NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Medical technology guidance

SCOPE

Ambu aScope2 in unexpected difficult airways management

1 Technology

1.1 Description of the technology

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 directly or through an intubating laryngeal mask. It is a portable device that can be used wherever a flexible fibreoptic endoscope is needed for airway management (unless an Aintree catheter, through which the current device is too large to pass, is being used). This may be in the anaesthetic room, critical care or emergency departments or in other areas of the hospital where emergency airway management is undertaken. It 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 consists of two components; the aScope and the accompanying aScope monitor for displaying the images. The two are used together and must be available in the same location to generate images. The aScope has an outer diameter of 5.4 mm, a bending section that can be manipulated through an angle of 120° upwards and downwards, a built in camera with two light-emitting diodes.

The Ambu aScope2 uses video camera technology to create the image which is displayed on the high-resolution aScope Monitor. The monitor, which is portable, indicates the rechargeable battery capacity (maximum claimed 2

hours) and also has a video output to transfer images to a larger monitor or recording device. During procedures, the monitor can be powered by either battery or mains and is designed to be connected to the mains at other times.

Other features of the Ambu aScope2 include a clearing membrane that eases removal of secretions from the lens (ClearLens), and a Luer channel of 0.8 mm diameter which can be used for injection of topical anaesthesia or, by attaching a flow connector, to apply an air/oxygen flow. The purpose of this is to direct secretions away from the tip of the Ambu aScope2; the Ambu aScope2 is not designed for the purpose of oxygenation or ventilation.

The device is delivered sterile and ready for use.

1.2 Regulatory status

The Ambu aScope received a CE mark in December 2009 and is able to be used for difficult and unexpected airway management when a fibreoptic endoscope is needed immediately.

Ambu aScope2 superseded 'aScope' in May 2011. It is the same product and is covered by the same CE Mark, with a number of enhancements that include the ClearLens, the oxygen adapter and the removal of all time-out features (previously programmed to shut down the camera and LEDs after 30 minutes of continuous use).

1.3 Claimed benefits

The benefits to patients claimed by the sponsor are:

- Improved patient outcomes in emergency and unexpected scenarios of difficult airway management due to the immediate availability of a sterile fibreoptic endoscope that does not require 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 fibreoptic endoscopes.

The benefits to the healthcare system claimed by the sponsor are:

- Reduced costs associated with an improvement in clinical outcomes in emergency and unexpected scenarios of difficult airway management including those 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 aScope is delivered sterile and ready to use.

1.4 Relevant diseases and conditions

The clinical circumstances relevant to the use of the Ambu aScope2 are in the management of expected or unexpected difficulties with endotracheal intubation in patients with difficult airways or in assisting with percutaneous dilatory tracheostomy in awake or anaesthetised patients.

Approximately 2.9 million general anaesthetics are administered in the NHS each year. Endotracheal intubation is used for airway management in approximately 38% of cases. Difficulties with intubation are expected in approximately 2% of cases and in 10% of these, awake fibreoptic intubation is undertaken. (Source: 4th National Audit Project (NAP4) Report, 2011). Expert Advisers estimate that approximately 12,000 tracheostomies and 5-8,000 percutaneous dilational tracheostomies are carried out in the UK each year. (Summarised in table below).

Group	Estimated number each year in the UK, based on 4th National Audit Project (NAP4) Report, 2011 and expert advice	Source
Procedures where a general anaesthetic is given	2.9 million	Initial data taken from: 4th National Audit Project (NAP4) Report, 2011
Proportion of procedures where endotracheal intubation is used for airway management	1.1 million (38% of 2.9 million)	
Management of unexpected difficulties with endotracheal intubation in patients with difficult airways	Difficult intubation: 22,000 (2% of 1.1million), of which 2,200 cases involve awake fibreoptic intubation	
Tracheostomies performed in the UK in one year	12,000 (approximately)	Expert adviser estimates
Assisting with percutaneous dilatory tracheostomy in awake and anaesthetised patients	5,000-8,000 (approximately	

Table. Clinical circumstances relevant to the use of the Ambu aScope2
Note: estimated populations in individual circumstances are not mutually exclusive

The National Patient Safety Agency examined critical incidents relating to airways events in intensive care units over a two-year period between 2005 and 2007 (McGrath and Thomas, 2010). The study indicated that there were 453 incidents, 338 that led to harm and 15 that may have contributed to death. Of these 453 incidents, 276 (60%) involved tracheostomies becoming blocked or displaced.

Problems with airway management can lead to significant consequences for patients ranging from upper airway soft tissue trauma to hypoxic brain damage and death. One of the conclusions of the 4th National Audit Project (NAP4) Report, published in 2011 by the Royal College of Anaesthetists and the Difficult Airway Society was that a lack of essential airway equipment repeatedly contributed to poor outcome in patients whose tracheostomies became displaced.

1.5 Current management

Placement of an endotracheal tube guided by a flexible fibreoptic endoscope is the gold standard for managing patients with difficult intubation. The use of a fibreoptic endoscope allows the visualisation and crossing of the vocal

chords followed by the accurate placement of an endotracheal tube. Visualisation is currently achieved using fibre optic technology (fibreoptic endoscopes) or video technology (video scopes). Difficulties with intubation can arise in patients who are obese, have limited mouth opening or cervical spine movements, have experienced trauma to the face or neck, have respiratory tract infections or cancers and in those with tracheostomies.

Difficulties with airways management can therefore be predicted when intubation is undertaken in a planned and elective manner. Difficulties may also be encountered, however, in unexpected situations when emergency intubation is required. Under these circumstances a multiple-use fibreoptic endoscope may not be immediately available and grave clinical consequences including death and hypoxic brain injury may ensue from the failure to successfully manage a difficult airway. Such circumstances may arise for example in the Accident and Emergency department or in Intensive Care Units or general wards where multiple-use fibreoptic endoscope are not necessarily stocked but where emergency airway management is sometimes required.

2 Reasons for developing guidance on Ambu aScope2 in unexpected difficult airways management

The Committee considered that the Ambu aScope2 may offer patient and system benefits compared with current practice.

The Committee was advised that, within anaesthetic practice, multiple-use fibreoptic endoscopes are most likely to be used for the management of planned elective intubation in patients with difficult airways. Expert Advisers stated that it is unlikely that the Ambu aScope2 would be used to replace the multiple-use fibreoptic endoscope in this scenario. The Committee also considered that the resource consequences of this device in planned difficult airways management were more complex and it was uncertain whether the Medical Technologies Guidance methodology would be suitable. The use of

Ambu aScope2 in planned difficult airways management is not, therefore included in this scope.

The Committee was advised, however, that multiple-use fibreoptic endoscopes are expensive, and are not necessarily immediately available in all clinical areas where difficult intubation may be encountered. This delay in accessibility may have important clinical consequences.

The Committee considered that the main potential benefit of the Ambu aScope2 was its immediate availability for use and that this may be of particular value in emergency airways management in a variety of clinical settings including Accident and Emergency departments, isolated sites within a hospital and Intensive Care Units.

The Committee heard from experts that there is a significant downtime of up to four hours associated with the cleaning and sterilising of the multiple-use fibreoptic endoscope and that that this needs to be repeated every 72 hours even if the device is not used. The Committee was advised that this may change depending on local storage and decontamination facilities and processes. The Committee considered that the avoidance of this process may be a significant advantage of the Ambu aScope2.

The Committee considered that an improvement in clinical outcomes associated with the use of Ambu aScope2 for the emergency intubation of difficult airways may contribute to overall cost savings as compared with current practice. Furthermore the Committee considered that the use of the Ambu aScope2 may be associated with reduced costs due to the need for fewer expensive reusable instruments as well as the avoidance of cleaning and sterilising in emergency airways management.

The Committee concluded that a relevant model of care may include the complementary use of multiple-use fibreoptic endoscopes and the Ambu aScope2 in different clinical scenarios.

The Committee considered that an additional clinical advantage of the Ambu aScope2 may be a reduction in the incidence of contamination and cross-infection.

3 Statement of the decision problem

	Final scope issued by NICE
Population	Patients with unexpected difficult airways requiring emergency intubation including awake or anaesthetised patients with displaced tracheostomies. This device can be used in adults or children who have been clinically evaluated for endotracheal tubes size 6 or above.
Intervention	The Ambu aScope2
Comparator(s)	• Multiple-use flexible endoscopes (fibrescopes using fibre optic technology or video scopes using video technology). (see also 'Cost analysis' below)

Outcomes	The outcome measures to be considered in patients undergoing emergency intubation with difficult airways include:
	• incidence of delayed or failed intubation
	• clinical consequences associated with delayed or failed intubation:
	  ○ death
	  ○ hypoxic brain injury
	  ○ ITU and hospital length of stay
	• Incidence of successful intubation
	• incidence of contamination and cross-infection
	• device-related adverse events.

Cost analysis	Comparator(s): Multiple-use flexible endoscopes and include stack system costs where required. Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Consideration should be given to: • the costs attached to acute recovery, clinical management, rehabilitation and long-term care of those with hypoxic brain injury • the cost of cleaning/sterilisation of the current multiple-use fibreoptic endoscopes • the repair costs and maintenance of the re-usable endoscopes • the start-up costs of re-usable endoscopes which include the endoscope, light source, camera unit and processor, washer, HEPA filtered system and storage cabinet Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed, including an analysis of how many monitors are required to allow the use of the Ambu aScope2 in all relevant clinical areas within a typical hospital.
Subgroups to be considered	• None identified

Special considerations, including issues related to equality	People at greater risk of airway complications are those with conditions affecting cervical spine mobility, this may include: pregnant women, or people who are obese, people in whom trauma to the face or neck has occurred, and people with respiratory tract infections or cancers. Other groups covered by the disability act are patients with rheumatoid arthritis with limited spine movements and longer term tracheostomy patients.

4 Related NICE guidance

There is no related guidance for this technology.

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- The Royal College of Anaesthetists
- Association of Anaesthetists of Great Britain and Ireland

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- The Royal College of Anaesthetists
- Association of Anaesthetists of Great Britain and Ireland
- Intensive care society
- British Society of Rehabilitation Medicine
- Institute of Decontamination Science

5.2 Patient organisations

At the selection stage, NICE's Patient and Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Brain and Spinal Injury Charity
- Brain and Spine Foundation
- Brain Injury Rehabilitation Trust
- British Lung Foundation
- Cancer Laryngectomee Trust
- CritPaL - Patient Liaison Committee of the Intensive Care Society
- Get A-Head
- Guillain-Barré Syndrome Support Group
- Headway - The Brain Injury Association
- ICU Steps
- Motor Neurone Disease Association
- Mouth Cancer Foundation
- National Association of Laryngectomee Clubs
- National Obesity Forum
- Neurological Alliance
- Neurosupport
- Ochre
- Oesophageal Patients Association
- Royal College of Anaesthetists Patient Liaison Group
- Royal College of Surgeons Patient Liaison Group
- Stroke Association
- The Overweight and Obesity Organisation
- UK Acquired Brain Injury Forum