Healthcare Improvement Scotland | SHTG Advice on health technologies

SHTG Assessment
February 2024

# An assessment of outpatient biopsies under local anaesthetic of suspicious laryngeal and pharyngeal lesions

## Key messages

1. Biopsies under local anaesthetic can be undertaken in an outpatient setting, as an alternative to inpatient or day case biopsy procedures which require theatre time and a hospital bed.
2. Biopsies under local anaesthetic are effective in identifying people who do not require further follow up. This means that patients can have their biopsy taken under local anaesthetic at the time of initial outpatient investigation and avoid needing a confirmatory biopsy under general anaesthetic in an operating theatre.
3. Undertaking biopsies in an outpatient setting provides an opportunity to ease hospital resource pressures and reduce waiting times to diagnosis and treatment. A reduction in the number of patients requiring inpatient biopsy procedures will lead to substantial resource savings for NHSScotland.
4. In circumstances where the use of reusable biopsy equipment is not feasible (for example, during the COVID-19 pandemic) disposable biopsy equipment provides an alternative means to perform biopsies. It should be noted that:
    a. no evidence is currently available to determine whether disposable biopsy equipment is as effective as reusable biopsy equipment
    b. the use of disposable biopsy equipment is more costly than the use of reusable equipment
    c. over the lifecycle, reusable equipment produces fewer carbon emissions compared with disposable equipment.

## What were we asked to look at?

The Scottish Health Technologies Group (SHTG) was asked by Ear, Nose and Throat (ENT) clinicians in NHS Greater Glasgow and Clyde (GGC) to assess the evidence on the clinical and cost effectiveness of outpatient local anaesthetic biopsies of suspicious laryngeal and pharyngeal lesions. As part of our assessment, we were asked to consider the evidence surrounding disposable (that is, single use) rhino laryngoscopes.

## Why is this important?

The incidence of head and neck cancer in the Scottish population is increasing.[1] The Scottish Government has set targets for waiting times to diagnosis and treatment that are becoming increasingly challenging to deliver given current service pressures. Undertaking biopsies in an outpatient setting instead of an inpatient setting may help to lessen resource pressure.

Patients who are referred to ENT or head and neck outpatient clinics, based on their symptoms, commonly undergo transnasal endoscopy to visualise the larynx, pharynx and tongue base. When suspected malignant lesions are identified, the 'gold standard' investigation is direct laryngoscopy under general anaesthetic in the operating theatre. This requires scheduled theatre time, an overnight or day case hospital bed, and pre-procedure assessment. Developments in the technology for transnasal endoscopy include the incorporation of an instrument channel through which biopsy forceps may be used. This means that, for some patients, a biopsy can be taken under local anaesthetic at the time of initial outpatient investigation.

## What was our approach?

We reviewed the evidence on the effectiveness, safety, and cost effectiveness of biopsy procedures with reusable rhino laryngoscopes, performed under local anaesthetic, in patients with suspicious laryngeal and pharyngeal cancers. The review updated a previous SHTG assessment published in 2018. We also looked for evidence on the use of disposable rhino laryngoscopes. We updated the 2018 SHTG budget impact to compare the costs of inpatient procedures, outpatient procedures with reusable laryngoscopes, and outpatient procedures with disposable laryngoscopes. Our assessment also includes an exploratory environmental impact assessment (EIA) comparing reusable and disposable equipment.

## What next?

SHTG's assessment will be shared with ENT specialists within NHSScotland to inform future decision making on the provision of outpatient biopsy procedures.

## Key findings

### Effectiveness and safety of biopsies under local anaesthetic using reusable rhino laryngoscopes

- A 2022 systematic review found that procedures for biopsy under local anaesthetic are safe and well tolerated by patients, with high specificity (the procedure can correctly identify people who do not have the disease) of 96.7% but lower sensitivity (the procedure can correctly identify people who do have the disease) of 73.0%, compared with inpatient biopsy procedures:[3]
  - low sensitivity means that confirmatory inpatient procedures may be necessary for negative biopsy results.
  - high specificity means that patients may avoid needing a confirmatory biopsy under general anaesthetic in the operating theatre.
  - more patients can be biopsied in the same time frame using biopsy under local versus general anaesthesia, allowing more rapid diagnosis. Local evaluation data from NHS GGC suggests that biopsies under local anaesthetic may reduce waiting times to diagnosis and/or treatment compared with inpatient biopsy procedures.[4]

### Effectiveness and safety of local anaesthetic biopsies using disposable rhino laryngoscopes

- No clinical evidence (including accuracy outcomes) was found that related to the comparative effectiveness and/or safety of biopsies of the larynx and pharynx using disposable channeled rhino laryngoscopes and a portable monitor, compared with non-disposable equipment.
- Qualitative evidence on the use of disposable rhino laryngoscopes to visualise the upper airways (without biopsy) alongside a portable monitor indicates that portable equipment may be inferior in terms of image quality, similar in terms of ergonomics and maneuverability and superior in set up and convenience when compared with reusable biopsy equipment (flexible rhino laryngoscope and an image stack).[5]

### Cost effectiveness

- A 2022 UK-based cost effectiveness analysis indicated that biopsies under local anaesthetic with reusable rhino laryngoscopes were cost effective, as a small reduction (-0.04) in quality adjusted life years (QALYs) was offset by a reduction in costs (-£816), compared with inpatient biopsy procedures.[6]
- No published cost effectiveness evidence was available relating to biopsies with disposable rhino laryngoscopes and a portable monitor.

### Budget impact assessment

- The roll out of outpatient biopsy procedures (with reusable rhino laryngoscopes) across Scotland is similar in cost (and potentially cost saving) when compared with inpatient biopsy procedures, depending on the assumption that all negative results are followed up by an inpatient biopsy.
- Potential annual resource savings of £573,000, £1.4 million, and £1.9 million were estimated based on the proportion of patients with a negative outpatient biopsy result requiring inpatient follow-up procedure falling to 80%, 50% and 33% respectively.
- Performing all biopsy procedures in NHSScotland with disposable rhino laryngoscopes would be more costly per year than using reusable flexible rhino laryngoscopes in an outpatient setting (cost increase of approximately £30,000) or inpatient biopsy procedures (cost increase of approximately £32,000).

### Exploratory environmental impact assessment

- The estimated annual carbon impact of using disposable rhino laryngoscopes for biopsy procedures is higher compared with reusable rhino laryngoscopes (13,652Kg$CO_2{}^e$ versus 7,381Kg$CO_2{}^e$).
- Over a life cycle assessment (LCA), a reusable flexible rhino laryngoscope emits 48 % less carbon emissions compared with disposable rhino laryngoscopes.
- Use of disposable devices in all biopsy procedures involving patients in Scotland who have suspected larygeal and pharyngeal cancers produces 12.6 tonnes of clinical waste per year compared to a negligible volume of waste for reusable devices.

# Contents

# Introduction

The gold standard for tissue sampling of patients with suspicious laryngeal and/or pharyngeal lesions is inpatient direct laryngoscopy or pharyngoscopy under general anaesthesia, referred to in this assessment as an inpatient biopsy procedure. The diagnostic pathway includes a consultant-led appointment to visually inspect the affected area. If suspicious lesions are present that need further investigation this is followed by an inpatient procedure under general anaesthetic.

The introduction of flexible rhino laryngoscopes made outpatient procedures possible for eligible patients using local anaesthetic. Outpatient procedures are performed in designated rooms within outpatient clinics. Biopsies can be taken during the first diagnostic consultant-led appointment without the need to wait for further hospital visits. Outpatient biopsy may expedite diagnosis and allow selected patients to avoid undergoing a general anaesthetic.

Upper airway procedures were associated with a high risk of viral transmission during the COVID-19 pandemic and are on the UK aerosol generating procedures list.[7] ENT clinicians in NHS GGC advised that this had led to delays with scheduling both outpatient and inpatient procedures, due to the need to ventilate the designated area before the next procedure. The use of disposable channeled rhino laryngoscopes with a portable monitor with mobile high definition (HD) imaging can be used in any hospital or clinic setting to obtain tissue samples, offering an opportunity to reduce wait times between procedures.

This assessment considers the evidence on the effectiveness, safety, and cost effectiveness of biopsy procedures done under local anaesthetic using reusable rhino laryngoscopes in patients with suspicious laryngeal and pharyngeal cancer, compared with inpatient biopsy procedures. We also looked for comparative evidence on the use of disposable rhino laryngoscopes in either setting. We compared the costs of inpatient procedures and outpatient procedures with reusable rhino laryngoscopes, alongside the costs of using disposable rhino laryngoscopes. Our assessment also includes an exploratory EIA to help inform the use of disposable rhino laryngoscopes in Scotland. The EIA was carried out by a colleague at The University of Glasgow.

# Research questions

What is the clinical effectiveness, safety, and cost effectiveness of biopsies under local anaesthetic of suspicious laryngeal and/or pharyngeal lesions compared with inpatient biopsy procedures?

What is the clinical effectiveness, safety, cost effectiveness, and environmental impact of flexible reusable or disposable rhino laryngoscopes for the biopsies of suspicious pharyngeal and/or laryngeal lesions?

## Literature search

An updated systematic search of the secondary literature was carried out in May 2023 to identify systematic reviews, health technology assessments and other evidence based reports, that were published since the initial 2018 SHTG assessment[2]. The Medline, Medline in process, Embase, Cinahl and Web of Science databases were searched for systematic reviews and meta-analyses. Medline was systematically searched for primary diagnostic studies. Results were limited to primary diagnostic studies in English from 2008 onwards.

Key websites were searched for guidelines, policy documents, clinical summaries, economic studies and ongoing trials.

Concepts used in all searches included: flexible laryngoscopy, office-based, in-office, outpatient, operating room biopsy, single use/disposable biopsy, direct laryngoscopy/micro laryngoscopy, panendoscopy, narrow band, and image guided. A full list of resources searched and terms used are available on request.

## Epidemiology

In 2021 there were 422 people (323 males, 99 females) with new diagnoses of oropharyngeal cancer (encompassing tongue base) and 313 people (229 males, 84 females) with new diagnoses of laryngeal cancers in Scotland. This represents a European age-standardised incidence rate (EASR) of 7.6 (95 % confidence interval (CI) 6.9 to 8.4) new oropharyngeal and 3.4 (95 % CI 2.7 to 4.1) laryngeal cancer diagnoses per 100,000 person-years at risk.[8] The incidence of all head and neck cancers in 2021 was 1,400 (956 males, 444 females).

In 2021, 124 deaths of people with oropharyngeal cancer and 119 deaths of people with laryngeal cancer were recorded in Scotland. This is a decrease of 1.6 % and an increase of 5 % from the previous year, respectively. Data show regional differences in 5-year (2017-2021) outcomes. The West of Scotland has a higher incidence of mortality (EASR 2.9 (95 % CI 2.6 to 3.3)) compared with the North of Scotland (EASR 1.7 (95% CI 1.4 to 2.0)) and the Southeast of Scotland (EASR 1.8 (95% CI 1.5 2.1)).

The incidence of head and neck cancers in Scotland remains high due to factors such as social deprivation, smoking, drug use, and chewing tobacco.[9]

In December 2019, the total number of patients diagnosed with laryngeal cancers was 2,015 (1,627 males and 388 females) and there were 2,371 (1,805 male and 566 females) patients with oropharyngeal cancer.

# Health technology description

## Reusable equipment for biopsy under local anaesthetic

Reusable biopsy equipment includes a camera stack and monitor (the imaging device), a source of light (including white light, narrow band imaging), a flexible rhino laryngoscope with a working channel, a recorder and forceps.

The flexible endoscope is connected to the camera stack and monitor, and disposable forceps are used to obtain tissue samples through the channeled endoscope (rhino laryngoscope), guided by the imaging. The procedure is conducted under local anaesthetic. The channeled endoscope needs to be thoroughly decontaminated, as described in national guidelines after use.[10] The equipment is set up in a designated outpatient clinic room.

The camera stack and monitor can be used for other diagnostic procedures such as video endoscopies, where a biopsy is not taken, and can be used by other specialties. Olympus, Karl Storz and PENTAX supply the technology in Scotland at present.

Example of the technology systems available in Scotland include:

- Olympus® ENF Type VT2 EVIS Exera II Narrow band imaging (NBI)
- PENTAX® FNL-15RP3 EPK-3000 DEFINA iScan
- Karl Storz® 11101VP/VPS Image 1S Spectra A / Spectra B.

## Disposable and portable biopsy equipment

Portable biopsy equipment consists of a lightweight ergonomic disposable rhino laryngoscope with a working channel, connected to a HD portable monitor. The equipment is compact and can be used in any clinical setting (emergency, inpatient or outpatient). The flexible endoscope contains a camera and LED lights at its distal end. It is disposed of immediately after use and requires no post-procedural handling. The monitor can be disinfected using disposable wipes. The scopes are sterilised only once by the manufacturer before packaging.

The main supplier of portable biopsy equipment in NHSScotland at present is Ambu®. Karl Storz® also manufactures this equipment.

# Clinical effectiveness

## Biopsies performed under local anaesthetic with reusable rhino laryngoscopes compared with inpatient biopsy procedures

Diagnostic accuracy

In 2018, SHTG reported that biopsy procedures performed under local anaesthetic were associated with high specificity (97 %), which indicates that a diagnosis can be made based on a positive result. The sensitivity of the procedure was typically around 71 % which indicates that negative results require follow-up inpatient procedures for confirmation.

A subsequent review[3] was identified. The review examined the published literature up to 2021 and included 16 studies based on the following inclusion criteria: adult patients, English language, sensitivity, specificity and rate of successful biopsies reported. Eleven of the studies included in the literature review were included in the 2018 SHTG review. All 16 studies had been assessed for methodological quality using the Newcastle-Ottawa scale. Twelve (75 %) scored <6/9 points, indicating that the majority of included studies were at high risk of bias. Results were not presented separately for the four good quality studies.

Across all studies, a total of 1,796 biopsies (n=1,682 patients) were performed. Of these, 1,572 (87.5 %) led to a successful tissue sampling for pathology analysis from biopsies performed under local anaesthetic with 1,283 (81.6 %) resulting in affirmative diagnosis. Repeat biopsies were needed by 275 patients and 98% were performed in theatre under general anaesthesia. Only one patient received a repeat biopsy under local anaesthetic but the rationale for this was not clear. Most repeat biopsies were performed for clinically highly suspicious lesions with a negative initial biopsy result. Key findings of the review are summarised in *Table 1*.

Table 1: Diagnostic accuracy measures in Owusu-Ayim (2022)[3]

| Accuracy measure | Value |
|---|---|
| Sensitivity | Median 73 % (range 60 % to 100 %) |
| Specificity | Median 96.7 % (range 75.6 % to 100 %) |
| False positive rate | 1.08 % |
| False negative rate | 13.6 % |
| Negative predictive value | Median 62 % (range 0 % to 100 %)* |

| | |
|---|---|
| Positive predictive value | Median 93.5 % (range 77 % to 100 %) |

*Authors report the outlier value of 0% could be explained by one review study having a sample size of 11.

Time to diagnosis and treatment - association with patient outcomes

The Scottish Government's targets for urgent suspicion of cancer pathway (USCP) referrals is for at least 95 % of patients with newly diagnosed primary cancers to commence treatment within 62 days of initial referral.[1] Data on waiting times specifically for people with laryngeal and pharyngeal cancers waiting for laryngoscopy or pharyngoscopy are not routinely collected. The most recent aggregate data on waiting times targets (December 2022) for all people with head and neck cancers in Scotland show that the 62-day target for urgent referral to treatment has been missed (78.7% vs 95%). Annual data over the 2017-2021 period show that the 62-day figures remained below target (85% - 88%).[1] Delays in tissue sampling may contribute to these figures remaining below target.

One systematic literature review[11] and a retrospective cohort study[4] examined the effect of using biopsies under local anaesthetic for people with head and neck cancer on the waiting times for diagnosis and treatment. The systematic review identified four relevant studies. Across studies there was a time to diagnosis range of 2 to 7.5 days (from the time since biopsy collection) for biopsies under local anaesthetic, compared with 9 to 23 days for inpatient biopsy procedures. In three of the studies, biopsies under local anaesthetic were associated with reduced time to treatment compared with inpatient biopsy procedures (21 to 27 days compared with 34 to 49 days). In the remaining study, although biopsies under local anaesthetic were associated with reduced time to diagnosis, there were no clinically significant differences in time to treatment. The authors concluded that this was due to a combination of system factors and referral bias.

The retrospective cohort study[4] was conducted in NHS GGC. It compared the waiting times for biopsies under local anaesthetic in patients urgently referred due to suspicion of head and neck cancer with the traditional general anaesthetic pathway between June 2018 and December 2020. The study included 45 patients biopsied under local anaesthetic and 142 patients biopsied as inpatients. The cancer pathway for biopsy under local anaesthetic of 35.7 days was significantly shorter than the inpatient biopsy cancer pathway of 61.5 days ($p<0.05$). The majority of patients in the study who received a biopsy under local anaesthetic in an outpatient setting had lesions that were located in the oral cavity (51.1 %) with only 11.1 % of lesions located in the pharynx. In contrast, only 5.6 % of patients in the inpatient biopsy procedures group had lesions located in the oral cavity. The oral cavity is relatively easy to access in an outpatient setting and may only require the use of long forceps and not endoscopic equipment. This indicates that the two groups may not be

directly comparable. The study reports that patients in the cohort had been included if there was an urgent suspicion of cancer referrals and biopsies were taken from the oral cavity, oropharynx, nasopharynx, hypopharynx and glottis. Patients were excluded if they were not new patients, had received a diagnosis outwith the health board area, died before biopsy could take place (or were not able to have a biopsy for other reasons), if they had a benign diagnosis or had not been referred via the usual pathway for patients with an urgent suspicion of cancer. It is therefore unclear how the difference in the proportion of patients with lesions in the oral cavity occurred.

Delays in diagnosis and/or treatment of people with laryngeal or pharyngeal cancers may have an impact on long-term outcomes such as survival and progression-free survival. No direct evidence comparing long-term outcomes after biopsies under local anaesthetic or inpatient biopsy procedures was identified. One retrospective study[12] looked at the impact of delays to surgery, radiotherapy and completion of therapy from the point of biopsy in patients with oral cavity (36.5 %), oropharynx (32.9 %), larynx (29.6 %) or hypopharynx (1.1 %) cancers on locoregional recurrence, distant metastasis and cancer-specific mortality. In patients (n=277) treated with surgery and adjuvant therapy between 2006 and 2014 in Texas, USA, time from biopsy to treatment longer than 50 days was associated with an increase in the proportion of patients diagnosed with distant metastasis. The study did not look at the association of time to biopsy from initial presentation and long-term outcomes.

## Biopsies under local anaesthetic with reusable versus disposable rhino laryngoscopes

No direct or indirect comparative evidence was identified.

## Biopsies under local anaesthetic with disposable rhino laryngoscope versus inpatient biopsies

No direct or indirect comparative evidence was identified.

## Safety and tolerability

The systematic review by Owusu-Ayim[3] concluded that biopsies under local anaesthetic were well tolerated by patients, with only coughing and gag reflex identified as side effects. The rate of complications was very low with seven out of 1,682 patients (0.41 %) experiencing epistaxis, aspiration, choking or dizziness.

One study[13] looked at the tolerability of mode of access for 178 patients undergoing laryngeal outpatient procedures (transnasal (n=128), transoral (n=16), percutaneous (n=19), missing data (n=15)). These included biopsies performed using a fibre optic endoscope with a working channel (n=33), but in nine cases the patient also other outpatient-based laryngeal procedures including laser therapy (n=8), and laser therapy plus a steroid injection (n=1). Using a custom scale within an hour of each procedure, whereby overall experience, procedure discomfort, anxiety, and tolerability were reported by the patient using a scale of 1-5 (with 1 being very comfortable and 5 very uncomfortable), the study did not find any difference in overall experience, anaesthesia discomfort, anxiety or tolerability between the different approaches (transnasal, transoral or percutaneous approach).

A systematic review of safety and tolerability of outpatient biopsy procedures for patients with suspicious laryngeal and pharyngeal lesions included 22 retrospective studies.[11] Tolerability was defined as the ability to successfully obtain adequate tissue samples for pathological analysis. The systematic literature review reported 23 abandoned procedures due to lack of tolerability in 2,272 patients (<1 %). One study reported one case where a patient with laryngeal oedema requiring urgent tracheostomy (out of 201 procedures). Other less serious complications, which required management, included anterior epistaxis, laryngeal bleeding following injection of topical anaesthesia and post-procedure dizziness and hypotension.

All the safety evidence relates to procedures conducted with reusable flexible rhino laryngoscopes and static camera stack in an outpatient setting. No directly relevant published evidence was identified for disposable equipment.

## Qualitative evidence (disposable biopsy equipment)

One study[14] looked at the image quality, ergonomics and advancing and navigation of the Ambu® RhinoLaryngo 4 Slim and aView® portable monitor in a tertiary otolaryngology centre in the UK. A five-point Likert scale survey was distributed to 16 ENT specialists (9 otolaryngology consultants, six otolaryngology registrars and one core surgical trainee) following 200 endoscopies. The survey was completed 61 times (a compliance rate of 30.5 %

given that 200 endoscopies were undertaken). Compared with the reusable endoscopic equipment, the ENT specialists found the disposable portable system to be worse or much worse in terms of image quality (34 % of responses), ergonomics (34 % of responses) and navigation (41 % of responses). There was no perceived difference between the reusable and disposable equipment in terms of image quality (32 % of responses), ergonomics (53 % of responses) and navigation (47 % of responses).The disposable, portable system was considered better or much better in terms of image quality (34% of responses), for ergonomics (13% of responses) and for navigation (12% of responses).

A small proportion of respondents (3 %) had to change to reusable scopes due to patient intolerance.

Another study from the USA[5], similar in design, found the disposable rhino laryngoscope (Ambu® RhinoLaryngo 4 Slim) comparable to the reusable technology in terms of ergonomics and maneuverability, superior in set up, convenience and overall score, but inferior in image quality. The results were based on 31 responses from junior doctors (these were the doctors considered most likely to be performing the procedures within a US healthcare setting). The survey had used a 5-point Likert scale to assess doctors' feedback on imaging quality, maneuverability, ergonomics, setup, convenience, and overall rating.

# Cost effectiveness

## Published literature

Biopsies under local anaesthetic with reusable rhino laryngoscopes versus inpatient biopsies under general anaesthesia

One UK study[6] was identified that compared the cost effectiveness of biopsies under local anaesthetic with reusable scopes and inpatient biopsies under general anaesthesia.

Health Technology Wales conducted a de-novo cost-utility analysis comparing biopsies under local anaesthetic (reusable rhino laryngoscopes) with inpatient procedures under general anaesthesia. The analysis adopted a decision-tree structure with 40-year time horizon, and was based on the 2018 SHTG budget impact model. At the start of the cost-utility model, patients with suspicious lesions of the larynx, pharynx and tongue base undergo an outpatient biopsy procedure or an operating theatre biopsy. People with advanced stage diagnoses undergo a positron emission tomography (PET) scan. Conventional staging is assumed for all other positive cases and 20 % of false positives were assumed to be missed. Confirmatory outpatient biopsies are performed for patients whose negative test result does not match the strongly suspicious clinical presentation of the lesion (33 %).

Clinical data used in the model included the sensitivity (76.12 %) and specificity (97.93 %) of outpatient biopsies. In the comparator arm of the model, perfect sensitivity and specificity (100 %) were assumed. Complication rates were obtained from the SHTG budget impact model. In the biopsy under local anaesthetic arm, 13.4 % of patients were assumed to experience procedure-related complication of intolerance, whereas 1 % and 2.7 % of patients were assumed to experience minor and major complications respectively, associated with inpatient biopsy. Mortality in the model was included using Wales-specific cancer survival data.

Costs included in the analysis were those associated with equipment (including rhino laryngoscopes, imaging stacks, and forceps), outpatient appointments, PET scans, medical staff time, inpatient visits, outpatient visits and day case visits.

Base case results showed that outpatient biopsies were a cost effective diagnostic procedure compared with inpatient biopsy procedures, yielding lower QALYs (-0.04) at a lower overall cost (-£816).

Biopsies under local anaesthetic with disposable rhino laryngoscopes

No relevant evidence was identified.

# SHTG budget impact model (2023 update)

## Methods

The budget impact assessment developed by SHTG in 2018 sought to establish the cost of initial investment to NHSScotland of new equipment required to provide outpatient-based biopsies for patients with suspicious laryngeal and/or pharyngeal cancers. The budget impact analysis illustrated the potential savings associated with outpatient procedures compared with inpatient procedures.

The budget impact model has been updated to include:

1. up-to-date costs of equipment, medical staff and healthcare resource use
2. the most recent clinical data and assumptions that most closely reflect current clinical practice
3. disposable rhino laryngoscopes as an option for tissue sampling of suspicious laryngeal and pharyngeal lesions.

Number of relevant procedures

The relevant number of biopsy procedures for the analysis was estimated based on data from Public Health Scotland based on procedure codes using the OSPC-4 classification system for all diagnostic laryngoscopy (E34 and E35) and diagnostic pharyngoscopy (E25). In the 2017-2021 period there were an annual average of 1,756 day case and inpatient procedures. The precise number of biopsy procedures for suspicious laryngeal or pharyngeal lesions in Scotland is unknown.

Diagnostic accuracy

The sensitivity (73 %) and specificity (97 %) findings from the most recent published systematic literature review[3] of outpatient biopsies with reusable endoscopes was used in the updated budget impact analysis. Due to the lack of clinical data for biopsies carried out using disposable equipment, it was assumed that disposable scope procedures have the same diagnostic accuracy as those performed with reusable scopes. Consistent with our analysis in 2018, it was assumed that all patients with initial negative result undergo a confirmatory inpatient biopsy procedure. In clinical practice, it may be that only patients with highly suspicious lesions undergo a follow-up inpatient biopsy procedure. The impact of this assumption was explored in a scenario analysis.

Safety

The literature review indicated that outpatient biopsy procedures (with reusable rhino laryngoscopes) are safe and well tolerated with only small numbers of cases of abandoned procedures or complications. For the purpose of the model, it was anticipated that the rate of intolerance may be higher in clinical practice. An intolerance rate of 12.5 % was assumed in-keeping with the 2018 analysis. No data specific to disposable scopes was identified; it was assumed that there is no difference in tolerance of procedures with disposable or reusable scopes.

Consistent with the approach taken in the 2018 SHTG budget impact model, the risk of major complications was based on clinical advice about the frequency of oesophageal perforation (1 % to 3 % of cases) and difficult airway cases (10 % to 20 %), of which 5 % were assumed to require a tracheotomy. The risk of minor complications from outpatient biopsy was assumed to be consistent with the rate derived from the literature described above, that is, between 0.05 % and 2.6 %. It was assumed that there is no difference in tolerance of procedures with disposable or reusable scopes.

A perceived benefit of disposable scopes is the elimination of the risk of infection due to failed endoscope reprocessing. Rate of infections is difficult to measure due to symptoms of infections showing days after the procedure, which necessitates a review of patient records.

No rhino laryngoscope-specific infection rates were found in the literature. One recent paper reported infection rate of between 0 % and 8 % associated with upper gastrointestinal diagnostic procedures, with and without biopsy.[15] The most common infections included *Escherichia coli*, Klebsiella, other Enterobacteriaceae and enterococci but patients were mostly asymptomatic. Due to the lack of recent relevant infection risk estimates, improvement in clinical practice to reduce risk (for example, use of disposable forceps) and the overall low patient numbers in Scotland, no costs associated with infections post-rhino laryngoscopy with a reusable endoscope (outpatient or inpatient) have been included. It should be noted that this assumption does not allows for any increased risk of contamination during periods such as the COVID-19 pandemic.

Costs

*Equipment and decontamination*

The cost of channeled rhino laryngoscopes (disposable or reusable) is the main equipment cost compared in the analysis. One reusable endoscope can be used multiple times, following appropriate decontamination, has a one-off cost of purchase, per procedure cost of decontamination and an annual maintenance cost. The equipment cost per procedure is volume-based. Consistent with the SHTG budget impact model in 2018, it was assumed that, on average, two channeled reusable rhino laryngoscopes per health board need to be purchased. The cost of decontamination was included based on data from GGC. Disposable rhino laryngoscopes have a cost per unit and no maintenance or reprocessing cost as they are disposed of after use.

The cost of imaging stacks was also considered in the analysis. The initial investment in an imaging stack has a financial cost. An imaging stack in an outpatient setting can be used for diagnostic procedures (with or without biopsies) by various specialties (for example, head and neck, upper gastro intestine, lower gastro intestine). On average, between 2017-2020, there were 36,400 diagnostic video laryngoscopies and pharyngoscopies. Assigning the cost of imaging stack per endoscopic biopsy procedure of the larynx and pharynx without consideration of video endoscopies and other various uses would result in an overestimation of the cost of outpatient biopsies with reusable rhino laryngoscopes. Therefore, the cost of the imaging stack was adjusted accordingly.

Cost of consumables (such as single use forceps and topical anaesthesia) was also included.

*Resource use*

Consistent with the 2018 SHTG budget impact model, it was assumed that procedures were day case but that 15 % of patients will end up in hospital (due to individual circumstances

rather than solely complications). All patients are assumed to attend one outpatient visit without biopsy. *Appendix 2* presents further information on the budget impact model structure and variables included in the analysis.

## Results

The results of the budget impact analysis are presented in *Table 2*. The results show that if a confirmatory inpatient biopsy procedure is performed for every negative biopsy under local anaesthetic result, the economic impact of investment in biopsy under local anaesthetic equipment is cost neutral (negligible saving of £1,685) compared with inpatient biopsy procedures. Tissue sampling with disposable rhino laryngoscopes is more expensive compared with inpatient procedures or procedures under local anaesthetic using reusable rhino laryngoscopes.

### Table 2: Budget impact results

| NHSScotland | Year 1 | Years 2-5 | Mean |
|---|---|---|---|
| **Investment (in equipment) costs** | | | |
| Additional investment in reusable biopsy equipment | £573k (£384k to £773k)* | £264k (£246k to £358k)* | **£326k (£273k to £441k)*** |
| Additional investment in disposable biopsy equipment | £527k | £314k | **£357k** |
| Net cost of reusable vs disposable rhino laryngoscopes (equipment only) | £46k (-£145k to £244k)* | -£50k (-£69k to £44k)* | **-£32k (-£84k to £84k)*** |
| **Pathway costs** | | | |
| Overall cost of diagnostic pathway (local anaesthetic biopsies) incl. 100 % inpatient confirmatory procedures for negative biopsies) | £3,479k | £3,479k | **£3,479k** |
| Overall cost of diagnostic pathway (inpatient biopsies) | £3,806k | £3,806k | **£3,806k** |
| **Overall cost impact** | | | |
| Net resource impact (**reusable outpatient** (investment costs and pathway costs) **vs inpatient biopsies** (pathway costs)) | +£246k (£57k to £446k)* | -£64k (-£82k to £30k)* | **-£2k (-£54k to £113k)** |
| Net resource impact (**disposable outpatient** (investment costs and pathway costs) **vs inpatient biopsies** (pathway costs)) | +£202k | -£13k | **+£30k** |

*Investment range based on number of rhino laryngoscopes purchased per health board (between one and three). Year one indicates initial investment, whereas years 2-5 indicate average spent on equipment maintenance.

No relevant data were identified on the proportion of confirmatory procedures required after an outpatient biopsy in Scotland. Using a less conservative assumption of 80 % of negative biopsies requiring an inpatient confirmatory procedure, the potential resource savings increase to £573k, rising to £1.4 million when the proportion requiring follow-up procedures decreases to 50 %. Health Technology Wales assumed a confirmatory procedure rate of 33 %, which would indicate a resource saving for Scotland of approximately £1.9 million (or an average per patient saving of £1,091).

The limitations of this budget impact analysis include lack of clarity on the current stock of outpatient biopsy equipment across NHSScotland, which may affect the extent of the necessary initial investment. Due to lack of diagnostic accuracy data for biopsies with disposable rhino laryngoscopes, it was assumed equal to that of biopsies under local anaesthetic with reusable equipment. Lower diagnostic accuracy would have a negative impact on patient outcomes and increase financial burden on the healthcare system.

# Environmental impact assessment (EIA)

## Reusable versus disposable rhino laryngoscopes

In 2022, the sixth Intergovernmental Panel on Climate Change Report highlighted that global warming is 0.3°C away from reaching 1.5°C above pre-industrial levels, the threshold that is critical to limiting the impact of global warming on sustained catastrophic health issues.[16] United Nations Framework Convention on Climate Change modelling suggests that greenhouse gas (GHG) emissions need to be cut 43 % by 2030 to avert irreversible environmental catastrophe. The NHS is responsible for 5 % of UK GHG emissions. Medical equipment contributes 10 % total NHS carbon emission.[17] The NHS is targeted to reach net zero carbon emissions by 2040.[18] Part of the NHS net zero strategy includes optimising resource use and target reducing scope 3 emissions (that is, emissions produced as a consequence of the activities of the company, but may occur from sources not owned or controlled by the company).[17] Studies report replacing single use devices with a reusable equivalent reduces carbon emissions between 50 %–97 %.[18-20]

The EIA summarised in this assessment was conducted by a colleague at The University of Glasgow. The EIA used the Publicly Available Specification (PAS) 2050:2011 standards and GHG Protocol Corporate Standard (Product Standard)[21] for the assessment of GHG emissions, to compare equivalent functional units of a disposable flexible rhino laryngoscope device and a reusable flexible rhino laryngoscope device.

## Methods

All scope 3 emission processes were compared in a life cycle assessment (LCA) of a disposable flexible rhino laryngoscope device and a reusable flexible rhino laryngoscope device. Granular activity data were used where possible, and a systematic search to include all relevant published/non-published literature for the analysis was conducted. The use of appropriate carbon conversion databases was ensured. Three comparable alternative LCA scenarios, including best- and worst-case carbon emissions impact scenarios, were provided. Please refer to *Appendix 3* for more details.

## Results

- The disposable rhino laryngoscope device emits 6.03 $KgCO_2^e$ per device compared with its reusable equivalent of 3.26 $KgCO_2^e$, categorising the devices as very high (>5 $kgCO_2^e$) and high (1-3 $KgCO_2^e$) in terms of carbon emissions, respectively.
- The life cycle GHG emissions of the disposable device is 48 % times higher in terms of GHG emissions compared to its reusable equivalent.
- The downstream transportation stage of the disposable device reorder quantity (58 boxes of five to the NHSScotland National Distribution Centre) generates a total of 575.62 $KgCO_2^e$ per delivery.
- Sterilisation of one reusable device in an automated endoscopic reprocessor (AER) requires 11 kW for 25 minutes generating 41 % GHG (1.33 $KgCO_2^e$) per device use.
- Emissions generated per reusable device increases by 2.11 $KgCO_2^e$ per device to 5.71 $KgCO_2^e$ if the number of uses per lifetime is reduced to 980 uses per lifetime (a quarter baseline of 3,920 uses per lifetime = 980 uses). This is still lower than the equivalent disposable device.
- The use of single use personal protective equipment (PPE) adds significant carbon footprint to both functional unit LCAs.
- Based on the figure of 2,264 biopsy procedures throughout NHSScotland/per annum, The estimated waste volumes for the use of disposable rhino laryngoscopes is 12,5578 Kgs (12.56 tonnes) of clinical waste per annum and negligible for the reusable device.

Based on the findings of the EIA, from the perspective of reducing NHS-associated scope 3 carbon emissions and clinical waste volumes, the use of a reusable flexible rhino laryngoscope device for biopsies is highly preferable over the use of a disposable equivalent.

# Conclusions

The diagnostic accuracy of laryngeal or pharyngeal biopsies under local anaesthetic in an outpatient setting (with reusable rhino laryngoscopes) is associated with high specificity (96.7 %) but low sensitivity (73.0 %), compared with inpatient biopsy procedures. The low sensitivity may necessitate the need for confirmatory inpatient procedures for negative outpatient results, yet the high specificity means that there is an opportunity for more rapid diagnosis and patients may avoid biopsy under general anaesthetic in the operating theatre.

Outpatient biopsies are possible in any clinical setting due to the introduction of disposable rhino laryngoscopes and portable monitors. Evidence on their diagnostic accuracy, safety, tolerability and cost effectiveness is not available at present.

Economic evidence suggests that outpatient biopsies with reusable rhino laryngoscopes are cost neutral and potentially cost saving when compared with inpatient biopsy procedures. Performing all procedures with disposable rhino laryngoscopes with a portable monitor is likely more expensive than biopsies with reusable rhino laryngoscopes in an outpatient clinic.

Based on an EIA, the carbon impact of reusable flexible rhino laryngoscope devices is substantially lower than the carbon impact of the equivalent disposable devices.

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# References


1. Public Health Scotland. Cancer Waiting Times in NHS Scotland. 1 July to 30 September 2022. 2022 [cited 2023 May 25]; Available from: https://publichealthscotland.scot/media/16840/2022-12-13-cwt-report.pdf.
2. Scottish Health Technologies Group. Outpatient biopsy for diagnosis of suspicious lesions of the larynx pharynx and tongue base. 2022 [cited 2023 May 25]; Available from: https://shtg.scot/our-advice/outpatient-biopsy-for-diagnosis-of-suspicious-lesions-of-the-larynx-pharynx-and-tongue-base/.
3. Owusu-Ayim M, Ranjan SR, Lim AE, Rogers ADG, Montgomery J, Flach S*, et al.* Diagnostic accuracy outcomes of office-based (outpatient) biopsies in patients with laryngopharyngeal lesions: A systematic review. Clinical Otolaryngology. 2022;47(2):264-78. https://doi.org/10.1111/coa.13897
4. Lim AE, Zahra B, Moen C, Montgomery J. The effect of local anaesthetic biopsy in head and neck cancer on cancer pathway waiting times. Ann R Coll Surg Engl. 2023;105(4):331-5. Epub 20220526. 10.1308/rcsann.2022.0014
5. Walczak R, Arnold, M., Grewal, J., Yuan, X., Suryadevara, A. and Marzouk, H. Reusable vs disposable nasopharyngolaryngoscopes: Cost analysis and resident survey. Laryngoscope Investigative Otolaryngology. 2021;6(1):88-93.
6. Health Technology Wales. Laryngeal biopsies in the outpatient setting in people with suspected head and neck dysplasia/cancer. 2022 [cited 2023 May 25]; Available from: https://healthtechnology.wales/reports-guidance/outpatient-laryngeal-biopsy/.
7. NHS England. A rapid review of aerosol generating procedures (AGPs). An assessment of the UK AGP list conducted on behalf of the UK IPC Cell. 2022 [cited 2023 Jun 26 ]; Available from: https://www.england.nhs.uk/wp-content/uploads/2022/04/C1632_rapid-review-of-aerosol-generating-procedures.pdf.
8. Public Health Scotland. Cancer incidence in Scotland. To December 2021. 2023 [cited 2023 May 25]; Available from: https://publichealthscotland.scot/publications/cancer-incidence-in-scotland/cancer-incidence-in-scotland-to-december-2021/data-files/#Head,%20neck%20and%20CNS.
9. NHSScotland. Scottish Referral Guidelines for Suspected Cancer. Head and neck cancers. 2019 [cited 2023 May 25]; Available from: https://www.cancerreferral.scot.nhs.uk/head-and-neck-cancers/?alttemplate=Guideline#:~:text=The%20incidence%20of%20head%20and,around%20240%20with%20thyroid%20cancers.
10. NHSScotland. NHSScotland Endoscope Decontamination Documentation System (EDDS): Decontamination Policy for flexible thermolabile endoscopes PRO 179-1. 2017 [cited 2023 Jun 26 ]; Available from: https://www.nss.nhs.scot/media/2973/pro-179-1-v10-apr-2017.pdf.
11. Lim AE, Rogers ADG, Owusu-Ayim M, Ranjan S, Manickavasagam J, Montgomery J. A systematic review: impact of in-office biopsy on safety and waiting times in head and neck cancer. J Laryngol Otol. 2022;136(10):909-16. Epub 20220110. 10.1017/s002221512100428x
12. Tumati V, Hoang L, Sumer BD, Truelson JM, Myers LL, Khan S*, et al.* Association between treatment delays and oncologic outcome in patients treated with surgery and radiotherapy for head and neck cancer. Head Neck. 2019;41(2):315-21. Epub 20181213. 10.1002/hed.25457

13. Hamdan AL, Jabbour C, Khalifee E, Ghanem A, Hage AE. Tolerance of Patients Using Different Approaches in Laryngeal Office-Based Procedures. J Voice. 2023;37(2):263-7. Epub 20210213. 10.1016/j.jvoice.2020.12.009
14. Mistry R, Russell RV, Walker N, Ofo E. The single-use rhinolaryngoscope: an evaluation and cost comparison. J Laryngol Otol. 2020;134(9):1-8. Epub 20200928. 10.1017/s0022215120001656
15. Kovaleva J, Peters FT, van der Mei HC, Degener JE. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev. 2013;26(2):231-54. 10.1128/cmr.00085-12
16. The Intergovernmental Panel on Climate Change. Global Warming of 1.5 ºC. 2022 [cited 2023 May 25]; Available from: https://www.ipcc.ch/sr15/.
17. NHS England. Delivering a 'Net Zero' National Health Service. 2022 [cited 2023 May 25]; Available from: https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2022/07/B1728-delivering-a-net-zero-nhs-july-2022.pdf.
18. Ibbotson S, Dettmer T, Kara S, Herrmann C. Eco-efficiency of disposable and reusable surgical instruments—a scissors case. The International Journal of Life Cycle Assessment. 2013;18(5):1137-48. 10.1007/s11367-013-0547-7
19. Ison E, Miller A. THE USE OF LCA TO INTRODUCE LIFE-CYCLE THINKING INTO DECISION-MAKING FOR THE PURCHASE OF MEDICAL DEVICES IN THE NHS. Journal of Environmental Assessment Policy and Management. 2000;02(04):453-76. 10.1142/S1464333200000497
20. Kümmerer K, Dettenkofer M, Scherrer M. Comparison of reusable and disposable laparatomy pads. The International Journal of Life Cycle Assessment. 1996;1(2):67-73. 10.1007/BF02978647
21. World Resources Institute WBCfSD. Corporate Value Chain (Scope 3) Accounting and Reporting Standard. 2011 [cited 2023 May 25]; Available from: https://ghgprotocol.org/sites/default/files/standards/Corporate-Value-Chain-Accounting-Reporing-Standard_041613_2.pdf.
22. Pradere B, Mallet R, de La Taille A, Bladou F, Prunet D, Beurrier S*, et al.* Climate-smart Actions in the Operating Theatre for Improving Sustainability Practices: A Systematic Review. Eur Urol. 2023;83(4):331-42. Epub 20220210. 10.1016/j.eururo.2022.01.027
23. NICE. Surgical site infections: prevention and treatment. 2020 [cited 2023 May 25]; Available from: https://www.nice.org.uk/guidance/ng125.
24. Duane B, Ashley P, Ramasubbu D, Fennell-Wells A, Maloney B, McKerlie T*, et al.* A review of HTM 01-05 through an environmentally sustainable lens. British Dental Journal. 2022;233(4):343-50. 10.1038/s41415-022-4903-5
25. Rizan C, Brophy T, Lillywhite R, Reed M, Bhutta MF. Life cycle assessment and life cycle cost of repairing surgical scissors. The International Journal of Life Cycle Assessment. 2022;27(6):780-95. 10.1007/s11367-022-02064-7
26. Institute of Environmental Management & Assessment. Guide to: Effective Scoping of Human Health in Environmental Impact Assessment.. 2022 [cited 2023 May 25]; Available from: https://www.iema.net/.
27. Bäck LJJ, Rekola J, Raittinen L, Halme E, Pietarinen P, Keski-Säntti H*, et al.* The feasibility of NBI in patients with suspected upper airway lesions: A multicenter study. Laryngoscope. 2017;127(8):1821-5. Epub 20170222. 10.1002/lary.26526

28. Refaat AM, Negm A. Transoral Versus Transnasal Approaches in Office-Based Laryngeal Biopsy: A Cohort-Selection Cross-Sectional Diagnostic Accuracy Study. J Voice. 2022;36(5):726-31. Epub 20200913. 10.1016/j.jvoice.2020.09.001
29. Mozzanica F, Ottaviani F, Ginocchio D, Schindler A. Office-Based Laryngeal Biopsy in Patients Ineligible for General Anesthesia. Iran J Otorhinolaryngol. 2020;32(113):373-8. 10.22038/ijorl.2020.42544.2436
30. British Standards Institution. The Guide to PAS 2050:2011 How to carbon footprint your products, identify hotspots and reduce emissions in your supply chain. 2011 [cited 2023 May 25]; Available from: https://www.bsigroup.com/globalassets/localfiles/en-th/carbon-footprint/pas-2050-2011-guide.pdf.
31. 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. Environ Health Perspect. 2021;129(7):76001. Epub 20210712. 10.1289/ehp8666
32. Hogan D, Rauf H, Kinnear N, Hennessey DB. The Carbon Footprint of Single-Use Flexible Cystoscopes Compared with Reusable Cystoscopes. J Endourol. 2022;36(11):1460-4. Epub 20220613. 10.1089/end.2021.0891
33. Rizan C, Bhutta MF. Re: The Carbon Footprint of Single-Use Flexible Cystoscopes Compared with Reusable Cystoscopes: Methodological Flaws Led to the Erroneous Conclusion That Single-Use Is "Better". J Endourol. 2022;36(11):1466-7. Epub 20220822. 10.1089/end.2022.0482
34. 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. J Endourol. 2018;32(3):214-7. Epub 20180221. 10.1089/end.2018.0001
35. Ambu A/S. Ambu® aScope™ 4 RhinoLaryngo Intervention. 2019 [cited 2023 May 25]; Available from: https://www.ambu.co.uk/endoscopy/ent-otorhinolaryngology/rhinolaryngoscopes/product/ambu-ascope-4-rhinolaryngo-intervention.
36. Kemble JP, Winoker JS, Patel SH, Su ZT, Matlaga BR, Potretzke AM*, et al.* Environmental impact of single-use and reusable flexible cystoscopes. BJU International. 2023;131(5):617-22. https://doi.org/10.1111/bju.15949
37. Bsigroup N. The Guide to PAS 2050: 2011 How to carbon footprint your products, identify hotspots and reduce emissions in your supply chain, British Standards Institution. 2011.

# Appendix 1: Definitions and abbreviations

## Definitions

**Biopsies:** Tissue sampling of suspicious lesions, investigated for malignancy.

**Gold (or "reference") standard**: A test that has a hypothetical 100% sensitivity and 100% specificity. In clinical practice the gold standard term is typically used for the current reference standard test (i.e. the test that is used in clinical practice that is considered most diagnostically accurate among available tests and so is the test of choice for any new tests to be compared against).

**Outpatient biopsies:** biopsies conducted under local anaesthetic in designated area in a clinic or hospital where the required equipment is set up. The terms outpatient biopsies and in-office biopsies are used interchangeably in the published literature. In this assessment, these are referred to as biopsies under local anaesthetic with reusable rhino laryngoscopes to differentiate them from biopsy procedures under local anaesthetic with single use rhino laryngoscopes, which can be conducted in any clinical setting.

**Inpatient biopsies:** biopsies conducted in hospital theatre under general anaesthesia where there is a suspicion the patient has a head and neck cancer.. Other terms used in the literature include general anaesthesia biopsies, panendoscopies with biopsy, direct laryngosocpies, direct pharyngoscopies, etc.

**Sensitivity:** the probability that a person having a disease will be correctly identified by a clinical test, that is the number of true positive results divided by the total number with the disease.

**Specificity:** the probability that a person not having a disease will be correctly identified by a clinical test, that is the number of true negative results divided by the total number of those without the disease.

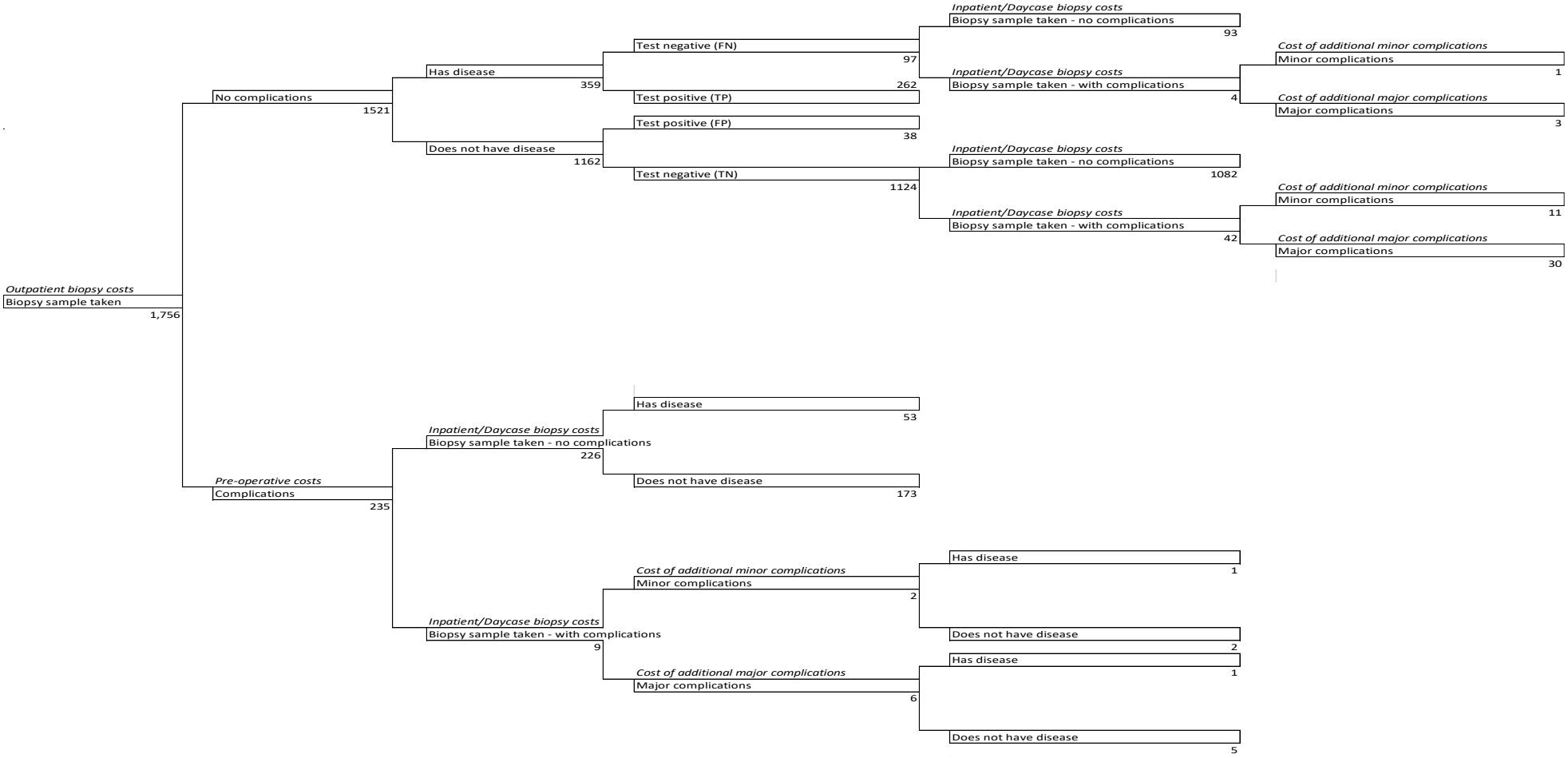
## Abbreviations

| | |
|---|---|
| AER | Automated Endoscopic Reprocessor |
| AGP | Aerosol generating procedures |
| BEIS | Business, Energy, and Industrial Strategy |
| EASR | European age-standardised incidence rate |
| EIA | Environmental impact assessment |
| ENT | Ear, Nose and Throat |
| GA | General anaesthesia |

| | |
|---|---|
| GGC | Greater Glasgow and Clyde |
| HD | High definition |
| HFCs | Hydrofluorocarbons |
| HPV | Human papilloma virus |
| HTA | Health technology assessment |
| ICE | Inventory of Carbon and Energy |
| IEMA | Institute of Environmental Management and Assessment |
| ISD | Information Services Division |
| ISO | International Organization for Standardisation |
| LCA | Life cycle assessment |
| NBI | Narrow band imaging |
| NDC | National Distribution Centre |
| NHS | National Health Service |
| PAS | Publicly Available Specification |
| PET | Positron emission tomography |
| PFCs | Perfluorocarbons |
| PPE | Personal protective equipment |
| PSSRU | Personal and Social Services Research Unit |
| PU | Polyurethane |
| PVC | Polyvinyl chloride |
| QALY | Quality adjusted life years |
| SHTG | Scottish Health Technologies Group |
| USCP | Urgent suspicion of cancer pathway |
| WLE | White light endoscopy |

# Appendix 2: Budget impact analysis

## 1. Decision tree structure



## 2. Budget impact analysis data inputs

| Input | Value | Source |
|---|---|---|
| Sensitivity | 0.73 | Systematic review |
| Specificity | 0.97 | Systematic review |
| Disease prevalence | 0.236 | SHTG assessment 2018 |
| Number of items per board | 2 (1 to 3) | Assumption |
| Outpatient diagnostic procedures (without biopsy) | 36 400 | Public Health Scotland, 2023 (Personal communication) |
| Annual inpatient and bed days procedures 2017-2021 | 1756 | Public Health Scotland, 2023 (Personal communication) Assumption; |
| Cost of image stack, reusable flexible rhino laryngoscope and maintenance costs | Commercial in confidence | Olympus® and Karl Storz® 2022 (Personal communication) |
| Cost of disposable forceps | £13.1 | National procurement Scotland 2022 |
| Cost of single use rhino laryngoscopes and portable monitor | Commercial in confidence | Ambu® 2022 (Personal communication) |
| Cost of topical anaesthesia | £9.70 | British National Formulary, 2022 |
| Cost of decontamination of reusable rhino laryngoscopes | £46 | NHS GGC (Personal communication) |
| Cost of inpatient biopsy procedure | £1,758 | Estimated based on NHS England Reference costs of inpatient and day case visits. |
| Additional time required for tissue sampling (minutes) | 15 | Clinical expert opinion/Assumption |
| Per minute cost of consultant time | £1.78 | PSSRU 2022 |
| Additional bed days for minor complications | 1 | Clinical expert opinion/Assumption |
| Additional bed days for major complications | 6 | Clinical expert opinion/Assumption |
| Probability of disease being present among population attending for suspicious laryngeal/pharyngeal lesions | 0.306 | ISD Cancer Incidence Data/Assumption |
| Probability of overnight stay due to patient-specific circumstances | 0.15 | Clinical expert opinion |

*Abbreviations: SHTG = Scottish Health Technologies Group; GGC = Greater Glasgow and Clyde; PSSRU = Personal Social Services Research Unit; ISD = Information Services Division;*

# Appendix 3: Environmental Impact Assessment (EIA)

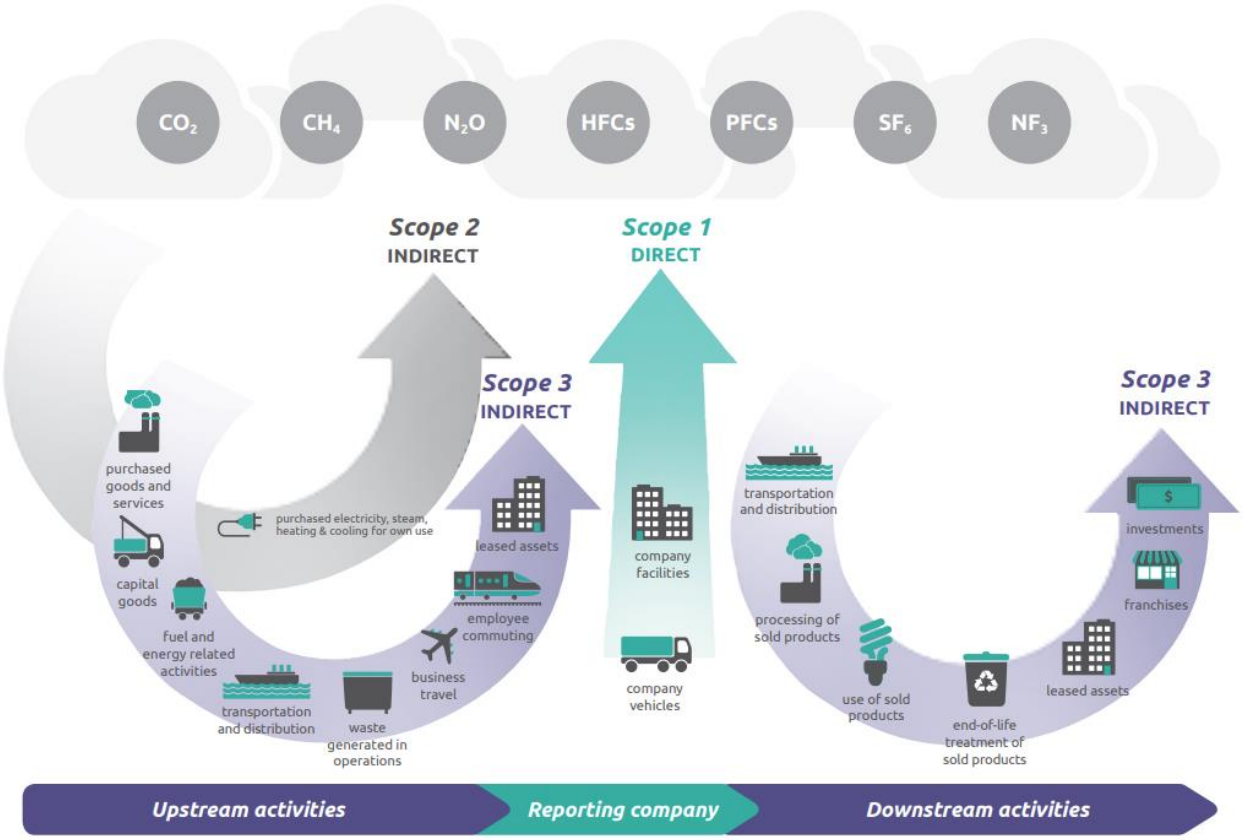
### 1.0 Methodology: boundaries, scope, and prioritisation

This EIA makes use of the Publicly Available Specification (PAS) 2050:2011 standards[30] for the assessment of the life cycle GHG emissions of goods and services: essentially drawing on two sources: ISO 14,044 (PAS 2050) and based on the GHG Protocol Corporate Standard (Product Standard)[21] framework.

### 1.1 Focus on scope 3 carbon emissions

This EIA focuses on the evaluation and reporting of scope 3 (*see Figure A3.1*) carbon dioxide equivalents ($CO_2^e$) accounting for the emissions generated from corporate value chain activities. Greater than 80 % GHG emission impacts occur outside of the company own operations[21]. On the basis of global warming potential, using the metric $CO_2^e$ incorporates the six main greenhouse gases in providing a single measurement for the carbon dioxide ($CO_2$ ) equivalent emissions of the following GHGs (including $CO_2$): methane ($CH_4$), nitrous oxide ($N_2O$), hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), and sulphur hexafluoride ($SF_6$).

Figure A3.1: Overview of GHG Protocol scopes and emissions across the value chain[21]



### 1.2 Scope of analysis

This report does not represent a full EIA. A full EIA may take into consideration the health impacts and assessment of common environmental impact categories including ozone depletion and freshwater ecotoxicity potential.

This report represents an important step towards including EIAs within health technology assessments (HTAs), and provides key information for decision making based on the best available evidence of carbon emission for resources and processes including:

1. Scope 3 – Upstream processes and materials

   1a. Raw material acquisition + manufacturing

   1b. Pre-packaging sterilisation

   1c. PPE use during rep-packaging sterilisation

   1d. Sterile barrier system

2. Scope 3 – Downstream processes and materials

   2a. Mode of transportation, travel routes and resources

   2b. Use phase sterilisation processes

   2c. PPE use during sterilisation process

   2d. Sterile barrier systems

3. Waste volumes

### 1.3 Objectives

- To provide three alternative life cycle analysis (LCA) scenarios reporting GHG emissions comparing disposable flexible rhino laryngoscopes with reusable flexible rhino laryngoscopes.
- To report end of life waste (clinical) volumes generated by the use of the devices.
- To provide recommendations in support of reducing the environmental impact of using disposable and reusable flexible rhino laryngoscopes.

### 1.4 Not included in the analysis

- company reporting Scope 1 and 2 emissions. For example, emissions created as a result of the manufacturing site and product waste from operations at the manufacturing sites
- EIA of capital equipment

- EIA of consumables including detergent and gas use for sterilisation processes for the reusable and single use device, respectively
- EIA of the entire clinical pathway: outpatient biopsy for diagnosis of suspicious lesions of the larynx pharynx and tongue base
- a time horizon of environmental impacts including scope 3 categories where reported emissions have not yet happened, although, are expected to happen as a result of waste generated in operations (processes), downstream transportation and distribution, processing of sold products, use of sold products and end of life treatment of sold products
- effects of environmental harm caused to biodiversity and human health
- other assessment of common environmental impact categories including ozone depletion, freshwater ecotoxicity potential photochemical oxidant creation potential, eutrophication potential acidification potential and particulate matter formation.

**1.5 Sources of information and data**

Included data are based on real world evidence, current and appropriate evidence based research, or a combination of both types of data. A search was performed to capture all relevant publications and grey literature. Relevant studies were identified using the key words: “scope*”, “environmental impact” “sustainability” (title, abstract, keyword) and any equivalent subject index terms.

A search of the published literature (English only) was undertaken in Web of Science (all databases) ( 63 results) and PubMed databases, spanning a time frame of 18 years from 01-01-2005 – 26-02-2023: Web of science (all databases), PubMed (30 results) Search terms used were: endoscope* OR cystoscope* OR ureteroscope* OR duodenoscope* OR rhinolaryngoscope* OR laryngoscope* OR bronchoscope* OR colonoscope* OR endoscopy OR arthroscope* "environment* impact" OR "cost of carbon" OR "environmental cost" OR "sustainab" OR "greenhouse gas emissions" OR "environmental assessment" OR "life cycle assessment" OR "carbon footprint*" OR “life cycle assessment” OR “carbon emissions”

Google scholar was searched for the first 10 results using the following combination of key words at a time:

1. endoscope + carbon + impact + environment
2. cystoscope + carbon + impact + environmental
3. duodenoscope + carbon + impact + environmental
4. laryngoscope + carbon + impact + environmental
5. ureteroscope + carbon + impact + environmental

### 1.6 Real world data

Real world data was obtained from multidisciplinary teams at NHS GGC. All data provided by multidisciplinary teams involved in the life cycle assessment (LCA) of the scopes is outlined in supplementary materials. Industry representatives were sent a set of EIA questions by email.

### 1.7 Total procedural volume and estimated usage of devices

An estimated procedural volume, reported in this SHTG assessment, of 2,264 (444 to 3,029) outpatient biopsies for diagnosis of suspicious lesions of the larynx pharynx and tongue base in NHSScotland has been used in this report. In order to provide an extrapolation of the carbon impact across NHSScotland in using these devices for this procedure, it has been assumed a rhino laryngoscope device has been used for every diagnosis of suspicious lesions.

### 1.8 NHS Greater Glasgow and Clyde

NHS GGC has been used as a site of assessment for this report in order to undertake a practical and real world evidence approach to the EIA. This included asking staff members questions about their protocols and practices, as well as obtaining local health board targets to provide comprehensive priority setting for the analysis and recommendations.

### 1.9 Quality of published data

There is significant heterogeneity in the conduct and reporting of carbon footprint within healthcare.[31] Many studies published in this field exhibit bias as a result of current or legacy conflict of interest and industry sponsored research. There are reports of methodological concerns in relation to a number of published studies in this field. For example, one study[32] contradicts the general trend that reusable surgical products have lower carbon footprint compared with single use equivalents. Another study[33] highlights a number of flaws in the methods used in that study and data used for the single use versus reusable cystoscope comparison. This includes reporting an unreasonable energy consumption for the sterilisation process of the reusable device and a 50 % lower manufacturing process carbon footprint for the single use device than published in a previous study. Another study[34] contains methodological weaknesses including assuming the proportion of material components to be the same between the single use and reusable ureteroscope and a lack of uncertainty in modelling and carbon emissions factors. The provision of supplementary material for most publications in this field of research is lacking. It is challenging to assess the appropriateness of methods and quality of published data for this analysis. Carbon footprint estimates in this report require some caution, particularly in comparing results

between studies due to substantial differences in inventory boundaries, assumptions and other methodological considerations.

### 1.10 Primary data analysis

Suppliers were approached as early on in the process as possible as part of the scoping exercise providing the supplier with enough opportunity to get engaged and collaborate. A member of staff from NHS GGC weighed the reusable device and confirmed it to be 0.82 kg. The weight of the single use device was confirmed as 0.18 kg including the sterile barrier system. The weight of the device on its own was assumed to be 0.16 kg (i.e. excluding the sterile barrier system) and as reported in another study.

### 1.11 Data sources for estimates

Where possible, emission factors for materials using average data for materials supplied to the UK were used as primary sources. Activity data was obtained from primary sources at the point of use where possible. Conversion factor data was obtained from the sources listed below, with consideration of technological, temporal and geographical representativeness, completeness and reliability as outlined in the data quality indicators within the GHG Protocol.[21]

- Department for Environmental, Food and Rural Affairs (DEFRA)/Department for Business, Energy, and Industrial Strategy (BEIS) database
- The Inventory of Carbon and Energy (ICE) database, version 3
- Ecoinvent, version 3.6
- Publications citing data taken from databases
- Grey literature citing data from databases

### 1.12 HealthcareLCA database

HealthcareLCA database brings together environmental assessments of health systems, hospitals, healthcare services, surgical procedures, medical equipment and pharmaceuticals into an open-access repository. The word “scopes” was searched in this database to source all EIA methods and data of any medical scopes published, globally. The following terms were searched (the database is not sensitive to search terms) within the database to capture a wide range of scope applications and reported environmental impacts: “duodenoscope”, “ureteroscope”, “endoscope”, “rhinolaryngoscope” and “bronchoscope.”

### 1.13 Overall assumptions for the inclusion of published, non-published and real world data

For the purpose of this report, it has been assumed the environmental impact of the production, use and disposal of single use and reusable rhino laryngoscopes (based on the

same or similar processes, energy needs, materials and waste management methods being used and applied) is similar to data published on various types of scopes including (not an exhaustive list) cystoscopes, endoscopes, ureteroscopes, duodenoscopes. Supplier representation provided consensus on the characteristics of a cystoscope exhibiting the most similar in technological representation as a rhino laryngoscope.

**1.14 Functional unit to be compared[30]**

A single use flexible rhino laryngoscope manufactured by Ambu® is compared with a reusable flexible rhino laryngoscope manufactured by Olympus®. The functional unit in this assessment is a single rhino laryngoscope. The functional unit quantifies the performance of a product system for use as a reference unit. By defining the unit of comparison as the functional unit, rather than a unit of volume, the performance and characteristics of each product are considered, and a fair comparison can be drawn.

**1.15 Data on the composition and carbon emissions of the functional unit**

Both primary data and secondary LCA of rhino laryngoscopes is lacking. The available evidence used in conjunction with comparable published data on a similar types of technology in endoscopy, provides reasonable technological representativeness and is considered acceptable as an indicator of data quality. This supports an estimation of environmental impact of the device being assessed in order to complete LCA knowledge gaps. The single use devices are generally comprised mostly of thermoplastic (approximately 90 %), PVC and PU (6 %) and electronics (4 %). The Ambu® aScope™ 4 RhinoLaryngo intervention single use endoscope instructions for use document helped support the provision of an estimation of composition of materials of the single use device.[35] Information on the components and materials that make up the reusable device from Olympus is lacking. The study into the LCA of cystoscopes[36] provides suitable LCA data to reasonably assume comparable device materials and composition.

**1.16 Assessment thresholds for the functional unit (emissions per device)**

This report makes use of the PAS 2050:2011 $CO_2^e$ threshold limits to determine the level of functional unit emissions output. See *Table A3.1* below.

Table A3.1: Examples of high- and low-intensity materials and processes in threshold categories for carbon emissions reported in $CO_2^e$. Source of diagram: PAS 2050:2011

| Very high (>5 kg $CO_2$e per kg) | High (1–3 kg $CO_2$e per kg) | Medium (<1 kg $CO_2$e per kg) | Low (<0.1 kg $CO_2$e per kg) |
|---|---|---|---|
| Refrigerants | Plastics | UK/EU field crops | Unprocessed minerals (e.g. gravel, sand) |
| Electronic components | Most chemicals | Glass | By-products (e.g. straw, woodchips, some animal feeds) |
| Meat products | Fuels | Paper and cardboard | Water production and processing |
| Aluminium | Dairy products | Plastics processing | Transport <1,000 km by articulated lorry, or <20,000 km by sea |
| Other metals (except steel) | Greenhouse crops | Landfill of biodegradable materials | Landfill of non biodegradable materials |
| Pigments/dyes | Rice | | |
| Some concentrated foodstuffs | Peat | | |
| Laundry/hot water treatment | Freezing | | |
| | Cooking | | |

**1.17 Product life cycle analysis**

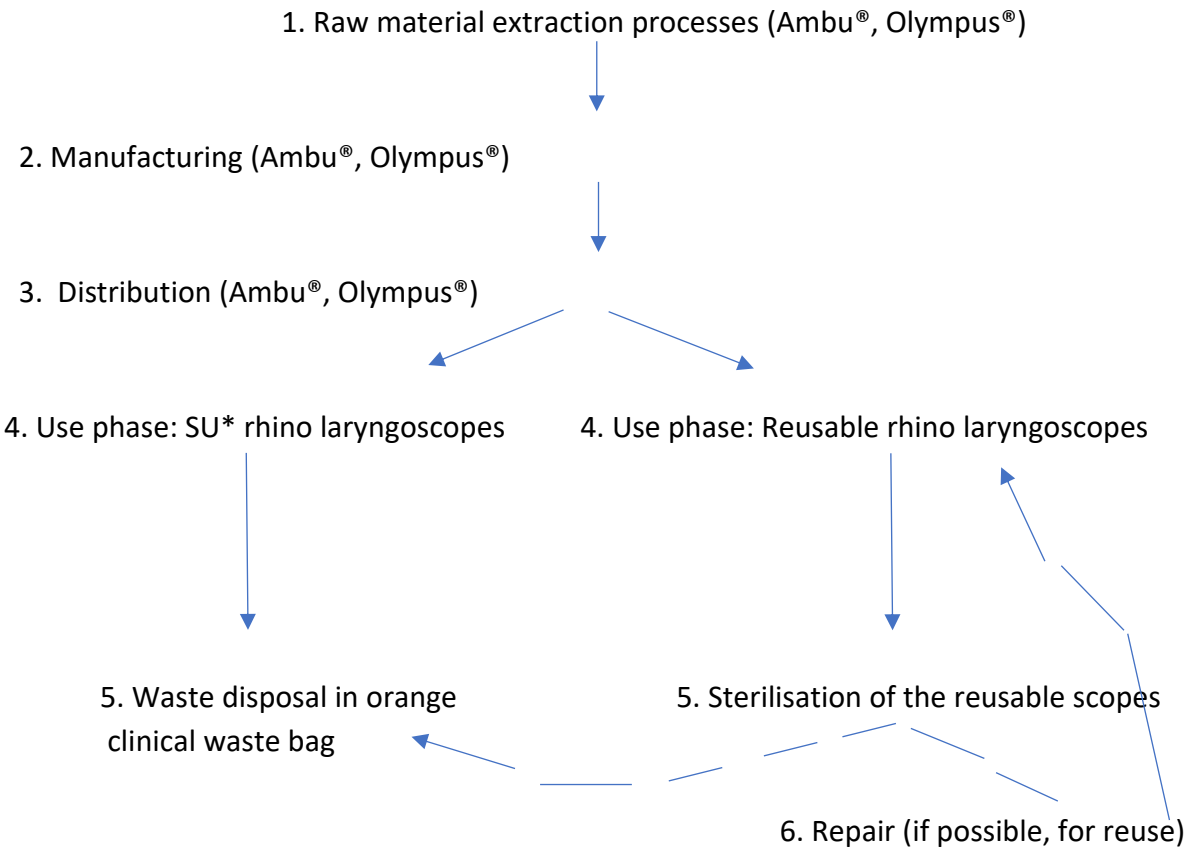
Ideally, the system boundaries within the report would include all 'material' emissions generated as a direct or indirect result of the rhino laryngoscope being produced, used and disposed of or recycled. To avoid confounding, the same primary data sources would be used across the calculations. However, this is not realistically possible in practice.

Figure A3.2: Process map steps for business to consumer goods. Source of diagram: PAS 2050:201,128[30]


*Process map steps for business-to-consumer goods*

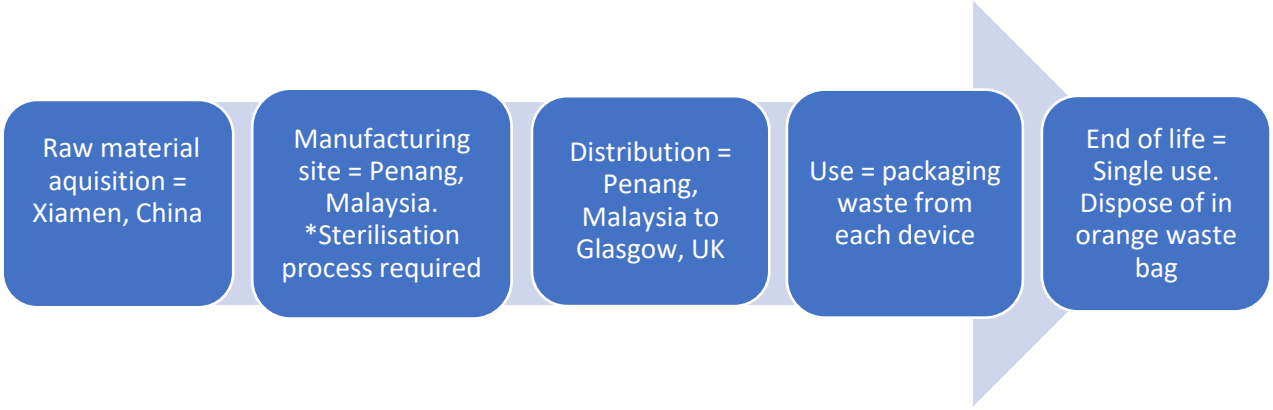
A simplified process map below (*Figure A3.3*) maps out the single use flexible rhino laryngoscope (Ambu®) and the reusable flexible rhino laryngoscope (Olympus®) steps to be included in the GHG emissions LCA comparison of the devices.

Figure A3.3: Simplified processing mapping exercise to outlines the processes involved in the LCA for both the single use and reusable devices (*single use)




Scope 3 emissions stages for the evaluation of the single use device are outlined below in Figure A3.4:

Figure A3.4. Assumed key stages, locations and processes for the single use device LCA



Scope 3 emissions key stages for the evaluation of the reusable device are outlined below in Figure A3.5:

Figure A3.5. Assumed key stages, locations and processes for the reusable device LCA


**1.18 Methodology assumptions**

Stating clearly defined methodological assumptions for the LCA of each device is essential as it can have a significant impact on the outcome of the analysis. For example, high carbon non-renewable energy sources such as coal emit three times the carbon emissions of renewable energy sources.

The assumptions used in the main analysis are as follows:

1) **Energy sources**

The methods used for generating appropriate carbon emissions include the generalisation of energy sources used in the country of analysis. For example, if manufacturing and production are located in areas where the majority of energy is sourced from non-renewable origin, it is assumed a large proportion of non-renewable high carbon energy sources (coal) are used for the raw material, manufacturing, production and distribution stages of the life cycle of both devices. It is important to use the appropriate DEFRA UK conversion factors for the generation of carbon emissions for the use phase sterilisation process required for the reusable device.

2) **Transportation process mapping**

The mode and distance of international transportation from site of manufacture to the UK was determined through discussion with product suppliers, information from supplier web sites and google maps. It is assumed that both suppliers used their own UK supplier distribution centres, i.e. goods are transported to the manufacturer's UK distribution centre first and then couriered by lorry to NHSScotland's National Distribution Centre in Larkhall,

before the goods are couriered to the site chosen for analysis (NHS GGC). Likely quantities shipped for each leg of the journey were taken into consideration for the analysis of each devices' supply chain carbon emissions.

3) **Personal protective equipment**

It is assumed that single use PPE is used during sterilisation processes in both instances, ie during the single use device manufacturing sterilisation process and during the sterilisation process for the reusable device.

4) **Sterilisation processes**

It is assumed the single use devices are sterilised using ethylene oxide before they are prepacked. Real world data for the reusable device sterilisation process was obtained from management staff in the decontamination unit at NHS GGC. This includes sterilising one device at a time in a 11 kW AER for 25 minutes. It is assumed this process is similar to the decontamination processes undertaken across NHSScotland.

5) **Sterile barrier systems**

Data regarding the process for a sterile barrier system for the reusable device was obtained from management staff in the decontamination unit at NHS GGC.

6) **Waste management processes**

Data on appropriate waste management processes for the correct disposal of both devices was obtained from local NHS waste management and the sustainability teams. It is assumed that similar processes are undertaken across NHSScotland.

### 2.19 Sensitivity analysis

Three sensitivity analyses were considered to investigate the sensitivity of the results on determinant parameters. The three alternative scenarios differed in terms of the processes and resources included in each stage of the LCA. For example, the mode of transport, the sterilisation carbon emissions for each device, and the weight of the reusable device were altered for different scenarios. The main LCA includes the weight of the reusable device as 0.82 kg and the weight of the single use device as 0.16 kg (0.18 kg including sterile packaging). A sensitivity analysis was also undertaken to calculate the impact on carbon emissions when the uses per lifetime of the reusable device was altered to half and a quarter of its potential life span of 3,920 uses (including repairs).

### 2.20 General recommendations of good practice

General recommendations of good practice to help reduce the carbon impact of healthcare provision include:

- where possible across both device life cycles, reusable PPE should be used instead of single use PPE including reusable gowns, aprons, hats, and masks[22]
- where disposable device use is absolutely necessary, maximise stock levels to reduce the levels of reordering required (and carbon emissions) per annum
- purchasers should work with industry to reduce the carbon intensity of LCA stages, for example, suppliers should ship goods by sea rather than air to significantly reduce carbon footprint
- optimise the use of automated endoscope reprocessors (AER) for the reusable device sterilisation process by cleaning two devices at once rather than one
- future purchasing decisions for AERs across NHSScotland should consider the installation of compact AERs that only require 3 KW power for each cycle.