National Institute for Health and Care Excellence

Medical Technologies Evaluation Programme

MT 158 – Ambu aScope2 for use in unexpected difficult airways
Consultation Comments table

MTAC date: 16 May 2013

There were 26 consultation comments from 5 consultees (4 NHS professionals and 1 manufacturer). The comments are reproduced in full, arranged in guidance section order.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
1	Consultee 2 Clinical Research Specialist, Ambu Ltd	**1** **Section 1.3. Page 3**	It is stated: "*As an example from 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*". **Sponsor Comment:** The sponsor believes that it is more relevant to present data of the cost saving threshold for this scenario rather that the saving at 700 intubations, since there are significant cost savings for less number of intubation as well. In other words, there are potential cost-savings in the intensive care setting for units performing more than 50 intubations per year, where there are two or fewer reusable scopes available. **Sponsor suggestion:** The sentence we	Thank you for your comment. The Committee carefully considered this comment and decided not to change the guidance. It noted that the estimated cost savings are described in detail in sections 5.16-5.20. Section 1.3 is intended to provide only one example of a clinical scenario where cost savings are expected.

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			propose is: "*As an example, considering a 20% probability of difficult intubation, the data shows potential cost saving for intensive care units performing more than 50 intubations a year when 2 reusable scopes are available, and for units performing more than 25 intubations where 1 reusable scope is available*".	
2	Consultee 3 Technology Implementation Manager, NHS	**1**	**The Ambu aScope2 will be of use in situations where a multi-use fibre optic endoscope is unavailable**. In addition to this, it may be worth specifically stating that the Ambu aScope2 would be useful in situations where a multi-use scope ***is*** normally available but for various reasons becomes unavailable. Eg. Cleaning, breakdown, maintenance, in-use.	Thank you for your comment. The Committee considered this comment and decided not to change the guidance because the additional cost modeling carried out by the External Assessment Centre considered scenarios in which there are no multi-use scopes **and** in which multi-use scopes are normally present but may be unavailable due to cleaning or repair. The Committee noted that the circumstances where a multiple use scope is present but not available for immediate use are referred to in sections 3.16, 4.5, 4.7, 4.8, 5.22 and 5.26 of the guidance.
3	Consultee 3 Technology Implementation Manager, NHS	**1**	**Replacement of dislodged tracheostomy tubes.** In addition to the replacement of dislodged t-tubes, there are also benefits in using Ambu aScope2 for the initial placement of percutaneous tracheostomy tubes. Use during placement avoids the risk of damage to multi-use scopes.	Thank you for your comment. The Committee considered this comment and decided not to change the guidance because the patient population defined in the scope is people with unexpected difficult airways. The initial placement of tracheostomy tubes is considered to be an expected difficult airway and therefore was

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				not included in the scope.
4	Consultee 3 Technology Implementation Manager, NHS	**1.3**	**Costing Model.** It would be useful to clearly state that the EAC predicted 'cost savings' do not equate to 'cost efficiencies' and that the use of this technology will not facilitate the decommissioning of currently used equipment. The modelled savings are based upon the avoidance of future care costs caused by very rare adverse events. More suitable terminology may therefore be an 'invest to save' or even 'insurance policy' rather than 'cost saving'. It could be seen as misleading to suggest that cost savings are achievable if they are unlikely to become a reality.	Thank you for your comment. Please refer to the responses to comments 21 and 24. The Committee carefully considered this comment and decided not to change section 1.3 of the guidance. The comparator in the scope is a multiple-use fibre optic endoscope; specific cost outcomes arising from the decommissioning of such equipment, with complete replacement by the Ambu aScope2, were not included in the scope. The estimated cost savings referred to in Section 1.3 arise from the costing model (described in detail in sections 5.11 to 5.13) and from the avoidance of very rare but costly adverse events including hypoxic brain damage. However in response to the comment, the Committee decided to change section 5.24 to provide further clarification about the frequency of potential adverse events, even if a clinical unit does not have access to an endoscope. Section 5.24 was also expanded to provide further clarification that the cost modelling was based on overall use in the NHS and that the cost consequences for each individual hospital unit may vary.
5	Consultee 2 Clinical Research Specialist Ambu Ltd	**2** **Section 2.4,**	. It is stated: "*The cost of Ambu aScope2 stated in the sponsor's submission is £179 (including VAT) per single-use endoscope. The monitor has a list price of £799 but is currently provided*	Thank you for your comment. The Committee decided to change section 2.4 of the guidance to state that the price for the aScope2

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		page 5	*to NHS organisations free of charge with 5 Ambu aScope2 devices. Each monitor has a 12-month warranty and a 3-year shelf life".* **Sponsor comment**: We would like to change the wording since the price will vary (reduce) within the next short period of time. **Sponsor suggestion:** "*At the time of this evaluation, 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 a 3-year shelf life".*	and the monitor was £179 and £799, respectively, at the time of submission.
6	Consultee 3 Technology Implementation Manager, NHS	**2**	**Double lumen tubes.** Due to its size, the Ambu aScope2 is only compatible with the larger double lumen ET tubes and cannot be used for tube placement in smaller patients.	Thank you for your comment. The Committee decided not to change the guidance because it judged that the description of the technology's technical characteristics was sufficiently clear.
7	Consultee 4 Expert Clinical Adviser, NHS	**2.2**	2.2 Do we actually have a definition of what makes the monitor high-resolution?	Thank you for your comment. The Committee decided to change section 2.2 of the guidance to include the resolution of the monitor (640x480 pixels) rather than describe it as high resolution which was subject to different interpretations.

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8	Consultee 4 Expert Clinical Adviser, NHS	**2.3**	2.3 "which eases removal of secretions from the lens"- I know that the A2 is much better than the original a in terms of optics, but is there the evidence to say that the better clearing of secretions is down to the ClearLens technology?	Thank you for your comment. The Committee decided not to change the guidance because no evidence on this issue was presented by the sponsor.
9	Consultee 4 Expert Clinical Adviser, NHS	**2.4**	2.4 there was no comment on the shelf life of the scope itself which I thought was 2 years?	Thank you for your comment. The Committee decided to change section 2.4 to read: “Each monitor has a 12-month warranty and each single-use scope has a 3-year shelf life.”
10	Consultee 4 Expert Clinical Adviser, NHS	**2.5**	2.5 I would be very keen that this section carries the "in appropriately skilled hands " caveat as the device itself is simply a quick to use , readily available fibrescope, not a fibrescope that radically changes the technical skills required to perform a fibreoptic intubation	Thank you for your comment. The Committee considered this comment and decided not to change the guidance because the focus of the guidance is the case for adoption of the Ambu aScope 2, and not the skills and experience required for intubation. All NICE guidance carries an explanatory note: “….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.”
11	Consultee 4 Expert Clinical Adviser, NHS	**2.6**	2.6 ?? Vocal Cords not Vocal Chords	Thank you for your comment. Section 2.4 was changed to correct this.

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12	Consultee 4 Expert Clinical Adviser, NHS	**2.7**	2.7 Important to get the right sense of the 2004 guidelines where flexible endoscopy is listed as part of plan A, or in plan B though a dedicated device using a flexible fibrescope.	Thank you for your comment. The Committee agreed to change the final sentence of section 2.7 to further clarify that tracheal intubation can be attempted, rather than definitely completed, with the aid of a multiple-use endoscope.
13	Consultee 4 Expert Clinical Adviser NHS	**3.5**	3.5 Schoettker study specifically concluded in its summary that their findings "did not support the use of the ascope 2 as an alternative to the reusable fibrescope"- given that the guidance sees it as an addition I wondered whether it was worth stating that?	Thank you for your comment. The Committee considered this comment and decided not to change section 3.5 because it judged that the text was, in the context of the case for adoption, sufficiently clear.
14	Consultee 2 Clinical Research Specialist Ambu Ltd	**3** **Section 3.14. Page 12.**	In the section **Unpublished patient-based studies**, it is stated: "*The Committee considered detailed findings from a study by Kristensen (2011). This was presented as academic-in-confidence data. The Committee had access to the study data but no report is yet publicly available. NICE understands the authors will publish this study before NICE publishes its final guidance on Ambu aScope2 for use in unexpected difficult airways, which will contain a summary of the study results*". **Sponsor Comment:** The sponsor would like to inform that the article of Kristensen and Fredensborg is not to be considered academic-in-confidence since it already received the doi reference number. Thus, it can be referenced in	Thank you for your comment. The Committee considered this comment and decided not to change the guidance because the comment refers to a pre-publication copy of the MTCD. Section 3.1 of the guidance summarises the findings of the Kristensen study which was published in full just before the final Medical Technologies Consultation Document (MTCD) was published, prior to which the consultee had been sent a prepublication copy of the MTCD which did not include this change. The correct citation is given in the Assessment Report Overview.

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			the draft guidance. **Sponsor suggestion**: The summary of the article shall be moved to section **Patient-based randomised study**, and shall be referenced as follows: M.S. Kristensen and B.B. Fredensborg. "The disposable Ambu aScope vs. a conventional flexible videoscope for awake intubation - a randomized study." Acta Anaesthesiological Scandinavica. 2013. doi. 10.1111/aas.12094	
15	Consultee 3 Technology Implementation Manager, NHS	**4** **4.6**	During our discussions with NHS sites that currently use the Ambu aScope2 we found that in addition to the clinical benefits of a fibre optic scope being available immediately at the point of need, the avoidance of damage to reusable scopes during the initial placement (and replacement) of percutaneous tracheostomy tubes was seen as a major benefit.	Thank you for your comment. Please see the response to comment 3. The Committee considered this comment and decided not to change the guidance because the scope of the evaluation specifies that the patient population is people with unexpected difficult airways. The initial placement of tracheostomy tubes is considered to be an expected difficult airway and therefore was not included in the scope. Section 4.6 contains the Committee's consideration, based on expert advice, that multiple-use fibre optic endoscopes are often damaged in the intensive care unit when they are being used during percutaneous tracheostomy and that the use of the Ambu aScope2 has advantages in this scenario because the scopes are single use and damage to them is therefore of significantly

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				less consequence.
16	Consultee 2 Clinical Research Specialist Ambu Ltd	**4** **Section 4.9. Page 15.**	It is stated: "*It was advised that cross-infection was not an expected complication of using multiple-use fibre optic endoscopes, which are sterilised after each use".* **Sponsor Comment:** The sponsor believes that the literature available within cross contamination well documents the risk of cross contamination despite cleaning and sterilization procedures are performed. There are more than 59 published reports, totaling almost 1000 patients with at least 3 deaths documented[1]. Common pathogens involved are Pseudomonas aeruginosa and mycobacterium tuberculosis (TB). The literature published acknowledges that dues to the lack of prospective studies of pathogen transmission the actual incidence is unknown and likely under reported[1]. Even after being sterilized, reusable endoscopes are a potential source of cross contamination. Several factors influence insufficient sterilisation: a- Methods for disinfection of reusable bronchoscopes are laborious, time consuming and require attention to detail[2]; b- Automated endoscope reprocessors must be specifically approved for compatibility with corresponding bronchoscopes[1,2]; c- Procedures for manual cleaning and disinfection of bronchoscopes may	Thank you for your comment. The Committee decided to change section 4.9 by deleting the last sentence because it heard from expert advisers that cross infection could be a risk when multiple-use fibre optic endoscopes are used. However, it considered that the evidence submitted in support of this was limited. All of the studies mentioned in this comment were reviewed by the External Assessment Centre (including the two which were included in the sponsor submission). The consideration in section 4.9 reflects the Committee's view that not enough evidence was presented to support specifically the impact on resource use, and therefore the guidance shouldn't be changed.

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			not always be adhered to[2]; d- Bronchoscopes must be inspected for surface damage and leak-tested after each procedure[3]. For instance, the article of Larson et al., reports the contamination of 2 patients with Mycrobacterioum TB due to poor compliance between endoscope type and the manual cleaning procedure. Insufficient cleaning was confirmed since patient debris were identified on the suction connector of the reusable bronchoscope[2]. The article of Ramsey et al, describes cross contamination of 10 patients with Mycrobacterioum TB. All 10 patients underwent bronchoscopy with the same bronchoscope initially used in a patient with TB. The bronchoscope had an undiscovered hole in the distal sheath of the scope[3]. Despite the scope was sterilized 10 times (after each procedure), the hole provided space for accumulation of infected materials and leak testing was not performed as part of the reprocessing procedures[3]. Finally the study of Paikos et al., demonstrates that routine cleaning does not effectively remove biofilm from endoscope channels[4]. Despite cleaning and sterilization procedures are correctly followed, it is impossible to avoid the formation of biofilm on the internal surfaces of endoscopes' channels[4].The study shows that bacteria residing within biofilm are more	

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			resistant to chemical inactivation than bacteria in suspension, and that chemicals used for removal of biofilm are incompatible with materials used in the manufacturing of reusable endoscopes[4]. In the study biofilm was identified in 13 of 13 endoscopes despite appropriate cleaning procedures were followed[4]. 1. Culver DA et al. Am J Respir Crit Care Med 2003, 167:1050-1056 2. Larson JL et al. Infection Control and Hospital Epidemiology 2003; 24(11):825-830 3. Ramsey AH et al. Chest 2002 121(3):976-979 4. Pajkos A et al. Journal of hospital infection 2004; 58:224-229 **Sponsor suggestion:** The sentence we propose is: "*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. However, the Committee recognizes that cross-infection is an inherent risk of reusable endoscopes, even after sterilization*".	
17	Consultee 2 Clinical Research Specialist Ambu Ltd	**4** **Section 4.10. Page 16**	It is stated: "*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 no evidence was submitted to support this claim*". **Sponsor Comment:** The original sponsor	Thank you for your comment. The Committee carefully considered this comment and decided to change section 4.10 to state that limited evidence, rather than no evidence, was submitted by the sponsor to support the claim that using the Ambu aScope2 would reduce the time

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			submission modelled this aspect and whilst this evidence was limited, it was supported by the article published by Tvede et al. The article of Tvede at al.[1] gives detailed data of the time spent for cleaning and costs associated to repair reusable scopes. The article presents comparative costs between reusable scopes and the Ambu aScope. Table 1 of Tvede et al, includes time records for the following steps: Preparing for intubation, immediate rinsing after use, clearing-up and inserting FOS into washer-disinfector, emptying washer-disinfector and preparing FOS, daily control of washer-disinfector, monthly sample collection for microbiology analysis, transport to/from external departments. The total median [range] times reported are: 42,5 [37 – 85,7] minutes. The article also reports that the hospital's technical department assessed that one medical technician used half of her working hours for servicing the endoscopic equipment of the whole hospital. Table 3 presents the "Repair costs per year". (Table taken from Tvede et al.)	and resources spent on cleaning and repair of multiple-use fibre optic endoscopes. The Committee acknowledged that the the sponsor submitted cost modelling in support of this claim in its submission.

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			Table 3 Repair costs per year. Item — Cost (EUR) Flexible optical scopes — 17,891 Racks — 1557 Subgroup analysis Videoscopes — 1988 Videoscopes and racks — 3545 EUR, euro. **Sponsor suggestion:** The sentence we propose is: *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".*	
18	Consultee 4 Expert Clinical Adviser, NHS	**4**	I think the committee have worked hard to distil the very complex economics into a clinically digestible form, and this is to their credit	Thank you for your comment.
19	Consultee 2 Clinical Research Specialist Ambu Ltd	**5** **Section 5.12. Page 21 (bullet 3)**	It is stated: "*1 or 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*". **Sponsor Comment:** It seems that the word "more" is missing.	Thank you for your comment. Section 5.12 was changed to correct the omission of 'more'.

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			Sponsor suggestion: The sentence we propose is: "*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*".	
20	Consultee 2 Clinical Research Specialist Ambu Ltd	**5** **Section 5.13, page 21**	It is stated: *"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*." **Sponsor comment**: In the sponsor's opinion, it seems unrealistic that Ambu aScope would only be used in unexpected difficult airways in units with no reusable scopes. It could be expected that at least some expected difficult airways will also be handled with Ambu aScope, considering the discussed scenario where, even in units with reusable scopes, these may not be available. **Sponsor suggestion:** The sponsor suggests that the guidance draft acknowledges this possibility under point 5.13. We suggest the following paragraph: "*The economic model was used to evaluate the cost savings of purchasing the Ambu*	Thank you for your comment. The Committee decided not to change the guidance as the assumptions in the cost model (described in section 5.13) are based on the patient population defined in the scope - unexpected difficult airways.

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			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 for unexpected difficult intubation. Therefore, these cases were used as entry point into the decision tree. However, the Committee acknowledges that in hospital units with no access to reusable endoscopes, Ambu aScope would probably also be used for expected difficult airway intubations".	
21	Consultee 3 Technology Implementation Manager, NHS	**5** **5.15**	**Definition of 'unexpected difficult intubation'.** Section 5.15 states that these events happen 6 times per 1000 intubations (NAP4). The EAC costing model seems to be based upon a fibre optic scope being used in all 6 cases. This is not the case. An unexpected difficult intubation is approached in a systematic way that employs different techniques and equipment in order to secure the airway. There is a range of equipment that may be deployed (as per DAS guidelines) prior to a fibre optic scope being required. As there is no standard definition, these airways may also be described as 'difficult' and would therefore be counted towards the 6 without requiring the use of a fibre optic scope. **EAC cost model.** The model is based upon a worst case scenario in which a patient suffers brain damage due to failed intubation where no fibre optic scope is available. The predicted cost	Thank you for your comment. Please refer to the responses to comments 4 and 24. The Committee carefully considered this comment and decided not to change section 5.15 of the guidance. It heard from the External Assessment Centre (EAC) which stated that the interpretation of the cost model by the consultee is correct and acknowledges that the absence of a standard definition of 'unexpected difficult intubation' is a limitation of the analysis. However, with respect to the consultee's suggestion that the analysis over-reports the need for fibreoptic scopes, the EAC considers that it is not obvious that the bias goes in this direction. Expert clinical advice suggested that NAP4 under-reported unexpected difficult airways, meaning the analysis might instead be under-

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			savings are based upon the avoidance of the associated care costs when an Ambu aScope2 is used. Based upon the numbers of intubations used for the EAC base cases (300, 400, 1000, 700) and the figure of 6/1000 unexpected difficult intubations, the number of actual occurrences of unexpected difficult intubation in these settings (non ICU) would be very low. The *actual* requirement for the use of a fibre optic scope may be even lower. The subsequent likelihood of intubation failure and then of harm occurring as a result reduces the overall likelihood of a worst case scenario to a very low level. The EAC 'additional work' paper (p25) states that for scenario 1 (300 intubations, maintaining current status quo) unexpected difficulties would arise twice per year. If both of these required the use of an 'unavailable' scope (which under DAS guidelines they may not), there would be an intubation failure once every 3-4 years with a death once in every 167 years and brain damage once in every 334 years. The savings presented in scenario 1 therefore represent the avoided costs of care of an event that has an extremely small chance of happening.	estimating fibreoptic scope need.
22	Consultee 2 Clinical Research Specialist Ambu Ltd	**5** **Section 5.22, page 25**	It is stated: *This modelling considered the cost consequences for two 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*	Thank you for your comment. The Committee decided not to change the guidance. The External Assessment Centre model of the intensive care scenario with one or more

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			endoscopes are normally available in a clinical setting but for some reason inaccessible." Then bullet points 4 and 5 state: *"Intensive care units with 2 multiple-use endoscopes: 50 intubations (20% difficult intubation probability) and 250 (5% difficult intubation probability)". & "Replacement of displaced tracheostomy tubes in an intensive care unit (assuming a 15% per year displacement rate) with 2 multiple-use endoscopes: 70 tracheostomies."* **Sponsor comment**: In the sponsor's opinion, information of the settings assuming: *"Intensive care units with no multiple-use endoscope". & "Replacement of displaced tracheostomy tubes in an intensive care unit with no multiple-use endoscopes"* is missing. In the sponsor's opinion, these 2 scenarios are highly relevant. In fact, the draft states so in point 5.23 "*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.* **Sponsor suggestion:** The sponsor suggests that information of the above mentioned scenarios is also provided.	multiple-use scopes already accounts for the possibility that multiple-use scopes are unavailable due to repair (and thus that there may be periods of time in which an ICU normally equipped with one or more multiple-use scope is left with no scopes due to temporary unavailability). The Committee accepted that there were significant uncertainties in the modelling but that the scenarios developed were plausible.
23	Consultee 4 Expert Clinical Adviser, NHS	**5**	the conclusions seem entirely reasonable.	Thank you for your comment.
24	Consultee 3 Technology	**6**	To publish predicted savings that are based upon an event that may occur once in 334 years	Thank you for your comment.

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	Implementation Manager, NHS		without any narrative regarding likelihood may mislead the reader into expecting these savings to be achievable in the short or medium term. From a clinical perspective, the Ambu aScope2 improves patient safety and reduces clinical risk by ensuring patients get the correct treatment at the correct time. However there is a risk that the excellent clinical case may be undermined if the emphasis and motive for change is linked to the financial case with the associated "huge uncertainty" surrounding the costing model parameters.	Please refer to the responses to comment 4 and 21. The Committee carefully considered this comment and decided not to change section 6 of the guidance. It noted that the costing model was described in detail in sections 5.11 to 5.13 and that the estimated costs arise from the avoidance of very rare but costly adverse events including hypoxic brain damage. However, in response to the comment, the Committee decided to change section 5.24 to provide further clarification about how rare potential adverse events may be even if a clinical unit does not have access to an endoscope.
25	Consultee 1,	**General**	Can you clarify for me (I may have missed it in the document itself) whether any of the named advisors have declared any financial relationship with the company Ambu? If not within the document, where is this information made available?	Thank you for your comment. NICE has responded separately to this comment.
26	Consultee 5 Department of Health	**General**	Thank you for the opportunity to comment on various consultation documents relating to the above medical technology. **I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.**	Thank you for your comment.

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