients and providers when talking about the procedure. How to discuss with patients, the balance between infection control and environmental impact, is an unexplored area in the literature and identified by our clinical stakeholders as an unmet service delivery need. Our NHS staff contributors will help interpret and disseminate the findings with the support of Green Gastroenterology Group.

4. ETHICAL AND REGULATORY CONSIDERATIONS

4.1 Ethical approval and research governance

As work package 4 will involve conducting patient interviews and staff focus groups, we will apply for the relevant regulatory authorisations, including Sponsorship through the University Hospitals Coventry & Warwickshire NHS Trust (UHCW), the HRA and REC.

4.2 Public and Patient Involvement

We have involved patients with personal experience of endoscopy in shaping the protocol. Members of the research team have ongoing relationships with a group of public and patient contributors (PPRAG) who have been vital in shaping our ideas. Contributors provided feedback on the initial research ideas and together, we assessed the face validity of the study and determined if the research aims were relevant to patients and addressed the needs of patients and NHS service delivery.

Discussion of research project design helped to plan a project that is relevant to patients and where the methods are acceptable and ethical in the NHS. We aim to have three representatives to enable flexible regional and national involvement at project meetings and advisory group reviews. We will communicate SUMU-Endo project updates regularly via e-newsletters, social media and public contributor website hosted at University of Warwick. A training need assessment will be discussed individually and supported through training delivered by University of Warwick. and online resources offered by INVOLVE. A. Grove will be responsible for all patient involvement and provide project inductions for all public contributors, reimburse travel expenses, and offer honoraria payments for time.

In collaboration with the public contributors, we developed the following collection of involvement activities during SUMU-Endo:

1. Co-designing and developing research protocols and supplementary documentation.

2. Co-producing and reviewing topic guides/information sheets/consent for participation.

3. Contributing to analysis and data integration of work package findings to establish a) the importance and relevance of the findings b) social and ethical implications and c) priority setting.

4. Reviewing and commenting on final reports/plain English summary/publications to ensure findings are clear and make sense to non-specialist readers.

5. Participating in dissemination workshops and national events, and identifying patient and public networks to share research to help communicate the importance of sustainable NHS services from a patient's perspective

6. Evaluating and collectively reporting all public involvement using the GRIPP2 tool [46].

4.3 Equality, Diversity and Inclusion

We have considered ED&I throughout our protocol;

- Our co-applicant team demonstrates diversity in terms of membership, gender, ethnicity and seniority.
- Through our patient co-applicant we will ensure equality of patient views in this proposal and ensure contributor voices are heard throughout the research project.
- research conduct (WP4),
- recruitment of study participants (WP4),
- and feedback and dissemination plans (see WP5 and Section 'Dissemination').

Whilst we accept that inequalities in accessing procedures is an important issue, this study does not address the access to procedures. Rather, the decision for an endoscopy has already been made.

We have however included within WP4, an additional consultation around patient discussion or choice of type of endoscope that may be used. At present, our public and patient research advisory group (PPRAG) have confirmed such discussions do not take place.

5. DISSEMINATION POLICY

We will aim to publish results in scientific journals as usual, but we will also produce accessible summaries for staff and patients. We will convene a meeting (scoping workshop) of all interested parties, including industry and policy-

makers to present and discuss the draft findings. We will develop a communication strategy with our patient contributor group prior to the study start, ensuring consideration is given to accessibility and ED&I. At the start of the project, we will publish our study protocol and share it widely through our networks.

The outputs from this study will include the following, and possibly others. The list will be reviewed in the light of the findings, but our current expectation is that we will publish the following;

- A systematic review of the risk of clinically significant infection associated with single-use and multiple-use endoscopes;
- The costs to health care and the NHS of single-use and multiple-use endoscopes;
- A review of the technical performance and clinical effectiveness of single-use and multiple-use endoscopes
- The results of life cycle analysis and environmental cost comparisons of single-use and multiple-use scopes;
- Staff views and experiences of handling, cleaning, disinfecting and disposal of endoscopes;
- Patient views of the use of single- and multiple-use endoscopes.

Our key audiences will be patients and the public, clinicians, research funders, and policy makers. Project dissemination will be supported by our international stakeholder group. We will publish lay and professional summaries of the research in written, audible and infographic formats. We will engage policy makers through co-applicant membership of the professional organisations and, where appropriate, flag research gaps that might be considered by the NIHR for a commissioned call through its prioritisation committees. We will disseminate information to clinical audiences through peer reviewed publications, podcasts, blogs, conference presentations and social media. We plan to develop an educational video using expertise at Warwick's digital and media centre.

The immediate impact will be on decisions on whether to use single-use endoscopes for some or all gastrointestinal endoscopies, considering all the costs and benefits of single-use versus reusable scopes. Our findings will have not just UK but international application and impact.

6. REFERENCES

1. Atwoli L, Baqui AH, Benfield T, Bosurgi R, Godlee F, Hancocks S, et al. Call for emergency action to limit global temperature increases, restore biodiversity, and protect health. BMJ. 2021;374:1734.
2. Crippa M, Guizzardi D, Solazzo E, Muntean M, Schaaf E, Monforti-Ferrario F, et al. GHG emissions of all world countries. Emissions Database for Global Atmospheric Research, version v6.0_FT_2020 (GHG time-series). Publications Office of the European Union, Luxembourg; 2021.
3. NHS England and NHS Improvement. Delivering a 'net zero' National Health Service. NHS England and NHS Improvement; 2020.
4. Hensher M. Incorporating environmental impacts into the economic evaluation of health care systems: Perspectives from ecological economics. Resources, Conservation and Recycling. 2020;154:104623.
5. The Lancet Gastroenterology & Hepatology. Scoping the problem: endoscopy associated infections. The Lancet Gastroenterology & Hepatology. 2018;3(7):445.
6. McCafferty CE, Aghajani MJ, Abi-Hanna D, Gosbell IB, Jensen SO. An update on gastrointestinal endoscopy-associated infections and their contributing factors. Annals of Clinical Microbiology and Antimicrobials. 2018;17(1):36.
7. Namburar S, von Renteln D, Damianos J, Bradish L, Barrett J, Aguilera-Fish A, et al. Estimating the environmental impact of disposable endoscopic equipment and endoscopes. Gut. 2021:gutjnl-2021-324729.
8. Bailey CR, Association of Anaesthetists' Working Party on infection prevention. Should we be switching from reusable bronchoscopes to disposable due to the risks of cross contamination? A reply. Anaesthesia. 2020;75(5):698.
9. Rizan C, Bhutta MF. Re: The Carbon Footprint of Single-Use Flexible Cystoscopes Compared to Reusable Cystoscopes: Methodological Flaws Led to the Erroneous Conclusion That Single-Use Is "Better". Journal of Endourology. 2022;22:22.
10. Rodriguez de Santiago E, Dinis-Ribeiro M, Pohl H, Agrawal D, Arvanitakis M, Baddeley R, et al. Reducing the environmental footprint of gastrointestinal endoscopy: European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) Position Statement. Endoscopy. 2022;54(8):797-826.
11. Siddhi S, Dhar A, Sebastian S. Best Practices in Environmental Advocacy and Research in Endoscopy. Techniques and Innovations in Gastrointestinal Endoscopy. 2021;23(4):376-84.
12. McGain F, Naylor C. Environmental sustainability in hospitals - a systematic review and research agenda. Journal of health services research & policy. 2014;19(4):245-52.
13. Drew J, Christie SD, Tyedmers P, Smith-Forrester J, Rainham D. Operating in a Climate Crisis: A State-of-the-Science Review of Life Cycle Assessment within Surgical and Anesthetic Care. Environmental health perspectives. 2021;129(7):76001.

14. McGain F, Muret J, Lawson C, Sherman JD. Environmental sustainability in anaesthesia and critical care. British journal of anaesthesia. 2020;125(5):680-92.
15. McGain F, Story D, Lim T, McAlister S. Financial and environmental costs of reusable and single-use anaesthetic equipment. BJA: British Journal of Anaesthesia. 2017;118(6):862-9.
16. Mouritsen JM, Ehlers L, Kovaleva J, Ahmad I, El-Boghdadly K. A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. Anaesthesia. 2020;75(4):529-40.
17. Sørensen BL, Grüttner H. Comparative study on environmental impacts of reusable and single-use bronchoscopes. American Journal of Environmental Protection. 2018;7(4):55-62.
18. Davis NF, Quinlan MR, Browne C, Bhatt NR, Manecksha RP, D'Arcy FT, et al. Single-use flexible ureteropyeloscopy: a systematic review. World J Urol. 2018;36(4):529-36.
19. Ravindran S, Thomas-Gibson S, Bano M, Robinson E, Jenkins A, Marshall S, et al. National census of UK endoscopy services 2021. Frontline astroenterology. 2022:flgastro-2022-102157.
20. Rehfuess EA, Booth A, Brereton L, Burns J, Gerhardus A, Mozygemba K, et al. Towards a taxonomy of logic models in systematic reviews and health technology assessments: A priori, staged, and iterative approaches. Res Synth Methods. 2018;9(1):13-24.
21. Huijbregts MAJ, Steinmann ZJN, Elshout PMF, Stam G, Verones F, Vieira M, et al. ReCiPe2016: a harmonised life cycle impact assessment method at midpoint and endpoint level. The International Journal of Life Cycle Assessment. 2017;22(2):138-47.
22. Klöpffer W. The Role of SETAC in the Development of LCA. The International Journal of Life Cycle Assessment. 2006;11(1):116-22.
23. Bang JY, Hawes R, Varadarajulu S. Equivalent performance of single-use and reusable duodenoscopes in a randomised trial. Gut. 2021;70(5):838-44.
24. Dhar A, Hayee BH, Wesley E, Stableforth W, Sebastian S. Reducing low risk of transmissible infection in duodenoscopes: at what cost to the planet? Gut. 2022;71(3):655-6.
25. Larsen S, Russell RV, Ockert LK, Spanos S, Travis HS, Ehlers LH, et al. Rate and impact of duodenoscope contamination: A systematic review and meta-analysis. eClinicalMedicine. 2020;25.
26. British Society of Gastroenterology Endoscopy Committee. BSG guidance for decontamination of equipment for gastrointestinal endoscopy. British Society of Gastroenterology 2020.
27. Le NNT, Hernandez L, Vakil N, Guda N, Patnode C, Jolliet O. Environmental and Health Outcomes of Single-Use versus Reusable Duodenoscopes. Gastrointestinal endoscopy. 2022:doi: https://doi.org/10.1016/j.gie.2022.06.014.
28. Barakat MT, Ghosh S, Banerjee S. Cost utility analysis of strategies for minimizing risk of duodenoscope-related infections. Gastrointestinal endoscopy. 2022;95(5):929-38.e2.

29. Pang S, England RW, Solomon A, Hong K, Singh H. Single-Use versus Reusable Endoscopes for Percutaneous Biliary Endoscopy with Lithotripsy: Technical Metrics, Clinical Outcomes, and Cost Comparison. J Vasc Interv Radiol. 2022;33(4):420-6.
30. Lichtenstein D, Alfa MJ. Cleaning and Disinfecting Gastrointestinal Endoscopy Equipment. Clinical Gastrointestinal Endoscopy. 2019:32-50.e5.
31. Ofstead CL, Quick MR, Eiland JE, Adams SJ. A glimpse at the true cost of reprocessing endoscopes: results of a pilot project. International Association of Healthcare Central Service Materiel Management; 2017.
32. Davis NF, McGrath S, Quinlan M, Jack G, Lawrentschuk N, Bolton DM. Carbon Footprint in Flexible Ureteroscopy: A Comparative Study on the Environmental Impact of Reusable and Single-Use Ureteroscopes. Journal of endourology / Endourological Society. 2018;32(3):214-7.
33. Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017;358:j4008.
34. Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008;336(7650):924.
35. Sherman JD, Raibley IV LA, Eckelman MJ. Life cycle assessment and costing methods for device procurement: comparing reusable and single-use disposable laryngoscopes. Anesthesia & Analgesia. 2018;127(2):434-43.
36. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. International Journal of Social Research Methodology. 2005;8(1):19-32.
37. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. Implementation science : IS. 2010;5.
38. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. Methods for the economic evaluation of health care programmes: Oxford university press; 2015.
39. The Green Book. Central Government Guidance on Appraisal and Evaluation. HM Treasury; 2022.
40. Coast J. Is economic evaluation in touch with society's health values? BMJ. 2004;329(7476):1233-6.
41. Cinelli M, Coles SR, Kirwan K. Analysis of the potentials of multi criteria decision analysis methods to conduct sustainability assessment. Ecological Indicators. 2014;46:138-48.
42. Cinelli M, Coles SR, Sadik O, Karn B, Kirwan K. A framework of criteria for the sustainability assessment of nanoproducts. Journal of Cleaner Production. 2016;126:277-87.
43. Braun V, Clarke V. Thematic analysis: a practical guide: SAGE Publications; 2021.
44. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. BMJ. 2017;358:j3453.

45. Caracelli VJ, Greene JC. Data Analysis Strategies for Mixed-Method Evaluation Designs. Educational Evaluation and Policy Analysis. 1993;15(2):195-207.
46. Johnson RE, Grove AL, Clarke A. Pillar Integration Process: A Joint Display Technique to Integrate Data in Mixed Methods Research. Journal of Mixed Methods Research. 2019;13(3):301-20.