NICE National Institute for Health and Care Excellence

NICE guidance

Ambu aScope2 for use in unexpected difficult airways

Medical technologies guidance

Published: 17 July 2013
nice.org.uk/guidance/mtg14

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

1.1 The case for adopting the Ambu aScope2 for use in people with unexpected difficult airways needing emergency intubation is supported by the evidence. This shows that the Ambu aScope2 is an acceptable alternative, where a multiple-use fibre optic endoscope is unavailable. There are also advantages during replacement of dislodged tracheostomy tubes in the intensive care setting. Making the Ambu aScope2 available for use across settings is likely to improve outcomes and patient safety.

1.2 Adoption of the Ambu aScope2 is supported by cost modelling for a range of common clinical settings in which there is no multiple-use endoscope or where existing multiple-use endoscopes are not available. These settings are: isolated units, operating theatre units, and intensive care units, where the uses include the repositioning of displaced tracheostomy tubes. Although there were some uncertainties in the cost modelling, cost savings are likely in all settings modelled. The amount saved will depend on the number of intubations performed and on the number (if any) of existing multiple-use fibre optic endoscopes in use.

1.3 The details of the cost modelling and estimated cost savings for each clinical setting are described in sections 5.16–5.20. As an example of the clinical area where savings could be greatest, using the Ambu aScope2 in the intensive care setting is estimated to be cost saving (£3128 per year) when more than 700 intubations are conducted each year, when there are 2 or fewer existing multiple-use fibre optic endoscopes, and assuming that 5% of intubations are difficult.

2 The technology

Description of the technology

2.1 The Ambu aScope2 (Ambu Ltd) is a sterile, flexible, disposable device that is used to overcome difficulties with endotracheal intubation in patients with difficult airways. It is used to visualise the airway and then to aid in the placement of an endotracheal tube, either directly or through an intubating laryngeal mask. It is a portable device that can be used wherever a flexible fibre optic endoscope is needed for airway management. This may be in anaesthetic rooms, critical care or emergency departments or in other areas of hospitals where emergency airway management is undertaken. The Ambu aScope2 can also be used to aid percutaneous dilatational tracheostomy and to check the position and patency of airway devices such as endotracheal tubes, double lumen tubes and tracheostomy tubes. The Ambu aScope2 is too large to pass through an Aintree catheter if one is being used.

2.2 The Ambu aScope2 system consists of 2 components – a single-use aScope (endoscope) and an accompanying aScope monitor for displaying the images. These are supplied together. The Ambu aScope2 uses video camera technology to create the image which is displayed on the 640×480 pixel aScope monitor. The portable monitor indicates the rechargeable battery capacity (claimed maximum 2 hours) and also has a video output to transfer images to a larger monitor or recording device. The 2 components are used together and must therefore be available in the same location for the system to be effective. The single-use endoscopes are supplied sterile and ready for use. The monitor is re-usable. During procedures, the monitor can be powered by either battery or mains and is designed to be connected to the mains to recharge at other times.

2.3 The Ambu aScope2 has a Luer channel of 0.8 mm diameter that can be used for injecting topical anaesthetic or, by attaching a flow connector, to apply an air or oxygen flow. The purpose of this is to direct secretions away from the tip of the Ambu aScope2; it is not designed for oxygenation or ventilation or therapeutic procedures such as biopsy. The Ambu aScope2 also has a polymer-clearing membrane (ClearLens) that covers the lens, which eases removal of secretions from the lens.

2.4 The cost of Ambu aScope2 stated in the sponsor's submission was

£179 (including VAT) per single-use endoscope. The monitor had a list price of £799 but was provided to NHS organisations free of charge with 5 Ambu aScope2 devices. Each monitor has a 12-month warranty and each single-use aScope2 has a 3-year shelf life.

2.5 The claimed benefits of Ambu aScope2 in the case for adoption presented by the sponsor are:

- Improved outcomes in emergencies and unexpected scenarios of difficult airway management due to the immediate availability of a sterile fibre optic endoscope that does not need calibration.
- Improved safety for patients with tracheostomies due to a reduction in morbidity and mortality associated with the failure to re-establish ventilation if the tracheostomy tube is displaced in a patient with a difficult airway.
- Reduced risk of cross-infection from contaminated multiple-use fibre optic endoscopes.
- Reduced costs associated with an improvement in clinical outcomes in emergencies and unexpected scenarios of difficult airway management including patients with tracheostomies.
- Reduced costs associated with a reduction in the incidence of cross-infection.
- Reduced time and resources spent on cleaning and repair and internal transfer between hospital departments as the Ambu aScope2 is delivered sterile and ready to use.

Current management

2.6 Placement of an endotracheal tube guided by a multiple-use fibre optic endoscope is the gold standard for managing difficult intubation. Using a fibre optic endoscope or a video scope allows visualisation of the vocal cords followed by accurate placement of an endotracheal tube.

2.7 The Difficult Airways Society guidelines (Henderson et al., 2004) outline the clinical pathway for unexpected difficult tracheal intubation during routine induction of anaesthesia in adults. The guidelines describe the initial tracheal intubation plan (Plan A) and the secondary tracheal intubation plan (Plan B).

Plan A describes direct laryngoscopy as the initial standard technique for intubation. Plan B is recommended after 4 failed attempts at intubation. This involves placement of a supraglottic airway device: if that is successfully achieved and the patient can be ventilated, then ventilation may be maintained via the supraglottic airway device, or else tracheal intubation can be attempted with the aid of a multiple-use fibre optic endoscope.

2.8 Tracheostomy is a surgical procedure performed on a patient's neck to create an airway directly into the trachea. The placement of a percutaneous tracheostomy tube can be guided by a multiple-use fibre optic endoscope. Percutaneous tracheostomy has now replaced the traditional open operation and is considered standard technique in many intensive care units worldwide. The use of an endoscope during percutaneous tracheostomy enables the user to visualise the procedure from within the trachea, and so prevent the needle and dilators from penetrating the back of the trachea as well as ensuring that the tracheostomy tube is correctly placed.

3 Clinical evidence

Summary of clinical evidence

3.1 Full details of all clinical outcomes considered by the Committee are available in the assessment report overview.

3.2 The key clinical outcomes presented in the decision problem for the Ambu aScope2 in patients undergoing emergency intubation with difficult airways were:

- incidence of delayed or failed intubation
- clinical consequences associated with delayed or failed intubation:
  - death
  - hypoxic brain injury
  - intensive care unit length of stay
  - hospital length of stay
- incidence of contamination and cross-infection
- device-related adverse events.

3.3 The clinical evidence for the Ambu aScope2 was based on 11 studies. These comprised 4 published and 2 unpublished randomised controlled trials and 5 published case series reports. Three of the studies evaluated the Ambu aScope2 and 8 evaluated the Ambu aScope, which is the immediate predecessor device.

Patient-based randomised studies

3.4 In a randomised controlled trial, Kristensen (2013) compared the Ambu aScope against a multiple-use fibre optic endoscope in 60 patients with expected normal airways and expected difficult airways. All patients were successfully intubated. The median total intubation time, including the administration of local anaesthetic, was 278 seconds for the Ambu aScope and 234 seconds for the multiple-use endoscope. Although this was statistically significant in favour

of the multiple-use fibre scope (p<0.03), the investigators concluded that it was not clinically important because the difference was likely to be less than the hypothesised non-inferiority margin of 120 seconds.

3.5 In a randomised controlled trial Schoettker et al. (2012) compared Ambu aScope2 against a multiple-use fibre optic endoscope in 100 patients with difficult airways (simulated by a semi-rigid cervical collar). The use of the Ambu aScope2 was associated with a longer time to intubation compared with the fibre optic endoscope (69.5 versus 49.5 seconds, mean difference of 20 seconds, p<0.05). Overall, the image quality provided by the Ambu aScope2 was lower than with the fibre optic endoscope although the quality was judged subjectively to be excellent in 24 out of 50 cases and acceptable in another 22 out of the 50 cases. Two attempts were needed in 4 out of 50 cases with the Ambu aScope2 compared against 8 out of 50 for the multiple-use fibre optic endoscopes. There was a 100% intubation success rate in less than 4 minutes for both devices.

Manikin-based studies

3.6 Piepho et al. (2010) conducted a randomised controlled trial that compared the Ambu aScope against a multiple-use fibre optic endoscope by examining the performance of 21 anaesthetists during an easy and a difficult intubation simulation in a manikin. The mean time to intubation for difficult airways was 63 seconds with the Ambu aScope compared against 56 seconds for the comparator (mean difference 7 seconds; 95% confidence interval [CI] −11.66 to 25.66), which was statistically non-significant. In the difficult intubation scenario, the intubation success rate was lower when using the Ambu aScope compared against using the fibre optic endoscope (67% versus 81%, p=0.02), which the authors concluded was mainly caused by the low image quality. Overall the Ambu aScope scored a rating of 'satisfactory' compared against a rating of 'good' for the multiple-use fibre optic endoscope.

3.7 Vijayakumar et al. (2011) conducted a randomised controlled trial that compared the manoeuvrability and ease of use of the Ambu aScope against a multiple-use fibre optic endoscope in manikins set to simulate difficult fibre optic endoscope placement of an endotracheal tube. The mean time to task completion was 63 seconds for the Ambu aScope compared against 53 seconds for the fibre optic endoscope (p=0.08). The estimated 95% CI (1.26 to 18.74) did

not overlap with a difference of more than 30 seconds between the Ambu aScope and the multiple-use fibre optic endoscope (which was considered to be a clinically important difference). The mean number of tip surface collisions was slightly higher with the Ambu aScope at 2.7 compared against the fibre optic endoscope at 2.5. The ease of use impression was rated at 65 for the Ambu aScope compared against 77 for the fibre optic endoscope (100 being extremely easy to use).

3.8 A study by Scutt et al. (2011) compared the Ambu aScope against a multiple-use fibre optic endoscope in 2 simulated settings. In the first setting, 22 participants (all who were familiar with, or skilled in, fibre optic intubation) performed paired oral and nasal fibre optic intubations in 3 different airway training manikins (a total of 264 intubations). In the second setting 21 participants intubated 1 airway trainer manikin using 3 supraglottic airway devices: classic and intubating laryngeal mask airways, and i-gel (a total of 66 intubations). For each intubation the time to intubate was recorded from starting the endoscopy with a preloaded tracheal tube to the first lung ventilation. In both settings, time to intubation was similar between the Ambu aScope and the multiple-use fibre optic endoscope (p=0.18). Use of the Ambu aScope was associated with more reported problems than the multiple-use fibre optic endoscope (32% versus 17% respectively, p=0.04), including difficulties with manipulation, railroading tubes and picture quality. The Ambu aScope was rated a mean score of 7.7 versus 8.5 for the multiple-use endoscope (10 being the highest in terms of ease of use and image quality). In the first setting, 88% of intubations were successful on the initial attempt. In the second setting, there were 4 failures at the first intubation attempt in 126 attempts (3%).

Small case series

3.9 Piepho et al. (2010) described a case series in which the Ambu aScope was used in 5 patients with expected and unexpected difficult airways. Typical landmarks such as the uvula, tongue, epiglottis and larynx were adequately identified in all 5 patients using the Ambu aScope. Intubations via a nasal route were performed in 3 awake patients and advancing the tracheal tube was smooth and easy in these patients. The Ambu aScope was also used in 2 patients via an oral route and in 1 of these patients, airway secretions obstructed vision on the monitor. This was resolved following suctioning and cleaning of the Ambu aScope lens using a sterile swab. Tracheal intubation was successfully achieved in all

5 patients.

3.10 In a case series of 10 patients by Pujol et al. (2010), 9 of 10 intubations with the Ambu aScope were performed and completed without incident. Intubation could not be accomplished in 1 patient. Tube insertion was considered easy in 8 patients, easy but with some manoeuvres needed in 1 patient and impossible in 1 patient. In all 10 patients, a complete view of the glottis was obtained. The image quality was considered adequate in 5 patients and poor in another 5 patients. Fogging of the lens occurred in 6 patients and was cleared easily by gently touching the airway mucosa in 4 patients and by removing the endoscope and cleaning the tip in the other 2 patients. In 2 cases there were secretions that could not be suctioned but they did not result in difficult tube insertion.

3.11 Jamadarkhana et al. (2011) described a case series of 10 patients in whom Ambu aScope2 was used to perform percutaneous dilatational tracheostomy. The average time to set up the endoscope and monitor was less than 5 minutes. The procedure time from needle puncture of the trachea to tracheostomy tube placement ranged from 5 to 10 minutes. All the anaesthetists reported easy handling and manoeuvrability because Ambu aScope2 was light-weight. They scored the clarity and quality of endoscopic view to be between 8 and 10 out of a maximum of 10. No complications were reported during use of the Ambu aScope2.

3.12 In a case series of 10 patients needing a percutaneous tracheostomy, Perbet et al. (2011) found that 7 of the 10 operators rated the Ambu aScope 'very satisfactory', and 3 rated it as 'satisfactory' across all parameters. The presence of the screen was deemed useful in all of the cases.

3.13 Vincent et al. (2011) described a case series of 8 patients with expected difficult airways. All 8 patients were successfully intubated while awake using the Ambu aScope2; 7 by the nasal route and 1 orally. The mean time it took to position the endoscope to visualise the carina was 254.5 seconds, with the shortest time taken being 62 seconds. The mean time for confirming the position of the tube in the trachea after visualising the carina was 51.5 seconds. Of the 8 operators, 6 reported an excellent view of anatomical landmarks, and 2 reported the view as poor, but adequate for intubating the trachea. The mean score for manoeuvrability was 6.8 (range 3–9 with 10 classed as extremely manoeuvrable) and the mean score for usefulness of the endoscope was

7.4 (3–10 with 10 classed as extremely useful).

Unpublished patient-based study

3.14 A study by Lenhardt et al. (2011) has been published as a poster presentation but the Committee considered detailed findings presented as academic-in-confidence data. The randomised controlled trial compared the Ambu aScope against a pre-formed stylet (multiple-use fibre optic endoscope) in 140 patients with expected difficult airways. All patients were successfully intubated and no serious complications were encountered. The time to intubation was similar for the use of the Ambu aScope and a pre-formed rigid stylet (95±63 seconds versus 104±100 seconds, p=0.6). The rating for ease of use was found to be similar for the Ambu aScope and the pre-formed stylet.

Adverse events

3.15 No adverse event reports relating to the Ambu aScope were reported in a search of the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. The Medicines and Healthcare products Regulatory Agency (MHRA) has not received any reports of adverse events relating to the Ambu aScope2.

Committee considerations

3.16 The Committee noted that the clinical evidence was from studies in manikins or patients with expected (or simulated) difficult airways. There were no controlled trials in patients with unexpected difficult airways but the Committee recognised the considerable difficulties of conducting such studies.

3.17 The Committee judged that the studies provided evidence that the Ambu aScope2 was an acceptable alternative to multiple-use fibre optic endoscopes. In addition, the Committee received expert advice that although the Ambu aScope2 has poorer image quality than standard multiple-use fibre optic endoscopes and its lens needs cleaning during use, it is an acceptable alternative in situations in which a multiple-use fibre optic endoscope is not available.

3.18 The Committee noted that in the studies in which manikins were used, the anaesthetists had previous experience of using standard multiple-use fibre optic

endoscopes, but lacked experience of using the Ambu aScope. Therefore, the longer time to intubation observed for the Ambu aScope might have been influenced by the anaesthetists' lack of experience in using the device.

3.19 The Committee was mindful that potential consequences of failed intubation include severe brain injury and death. It accepted that the immediate availability of the Ambu aScope2 in situations where multiple-use fibre optic endoscopes are not available may lower the risk of these consequences occurring. The Committee noted that clinical evidence on these outcomes was not available.

3.20 The Committee considered the fact that the Ambu aScope (the predecessor of the Ambu aScope2) was used in 8 of the 11 studies presented. It judged that the data derived from these studies were relevant and valid for this submission because the Ambu aScope2 has the same mode of action and design as the Ambu aScope, but with certain modifications which were likely to improve, rather than impair, its performance.

4 NHS considerations

System impact

4.1 The sponsor claimed that using the Ambu aScope2 would lead to an improvement in clinical outcomes. This may be relevant in emergencies and unexpected scenarios of difficult airway management, including those patients with tracheostomies.

4.2 The sponsor claimed that an improvement in clinical outcomes by reducing the risk of severe brain injury and death may lead to overall costs being reduced.

4.3 The sponsor claimed that because the Ambu aScope2 is single use, there would be a decrease in costs associated with a reduction in the incidence of cross-infection.

4.4 The sponsor claimed that using the Ambu aScope2 would reduce the time and resources spent on cleaning and repair of multiple-use fibre optic endoscopes, and on their internal transfer between hospital departments, because the Ambu aScope2 is delivered sterile and ready to use.

Committee considerations

4.5 The Committee noted that multiple-use fibre optic endoscopes may be located on a different floor or in a different building to that in which emergency airway management is needed. Therefore, it may not be possible to obtain a fibre optic endoscope in time to use it in an emergency. The Committee considered that the main potential benefit of the Ambu aScope2 was its immediate availability for use in locations remote from fibre optic endoscopes. The Committee noted that the Ambu aScope2 may therefore be of particular value in a variety of clinical settings such as accident and emergency departments, isolated units within large hospitals and remote hospitals that have no fibre optic endoscopes.

4.6 The Committee received expert advice that multiple-use fibre optic endoscopes are often damaged in the intensive care unit when they are being used during percutaneous tracheostomy; costly repair or even replacement is then necessary. Use of the Ambu aScope2 has advantages in this scenario because the scopes are single use and damage to them is therefore of significantly less

consequence.

4.7 The Committee received expert advice that in clinical settings where difficult intubations may be encountered but multiple-use fibre optic endoscopes are not available, a delay in accessing a fibre optic endoscope may have important clinical consequences including brain injury or death. The Committee noted that no published evidence or clinical studies had been submitted to support this.

4.8 The Committee considered that using the Ambu aScope2 in the clinical settings described in 4.7 could lead to an improvement in clinical outcomes but it noted that no evidence had been submitted that overall costs would be reduced.

4.9 The Committee noted that no evidence was presented to support the claim that there would be a decrease in costs associated with a reduction in the incidence of cross-infection.

4.10 The Committee acknowledged the possibility that using the Ambu aScope2 would reduce the time and resources spent on cleaning and repair of multiple-use fibre optic endoscopes, but limited evidence was submitted to support this claim.

5 Cost considerations

Cost evidence

Published evidence

5.1 The sponsor identified 3 published economic studies that focused on estimating the cost of the Ambu aScope or the multiple-use fibre optic endoscope. No modelling of the cost consequences of adoption was included in the studies.

Sponsor cost model

5.2 The sponsor submitted a de novo cost analysis for Ambu aScope2 that estimated the costs and consequences associated with the use of the Ambu aScope2 and multiple-use fibre optic endoscopes. The analysis was from an NHS and personal social services perspective. Full details of all cost evidence and modelling considered by the Committee are available in the assessment report overview.

5.3 The sponsor submitted a base-case analysis for 3 scenarios: unexpected difficult intubation in the operating theatre units, unexpected difficult intubation in the intensive care unit, and replacing a dislodged tracheostomy tube in the intensive care unit. The model for unexpected difficult airways needing emergency intubation separated patients according to those who had successful intubations and those who had delayed or failed intubations; the latter group were separated further according to those who survived and had no brain injury, and those with brain injury or who died. A separate model was designed for replacing dislodged tracheostomy tubes because this is not managed in the same way as an intubation and is associated with different costs and outcomes. The model for dislodged tracheostomy tubes separated patients into those who were successfully managed, those who had extended intensive care unit stay and those with brain injury or who died. The analysis reported the costs associated with equipment and clinical outcomes, which were delayed or failed intubation and the replacement of dislodged tracheostomy tubes.

5.4 The sponsor's base-case analysis included several key assumptions:

- The number of procedures performed per year with multiple-use fibre optic endoscopes was 150.

- The number of multiple-use endoscopes available was 5.
- The multiple-use fibre optic endoscope cost (including weighted costs including stack systems, cameras and so on) was £12,105.
- The Ambu aScope2 cost per endoscope with monitor was £179 (including VAT).
- The rate of intensive care unit admission or prolongation of stay was 74% for people who have had a failed intubation and 75% for people who have had a dislodged tracheostomy tube replaced.
- The cost of the intensive care unit per day was £1321.

5.5 The model for unexpected difficult intubations had the following assumptions:

- The rate of delayed or failed intubation when using multiple-use fibre optic endoscopes in the operating theatre units was 6.25%.
- The rate of delayed or failed intubation when using multiple-use fibre optic endoscopes in the intensive care unit was 16.6%.
- The average intensive care unit length of stay was 6.2 days.
- The rate of brain injury or death in patients who had difficult intubations and in whom intubation has failed was 28%.
- The reduction in risk of delayed or failed intubation leading to patient harm with the Ambu aScope2 was 10%.

5.6 The model for dislodged tracheostomies had the following assumptions:

- The rate of brain injury or death because of dislodged tracheostomy was 13%.
- The average intensive care unit length of stay was 15.4 days.
- The reduction in risk of dislodged tracheostomy leading to patient harm with Ambu aScope2 was 10%.

5.7 The sponsor's base-case analysis estimated the incremental cost saving of the Ambu aScope2 compared against multiple-use fibre optic endoscopes to be £30 per intubation for equipment and staff costs only. This was consistent across the 3 settings. If the Ambu aScope2 was used instead of a multiple-use endoscope and if the equipment and staff costs and the modelled costs

associated with hospitalisations were included, then:

- for unexpected and difficult intubation in the operating theatre units there are potential incremental cost savings of £68 per patient
- for unexpected difficult airways in the intensive care unit there are potential incremental cost savings of £130.70 per patient
- for dislodged tracheostomy there are potential incremental cost savings of £1555.80 per patient.

5.8 A deterministic sensitivity analysis explored parameter uncertainty and the effect of these changes on the cost of the Ambu aScope2. The parameters included the failure rate of intubation, the reduced risk rates of failed intubation with the Ambu aScope2, the length of hospitalisation and the costs associated with multiple-use fibre optic endoscopes. The sensitivity analysis showed that the findings were responsive to the parameter changes in all 3 clinical settings. The Ambu aScope2 remained cost saving in most scenarios, with the exceptions being long equipment lifetime or a substantially low equipment cost for the multiple-use fibre optic endoscope

5.9 The External Assessment Centre carried out additional analyses to examine the impact of changing the following parameters of the sponsor's base case:

- Rate of delayed intubation in patients with unexpected difficult intubations in the operating theatre units and intensive care units for multiple-use fibre optic endoscopes (10%).
- Rate of harm needing extended hospital stay in patients with difficult intubations when intubation was delayed (50%).

5.10 The External Assessment Centre's base-case analysis in unexpected difficult intubation in an operating theatre unit indicated a cost saving of £401 when using the Ambu aScope2. In unexpected difficult intubation in an intensive care unit, the mean cost per patient when using the Ambu aScope2 was £1185 and the mean cost of a multiple-use fibre optic endoscope was £1524. This indicates a cost saving of £339 when using an Ambu aScope2 in this scenario. The External Assessment Centre stated that the results were based on clinical expert opinion and the sponsor's assumptions, and the model was subject to uncertainty. After reviewing the sponsor's de novo model (see section 5.21), the

Committee asked for further information on the cost consequences using a different model structure, assumptions and parameters.

External Assessment Centre cost model

5.11 The sponsor's de novo cost analysis modelled a scenario in which multiple-use fibre optic endoscopes were completely replaced by the Ambu aScope2. It did not consider the cost consequences of using the Ambu aScope2 if both multiple-use fibre optic endoscopes and the Ambu aScope2 were available. The External Assessment Centre was therefore asked to carry out additional analyses to estimate any potential cost savings of purchasing the Ambu aScope2 in different settings:

- in small hospital units that do not have access to any multiple-use fibre optic endoscopes for unexpected difficult airway management
- in addition to the existing stock of multiple-use fibre optic endoscopes in operating theatre units and intensive care units for unexpected difficult intubations and displaced tracheostomy tubes.

5.12 The External Assessment Centre modeled costs in 5 clinical settings:

- an isolated hospital unit
- an obstetric unit
- an operating theatre unit
- an intensive care unit
- displaced tracheostomy tubes (in an intensive care unit).

All of the above settings are of indeterminate size. For example, an operating theatre unit is likely to consist of more than 1 operating theatre but the modelling is based on the number of intubations within each unit rather than of the size of the unit. A displaced tracheostomy tube is not a clinical setting and is not specific to an intensive care unit but for the purposes of the cost modelling this procedure has been classed as a clinical setting.

Potential cost savings were considered from purchasing:

- 1 or more Ambu aScope2 devices for use in managing unexpected difficult intubation in a specified clinical setting with no multiple-use fibre optic endoscopes available
- 1 or more Ambu aScope2 devices for use in managing unexpected difficult intubation in a specified clinical setting with 1 or more multiple-use fibre optic endoscopes available
- 1 or more Ambu aScope2 devices for use in managing displaced tracheostomy tubes in an intensive care unit with 1 or more multiple-use fibre optic endoscopes, but where none of these endoscopes may be immediately available.

5.13 The economic model was used to evaluate the cost savings of purchasing the Ambu aScope2 for hospital units that do not have access to multiple-use fibre optic endoscopes. In these hospital units, it was assumed that, if an Ambu aScope2 was available, it would be used if and only if an unexpected difficult intubation occurred. Unexpected difficult intubations were therefore the entry point into the decision tree. The model was also used to evaluate purchasing the Ambu aScope2 as an addition for those hospital units that do have access to multiple-use endoscopes. These hospital units are likely to have a high throughput of patients needing intubation (for example, a busy operating theatre) and/or a high probability of expected difficult intubations. For modelling purposes, the number of multiple-use endoscopes was considered fixed for each clinical setting to allow the model to focus on the benefit of purchasing Ambu aScope2s as an addition to existing multiple-use endoscopes. The number of unexpectedly difficult intubations arising for which there was no multiple-use endoscope available was modelled as a function of the number of multiple-use endoscopes, numbers of intubations carried out in the unit, and multiple-use endoscope non-availability (which was modelled using a queuing simulation). Difficult intubation events occurred at random intervals according to a Poisson process.

5.14 There were uncertainties in several parameters used in the cost modelling, often caused by there being limited or no clinical data to support the assumptions. Cost savings were considered likely in all the clinical settings that were modelled, but these depended on the number of intubations performed and on the number (if any) of existing multiple-use fibre optic endoscopes.

5.15 The base-case analysis of all of the clinical settings showed that the potential cost savings from purchasing the Ambu aScope2 came from using it when

multiple-use fibre optic endoscopes were not available, therefore avoiding the consequences of failed intubation such as severe brain injury. It was assumed that an unexpected difficult intubation arises on average 6 times per 1000 intubations.

5.16 The base-case analysis of using the Ambu aScope2 in an isolated hospital unit assumed 300 intubations per year and that no multiple-use fibre optic endoscopes were available. The cost saving per year was £749 per unit if the cost of the monitor was excluded and £653 if it was included. The number of intubations per year above which purchasing a bundle of 5 Ambu aScope2s was cost saving was 95 if the monitor was excluded and 115 if the monitor was included.

5.17 Two base-case analyses were performed for using the Ambu aScope2 in an obstetrics unit: one assumed 400 intubations per year and no multiple-use fibre optic endoscopes, and the second analysis assumed 400 intubations per year and 1 multiple-use endoscope. If there were no multiple-use endoscopes, the cost saving per annum was £1452 if the cost of the monitor was excluded and £1356 if it was included. If there were no multiple-use endoscopes, the number of intubations per year above which purchasing a bundle of 5 Ambu aScope2s was cost saving was 80. If a multiple-use endoscope was available then the Ambu aScope2 was estimated to be cost incurring unless a minimum of 500 intubations per year were done in the unit.

5.18 The base-case analysis for using the Ambu aScope2 in operating theatre units assumed that there were 2 multiple-use fibre optic endoscopes and that 1000 intubations per year were conducted. Based on this, the Ambu aScope2 was considered to be cost incurring by £203 per unit per year if the cost of the monitor was excluded and £299 if it was included. The number of intubations per year above which purchasing a bundle of 5 Ambu aScope2s was cost saving was 1250 if the monitor was excluded and 1350 if the monitor was included.

5.19 The base-case analysis for using the Ambu aScope2 in intensive care units assumed that there were 2 multiple-use fibre optic endoscopes and 700 intubations per year. Two assumptions considering the probability of difficult intubation were presented: 20% and 5%. If the probability of difficult intubation was 20%, the cost saving per year was £3219 if the cost of the

monitor was excluded and £3123 if it was included. If the probability of difficult intubation was 5%, the cost saving per year was £3128 if the cost of the monitor was excluded and £3031 if it was included. The number of intubations per year above which purchasing a bundle of 5 Ambu aScope2s was cost saving was 50–100 with 20% probability and 250–300 with 5% probability.

5.20 The base-case analysis for using the Ambu aScope2 to aid the replacement of displaced tracheostomy tubes assumed a displacement rate of 15% per year for an intensive care unit with 2 multiple-use fibre optic endoscopes. For a base case of 200 tracheostomies per year, the cost saving per year was £5281 per unit if the cost of the monitor was excluded and £5185 if it was included. The number of tracheostomies per year above which purchasing a bundle of 5 Ambu aScope2s was cost saving was 70.

Committee considerations

5.21 The Committee considered the sponsor's economic analysis in which the Ambu aScope2 completely replaced multiple-use fibre optic endoscopes in operating theatre units and intensive care units. It noted that the sponsor's model did not consider the cost consequences of using the Ambu aScope2 if both the multiple-use endoscopes and the Ambu aScope2 are available. The Committee received advice from several clinical experts that a multiple-use endoscope would, where available, be preferred by clinicians, and concluded that the sponsor's model was not realistic. The Committee also considered that there were too many uncertainties in the sponsor's economic model to use the outcomes as the basis to make recommendations.

5.22 The Committee requested further modelling, which was carried out by the External Assessment Centre, to establish any potential cost savings of purchasing the Ambu aScope2 in 5 clinical settings. This modelling considered the cost consequences for 2 scenarios: using the Ambu aScope2 where multiple-use endoscopes are not available for use in a clinical setting; and using the Ambu aScope2 where multiple-use endoscopes are normally available in a clinical setting but for some reason are inaccessible. The Committee judged that if the Ambu aScope2 was available for use, there are likely to be cost savings in all the settings modelled, based on the following assumptions about the number of intubations or tracheostomies performed each year:

- Isolated hospital unit with no multiple-use endoscopes: 95 intubations.
- Obstetrics unit with no multiple-use endoscopes: 80 intubations.
- Obstetrics unit with 1 multiple-use endoscope: 500 intubations.
- Operating theatre unit with 2 multiple-use endoscopes: 1250 intubations.
- Intensive care units with 2 multiple-use endoscopes: 50 intubations (20% difficult intubation probability) and 250 intubations (5% difficult intubation probability).
- Replacement of displaced tracheostomy tubes (assuming a 15% per year displacement rate) in an intensive care unit with 2 multiple-use endoscopes: 70 tracheostomies.

5.23 The Committee noted that the analyses showed specific advantages for the Ambu aScope2 in the replacement of displaced tracheostomy tubes (section 4.6). The Committee accepted expert advice that multiple-use fibre optic endoscopes are often damaged in the intensive care unit when they are used during tracheostomy replacement. The modelling assumed that there were 2 existing multiple-use endoscopes and that the Ambu aScope2 is used when a multiple-use endoscope is unavailable. Combining the described advantages with its other use in intensive care units, the Committee judged that the Ambu aScope2 has the potential for most cost savings in intensive care units.

5.24 The Committee recognised uncertainties in a number of the parameters in the External Assessment Centre's economic model. The Committee noted that adverse events are rare but that some of these events, such as hypoxic brain damage, may result in considerable costs. It accepted that the cost modelling provided by the External Assessment Centre took account of this. The cost modelling was based on overall risks in the NHS and it should be noted that cost consequences may vary between units.

5.25 The Committee noted that the External Assessment Centre's economic model was based on assumptions of a certain number of intubations per year. It recognised that most hospitals in England have been designed with several operating theatres adjacent to each other (that is, operating theatre units) with shared availability of multiple-use fibre optic endoscopes. The numbers of intubations performed annually in these operating theatre units typically far exceeds the threshold number determined from the cost modelling. The Committee therefore considered that, when this is the case, the cost savings will

be greater than those estimated.

5.26 The Committee was also advised that in certain situations in which a multiple-use fibre optic endoscope is not available, planned operations may be cancelled. This can result in unused operating theatre unit time, and increased length of stay or readmission for patients, leading to additional costs. The Committee considered this was an additional reason that the cost savings associated with introducing the Ambu aScope2 to operating theatre units may have been underestimated.

6 Conclusions

6.1 The Committee concluded that the evidence shows that the Ambu aScope2 is an acceptable alternative when a multiple-use fibre optic endoscope is not available to manage unexpected difficult endotracheal intubation and displaced tracheostomies.

6.2 The Committee concluded that, although some cost model parameters were uncertain, the availability of the Ambu aScope2 in isolated hospital units, obstetric units, operating theatre units and intensive care units is likely to be cost saving.

6.3 The Committee considered that use of the Ambu aScope2 has particular advantages for replacing dislodged tracheostomy tubes in intensive care units, with potential for significant cost savings in this setting.

6.4 The Committee considered that, because of the serious clinical consequences of inadequate management of unplanned difficult airways, patient safety would be improved by the adoption of the Ambu aScope2 in all clinical settings studied, particularly in isolated hospital units where there is currently no access to any endoscope.

7 Committee members and NICE lead team

Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)
Consultant Vascular Surgeon, Royal Devon and Exeter Hospital

Dr Peter Groves (Vice Chair)
Consultant Cardiologist, Cardiff and Vale NHS Trust

Professor Dilly Anumba
Chair of Obstetrics and Gynaecology/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

Ms Susan Bennett
Lay member

Professor Bipin Bhakta (until April 2013)
Charterhouse Professor in Rehabilitation Medicine and NHS Consultant Physician, Rehabilitation Specialist, Leeds Institute of Molecular Medicine

Dr Keith Blanshard
Consultant Interventional Radiologist, Leicester Royal Infirmary

Mr Matthew Campbell-Hill
Lay member

Professor Daniel Clark

Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Professor Tony Freemont
Professor of Osteoarticular Pathology, University of Manchester

Professor Peter Gaines
Consultant Vascular Interventional Radiologist, Sheffield, Vascular Institute and Sheffield Hallam University

Professor Shaheen Hamdy
Professor of Neurogastroenterology, University of Manchester

Dr Jerry Hutchinson
Independent Medical Technology Advisor, Independent

Dr Cynthia Iglesias
Health Economist, University of York

Professor Mohammad Ilyas
Professor of Pathology, University of Nottingham

Dr Greg Irving
General Practitioner, University of Liverpool

Dr Eva Kaltenthaler
Reader in Health Technology Assessment, ScHARR, University of Sheffield

Dr Paul Knox
Reader in Vision Science, University of Liverpool

Mrs Jacqui Nettleton
Programme Director, Commissioning, Western Sussex Hospitals NHS Trust

Professor Brian J Pollard
Professor of Anaesthesia, University of Manchester. Consultant Anaesthetist, Central Manchester University Hospitals

Mr Brian Selman

Managing Director, Sectra & Co

Professor Wendy Tindale
Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Allan Wailoo
Professor of Health Economics, School of Health and Related Research (ScHARR), University of Sheffield

Dr Janelle Yorke
Senior Lecturer and Researcher in Nursing, University of Manchester

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

Jo Burnett
Technical Analyst

Sally Doss
Technical Adviser

Dr Alistair McNarry and Dr Brendan McGrath
Lead Expert Advisers

Professor Anthony Freemont
Non-Expert MTAC Member

Professor Richard Lilford
External Assessment Centre Representative

Dr Carole Cummins
External Assessment Centre Representative

Samantha Burn

External Assessment Centre Representative

Amanda Chapman
External Assessment Centre Representative

8 Sources of evidence considered by the Committee

The External Assessment Centre report for this assessment was prepared by Birmingham and Brunel consortium:

- Shihua Zhu, Fujian Song, Guiqing Lily Yao et al. Ambu aScope2 in unexpected difficult airways management. (August 2012)
- Samantha Burn, Amanda Chapman, Zulian Liu et al. Ambu aScope2 in unexpected difficult airways management. (February 2013)

Submissions from the following sponsor:

- Ambu Ltd

The following individuals gave their expert personal view on Ambu aScope2 by providing their expert comments on the draft scope and assessment report.

- Dr Andrew Bentley, ratified by Association of Anaesthetists of Great Britain and Ireland – clinical expert
- Dr Ali Diba, ratified by Association of Anaesthetists of Great Britain and Ireland – clinical expert
- Dr Brendan McGrath, ratified by the Royal College of Anaesthetists – clinical expert
- Dr Alistair McNarry, ratified by Association of Anaesthetists of Great Britain and Ireland – clinical expert

The following individuals gave their expert personal view on Ambu aScope2 in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Dr Andrew Bentley, ratified by Association of Anaesthetists of Great Britain and Ireland – clinical expert
- Dr Ali Diba, ratified by Association of Anaesthetists of Great Britain and Ireland – clinical expert
- Dr Brendan McGrath, ratified by the Royal College of Anaesthetists – clinical expert
- Dr Alistair McNarry, ratified by Association of Anaesthetists of Great Britain and Ireland – clinical expert

About this guidance

This guidance on the Ambu aScope2 for use in difficult airways was developed using the NICE medical technologies guidance process. During this process, NICE became aware of the development of the Ambu aScope3 product which is described in the implementation products supporting the guidance.

We have produced a summary of this guidance for the public. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Related NICE guidance

For related NICE guidance, please see the NICE website.

Changes after publication

April 2015: Minor maintenance

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgment. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

Copyright

ISBN 978-1-4731-0216-3

Accreditation