



Ambu aScope 4 RhinoLaryngo for visualising upper airways during rhinolaryngoscopy

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Ambu aScope 4 RhinoLaryngo. It is used for visualising upper airway anatomy during rhinolaryngoscopy procedures in adults.
- The **innovative aspect** is that it is a single-use rhinolaryngoscope and so reduces the risk of cross-infection and removes the need for reprocessing, as done with reusable rhinolaryngoscopes.
- The intended **place in therapy** would be as an alternative to reusable rhinolaryngoscopes in adults needing a diagnostic or therapeutic rhinolaryngoscopy procedure.

- The **main points from the evidence** summarised in this briefing are from 3 studies (including 1 non-blinded prospective single-arm evaluation and 2 surveys). These include a total of 59 investigators and approximately 218 procedures in the UK, US and Germany. The studies show that there is potential for this technology to be easier to use and cost saving compared with existing rhinolaryngoscopes in adults.
- **Key uncertainties** around the evidence or technology are that there is a lack of clinical evidence, including comparative evidence and patient-related outcomes, as well as evidence on the environmental impact, of the Ambu aScope 4 RhinoLaryngo.
- **Experts advised** that the technology is already used extensively in practice. They also noted some possible adoption issues, specifically around potential environmental impact and uncertainty about overall costs.
- The **cost** of Ambu aScope 4 RhinoLaryngo Slim is £105 per unit (excluding VAT). The cost of Ambu aScope 4 RhinoLaryngo Intervention is £179 per unit (excluding VAT). The cost for the reusable aView 2 Advance monitor is £4,000.

The technology

The Ambu aScope 4 RhinoLaryngo (Ambu Ltd) is a sterile, flexible and single-use rhinolaryngoscope. It is used to visualise the upper airway anatomy during rhinolaryngoscopy procedures in adults. According to the company, this device can be used for acute emergency ear, nose and throat (ENT) conditions within emergency departments as well as for non-urgent ENT conditions in outpatient clinics. There are 2 designs: the Ambu aScope 4 RhinoLaryngo Slim endoscope is for nasal endoscopy and laryngoscopy, and the Ambu aScope 4 RhinoLaryngo Intervention endoscope is for therapeutic procedures such as biopsy and suction. The endoscopes need to be connected to the Ambu aView 2 Advance portable monitor to display the images. The imaging data can be sent to the hospital picture archiving and communication system (PACS) to give access from the hospital's electronic healthcare records.

Innovations

The aim of the single-use Ambu aScope 4 RhinoLaryngo is to reduce the risk of cross-infection and remove the need for complex reprocessing associated with conventional reusable rhinolaryngoscopes.

Current care pathway

Flexible nasal endoscopes are used to look inside the nose, at the back of the nose and throat, and at the voice box and the tongue. Reusable rhinolaryngoscopes are reprocessed and decontaminated before repeated use.

Population, setting and intended user

The technology is intended for people aged 18 and over having routine diagnostic and therapeutic rhinolaryngoscopy procedures. It is used for visualising the upper airways or for therapeutic rhinolaryngoscopy procedures in adults. The technology can be used for acute emergency ENT conditions within emergency departments and may also be used for ENT conditions in outpatient clinics. The device may also be used in non-traditional environments, leading to a potential increased capacity for the delivery of care.

Costs

Technology costs

The cost of Ambu aScope 4 RhinoLaryngo Slim is £105 (excluding VAT). The cost of Ambu aScope 4 RhinoLaryngo Intervention is £179 (excluding VAT). The cost for the reusable aView 2 Advance monitor is £4,000. Within the first year of purchase, the aView 2 Advance monitor is under manufacturer warranty and is replaced free of charge in the event of failure. Beyond 12 months, spare parts and new monitors are chargeable.

Costs of standard care

An evaluation and cost comparison analysis ([Mistry et al. 2020](#)) reports that in outpatient clinics, incremental costs of reusable rhinolaryngoscope eyepieces and videoscopes when compared with single-use rhinolaryngoscopes are £30 and £11. It also reports that in acute surgical units, incremental costs of reusable rhinolaryngoscope eyepieces and videoscopes when compared with single-use rhinolaryngoscopes are -£4 and -£73. The costs vary by clinical setting because the staff time needed to carry out the procedure is different in each setting.

Resource consequences

The technology has launched in the UK. This technology is routinely used by clinicians within NHS trusts. If adopted, the technology would be used in place of standard care and is not considered to need any significant changes to current infrastructure.

A potential benefit is that single-use rhinolaryngoscopes reduce the risk of cross-infection. During high-demand situations and out of hours, when there are limited resources for disinfection of equipment, a single-use option may be beneficial. There is potential to remove the complex and costly reprocessing associated with reusable rhinolaryngoscopes. A cost comparison analysis ([Mistry et al. 2020](#)) reported that single-use rhinolaryngoscopes provide a clinically comparable, potentially cost-minimising, alternative to the reusable rhinolaryngoscope for use in acute surgical assessment units.

Regulatory information

The Ambu aScope 4 RhinoLaryngo is a CE-marked class IIa device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination, and fostering good relations between people with particular protected characteristics and others. No equality issues were identified.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement for medtech innovation briefings](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Three studies reporting relevant clinical outcomes are summarised in this briefing. This comprises 1 prospective single-arm evaluation and 2 surveys. The clinical evidence and its

strengths and limitations are summarised in the overall assessment of the evidence.

Overall assessment of the evidence

Mistry et al. (2020)

Study size, design and location

UK-based, non-blinded, prospective, single-arm evaluation and cost comparison analysis, carried out over a 5-day period. The single-use rhinolaryngoscope was used on 200 occasions by a total of 16 investigators.

Intervention and comparator

Single-use rhinolaryngoscope.

Key outcomes

The study showed that 68% of investigators thought that the single-use rhinolaryngoscope was 'good' or 'very good', and 85% believed it could successfully replace the reusable rhinolaryngoscope. The study concludes that the single-use Ambu aScope 4 RhinoLaryngo provides a clinically comparable and potentially cost-minimising alternative to reusable rhinolaryngoscopes. Incremental costs of reusable rhinolaryngoscopes compared with single use were £30 and £11 in outpatient clinics and -£4 and -£73 in acute surgical assessment units.

Strengths and limitations

Although the investigators' views were positive, there were no comparisons of clinical or patient data, so it is not possible to state conclusively from the study that single-use rhinolaryngoscopes are better than the reusable rhinolaryngoscopes, without a comparative dataset. The study didn't consider investigators' learning curves or the nasal cavity structures visualised. A low level of compliance suggests that most procedures were not reported, which reduces internal and external validity. Healthcare setting and indication was not recorded on every feedback form. This is an important limitation as functionality of the reusable rhinolaryngoscope may have differed between clinical setting and between indications.

Walczak et al. (2021)

Study size, design and location

An online survey distributed to resident doctors at institutions throughout the US which use a disposable nasopharyngolaryngoscope (NPL; Ambu aScope 4 RhinoLaryngo). Cost analysis was done at a single academic centre. The survey was distributed to 109 resident doctors throughout the country.

Intervention and comparator

Ambu aScope 4 RhinoLaryngo compared against a reusable NPL.

Key outcomes

The online survey was completed by 33.9% (37/109) of resident doctors in the US who reported that the single-use Ambu aScope 4 rhinolaryngoscope was comparable to reusable rhinolaryngoscopes in ergonomics and manoeuvrability, inferior in imaging quality, superior in setup, convenient and rated better overall. The survey concluded disposable NPLs may offer an alternative option. Cost analysis favours disposable NPLs as the more cost-effective option.

Strengths and limitations

The main strength of the study was its inclusion of Ambu technology with a direct comparison to reusable NPLs. Limitations of the study include difficulty in distribution of the survey and difficulty in identifying who used the disposable NPL. It was difficult to estimate the cost of certain materials (detergents, acids and machinery for reprocessing) and so this was likely underestimated. There was also no patient data reported.

Becker et al. (2019)

Study size, design and location

Ten consecutive patients requiring rhinolaryngoscopy were examined with Ambu aScope 4 RhinoLaryngo Intervention by 6 different examiners in 18 procedures. Examiners then completed a questionnaire on image quality, manoeuvrability, ergonomics of the handle

and overall impression.

Intervention

Ambu aScope 4 RhinoLaryngo.

Key outcomes

The survey used a 5-point scale (in which 1 is very poor, 2 is poor, 3 is acceptable, 4 is good, and 5 is very good) and reported that image quality was rated 4.17, manoeuvrability 4.67, ergonomics of the handle 4.44 and overall impression 4.33. A mild nosebleed occurred in 1 procedure. Four out of 6 examiners gave positive feedback about the ease of storing pictures and videos on the monitor. The survey concluded that a flexible single-use rhinolaryngoscope can be a good alternative to conventional systems.

Strengths and limitations

The survey was specific to Ambu technology. It was also a very small study, with no patient or clinical data reported.

Sustainability

The company claims the technology has a comparable environmental impact to reusable rhinolaryngoscopes. [Sørensen et al. \(2018\)](#) compared the environmental impact of Ambu aScope 4 Broncho with reusable bronchoscopes. The study found that when 1 set of protective wear and disinfection material is used to clean 1 reusable bronchoscope, it has comparable or higher consumption of energy and material, emissions of carbon dioxide equivalents and values of resource consumption than the Ambu aScope 4. Cleaning 2 or more bronchoscopes per set makes the impact more comparable with the Ambu aScope 4.

In addition, Ambu has initiated a plastic-neutral partnership with Plastic Bank. This organisation reprocesses materials for reintroduction into the global manufacturing supply chain.

Recent and ongoing studies

[Procedural Efficiency and Organisational Impact of Rhino Laryngoscopes Procedures in](#)

Consults. ClinicalTrials.gov identifier: NCT05198219. Status: recruiting. Indication: laryngeal disease. Devices: Ambu aScope 4 RhinoLaryngo. Estimated completion date: September 2022 – results yet to be posted. Country: Denmark.

The company has said that there are non-Ambu affiliated ongoing studies which are yet to be added to ClinicalTrials.gov.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Three experts commented on this briefing. All of the experts were experienced in using single-use flexible rhinolaryngoscopes, and 2 were experienced in using Ambu aScope 4 RhinoLaryngo.

Level of innovation

Two experts said that the technology is a new concept for both diagnostic and therapeutic services. Comments from the experts included that the technology:

- opens up avenues for further endoscopic innovation and clinical research
- is a minor variation on an existing procedure and so is unlikely to alter the procedure's safety and efficacy
- is already established in practice
- is likely to replace current standard care because of its cost and clinical effectiveness, as well as patient-centric diagnostics and patient and clinician safety.

One expert said that the technology is most likely to be used as an addition to other procedures because the quality of the procedure is not as good as specialist examinations (such as laryngostroboscopy and chromoendoscopy) and procedures.

Potential patient impact

All experts said that Ambu aScope 4 RhinoLaryngo helps to avoid cross-contamination. One expert said that the connection to the electronic healthcare records is likely to lead to a speedier diagnosis and reduced anxiety for the person having the procedure. Another expert said this procedure is simpler and less convoluted, benefitting people who may find it difficult to navigate existing complex care pathways. This includes people with a developmental delay or impaired physical mobility, and older people.

Potential system impact

One expert said this technology would benefit people requiring any form of luminal navigation and visualisation of the upper airways. They said that it would also benefit people who require functional endoscopic evaluation of swallowing and voice. They said that it would benefit people who require evaluation of the airway during difficult airway endotracheal tube intubations and those who may require a nasogastric feeding tube to be passed into the oesophagus under direct vision. All experts said that the portable system is easy to use in a hospital environment, especially for bed-bound or frailer people, or people with a brain injury, as well as those who cannot attend upper airway assessments in hospital environments, such as older people.

All experts said that the procedure has the potential to change the current pathway to benefit the healthcare system. All experts said the technology allows for people to be seen in single visits, with better streamlined working. People can be routed to the appropriate specialist more quickly and so standards for faster diagnosis are met. One expert also said it would be useful in any potential future COVID-19 pandemics.

The experts differed in their thoughts on the cost of the procedure compared to standard care. One expert said the procedure would cost less than standard care because servicing and maintenance costs would be avoided. This expert also said saved costs can be redirected at upskilling healthcare professionals to carry out upper airway diagnostic endoscopy. One expert said that the cost would be the same as or less than standard care because there is no need for capital investment in camera stack systems, but another expert said that this could lead to a higher cost as the procedure will not replace existing stack systems but will be used in addition to them. Another expert referred to a study in which single-use rhinolaryngoscopes were shown to be cost-minimising compared with reusable rhinolaryngoscopes.

One expert said that changes to existing facilities would depend on the demand for endoscopy of the upper airways, which would likely increase with the uptake of this technology. Another said that there would be minimal change, apart from to the procedure for disposal.

General comments

One expert said that single-use rhinolaryngoscopes may be a little stiffer than traditional reusable rhinolaryngoscopes, but that this is compensated by them having a narrower diameter. In relation to sustainability and disposal of rhinolaryngoscopes, 1 expert said that there are company plans to recycle plastics with an industry partner but that further health economic research is needed to compare reusable and single-use rhinolaryngoscopes. All of the experts agreed on the safety and efficacy of the procedure. Two experts also flagged issues with data capture through audio and video and linkage with electronic healthcare records.

Two experts said that cost and potential environmental impact are reasons why hospital trusts may choose not to use the technology. One expert said that digital illiteracy or anxiety around using new, potentially disruptive technologies may be a problem.

All experts agree the technology could be used in clinical practice, although 1 expert said as an addition to existing reusable rhinolaryngoscopes.

Expert commentators

The following clinicians contributed to this briefing:

- Mr Taranjit Singh Tatla, consultant ear, nose and throat (ENT) and head and neck surgeon, London North West University Healthcare NHS Trust. A key opinion leader on the Ambu UK and KOL Global Insights board. Provided a consultancy service and advice to Ambu. No claim to date for consultancy activities. Academic support was received from Ambu for the ENT UK COVID-VU survey, which Mr Tatla co-authored. This included a support statistician and interpretation of data collected, as well as the peer-reviewed, open-access dissemination of research findings.

- Mr Julian McGlashan, consultant laryngologist and ENT surgeon, Nottingham University Hospitals NHS Trust. Invited to join Ambu UK and KOL Global Insights board (has not attended to date). Has given feedback on new Ambu products under development.
- Mr Muhammad Shakeel, consultant ENT and thyroid surgeon, Aberdeen Royal Infirmary, NHS Grampian. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement for medtech innovation briefings](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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