Ambu aScope2 in unexpected difficult airways management

Additional work by External Assessment Centre for the Medical Technologies Advisory Committee

Produced by: Birmingham and Brunel Consortium

Authors: Samantha Burn, Amanda Chapman, Zulian Liu, Carole Cummins, Shihua Zhu, Richard Lilford.

Correspondence to: Richard Lilford
Professor of Clinical Epidemiology, Vice-Dean for Applied Health Research
Director of Primary Care Clinical Trials Unit
Room 142, 1st Floor
Learning Centre/Primary Care Building
School of Health and Population Sciences
University of Birmingham
Birmingham
B15 2TT
+44 (0)121 414 6772
+44 (0) 7824 474289
r.j.lilford@bham.ac.uk

Date commissioned: 16/12/2013
Date of final draft: 01/02/2013. This is the revised version of this report, originally published in February 2013, and republished by NICE in June 2103 with a technical correction to improve the legibility of the diagrams on pages 10 and 12. The remainder of the report is unchanged.

Declared interests of the authors
None

Acknowledgements
We are extremely grateful to the following clinical experts for their expert opinion on the model parameters (listed alphabetically): Dr. Andrew Bentley, Dr. Ali Diba, Dr. Brendan McGrath, Dr. Alistair McNarry, Dr. Philip Moore and Dr Matthew Wilson. We are also grateful to Dr. Pelham Barton for his advice on the queuing model developed for this work package. Finally, we thank committee member Prof. Brian Pollard, who provided input in his capacity as a clinical expert with the relevant expertise.

CONTENTS

ABBREVIATIONS

A&E	Accident and Emergency departments
BBC EAC	University of Birmingham & Brunel University External Assessment Centre
BMI	Body mass index
CCU	Critical Care Unit
DL	Direct laryngoscopy
EAC	External Assessment Centre
ED	Emergency Department
ENT	Ear, Nose & Throat
FOS	Flexible fibreoptic scope
GA	General anaesthesia
HES	Hospital episode statistics
ICU	Intensive Care Unit
IVF	In Vitro Fertilisation
MTAC	Medical Technologies Advisory Committee
MTEP	Medical Technologies Evaluation Programme
N/A	Not applicable
NAP4	4th National Audit Project of the Royal College of Anaesthetists
NHS	National Health Service
NHSLA	National Health Service Litigation Authority
NICE	National Institute for Health and Clinical Excellence
NPSA	National Patient Safety Agency
OR	Operating room
OT	Operating theatre
PDT	Percutaneous Dilatational Tracheostomy
RSI	Rapid Sequence Induction
ST	Surgical Tracheostomy
u.d.i	Unexpectedly difficult intubation

EXECUTIVE SUMMARY

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 aid the placement of an endotracheal tube in patients who are awake or anaesthetised. It is a portable device that can be used wherever a flexible endoscope is needed for airway management which may be in the anaesthetic room, critical care or emergency departments or in other areas of the hospital where emergency resuscitation is undertaken. It can also be used to aid repositioning of displaced tracheostomies. The main comparator to this device is the re-usable intubating fibrescope, but the high cost of purchase and maintenance of re-usable devices means they are not currently immediately available in all clinical settings in which intubation is conducted.

The original sponsor submission considered the incremental cost-savings per fibreoptic intubation from replacing all re-usable scopes in a unit with disposable scopes. The committee considered this to be unrealistic because re-usable scopes are likely to be retained for expected difficult airway management in environments with high throughput of patients, with single-use scopes purchased as complements for use in an emergency when no re-usable scope is available. As Ambu aScope2's immediate availability may be of particular value in emergency airways management in clinical settings where re-usuable scopes are not currently available, the committee also requested the EAC to consider scenarios where re-usable fibrescopes are not available.

The EAC designed health economic models to evaluate the cost savings of purchasing Ambu aScope2 in small hospital units which do not have access to any fibrescope for unexpected difficult airways management and of purchasing Ambu aScope2 in addition to the existing stock of re-usable scopes in general operating theatre and ICU settings for unexpected difficult intubations and displaced tracheostomies. In all cases, the potential cost savings from purchase of the Ambu aScope2 come from using the scope to avoid costly harm (especially brain damage) in the event of an unexpected difficult airway. These cost savings are traded off against the possibility that the disposable scopes are not used before they expire.

In the small hospital unit case, a decision tree model of costs of unexpected difficult intubation with and without a scope was produced. Where the Ambu aScope2 was purchased in a complementary fashion alongside re-usable scopes, it was necessary in addition to model the probability that a re-usable scope would not be available when a patient with an unexpected difficult airway presented using a simple queuing theory model with intubation events arriving randomly according to a Poisson process. In order to obtain more plausible estimates for the parameters required for these models, further literature searches were carried out and clinical experts were consulted via a questionnaire.

Results for the five scenarios analysed are shown below.

Unit with no current re-usable scope provision: It was assumed that an unexpected difficult intubation arises on average 6 times per 1,000 intubations. Under this assumption, a bundle of five AmbuaScope2 devices becomes cost saving above a threshold number of total intubations of

between 95 and 115 per year. At this point, the average number of times an Ambu aScope2 is required per year is around 0.6.

For a base-case of 300 intubations per year, the annualised cost saving is £749 (without monitor) or £653 (with monitor). There is considerable uncertainty surrounding the parameters: a probabilistic sensitivity analysis showed Ambu aScope2 to be cost-saving in 59% of simulations with a 95% confidence interval around the cost savings of -£400 to £1800.

General operating theatre: For a general operating theatre which has a stock of two re-usable scopes, a bundle of five Ambu aScope 2 devices is cost saving above a threshold number of total intubations of between 1250 and 1350 per year. For only one re-usable scope, the cost-saving threshold is under 600 intubations per year. The thresholds are higher in the general operating theatre case than in the small unit case because re-usable scopes can be used for most intubations; the Ambu aScope2 is only used when none of the stock of re-usable scopes is available. Annualised cost saving for a theatre suite with two re-usable scopes and 1,000 intubations per year from a purchase of a bundle of five scopes is - £299 (including a monitor) to -£203; this is cost-incurring since it is below the cost-saving threshold.

Intensive care unit: For a stock of two re-usable scopes and a probability of difficult intubation of 20%, the cost-saving threshold is 50-100 intubations per annum. If probability of difficult intubation is lower at 5% of all intubations, the threshold for cost saving is 250-300 intubations per annum. Annualised cost saving for a ICU with two re-usable scopes and 700 intubations per year from a purchase of a bundle of five scopes is £3,219 (without monitor) if probability of difficult intubation is 20% and £3,128 if probability of difficult intubation is 5%. Annualised cost savings are higher and cost-saving thresholds are lower for ICU than in the case of general operating theatre, because the risk of harm in the event of a difficult intubation, especially brain damage, is higher for ICU patients, the rate at which unexpected difficult airways arise is higher, and scope down-time is higher due to the probability of breakage.

Obstetric setting: There is considerable uncertainty surrounding the usefulness of a scope in an obstetric setting, because of greater use of rapid sequence induction (RSI). Assuming that the rate of arrival of unexpected difficult intubations for which a scope is useful is the same in obstetrics as in the general operating theatre case, a bundle of Ambu aScope2 devices becomes cost saving at 80 intubations per annum where no scope is available and 500 intubations per annum where a re-usable scope is available. For a base-case of 400 intubations and zero scopes, annualized cost savings are £1,452 (without monitor) and £1,356 (with monitor). With a scope present, purchasing a bundle of disposable scopes is cost-incurring since there is such a low likelihood of them being used. The assumption that the rate of arrival of unexpected difficult intubations is the same as in the general operating theatre context may not be warranted.

Displaced tracheostomy in ICU setting: Assuming on average 15% of tracheostomies become displaced per year, for an ICU with two scopes, purchase of a bundle of Ambu aScope2 devices becomes cost saving at a threshold of around 70 tracheostomies per year. Cost savings from purchasing Ambu aScope2 devices in an ICU setting may be under-estimated since they can be used for both repositioning displaced tracheostomies and for unexpected difficult intubations, increasing the probability that they are used before they expire.

While the scenario analysis suggests that purchase of the scopes may be cost-saving above certain threshold numbers of intubations, there is a lot of uncertainty surrounding the parameters in all scenarios, both because of a lack of availability of good quality evidence and lack of statistical precision in those estimates available. This is particularly true of the parameters relating to risks of intubation failure and harm, and the effectiveness of the device in reducing the likelihood of intubation failure in an unexpected difficult intubation and the likelihood of harm in repositioning displaced tracheostomy. The potential cost savings are heavily dependent on operational differences between settings, specifically planned use of re-usable scope and throughput of patients.

Limited univariate sensitivity analysis suggests that the device is cost-saving under some plausible parameter estimates and not others. Probabilistic sensitivity analysis suggests that the confidence interval around annualised cost-savings is large and encompasses the possibility that purchase of the device is cost-incurring.

1. RATIONALE FOR ADDITIONAL WORK

At its meeting on 15 November 2012, the Medical Technologies Advisory Committee asked for further cost analysis before making its provisional recommendations. 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.

It noted that the economic analysis submitted by the sponsor modelled a scenario where re-usable endoscopes were completely replaced by Ambu aScope2. The Committee considered that hospitals would be very unlikely to replace re-usable endoscopes with Ambu aScope2 because the former will be retained for elective intubation in patients with difficult airways and because Expert Advisers stated that their preference, given a choice, would be a re-usable endoscope.

The Committee considered that, in the scope for the evaluation, a relevant model of care would include the **complementary use of re-usable fibreoptic endoscopes and the Ambu aScope2 in different clinical scenarios**. It judged that modelling of this scenario was not provided in either the sponsor submission or the assessment report and concluded that it would be valuable in its decision-making. It was advised that the limited number of re-usable endoscopes which may be available at larger hospitals resulted in a clinical need for the Ambu aScope2 as a complementary device when the re-usable endoscopes are in use, broken or for emergency use. This need might also arise in selected locations, remote from ready availability of re-usable scopes. In particular, The Committee discussed whether obstetrics units have acceptable access to endoscopes.

The Committee also considered that, in the scope for the evaluation, a second relevant scenario was that of **small hospital units which do not have access to any endoscope for unexpected difficult airways management**, where availability of the Ambu aScope2, in addition to current practice, would be clinically valuable.

The Committee heard from the Expert Adviser that fibreoptic endoscopes are often damaged in the Intensive Care Unit when they are being used to reposition a percutaneous dilatory tracheostomy leading to significant costs and downtime and that the Ambu aScope2 may provide a useful complement to re-usable endoscopes in this setting.

The Committee also noted that the External Assessment Centre expressed concerns about a number of parameters in the sponsor's model and that **further work was needed to obtain more plausible estimates for these parameters**.

1.1 How this report relates to and extends the previous report

In its original submission, the sponsor provided a cost analysis of Ambu aScope2 as compared with reusable scopes for the management of unexpected difficult airways. The base-case considered a hypothetical NHS Trust, which had 5 re-usable scopes available and which were used 150 times per year. The main assumption was that Ambu aScope2 (single-use, disposable scopes) would directly replace re-usable scopes for the management of *all* unexpected difficult intubations. For their base-case setting, the sponsor concluded that replacing re-usable scopes with Ambu aScope2s would be cost saving in all settings, but more so for displaced tracheostomy and in an ICU setting than in the operating theatre setting (due to the increased risk of intubation failure in these settings). Cost savings were based on the assumption that employment of Ambu aScope2 would lead to a 10% reduction in failed intubation, which would lead to reduced length of stay in hospital; this 10% estimate was said to be driven by the assumption that Ambu aScope2 would mitigate the availability problems that currently exist for re-usable scopes (in particular due to the requirement for periodic sterilisation), but this estimate was not evidence-based. A recently published cost analysis of reusable and disposable scopes (Tvede, Kristensen, & Nyhus-Andreasen 2012) presents a similar analysis, and finds that for their particular department (which conducts 360 intubations requiring a scope each year) costs associated with disposable scopes was greater, but that the break-even point (i.e. where the cost of using disposable and reusables are identical) is 22.5 intubations per month (270 per year).

The main limitation of the cost analyses described above is the implausibility that single-use scopes will directly replace re-usable scopes in *all* instances of unexpected difficult intubation; where re-usable scopes are available these will be used by clinicians in preference to single-use scopes. A more realistic scenario is therefore that Ambu aScope2 would be procured to supplement current practice. Thus, the main way in which this additional work differs from the cost analysis described above is to consider the probability that single-use scopes, having been procured, would be employed. This will depend on the likelihood that a re-usable scope will be available, which will vary according to the setting (both in terms of the number of re-usable scopes currently available in that setting as well as their case-load). This replaces the arbitrary assumption in the previous model that there will simply be a 10% reduction in failure rate if all re-usable scopes are replaced with single-use ones for unexpected difficult intubations. Additionally, the sponsor's model of costs of harm arising from failed intubation considered only an increase in ICU length of stay; our analysis considers the long-term costs of caring for individuals with brain damage and the litigation costs of critical airway incidents to the NHS.

2. OVERVIEW OF METHODS

In order to address the concerns of the committee, it was clear that there were a number of unknown parameters and complex interactions that would need to be modelled, for which a simple decision-tree analysis would not suffice. Specifically, the model described in this report makes use of operations research (in particular queuing theory) to determine the cost savings associated with *complementary* availability of Ambu aScope2. Consideration and quantification of the scenarios that are required to appreciate the potential cost-releasing potential of the Ambu aScope2 requires parameter inputs not present in the original manufacturer's submission and report.

In order to quantify the risks associated with difficult intubations and the resultant harm (both of which are likely to vary according to the setting) a broad literature search was required, and expert input was critical. Major databases were searched as part of the scoping process, and to identify the most appropriate parameter estimates for the model. These will be explained in chapter 3, with further and more detailed information provided in Appendix C. Due to the rarity of this emergency procedure, and the big variation expected between clinical settings, it was deemed important to contact clinical experts for input. Questionnaires (see Appendix A) were emailed to all of our clinical experts, who were then followed up with a phone call to discuss their responses (results summarised in Appendix B). Although most of the model parameters were derived from the literature, the clinical experts were crucial in informing the design of the model, sense-checking many of the parameters utilised, and providing us with an impression of the size of settings, and number of scopes available in various clinical scenarios.

3. DESCRIPTION OF THE MODEL

The committee asked for three additional pieces of cost analysis:

A. Potential cost savings from purchasing one or more single-use scopes for use in managing unexpected difficult intubation in a clinical setting with no re-usable scopes;
B. Potential cost savings from purchasing one or more single-use scopes for use in managing unexpected difficult intubation in a clinical setting with one or more re-usable scopes (considering the fact that these may not be available when needed, e.g. because they are in use or being cleaned);
C. Potential cost savings from purchasing one or more single-use scopes for use in managing displaced tracheostomy in an ICU with one or more re-usable scopes, but where none of these scopes may be immediately available.

The model structure is similar in all three cases: the Ambu aScope2[1] is purchased as insurance against the arrival of an unexpected difficult airway event that cannot be managed with a re-usable scope, either because re-usable scopes are not stocked in that clinical setting (situation A) or because the re-usable scopes are all temporarily unavailable (situations B and C).

There are two stages to modelling the expected cost savings:

[1] The terms 'single-use' and 'disposable' scopes are used interchangeably within this report to refer to the Ambu aScope2.

1. Generating the expected net cost savings per use of the Ambu aScope2 for management of an unexpected difficult airway. The expected cost savings result from a reduction in the probability of intubation failure (and resultant harm) by using the scope. However, this must be compared with the costs associated with using Ambu aScope2, which may be high if the scope is not very effective at preventing intubation failure, or the risk of intubation failure is very low even when the scope is not used.
2. Finding the probability that the scope is used before it expires (this will depend on the incidence of unexpected difficult intubation as well as the availability of re-usable scopes and the likelihood these will not be available). This will allow us to identify the expected cost savings from purchasing the scope over its lifetime.

3.1 Settings and scenarios

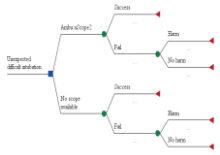
This section describes the specific settings that are to be considered by the model. The first relates to a hospital unit that currently has no re-usable fibrescopes (scenario 1). The second explains the supplementary purchase model (where re-usable fibrescopes are already available) in various settings: a general operating theatre (scenario 2), an intensive care unit (ICU) (scenario 3) and obstetrics (scenario 4). Finally, the model is described in relation to displaced tracheostomy (scenario 5).

A. Hospital unit without current re-usable fibrescope provision

Due to the large cost of acquiring a re-usable scope (estimated to be £12,105 in the sponsor submission) and the required decontamination facilities, some hospital units (typically smaller units providing relatively low risk services such as eye surgery or IVF procedures) are not equipped with any re-usable scopes, despite carrying out intubations. If they expect a difficult intubation, they are able to acquire a scope in advance or transfer the patient to another unit where the kit is available. However, this means that in the event of an *unexpected* difficult intubation, there are no scopes available. Thus, unlike the situation described within the sponsor's submission, the appropriate comparator for the Ambu aScope2 2 is not re-usable scopes but rather *no scopes.*

Figure 1 below shows the basic structure of the decision tree model. If a single-use scope (i.e. the Ambu aScope2) is available, it will be used if and only if an *unexpected* difficult intubation occurs (it is thought that for expected difficult intubations that can be planned for, arrangements will have been made in order to make a re-usable scope available, as this is preferred by clinicians). Unexpected difficult intubations are therefore the entry point into the decision tree.

Figure 1: Decision tree for isolated unit



In the calibration of the model used here, the expected cost of harm given an intubation failure (E[cost of harm|failure]) is the same whether a scope has been used or not. The cost of success is simply the cost of the scope if it is used (upper branch), and zero if it is not used (lower branch). The net cost associated with having the Ambu aScope2 available in the event of an unexpected difficult intubation is therefore:

$$\underbrace{P[failure|no\ scope]\ x\ E[cost\ of\ harm|failure]}_{\text{Cost (no scope)}} - \underbrace{P[failure|scope]\ x\ E[cost\ of\ harm|failure] - \ scope\ cost}_{\text{Cost (scope)}}$$

This expected cost saving per unexpected difficult intubation using the scope ($E[\Delta c\ per\ u.d.i.]$) can be simplified as follows:

$$E[\Delta c\ per\ u.d.i.] = \{P[failure|no\ scope] - P[failure|\ scope]\}E[cost\ of\ harm|failure] - scope\ cost$$

The difference in probability of failure with and without a scope can be re-written as $R\ x\ P[failure|no\ scope]$, where R is the percentage reduction in risk of failure when the scope is used. Cost saving per unexpected difficult intubation will only be positive if the expected benefits of using the scope (over its lifetime) outweigh the purchase cost of the scope.

In order to estimate the expected benefit of having a single-use scope, we must assess the likelihood that an unexpected difficult intubation occurs before the scope expires. The occurrence of intubation events can be modelled as a Poisson process. Let's say that the number of intubations per year in a unit is *x,* of which a fraction *q* is unexpectedly difficult. If the scope lasts l years, then the expected number of events (in this case an unexpectedly difficult intubation [u.d.i.]) per lifetime of the scope is *qxl,* and the probability of at least one event occurring over the lifetime of the scope can be calculated using the Poisson formula.

Thus the scope is cost saving if:

$$[\Delta c] = P[at\ least\ one\ u.d.i.in\ l\ years]\ x\ R\ x\ P[failure|no\ scope]\ x\ E[cost\ of\ harm|failure] > scope\ cost$$

In other words if the probability that the scope is used over its lifetime multiplied by the expected cost savings achieved, if and when it gets used, exceed the purchase cost, then the single-use scope is cost saving. If *n* scopes are bought together at the beginning of the period, then expected cost savings are positive if:

$$E[\Delta c] = \{P[at\ least\ \ one\ u.d.i.in\ l\ years] + P[at\ least\ \ two\ u.d.i.in\ l\ years] + \cdots + P[at\ least\ \ n\ u.d.i.in\ l\ years]\}[R]P[failure|no\ scope]E[cost\ of\ harm|failure] > n * scope\ cost.$$

A slight complication is that the expected cost of harm must be discounted according to when it occurs. Since the distribution of possible arrival times depends on the rate at which unexpected difficult intubations occur and the length of life of the scope, the discount factor applied also depends on these parameters.[2]

The exact re-ordering policy (i.e. how many to purchase at once and when to re-order) will depend on the time taken to re-order a scope once one has been used up and the caseload of the unit. This is a question of supply chain organisation, and one which we will not try to predict. In our model, we assume that the unit will buy a batch of 5 single-use scopes at the beginning of the period, and replace these with another 5 when they all expire (as according to the manufacturer they are sold in batches of 5). In many of the model outputs, we expect that there is a significant probability that at least one of these will go to waste and expire before they are all replaced. In cases where on average *more* than five unexpected difficult intubations occur within the scope lifetime, the model output would provide an underestimate of cost savings (assuming they are replaced). This is the case for all the scenarios that we describe in this report.

The model outlined above describes the potential cost-saving of Ambu aScope2 when used in a setting with no emergency access to re-usable scopes. The main output will be to explore: a) whether single-use scopes have resource-releasing potential in this setting, and if so, then b) to identify the minimum case-load of a unit for the Ambu aScope2 to be cost saving (i.e. a threshold number of intubations [expected to be carried out per year], below which any potential cost savings would be outweighed by the purchase cost of Ambu aScope2, and above which the Ambu aScope2 would be expected to save costs—the committee may then consider the type of setting most likely to benefit from single-use scopes).

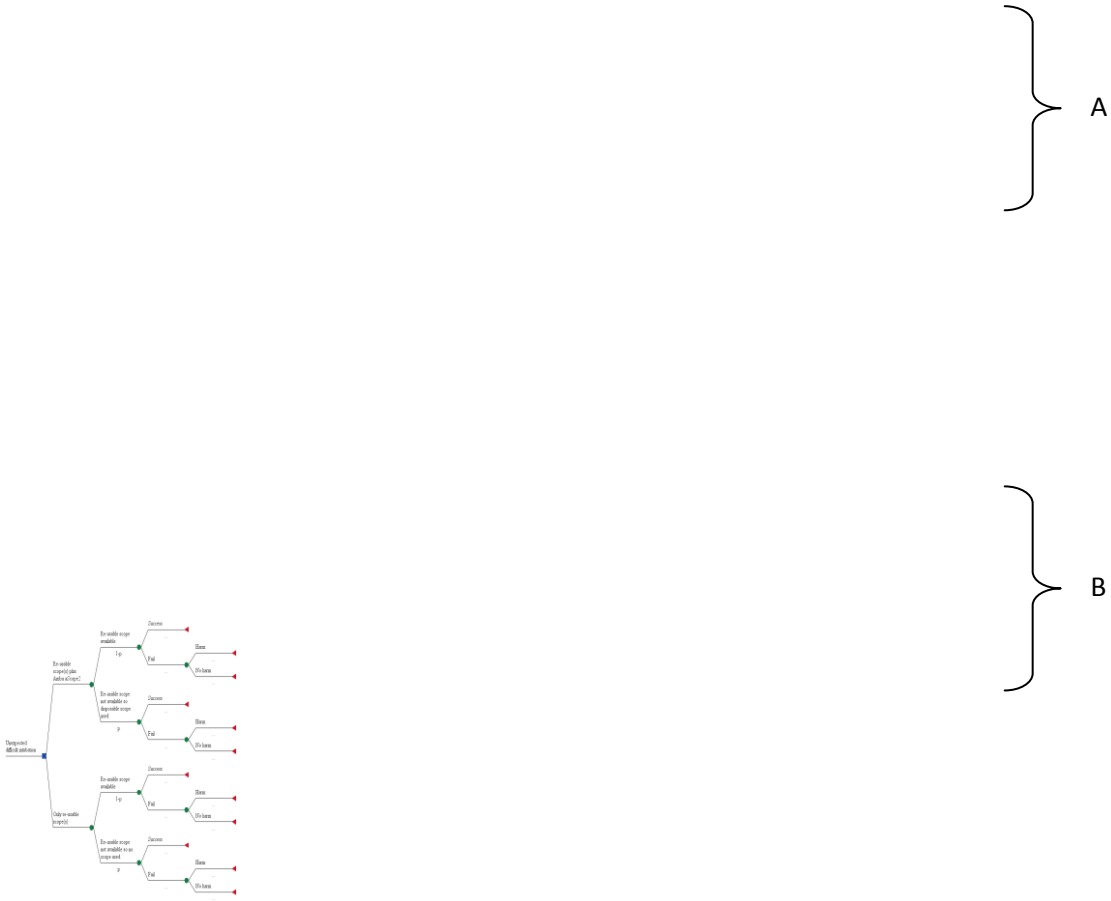
B. Supplementary purchase model (general operating theatre, intensive care unit , obstetrics)

In settings with a high throughput of patients requiring intubation (e.g. a busy operating theatre) and/or a high probability of expected difficult intubation (e.g. ENT clinic or ICU) one or more re-usable scopes are generally available. However, because scopes must be sterilised after use, there is

[2] The distribution of arrival times of the *kth* adverse event is modelled using the Erlang PDF

significant down-time[3] associated with each use of a re-usable scope. So there may be cases where an unexpected difficult intubation arises and there is no re-usable scope available. This is simply an extension of the small unit case, and is illustrated below:

Figure 2: Decision tree for unit containing one or more re-usable scopes



In the short run, the number of re-usable scopes is considered fixed for a given clinical setting, so the model can focus on the benefit of purchasing single-use scopes as a complement to existing re-usable scopes (although the optimal mix of re-usable and disposable scopes for a unit of a particular size is considered briefly later in the paper). This means that branches A and B are identical (if a re-usable scope is available then it will be used), so the policy choice between [re-usable plus single-use] and [re-usable only], actually reduces to the same model as in the small unit case:

[3] 'Down-time' is used to refer to the time in which the re-usable scope is not available, either because it is being used elsewhere, or because it is being sterilised. Sterilisation is required after every use, and/or every 72 hours of non-use.

$$E[\Delta c \; per \; u.d.i. | re - usable \; scope \; not \; available] = [R]P[failure|no \; scope]E[cost \; of \; harm|failure] - disposable \; scope \; cost$$

However, the complication is that the probability that a re-usable scope is not available when you need it depends on the clinical setting. It is *decreasing* in the number of re-usable scopes currently present in the unit (there is more likely to be a spare one), and *increasing* in the number of intubations carried out by the unit (more chance the scope will be in use/being sterilised). Additionally, the probability that the re-usable scope is not available is increasing in the proportion of intubations that are difficult (both expected [planned] and unexpected [unplanned], as both draw from the same limited pool of scopes).

The number of unexpectedly difficult intubations arising for which there is no re-usable scope available is modelled as a function of: number of re-usable scopes, numbers of intubations carried out in the unit, and re-usable scope down-time, which is modelled using a simple queuing simulation (carried out in Excel, as requested by NICE). Difficult intubation events arrive at random intervals according to a Poisson process. Each intubation event that arrives is randomly assigned to be either an anticipated difficult intubation, in which case the use of a re-usable scope can be scheduled in advance, or an unexpected difficult intubation event (the likelihood of each of these states is incorporated into the model based on estimates derived from the literature / clinical experts). Anticipated difficult intubations require a scope, but if a re-usable scope is not immediately available they enter a 'last-in-last-out' queue for the re-usable scopes. Unexpected difficult intubations require a scope immediately. If there is a re-usable scope available then they are assigned to this. If there is no re-usable scope available, then if the hospital has followed the policy of supplementary purchase of single-use scopes, then they are assigned a single-use scope. If the hospital has not purchased any single-use scopes, then they proceed to the 'no scope' situation, for which there is an increased probability of intubation failure and associated harm.

Once a re-usable scope has been used it must be re-sterilized, which involves it being unavailable for a period of time (this is referred to subsequently as scope 'down-time'). Additionally, re-usable scopes must be maintained and occasionally undergo major repairs. In the model, once a re-usable scope has been used to intubate a patient, it is randomly assigned to sterilization, maintenance or major repair. Until this has finished, it is unavailable for use by other patients.

For each scenario modelled, a sequence of 5,000 difficult intubation events is simulated 100 times and the number of unexpected difficult intubations (for which a re-usable scope is not available) is calculated. The outcome is then modelled in the same way as for the isolated unit model.[4]

The supplementary purchase model described above will be applied to three clinical settings: a general operating theatre (scenario 2), an ICU (scenario 3), and obstetrics (scenario 4). The settings will only differ by risk parameters that are assigned to the difficulty of intubations, and the likelihood/type of harm.

[4] This is complicated by the fact that under certain combinations of the parameters, queues for the scopes could build up over time, meaning that the probability of scope unavailability when an unexpected difficult intubation arises could increase over time, and approach one. While a theoretical possibility, it is not likely if the model is calibrated realistically; capacity of operating rooms should be planned such that the queue size does not explode over time.

C. Displaced tracheostomy model

The model structure for displaced tracheostomy in the ICU setting (scenario 5) is identical to the model of supplementary purchases, with calibration reflecting the different risks and costs of displaced tracheostomy compared with unexpected difficult intubation.

3.2 Assumptions of the model

After briefly outlining some of the structural assumptions of the model, the base-case parameter estimates will be presented and explained.

3.2.1 Structural assumptions

- *Re-sterilisation:* Even when re-usable scopes are not used, they must be re-sterilised every 72 hours. Since the average number of fibreoptic intubations is so low in the base-case calibration of the model, a significant fraction of scope down-time should be due to sterilisation when scopes have not been used. This is difficult to account for within the very simple queuing model presented here, because it requires considering optimising behaviour by managers who plan scope down-time to minimise the probability that all re-usable scopes are away for cleaning simultaneously.
- *Incompatibility of the single-use scope with the Aintree catheter is ignored*.

3.2.2 Parameter assumptions

Literature searches have been performed to elicit the model's parameters, which are described below (greater levels of detail are presented in Appendix C). Particular attention is given to the parameters of the sponsor's model criticised by the clinical experts: specifically the probabilities of death, brain damage and increased ICU length of stay as a result of intubation failure. For each set of input parameters (risk parameters, cost parameters and 'other'), a table provides the base-case point estimate, alongside which the manufacturer's estimate is presented (where relevant), and the lower and upper bounds to be considered within the sensitivity analysis is provided. Where the clinical setting is not specified, the probabilities are relevant across clinical settings.

I. Risk Parameters

The risk parameters relate to both the likelihood that a single-use scope would be required, and the magnitude of reduced risk of harm that a scope could provide by reducing intubation failure. Some of these parameters are likely to vary according to the clinical setting; these are summarised in Table 1. Where relevant, our point estimates are compared with those of the manufacturer. The upper and lower bounds to be utilised for the sensitivity analysis are also provided (LB-lower bound and UB-upper bound). The parameters were derived from the literature where possible. Clinical experts were also contacted, in order to aid interpretation of the literature, and to provide estimates of the required parameters where these were not provided by the literature (see Appendices A and B for correspondence with experts). Table 1 contains the parameter estimates for the first four scenarios. The risk parameters for displaced tracheostomy will be presented separately.

Table 1 Risk parameters

Parameter	Point estimate and source				Point estimate in sponsor submission (where applicable)
	Unit with no scope	**General operating theatre**	**ICU**	**Obstetric**	
Probability of expected difficult intubation (i.e. use of re-usable scope planned)	**N/A**	**2.2%** (NAP4 2011)* LB:1% UB:10%	**N/A** (assumed not able to re-schedule ICU intubations)	*Uncertainties discussed in results*	
Probability of unexpected difficult intubation	**0.6%** (NAP4 2011)* LB:0.4% UB:1%	**0.6%** (NAP4 2011)* LB:0.4% UB:1%	**20%** (Mayo et al. 2011) LB:5% 25%	**0.6%** (NAP4 2011)* LB:0.4% UB:1%	N/A because results described in terms of number of times scope used
Probability of failure given unexpected difficult intubation (no scope)	**16.6%** (Rose & Cohen 1994)[5] LB:5% UB:40%	**16.6%** (Rose & Cohen 1994) LB:5% UB:40%	**16.6%** (Rose & Cohen 1994) LB:5% UB:40%	**16.6%** (Rose & Cohen 1994) LB:5% UB:40%	Sponsor uses the ICU probability for the case when re-usable scopes are available; the papers utilised relate to direct laryngoscopy rather than use of a FOS
Percentage reduction in failure rate with scope	**70%** (Clinical opinion)* LB:40% UB:90%				Unclear: arbitrary 0.1 difference in failure rate between re-usable and disposable scope policies
Probability of death given intubation failure	**2%**[6] (Auroy et al. 2009;NAP4 2011;Thomas & McGrath 2009)*	**2%** (Auroy et al. 2009;NAP4 2011;Thomas & McGrath 2009)*	**14%** (NAP4 2011)*	**2%** (Auroy et al. 2009;NAP4 2011;Thomas & McGrath 2009)*	28% for combined probability; this was criticized by one of the co-authors of the paper utilised (Thomas & McGrath 2009)
Probability of brain damage given intubation failure	**1%** (Auroy et al. 2009;NAP4 2011;Thomas & McGrath 2009)* LB:0.5% UB:4%	**1%** (Auroy et al. 2009;NAP4 2011;Thomas & McGrath 2009)* LB:0.5% UB:4%	**4%** (NAP4 2011)*	**1%** (Auroy et al. 2009;NAP4 2011;Thomas & McGrath 2009)* LB:0.5% UB:4%	
Probability of other 'more than temporary harm' given intubation failure	**25%**[3] (NAP4 2011;Thomas & McGrath 2009)*	**25%** (NAP4 2011;Thomas & McGrath 2009)*	**10%** (NAP4 2011;Thomas & McGrath 2009)*	**25%** (NAP4 2011;Thomas & McGrath 2009)*	0.74 used as probability of increased length of stay in ICU; this was criticized by one of the co-authors (Thomas & McGrath 2009)
Probability that harm results in successful litigation case against NHS	**4.5%** (Cook, Scott, & Mihai 2010;NAP4 2011)				

*Those with an asterisk are estimates which could not be retrieved *directly* from the literature source provided, and which are explained in text below.

[5] Note: The estimates from Rose & Cohen (1994) is used as it is the only study identified where it is clear that there were no scopes available.

[6] Note: Sensitivity analysis not included for probability of death or 'more than temporary harm', as these are not a major drivers of the cost saving.

As is evident from Table 1, the risk parameter inputs for 'unit with no scope' and 'general operating theatre' are largely the same, the only difference being that the probability of an expected difficult intubation is not relevant for the first setting, as there are no re-usable scopes held in the unit. These settings are therefore discussed together in the brief explanation of parameter estimates that follows. The ICU and Obstetric settings will be discussed individually.

SCENARIOS 1 & 2: UNIT WITH NO SCOPE AND GENERAL OPERATING THEATRE

Probability of expected and unexpected difficult intubation

The probability of an unexpected difficult intubation (0.6%) was derived from NAP4. The estimate of 2.2% of intubations being *expectedly* difficult in the general operating theatre is also derived from information provided in the NAP4 report. In chapter 12 (relating to tracheal intubation) the authors suggest that of the 43 patients whose intubation was difficult, this difficulty was anticipated in 31 cases, implying that unexpected difficult intubations represent around 30% of total difficult intubation (NAP4 2011, p. 97). If 0.6% of intubations are unexpectedly difficult, this ratio is upheld if we assume that 2.2% intubations are expectedly difficult[7].

Percentage reduction in failure rate with scope

The relative risk reduction in failure when a scope is available (versus when it is not) could not be derived from the literature, and so was elicited from clinical experts at 70%. There seemed to be a general consensus that this may be an appropriate estimate, though responses ranged from a 40% to a 90% risk reduction.

Probability of harm

A rapid literature review of the published incidence rates of harm resulted from a failed tracheal intubation was conducted. The criteria for reporting to NAP4 are death, brain damage, emergency surgical airway, prolongation of ICU stay or unanticipated ICU admission[8]. Thus, intubation failures which result in none or minor harm are not reported in NAP4. Thomas and McGrath (2009) report critical incidents from the National Patient Safety Agency (NPSA) database. Their paper breaks down delayed or failed intubations into the following three categories: no harm (26% of failed intubations), temporary harm (46%) and more than temporary harm (28%). Unfortunately, the categorization is not consistent with NAP4. It may also be the case that intubation failure with no harm is under-reported in NPSA, the source used by Thomas and McGrath. This source may also under-report critical incidents. For the purposes of estimating death and brain damage, we assume that the 'more than temporary harm' category corresponds to inclusion in NAP4.

Auroy and colleagues (2009) present the overall incidence of tracheal tube death and tracheal tube brain damage as a proportion of all anaesthetic intubations (6.1 per million and 3 per million respectively). We know from NAP4 that tracheal tube events occur in 82.5 cases per million

[7] It is possible that some of the inputs that have populated this model have not excluded children in their calculation (Auroy et al. 2009;NAP4 2011;Thomas & McGrath 2009).

[8] Note: Clinical experts all state that critical incidents in NAP4 are under-reported; they disagree about the number and probable type of unreported incidents.

anaesthetic intubations. Combining these, we can infer that 7.39% (6.1/82.5) of tracheal tube events involve death, and 3.63% (3/82.5) of tracheal tube events involve brain damage. Thus, using the Thomas & McGrath study to relate these to (more than temporary) harm from *failed* intubations, we have that death as a percentage of failed intubation is 7.39% multiplied by 28% (=2%) and brain damage as a percentage of failed intubation is 3.63% multiplied by 28% (=1%). The 'other more than temporary harm' resulting from intubation failure is simply the remainder of the 28%, and is considered to involve a prolonged stay in ICU.

Probability that harm results in successful litigation case against NHS: explained in the section below describing cost inputs.

Although the risk parameters described above come from disparate sources, with data from NAP4 it is possible to see whether, combined, they provide a reasonable representation of reality. By using the risk parameters presented above to calculate the overall incidence of harm per million intubations, we have that there would be 1,301 incidences of harm when there is no scope, and 390 incidences of harm if a scope were available in all cases (assuming, as we do, that these reduce risk of failure by 70%). The NAP4 estimated an incidence of harm per million intubations of 82.5. Although this is way below the incidence rate provided by our model, the clinical experts with whom we consulted all emphasised that they believed NAP4 to present a severe underrepresentation of actual harm rates in clinical practice—some suggesting that realised harm may be up to 10 times that reported in NAP4.

SCENARIO 3: ICU

Compared with an operating theatre, the management of difficult intubations in an ICU setting is likely to be very different, and it is for this reason that the committee considered that a single-use scope may be of particular value in this setting. Whereas operating theatres will be better equipped to manage and predict difficult intubations, in an ICU setting the emergency nature of intubations may pose higher complications, and the availability of skilled and trained staff may be lower. The risk parameters outlined in Table 1 reflect these differences.

Given the factors described, the NAP4 report is clear to emphasise that rates of complication are much higher in an ICU setting, and that the harm associated with failed intubation is likely to be more serious (NAP4 2011). Due to the severity of a patient's condition, clinicians are likely to expect that a patient's airway may be difficult. However, given the emergency nature of intubations in ICU, difficult intubations are not 'expected' in the same way as they are in scenarios 1 & 2 (there is no chance to *plan* the use of a re-usable fibrescope). Therefore, all of our difficult intubations for the ICU scenario are input into the model as 'unexpected' difficult intubations (though we understand this is a simplification).

In our model we assume that the probability of failure given a difficult intubation is the same as in other settings, but that intubation failure is much more common given the much higher probability that an intubation will be difficult (probability of difficult intubation is elicited directly from a study presented by Mayo et al (2011): 20%). This is reflective of the ICU environment described above, as well as the case mix of patients. This case mix (the critically ill) additionally means that the severity of harm given intubation failure is presumed to be much greater. As we could identify no estimates

of harm given failed intubation specifically (within an ICU setting), we use NAP4's ICU-specific harm rates for all airway events (NAP4 2011, p. 43). The probability of other more than temporary harm is assigned the remainder of the 28% from Thomas & McGrath (2009) for simplicity.

It is important to note that there may be some difficulty in interpreting the harm rates in an ICU setting (as acknowledged within the NAP4 itself), as identifying harm *caused* by the airway management specifically is difficult, due to the critical state of patients and thus the much higher baseline risk of poor outcomes (though some attempt was made to isolate causal harm in the NAP4). Therefore, harm rates within this setting may have been overestimated.

SCENARIO 4: OBSTETRICS

The committee thought it important to also consider the potential value of the Ambu aScope2 in an obstetric setting, where a fibrescope may not be readily available. Given the lack of literature relating to intubation in the obstetric setting (the NAP4 contained just four obstetric cases), two clinical experts were sought for advice on appropriate parameter inputs. The difference in responses reflects the varying nature of obstetric departments, whose differences may stem from the size of the departments as well as local best practice.

One clinical expert discussed the situation at Birmingham Women's Hospital, which delivers 8,000 babies per year and conducts around 500 general anaesthetics per year in obstetrics (all of which require intubation). This hospital has access to one re-usable scope, but the expert indicated that this was used very rarely (only once in the last three to four years), despite the high expectation of intubations being difficult. This is because intubations are carried out as rapid sequence induction (RSI), for which their own policy dictates that after two failed attempts to intubate, they wake the patient up.

The other obstetric expert, whose facility conducts around 150 intubations per year, indicated that 2% involve an intubating fibrescope (but that this must be brought in from another department as they do not own one). This expert indicated that for 60% of unexpected difficult intubations there was no fibrescope available, indicating a greater potential for single-use scopes than in the unit described above.

There is clearly a high degree of variability in the potential for single-use scopes between obstetric departments. Therefore, the model variations discussed will be illustrative only.

SCENARIO 5: DISPLACED TRACHEOSTOMY

Table 2 Risk parameter – tracheostomy displacement in ICU

Parameter	Point estimate	Point estimate in sponsor submission
Probability of tracheostomy displacement	**0.15** (147 displacements in 968 tracheostomies[ǂ], Oct 2005 - Sep 2007)(McGrath & Thomas 2010) Note: the setting in this study was hospital wards rather than ICU	-
Probability of death	**0.14** (NAP4 2011;Thomas & McGrath 2009)*	0.13 (rate of brain injury or death) (Thomas & McGrath 2009)
Probability of more than temporary harm	**0.08** (NAP4 2011;Thomas & McGrath 2009)*	
Probability of prolongation of ICU stay	**0.06** (NAP4 2011;Thomas & McGrath 2009)*	0.75 (McGrath & Thomas 2010 (McGrath & Thomas 2010))

*Those with an asterisk are estimates which could not be retrieved *directly* from the literature source provided, and which are explained in text below.

[ǂ] The McGrath & Thomas paper reported 968 tracheostomy related incidents (NAPA database), and of these "453 directly affecting patients, with the remaining 515 not directly affecting individual patients." The paper stated that "*'patient safety incident' is defined as 'any unintended or unexpected incident which could have harmed or did lead to harm for one or more patients being cared for by the NHS'"*. The total number of tracheostomy during the study period was not stated but it can be assumed to be 968, although this might present an underestimate.

Thomas & McGrath report that the risk of more than temporary harm that resulted from unplanned removal of devices (both tracheostomy tube dislodgment and tracheal tube dislodgement) was 0.032 (8/249) (Thomas & McGrath 2009). Data from the NAP4 report suggest that the risk of hypoxic brain injury as a result of tracheostomy displacement was 0.286 (4/14) (NAP4 2011). As data in the NAP4 report only included major airway complications which led to death, brain damage etc, while data in the Thomas & McGrath paper included all airway-associated incidents, therefore, the point estimate for the probability of more than temporary harm is derived by 0.032 times 0.286 (= 0.08). This may represent an overestimate as the reported hypoxic brain injury may not all necessarily have caused permanent harm.

Data from the NAP4 report show the probability of death resulting from tracheostomy displacement was 0.5 (7/14). When this was adjusted by 28% (of all air-way associated incidents 28% were more than temporary harm (Thomas & McGrath 2009)) the point estimate for the probability of death is 0.14.

In the NAP4 report the 14 incidents of tracheostomy displacement resulted in 7 deaths and 4 incidents of hypoxic brain injury. As only major airway complications were included in the NAP4, the incidents of prolonged ICU stay resulted from tracheostomy displacement can be assumed to be 3 and therefore the probability of prolongation of ICU stay is 0.214 (3/14). This adjusted by 28% (Thomas & McGrath 2009) is 0.06.

It is important to note that the source used to estimate the probability of tracheostomy displacement was based on a study which did not consider the ICU setting specifically. The figure utilised is somewhat higher than other estimates from the literature (see Appendix C), so may be an overestimate.

II. Cost parameters

A summary of the cost parameter estimates is provided in Table 3; more detail is provided below where relevant. All costs are all normalised to 2010/2011 prices using Hospital & Community Care Services (HCHS) Pay&Prices index (PSSRU 2011).

Table 3 Cost parameters

Parameter	Point estimate and source				Point estimate in sponsor submission
	Unit with no scope	General operating theatre	ICU	Obstetric	
Cost of Ambu aScope2	**£179** (Ambu Ltd)				£179
Cost of monitor	**£799** (Ambu Ltd)*				N/A
Litigation: Mean cost of successful lawsuit in the event of harm due to intubation failure	**£134,000** (Cook, Scott, & Mihai 2010;NAP4 2011)*				N/A
Mean length of stay due to intubation failure (days)[9]	**2 days** (HES 2011)				6.2 days
Mean cost per day in ICU	**£1,213** NHS Reference costs 2010/11 (Department of Health 2011)				£1,321
Brain damage cost per year	**£36,320** (Beecham, Perkins, Snell, & Knapp 2009)*				N/A
Life expectancy of brain damaged patient (years)	**12.5 years** (ONS 2011;Shavelle, Strauss, Day, & Ojdana 2007)*			**26.4 years** (ONS 2011;Shavelle, Strauss, Day, & Ojdana 2007)*	N/A

*Those with an asterisk are estimates which could not be retrieved *directly* from the literature source provided, and which are explained in text below.

Table 4 Cost parameters for tracheostomy displacement

Mean length of stay for tracheostomy displacement	**6.7 days** (HES 2011) [code J95.0]
Life expectancy	**15.6 years** (HES 2011;ONS 2011;Shavelle, Strauss, Day, & Ojdana 2007)*

*See 'cost of brain damage' section below for life expectancy calculation methods

Table 3 shows that the only parameter to differ between scenarios is the life expectancy of brain damaged patients. The text below describes the parameter estimates for which an explanation is required.

[9] This is applied to brain damage and 'more than temporary harm' categories.

Cost of monitor

In the sponsor's original submission, the monitor was not included in the cost analysis, because the current arrangement was for the monitor to be supplied for free. As we are unsure whether this practice will continue, we present the cost analysis both with and without the need to purchase the monitor separately.

Litigation costs

The National Health Service Litigation Authority (NHSLA) is an organisation that manages all legal claims made against the NHS in England. In 2010 Cook, Scott & Mihai published a study which analysed the NHSLA dataset in order to identify all litigation cases related to airway and respiratory complications of anaesthesia between 1995 and 2007 (Cook, Scott, & Mihai 2010). We use this research to value the potential savings in litigation costs to the NHS resulting from reduced intubation-related airway complications.

As the authors do not break down airway claims that result in death and brain damage specifically, we take total (non-dental) airway claims and their average cost to value litigation costs for any harm. Airway claims '*…most frequently described events at induction of anaesthesia, involved airway management with a tracheal tube and typically led to hypoxia and patient death or brain injury'* (Cook, Scott, & Mihai 2010, p. 556). During the 12 year period from 1995 to 2006 there were 49 successful airway claims (around 70% of these resulted from death or brain damage). The sum of these claims totalled £4.9 million, implying an average cost of £100,000 per successful case.

Based on data from NAP4, there are approximately 91 tracheal tube events per year, which we consider to represent our incidence of (more than temporary) harm. Therefore over 12 years there can be expected to be around 1092 incidences of harm. According to the litigation data described above, this means that **4.5%** of all harms (49/1092) lead to a successful litigation case against the NHS, at an average cost of £100,000 per claim. As the authors do not present a reference year for their cost figures, we presume that these have not been inflated to today's prices, and take the reference year to be the mid-point of the time span over which litigation cases were analysed: 2001. Therefore the average cost to the NHS per successful litigation case in 2010/11 prices[10] is **£134,000**.

Cost of brain damage

There is a paucity of long term cost data for brain injury in the literature (Harris et al. 2012). This deficiency is widely recognised, and few studies attempt to quantify the cost to the NHS of this long term and highly variable condition. The most relevant study identified was that of Beecham and colleagues (2009), who describe the treatment paths and costs for young adults with acquired brain injury in the United Kingdom[11] (Beecham, Perkins, Snell, & Knapp 2009). The study was undertaken

[10] Inflated using Hospital & Community Care Services (HCHS) Pay&Prices index from 2001/2 to 2010/11 prices (PSSRU 2011).

[11] Although the study focuses on young adults, the authors state that data for young adults specifically was difficult to obtain, and that where age-specific data was not available it was assumed that data for all adults with acquired brain injury would provide valid estimates (Beecham, Perkins, Snell, & Knapp 2009).

in response to a call from the Department of Health to estimate the health and social care costs associated with supporting young adults with acquired brain injury. By following the treatment pathway of patients over a notional one year period, an overall yearly cost is presented for four groups of patients according to the location of their subsequent community care: (1) returned home and living independently [£240 p.a.]; (2) returned home but reliant on informal care [£17,160 p.a.]; (3) living in supported accommodation with formal (paid) personal carers [£32,900 p.a.]; and (4) living in nursing homes for young adults, specialist brain injury residential units, or mental health units [£33,900 p.a.].

The Beecham study considers the progression of any young adult admitted to A&E with any kind of acquired brain injury. A large proportion of the sample is therefore represented by patients who sustain a mild traumatic brain injury, who spend short periods of time in a hospital ward and then return home with no long-term disability; this is unlikely to be representative of the group of adults who suffer brain injury as a result of oxygen deprivation due to failed intubation. The NAP4 report, from which the incidence of brain damage for this model is derived, describes brain damage outcomes as '*permanent low conscious level, neuro-behavioural deficit, or persistent vegetative state*' (NAP4 2011, p.31). We therefore assume that these patients pertain to groups 3 and 4 described above, which represent those who are more seriously disabled: those living in supported accommodation and those living in special residential units.To determine the proportional representation of patients in groups 3 and 4, we simply take a weighted average of the cost associated with groups 3 and 4 from the rates described in Beecham et al.: 76% and 24% respectively.

Average yearly health and social care costs of (serious) brain injury	£ 33,144 [2006 prices] = **£ 36,620** [Inflated using Hospital & Community Care Services (HCHS) Pay&Prices index from 2006/7 to 2010/11 prices (PSSRU 2011)]

Although calculations by Beecham et al. describe the costs associated with the first 12 months of care for these patients (and therefore might be considered to overestimate healthcare resource use in subsequent years), the authors offer no break-down of the costs associated with each stage of the treatment pathway. Therefore, we assume that £36,620 represents the yearly cost for subsequent years as well (which may be appropriate given the level of care required for this group of patients; additionally, Beecham et al. note that the cost data may under-estimate costs as the most conservative unit costs were selected for each care location)[12].

Assuming that the severity of brain damage born by patients due to failed intubation is permanent, it is appropriate to consider the lifetime costs of looking after these patients based on their life expectancy (which is lower than that of the general population). According to HES data from 2010-

[12] £36,620 does appear to be a fairly conservative estimate, particularly considering that residential placements may cost up to £2,500 per week, which is often jointly funded by health and social services (Beecham, Perkins, Snell, & Knapp 2009). The lower reported figure may be explained by the fact that long-term residential / nursing care can be means-tested, suggesting the costs may be partly born by the patients themselves or their families.

11, the average age for patients experiencing a failed or difficult intubation (code T88.4) was 58. For failed and difficult intubation during labour /delivery (code O74.7), the average age is around 30[13].

Ventura et al. provide life expectancy estimates for patients having suffered traumatic brain injury at various ages, with those suffering the injury at aged 60 expecting to survive another 15 years (Ventura et al. 2010). However, the severity of brain injury is not described, and so this may be an overestimate. Shavelle and colleagues (2007) also provide life expectancy estimates for traumatic brain injury patients, and break these down into severity of disability: permanent vegetative state, fed by others, self-feeds, some walking ability, and walks well alone (Shavelle, Strauss, Day, & Ojdana 2007). The precise state of those that acquire brain injury in our model is not known, but considering the description in the NAP4 report and the suggested location of their care, it may be reasonable to assume that they may span the first four categories of those noted above: permanent vegetative state, fed by others, self-feeds and some walking ability.

Unfortunately the authors present life expectancy for patients up to an age of 50 only. By averaging the life expectancy of this age group across patients in permanent vegetative state (7 years), fed by others (11 years), self feeds (19 years) and some walking ability (21.5 years), the life expectancy is 14.6 years—equivalent to just over half of the life expectancy of the general public at that age. Repeating this procedure with 30 and 40 year olds from Shavelle's table, the average life expectancy across these four states is consistently around half that of the general population (0.54 for age 30, 0.52 for age 40, and 0.49 for age 50). Therefore, it may be reasonable to assume that our cohort of patients who acquire a brain injury at the (average) age of 58, will remain in such a state for approximately **12.5 years** (based on an average life expectancy of the general population of 24.95 years (ONS 2011)).

Average life expectancy of brain injured patients from failed intubation	12.5 years
Average life expectancy for brain injured patients from failed intubation during delivery in an obstetric department	26.4 years[14]

By multiplying the yearly cost to health and social care services of brain injured patients in our model by their life expectancy, lifetime costs of brain injury are estimated (using a 3.5% discount rate).

Expected cost of brain damage (general)	**£378,478**
Expected cost of brain damage (obstetrics)	**£646,224**

[13] As 2010/11 HES data for failed/difficult intubation during labour and delivery consists of just one observation, we take the mean age of patients within this code over the past 5 years, for which there are 20 patient episodes, whose mean age is 30.

[14] This is based on the same methodology as that described for the general brain injured population, and is based on an average life expectancy of the (female) general population at age 30 of 52.8 years.

III. Other parameters

Table 5 Other parameters

Parameter	Point estimate and source			
	Unit with no scope	**General operating theatre**	**ICU**	**Obstetric**
Lifetime of single-use scope (years)	**3** (Ambu Ltd)			
Lifetime of monitor (years)	10			
Re-usable scope down-time (days)**	N/A	1	1.5	1.5
Discount rate	3.5%			
Probability re-usable scope requires routine repair **	N/A	0.2		
Down-time with routine repair (days)**	N/A	4	5.5	5.5
Probability re-usable scope requires major repair**	N/A	0.1	0.15	0.1
Down-time with major repair (days)**	N/A	31	31.5	31.5

**Based on sponsor submission and discussion with clinicians

The variable down-time for re-usable scopes is used as a proxy for all the reasons that a scope might be unavailable. The figures are calibrated using clinical opinion, but are not based on a comprehensive survey of re-usable scope usage and repair. Given the potential importance of these assumptions, sensitivity analyses are performed and presented around these estimates in the results section.

4. RESULTS: SCENARIO ANALYSIS

This section describes the base-case results for each scenario in turn, along with sensitivity analyses than have been performed.

Table 6 Setting parameters

Parameter	Point estimate			
	Unit with no scope	**General operating theatre**	**ICU**	**Obstetric**
Number of intubations	300	600 – 2,000	700	400
Number of re-usable scopes	0	2 (analysis presented for 1-3)	2	1

Scenario 1: Hospital unit without current re-usable fibrescope provision (e.g. IVF, eye pavilion)

For a unit with no fibrescopes that conducts an average of 300 intubations per year, an unexpected difficult airway (for which a disposable scope would be useful) arises on average 2 times per year. Under the base-case parameters, if a scope is not available (the current status quo), an unexpected difficult intubation will lead to an intubation failure on average once every three to four years. Severe outcomes are exceptionally rare, with death due to unexpected difficult intubation occurring on average once every 167 years and brain damage once every 334 years.

Even though severe outcomes are extremely rare, the very high cost of brain damage means that the expected cost of harm given an intubation failure is £6,607. As our base-case assumptions dictate that using a scope would reduce the probability of an unexpected difficult intubation failing from 16% to 5%, the average cost saving per use of the scope in the event of an unexpected difficult intubation is £768 (or £589 net of purchase price).

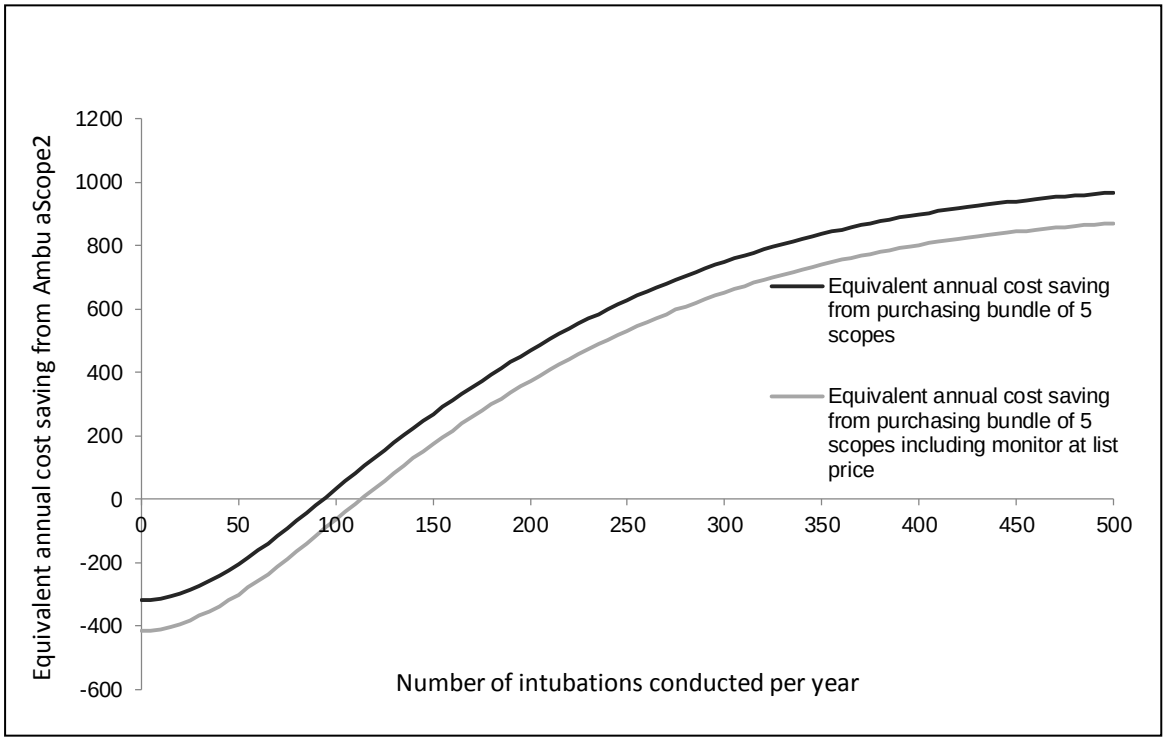
Cost savings from purchasing one or more Ambu aScope2s upfront depends on the probability that they are used before they expire. The higher the number of intubations carried out by a unit per year, the more likely it is that all scopes will be used before they expire. Figure 3 shows the annualised cost savings from purchasing a bundle of five single-use scopes (the standard unit of sale) by average number of intubations conducted within the unit annually. The lighter line shows annualised cost savings including the list price of the monitor (required to view the images from the Ambu aScope2s), and the darker line shows annualised cost savings excluding the monitor cost, since it is currently free with a 'starter pack' of 5 scopes to NHS trusts (Ambu Ltd).

Figure 3 shows that the threshold number of intubations per annum above which purchasing a bundle of five scopes is cost saving is around 95 excluding purchase of the monitor, and 115 including the monitor[15]. This means that if a unit (which has no immediate access to re-usable scopes) is expected to conduct over 95-115 intubations per year, then purchasing a bundle of Ambu aScope2s may be cost saving.

For the small unit 'base-case' of 300 intubations, the equivalent annual cost saving from purchasing a bundle of five scopes including a monitor at list price is £653 (without the monitor savings are £749 – the difference is small because the monitor cost is annualised over a ten-year lifespan). It should be emphasised that overall cost savings for the unit are potentially higher if the unit employs a policy of re-ordering scopes as they are used up: the savings shown are for the first five-pack of disposable scopes only.

[15] This is equivalent to an average of 0.7 difficult intubations per year; at this point there is a 15% chance that no scopes are required during the three-year lifespan of the scope (and thus that the scopes are all 'wasted'), but the high expected cost savings when one or more of the scopes is used means overall cost savings are zero.

Figure 3: Equivalent Annual cost savings of Ambu aScope2 in a small **unit with no re-usable fibreoptic scope**



A probabilistic sensitivity analysis was conducted for the base-case of 300 intubations per year, varying the risk parameters in the model and the uncertain subset of cost parameters. The distributions from which the parameters were drawn are summarised in Table 7 and Table 8. There is uncertainty surrounding the choice of distributional form for the parameters, given limited empirical information. The estimates chosen were mostly based on single studies considered to be the highest quality available, but there was considerable variation between studies and the heterogeneity of studies made a quantitative meta-analysis impossible.

Table 7: Distribution of risk parameters for probabilistic sensitivity analysis around scenario 1

		Beta distribution parameters		
	Point estimate	α	β	Source
Probability of unexpected difficult intubation	0.006	1	166	Parameters chosen to reflect extreme uncertainty surrounding estimate
Probability of failure given unexpected difficult intubation (no scope)	0.166	54	272	Rose (2004)
Percentage reduction in failure rate with scope	70%	70	30	Parameters chosen to reflect extreme uncertainty surrounding estimate
Probability of death given intubation failure	0.02	1.82	66	Based on incidents in Thomas (2009)
Probability of brain damage given intubation failure	0.01	1.04	66	Based on incidents in Thomas (2009)
Probability of other more than temporary harm given intubation failure	0.25	23.14	66	Based on incidents in Thomas (2009)
Probability that family brings successful suit against NHS given death/brain damage/more than temporary harm	4.5%	49	1043	Based on number of claims in Cook (2010)

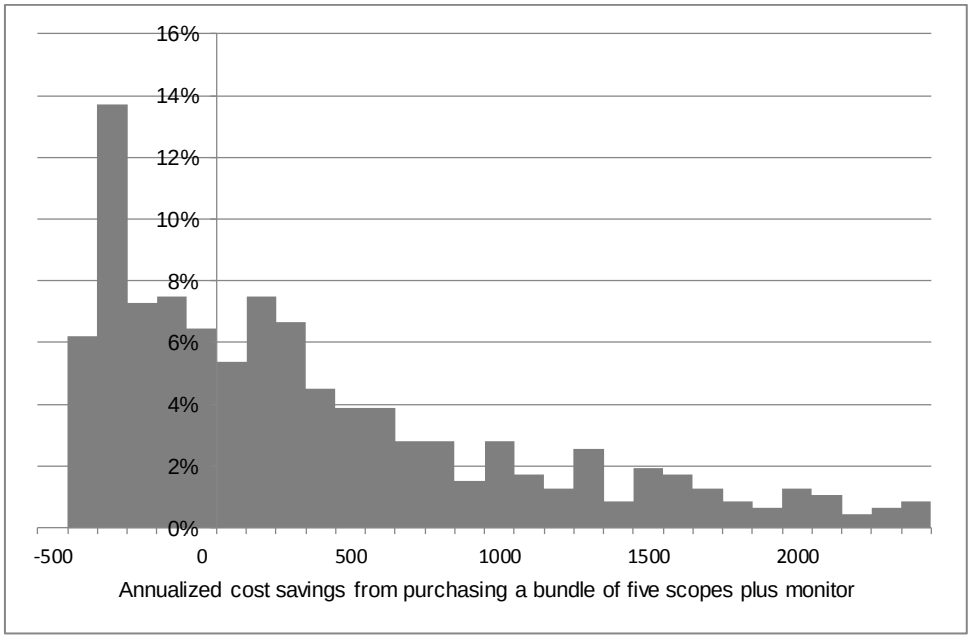
Table 8: Distribution of cost parameters for probabilistic sensitivity analysis around scenario 1

		Lognormal distribution parameters		
	Point estimate	μ*	σ	Source
Mean cost of successful lawsuit in the event of harm due to intubation failure	£134,000	11.8	0.4	No sound justification for σ; based on description analysis in Cook (2010)
Mean cost per day in ICU	£1,213	7.19	0.13	NHS Reference Costs (2010/2011)
Brain damage cost per year	£36,620	10.5	0.4	No sound justification for σ; based on description analysis in Beecham (2007)

* μ is the natural log of the point estimate

Figure 4 shows the results of 500 simulations of scenario 1 for a base-case of 300 intubations per year, with parameters drawn from the distributions outlined above. While the mean annualised cost savings (£542) and median (£194) are both positive, the implied 95% confidence interval is from -£400 (cost incurring) to £1,800 (cost saving), and 41% of the model runs that were simulated were actually cost-incurring. This implies that while purchasing the single-use scopes appears to be cost-saving on the basis of the point estimate given above, we are not able to say with confidence that the Ambu aScope2 will be cost saving, and the results should be interpreted with caution.

Figure 4: Probabilistic Sensitivity Analysis around scenario 1: Histogram of annualised cost savings



In conducting this probabilistic sensitivity analysis we acknowledge the difficulty that we encountered in identifying certain estimates in the literature. However, given our best estimates, our analysis showed that by procuring the Ambu aScope2 bundle of 5 scopes, cost savings may be expected in settings conducting as few as around 100 intubations per year (at which point less than one of the Ambu aScope2s was actually expected to be used before all 5 expired). The greater the

caseload of the unit, the more likely the purchase of single-use scopes for use in cases of unexpected difficult intubations will be cost saving, particularly if a re-ordering of scopes is necessary.

Scenario 2: General Operating Theatre

In larger operating theatre settings, there are generally one or more re-usable scopes available for use in planned and unplanned difficult intubations. The base-case here is an operating suite with two re-usable fibrescopes, conducting 600-2000 intubations per year, with analysis also conducted for 1 to 3 re-usable fibrescopes. The analysis presented here is not suitable for settings in which the probability of planned difficult intubations and use of awake fibreoptic intubation is especially high, such as Ear, Nose and Throat surgeries; these settings are likely to have more re-usable fibrescopes available.

The expected cost of harm given a failed intubation and the expected cost savings per use of the Ambu aScope2 is exactly the same as in the previous scenario; this is because the probabilities and costs of harmful events, the probability of failure given an unexpected difficult intubation, and the percentage reduction in failure as a result of using a fibrescope are all identical to the small unit scenario. The main difference between this and the previous setting is the presence of re-usable scopes. Having a re-usable scope simply reduces the probability that an Ambu aScope2 is required in the event of an unexpected difficult intubation, since a single-use scope is only required if there are no re-usable scopes available. This will have the result of reducing the cost savings associated with purchasing a bundle of single-use scopes *for a given intubation caseload.*

Figure 5 shows equivalent annual cost savings from purchasing a bundle of five scopes where there are two re-usable scopes available. For the base-case of 1,000 intubations per annum and two re-usable scopes present, annualised cost saving from purchasing the bundle of disposable scopes in addition to the re-usable scopes present is -£203 (without monitor) and -£299 (with monitor). In other words, purchase of the scope is cost-incurring because events requiring the scopes arise so rarely that they are unlikely to be used before they expire.

The threshold above which purchasing the single-use scopes when two re-usable scopes are already available becomes cost saving is 1250-1350 intubations per year, depending on whether the monitor price is included. At this threshold, the probability that no re-usable scope is available when required for an unexpected difficult intubation is around 7% and on average, a single-use scope is expected to be required around 0.7 times per year. As the number of intubations increases, the average number of unanticipated difficult intubations per year increases *and* the probability that there will be no re-usable scope available when they arise increases, both tending to increase cost savings from purchasing the Ambu aScope2s.

Figure 5: Equivalent annual cost savings from purchasing Ambu aScope2 cost savings in general operating theatre setting with two re-usable scopes

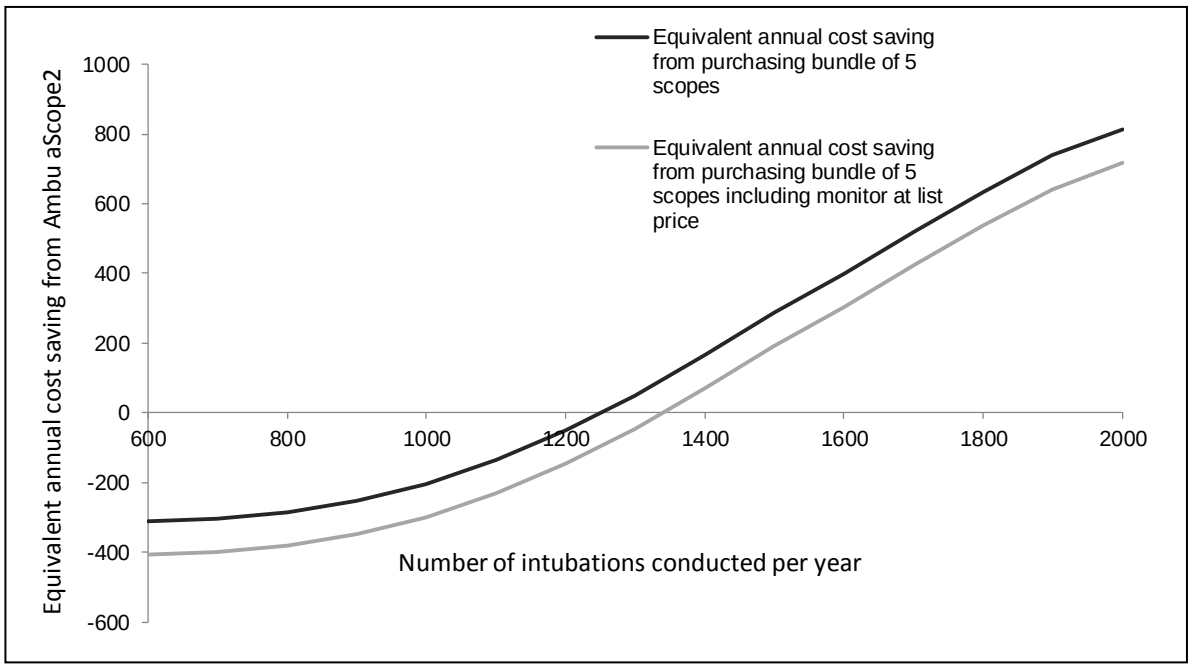
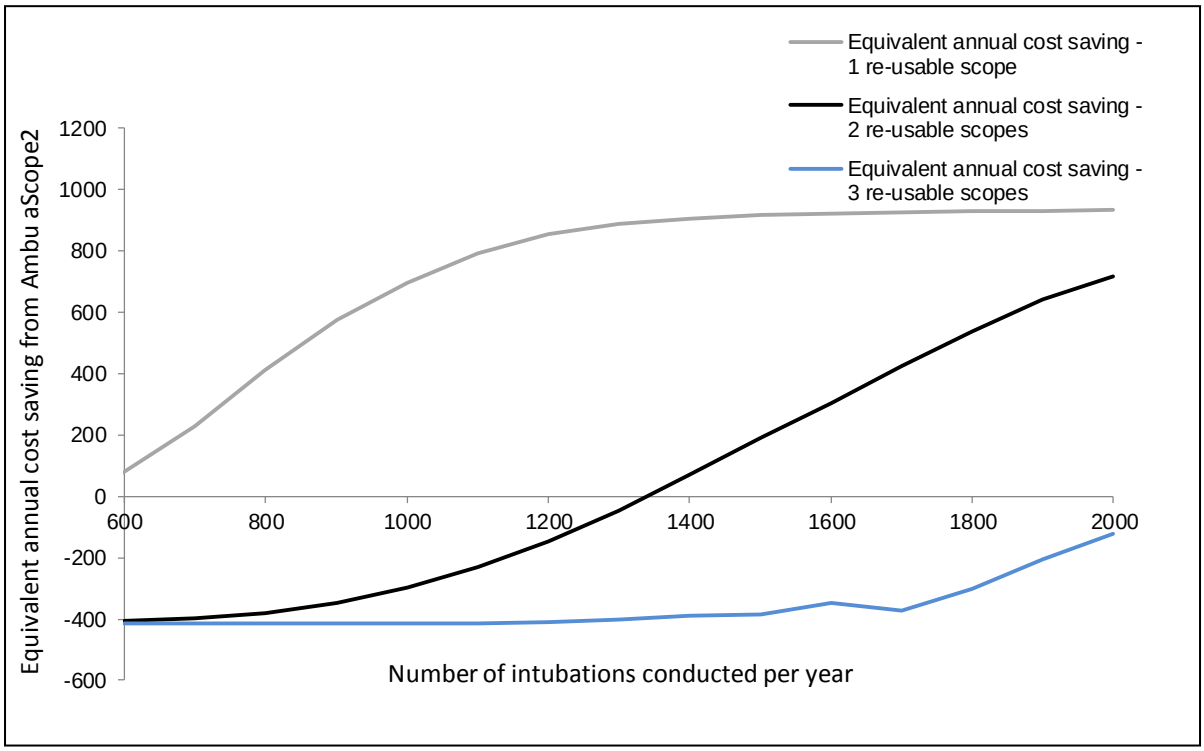


Figure 6 (below) shows annualised cost savings from purchasing a 5 scope bundle of Ambu aScope2s for settings with 1, 2 and 3 re-usable scopes. It is clear that with one re-usable scope, the likelihood of unavailability of the scope is very high, so the threshold above which the Ambu aScope2 becomes cost saving is much lower than for the settings with more than one re-usable scope (the threshold is just over 500 intubations, at which point there is an 18% chance that the re-usable scope is not available). With three re-usable scopes, the likelihood of unavailability of all three scopes is extremely low so the likelihood of using the single-use scopes before they expire is very low.

While the optimal mix of re-usable and disposable scopes is not formally modelled in this paper, the model presented here provides some indication that there could be potential cost savings from replacing one or more of the re-usable scopes in a unit with single-use scopes. For example, in the base-case of an operating suite with 1,000 intubations and two scopes, the first re-usable scope is used in 76% of intubations for which there is a re-usable scope available (i.e. about 21 intubations per year) and the second scope in only 22% of intubations (i.e. around 6 intubations per year); this makes the cost per use for the second less-used scope more than twice as high as for the first more-used scope. A hospital manager deciding whether to replace one or more re-usable scopes with disposable scopes must look at the cost-per-use of the *marginal* re-usable scope compared with purchasing single-use scopes and not the average cost-per-use over all scopes.

Figure 6: Equivalent annual cost savings from purchasing Ambu aScope2 cost savings in general operating theatre setting varying the number of re-usable scopes



Since most of the parameters in this scenario are identical to scenario 1, the same caveats regarding uncertainty surrounding the key parameters applies. In addition, the threshold numbers of intubation above which purchase of the single-use scopes is cost saving depends crucially on *planned* use of fibrescopes for difficult intubations, since planned and unplanned uses draw on the same limited pool of scopes. We suspect from our discussions with clinical experts that re-usable fibrescopes may be prepared and made available for use *just in case* there are airway difficulties, therefore more frequently than the 2.2% figure for expected airway difficulties implies; this 'just in case' provision implies that the scope may therefore more regularly be unavailable for unexpected difficult intubations in reality. This would increase the cost saving potential of a single-use scope.

The threshold number of intubations for the scope to be cost saving also depends on parameters relating to down-time of re-usable scopes due to sterilisation, maintenance and repair. Table 9 shows the results for a base-case of 1,000 intubations per annum and the results of a univariate sensitivity analysis around the key parameters. Sensitivity analyses showed some important changes in the direction of cost savings and in the threshold number of intubations at which acquisition of single-use scopes became cost saving. It was particularly notable that the model was sensitive to changes in the probability of expected difficult intubation and of unexpected difficult intubation. Further probabilistic sensitivity analysis is not shown for scenarios 2-5 in which there are one or more re-usable scopes present. Such analysis would be computationally intensive and the conclusions are the same as in scenario 1: uncertainty surrounding the parameters means that the confidence interval around expected cost-savings ranges from negative (i.e. the scopes are cost-incurring) to positive.

Table 9 Scenario 2: Hospital unit with re-usable scopes. Deterministic sensitivity analysis.

	Base case	P expected difficult intubation (base case .022)		P unexpected difficult intubation (base case .006)		P failure given unexpected difficult intubation (no scope) (base case .166)		P brain damage given intubation failure (base case .01)		P re-usable scope requires routine repair (base case 0.2)		P re-usable scope requires major repair	
		0.01	0.1	0.004	.01	.05	.40	.005	.04	.05	.35	.05	.15
With 2 re-usable scopes:													
Equivalent annual cost savings (1 scope)	£21	**-£ 48**	**£207**	**-£ 33**	**£210**	**-£ 39**	**£ 134**	**£19**	**-£9**	£2	£ 39	**-£ 35**	**£ 84**
Net present value of cost savings over 3 year life of scope (5 scopes)	-£569	**-£ 847**	**£2,730**	**-£ 799**	**£2,932**	-£ 800	-£ 139	-£ 578	-£ 684	-£659	-£469	-£ 805	-£ 150
Equivalent annual cost savings (5 scope package)	-£ 203	**-£ 302**	**£974**	**-£285**	**£1,047**	-£ 285	-£ 50	-£ 206	-£ 244	-£225	-£167	-£ 287	-£ 54
Equivalent annual cost savings (5 scope package including monitor at list price)	-£299	**-£398**	**£878**	**-£381**	**£951**	-£ 381	-£ 146	-£302	-£ 340	-£331	-£264	-£383	-£ 150
2 re-usable scope: probability scope not available	0.05	0.02	0.52	0.04	0.34	0.05	0.05	0.05	0.05	.04	.06	0.02	0.08
Threshold number of intubations above which Ambu aScope2 bundle is cost-saving	1200	1800	N/A	1600	N/A	1900	1000	1200	1400	1300	1200	1600	1000
Threshold number of intubations above which Ambu aScope2 bundle is cost-saving (monitor included)	1300	1900	N/A	1700	N/A	2000	1000	1300	1500	1400	1200	1700	1100

	Base case	P expected difficult intubation (base case .022)		P unexpected difficult intubation (base case .006)		P failure given unexpected difficult intubation (no scope) (base case .166)		P brain damage given intubation failure (base case .01)		P re-usable scope requires routine repair (base case 0.2)		P re-usable scope requires major repair	
		0.01	0.1	0.004	.01	.05	.40	.005	.04	.05	.35	.05	.15
With one re-usable scope:													
Equivalent annual cost savings (5 scope package including monitor at list price)	£698	£ 311	£929	£337	£953	**-£ 80**	**£2,273**	£695	£304	£645	£749	£451	£ 824
Threshold number of intubations above which Ambu aScope2 bundle is cost-saving (monitor included)	N/A	700	N/A	700	N/A	2000	N/A	N/A	700	N/A	N/A	700	N/A
With three re-usable scopes:													
3 re-usable scope: probability scope not available	0.01	0.00	0.17	0.00	0.16	0.00	0.01	0.00	0.01	<0.01	.01	0.00	0.01
3 re-usable scope: Equivalent annual cost savings (5 scope package including monitor at list price)	-£ 413	**-£ 415**	**£ 252**	**-£415**	**£946**	-£ 415	-£ 410	-£ 415	-£414	-£415	-£409	-£415	-£ 408
Notes: N/A = not available. This is usually because the threshold at which it became cost saving was below 500. **Bold** type indicates change in direction with cost saving.													

Scenario 3: Intensive Care Unit

There are several characteristics that distinguish ICU from an operating theatre. These are described fully in the parameter descriptions and explanations in section 3.22, above. Firstly, probability of difficult intubation is higher. Discussions with clinical experts suggest that this higher rate of difficult intubation may not always be associated with increased need for fibrescopes. For example, a large number of rapid sequence inductions (RSIs) are conducted in ICU, especially for patients with increased risk of aspiration; the speed of these intubations means that there may not be time to use a fibrescope if the initial attempt to intubate fails. For this reason, two assumptions for probability of difficult intubation are presented: one at 20% based on Mayo (2011) and the second at 5% based on discussions with ICU clinical experts.

Second, we make the assumption that in an ICU setting, difficult intubations are urgent and therefore cannot "queue" for use of the re-usable scopes in the same way as in an operating theatre context (i.e. it is more difficult to re-schedule urgent intubations for when a re-usable scope becomes available). The limitations of this are described more fully in section 3.22. Thirdly, the probabilities of serious harm given a failed intubation are higher. Fourthly, the likelihood that a re-usable scope is broken during an intubation is higher, reflecting the public discussion at the MTEP committee meeting on 15 November 2012.

Figure 7 and Figure 8 show annualised cost savings from purchase of a bundle of five single-use scopes plus monitor for the probabilities of urgent difficult intubation of 20% and 5%. With two re-usable scopes, the cost saving threshold is around 50 intubations per year assuming a 20% probability of difficult intubation, and around 270 assuming 5% probability of difficult intubation.

Annualised cost savings from purchasing the single-use scope are higher in the ICU setting than in the operating theatre, reflecting a greater rate of arrival of events requiring a scope, greater probability of harm in the event of an intubation failure, and greater down-time of re-usable scopes. In the base-case of 700 intubations per annum and two re-usable scopes with a 20% probability of difficult intubation, annualized cost savings from purchasing a bundle of five scopes are £3,219 (without monitor) and £3,123 (with monitor). With a probability of difficult intubation of 5%, annualized cost savings drop to £3,128 (without monitor) and £3,031 (with monitor).

These results suggest there may be potential for large cost-savings from purchasing the single-use scope in an ICU setting. As with the previous scenarios, it is important to stress the uncertainty surrounding the parameter estimates. In the ICU case, of particular concern is the uncertainty surrounding the incidence of difficult intubations where a fibrescope is appropriate. Even though the base-case point estimates for cost saving are higher in this setting than in the general operating and small unit cases, suggesting that there are potential for greater cost-savings in this setting, it is not possible to say with confidence that purchasing the Ambu aScope2 is cost-saving even in this case.

Figure 7: Equivalent annual cost savings from purchasing Ambu aScope2 cost savings in ICU: probability of urgent difficult intubation 20%

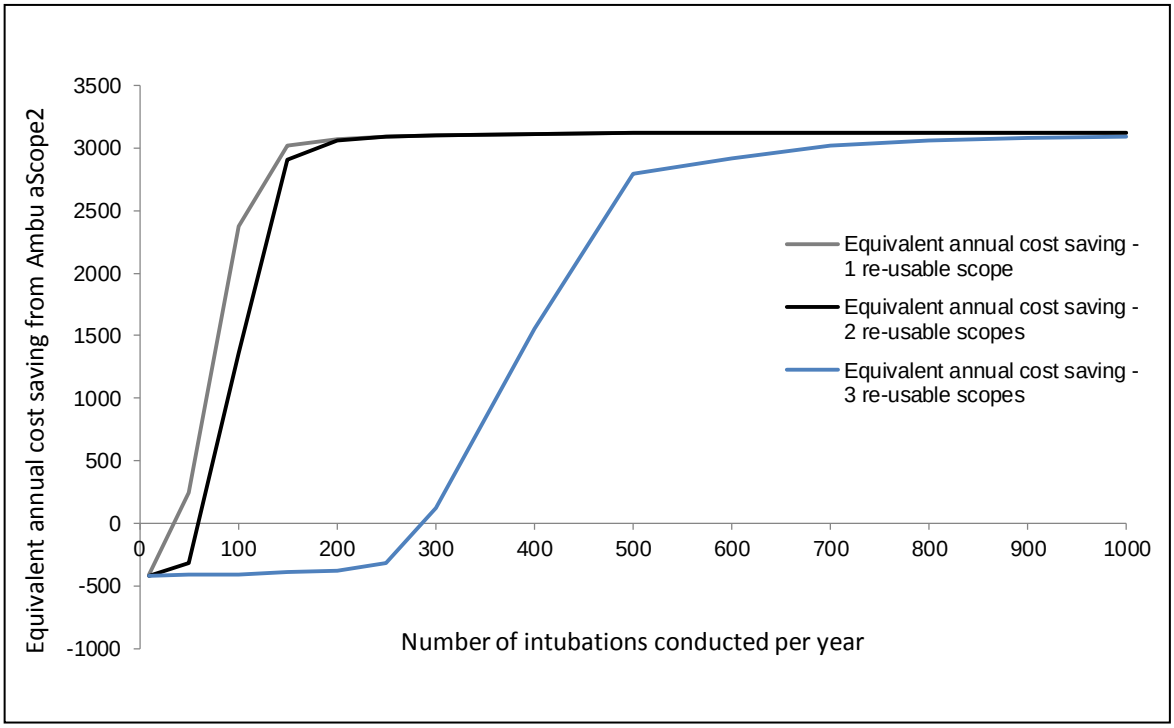
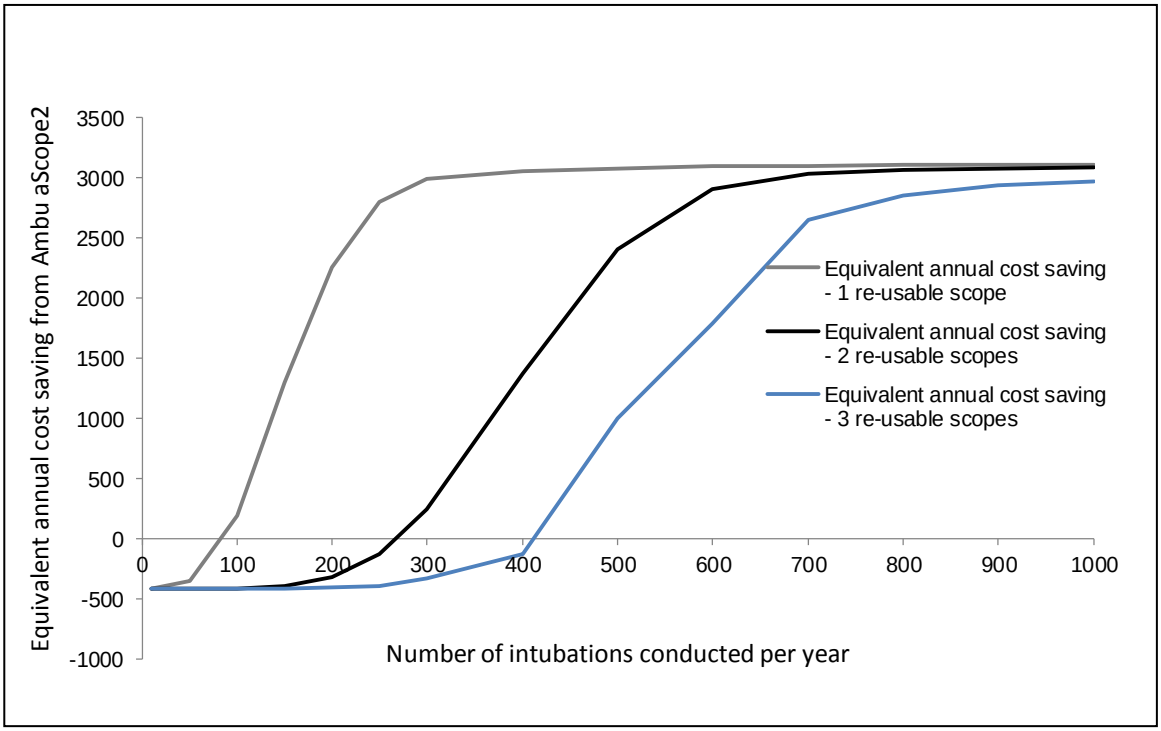


Figure 8: Equivalent annual cost savings from purchasing Ambu aScope2 cost savings in ICU: probability of urgent difficult intubation 5%



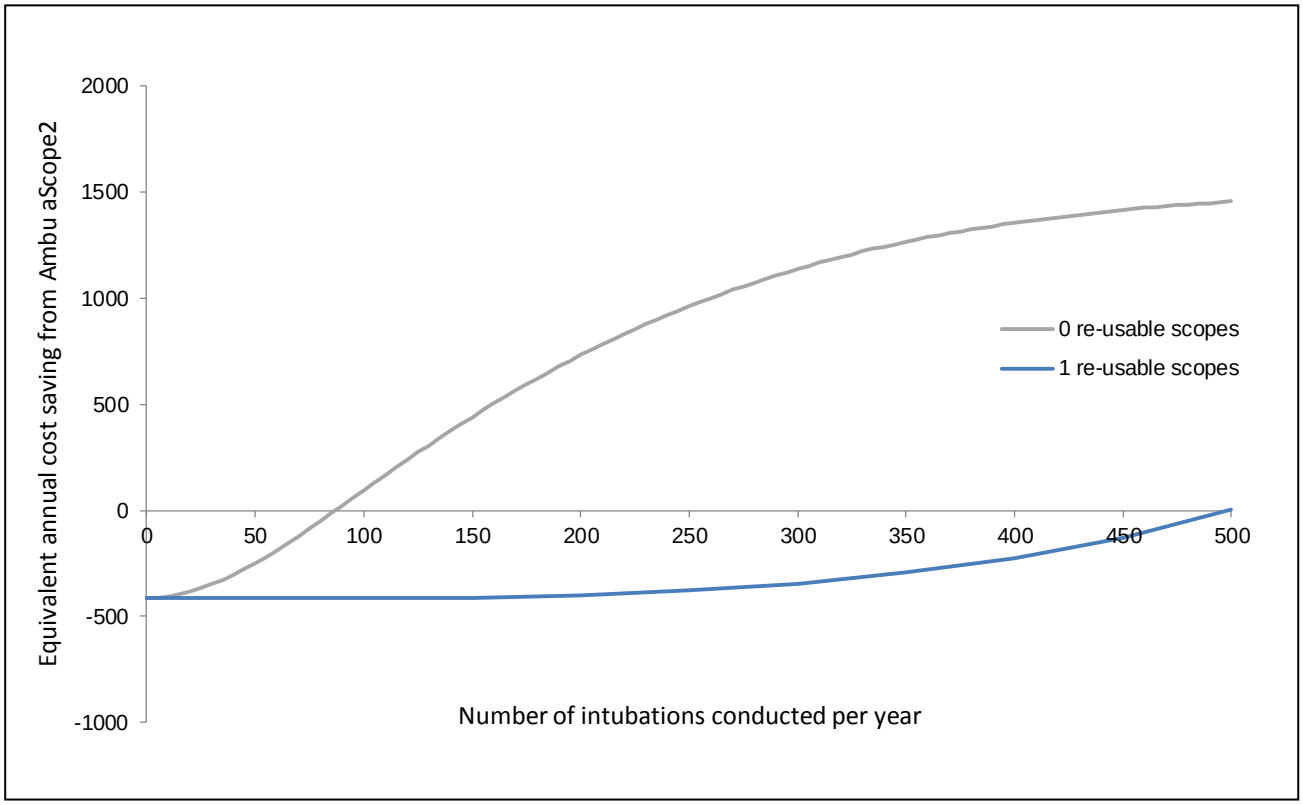
In an ICU setting, there is also a requirement for re-usable fibrescopes for performing tracheostomies and for repositioning displaced tracheostomies (see scenario 5). These all draw on the same pool of re-usable fibrescopes making it more likely that the scopes are not available when required; while this is not explicitly modelled, it is likely to increase cost savings associated with purchase of single-use fibrescopes to supplement the existing pool of re-usable fibrescopes.

Scenario 4: Obstetrics

As discussed earlier in this paper, there is little data on unexpected difficult intubation that relates directly to obstetrics. The analysis presented here is therefore illustrative only. Figure 9 shows the annualised cost savings from purchasing a bundle of single-use scopes in an obstetric setting with zero scopes and with 1 scope. The probability and cost parameters are all identical to scenarios 1 and 2, with the exception of life expectancy of brain-damaged patients, which is twice as high in an obstetrics setting than in the other settings, because of the younger age of the patients being intubated.

Figure 9: Equivalent annual cost savings in an obstetrics setting suggests that purchasing a bundle of scopes is cost saving above a threshold of around 80 intubations per year in a setting with no re-usable scopes, slightly lower than in scenario 1, and is cost saving above a threshold of around 500 intubations in a setting with 1 re-usable scope. For a base-case of 400 intubations and zero scopes, annualized cost savings are £1,452 (without monitor) and £1,356 (with monitor). With a scope present, purchasing a bundle of disposable scopes is cost-incurring since there is such a low likelihood of them being used. This preliminary analysis suggests that this is a setting in which the sponsor's original model may be applied: with such low fibrescope usage, it is very expensive to maintain a re-usable scope. Note, however, that the two obstetric anaesthesia clinical experts reported very different usage of intubating fibrescopes in their respective units, suggesting no single recommendation.

Figure 9: Equivalent annual cost savings in an obstetrics setting



Scenario 5: Displaced tracheostomy in an ICU setting

The tracheostomy setting is modelled in a similar way to use of Ambu aScope2 for urgent ICU intubation. It is assumed that all displaced tracheostomy events are urgent and there is no possibility for queuing for the next re-usable scope. Expected cost savings per use of the Ambu aScope2 to reposition a displaced tracheostomy are £3,029, net of the scope cost. Assuming a displacement rate of around 15% per annum for ICU patients with tracheostomies, this gives a cost-saving threshold of around 70 tracheostomies per year. For a base-case of 200 tracheostomies per year, annualised cost savings are £5,281 per year (without monitor) and £5,185 per year (with monitor). Again, this result is subject to the same uncertainty.

5. LIMITATIONS OF MODEL

There are a number of limitations to the above analysis. As well as the huge uncertainty surrounding the key parameters discussed above, the two major limitations of the analysis presented here are the absence of a fully-worked out model for optimal stock of single-use scopes and the absence of a model of the optimal combination of single-use and re-usable scopes within a clinical setting. It would be possible to model both of these; however, they would not affect the central conclusion that over a threshold number of intubations per year, which varies depending on how many re-usable scopes are present in the setting, the disposable scope is cost saving.

As explicitly modelled, the decision to purchase a single-use scope depends on trading off uncertain future cost savings against the certain cost of purchasing the device now. The marginal benefit from purchasing the first scope is highest; each additional scope purchased *upfront* has a lower marginal benefit since it is less likely that a second unexpected difficult intubation occurs during the scopes' lifetime, even less likely that a third occurs etc.

The exact number of scopes a unit will decide to purchase upfront and its subsequent re-ordering policy will depend on its caseload (i.e. how likely multiple unexpected difficult airways are to occur close to each other), the administrative cost of re-ordering scopes and the time taken to re-order scopes. The costs of re-ordering and the time taken to re-order are a hospital supply chain issue and are not part of the analysis presented here. If it is quick and cheap to re-order scopes, it is likely to be cheaper to re-order scopes as they are used up rather than purchasing a large number upfront.

The supplementary purchase model presented takes an extremely short-term view in that it only analyzes whether it is cost-saving to purchase the Ambu aScope2, *taking as fixed the current number of re-usable scopes* in a unit. This makes it an unusual HTA model, since the capital cost of purchasing the re-usable scopes is irrelevant. With a more sophisticated model, it would be possible to model the optimal (i.e. cost-minimizing) combination of different types of scope for the unit, allowing managers to move towards the optimal combination as the re-usable scopes already present in the unit reach the end of their useful life.

There may be other potential cost savings resulting from the availability of the single-use scope which are not modelled in this paper. Discussions with clinical experts (see the appendix) suggested that in current practice, re-usable scopes are made available for intubations more often than they are actually used. This is costly, because a re-usable scope must be re-sterilised once it is removed from storage *even if it is not used.* The Ambu aScope2 does not have to be removed from its packet if it is not used so is available for the next unexpected difficult airway event without having to be re-sterilised. Finally, there may be healthcare costs attached to intubation failure even when there is no harm to the patient, specifically in rescheduling operations and extra pre-operative inpatient stay.

6. DISCUSSION AND CONCLUSIONS

The model presented here analyses the cost savings of purchasing Ambu aScope2 in small hospital units which do not have access to any fibrescope for unexpected difficult airways management and of purchasing Ambu aScope2 in addition to the existing stock of re-usable scopes in general operating theatre and ICU settings for unexpected difficult intubations and displaced tracheostomies. The potential cost savings from purchase of the Ambu aScope2 come from using the scope to avoid costly harm in the event of a failed intubation. These cost savings are traded off against the possibility that the disposable scopes are not used before they expire.

In the case of a unit with no current re-usable scope provision, purchasing a bundle of scopes is cost-saving above a threshold of around 100 intubations per year. In a unit with two re-usable scopes present, this cost-saving threshold rises to around 1250-1350 intubations per year, because disposable scopes are only used when all re-usable scopes are unavailable, so the probability they are used before they expire is lower. In all settings, this risk of expiry could be mitigated by good hospital management, moving almost-expired scopes from units where they are infrequently used to units where they are used more frequently to try to ensure that all are used before expiry.

In an ICU with two re-usable scopes, the cost-saving threshold is 50-100 intubations per annum if probability of difficult intubation is assumed to be 20%, dropping to 250-300 intubations per annum if probability of difficult intubation is 5%. Cost-saving threshold is lower than the general operating case (and annualized cost savings are higher), because the risk of harm in the event of a difficult intubation, especially brain damage, is higher for ICU patients, the rate at which unexpected difficult airways arise is higher, and scope down-time is higher due to the probability of breakage. However, the model parameters are even more uncertain for an ICU context.). There also appear to be cost-savings from purchase of the Ambu aScope2 for repositioning displaced tracheostomies in ICU for units doing more than 70 tracheostomies.

The scenario analyses suggest scope purchase may be cost-saving above certain threshold numbers of intubations, but there is much uncertainty in all scenarios, because both good quality evidence and statistical precision are lacking. Parameters relating to risks of intubation failure and harm, the probability of an unexpected difficult intubation arising, and the effectiveness of the device in reducing intubation failure in an unexpected difficult intubation are particularly uncertain. Limited univariate sensitivity analysis conducted suggests that the device is cost-saving under some plausible parameter estimates and not under others. In a probabilistic sensitivity analysis conducted for the small unit scenario, 41% of simulations were cost-incurring.

The original sponsor submission analysed the incremental cost-savings per fibrescope use from replacing all re-usable fibrescopes with disposable fibrescopes. Therefore in their paper, cost savings from purchasing the Ambu aScope2 increased with the number of re-usable fibrescopes currently in use (since for a given caseload a higher number of re-usable scopes means a higher cost-per-use for each device). This paper analyses the cost-savings from purchasing single-use scopes in addition to the existing stock of re-usable scopes, for use in situations when re-usable scopes are not available due to sterilisation and repair. In this paper then, if the number of re-usable scopes is higher, the chance that all re-usables are unavailable is lower so cost savings from purchasing single use scopes *in addition* to the re-usables is lower.

In clinical practice, a unit manager deciding to purchase the Ambu aScope2 will have to consider both the cost savings from purchasing disposable scopes in addition to the existing stock of reusable scopes, and the potential cost savings from replacing one or more reusable scope with disposables. While modelling the optimal combination of re-usable and disposable scopes is beyond the remit of this paper, in this model we have shown that in a setting with more than one scope, the second and subsequent scopes are used much less frequently than the first, and thus there may be potential cost savings from replacing one or more re-usable scope. In other words, the unit manager must look at the average usage and hence cost-per-use of the *marginal* re-usable scope when considering whether to replace it with disposables, rather than looking at the average cost-per-use across the current stock of re-usables. Maximum cost savings will only be realised if single-use scopes are purchased in the context of an optimal procurement model.

This HTA differs in an important manner from standard HTAs. In particular, this does not represent a comparison between one treatment and another, but rather between one procurement policy and another. The potential benefits therefore are particularly dependent on operational differences between settings, with respect to the risk that no scope will be available for clinicians to use in case of an unexpected difficult intubation. This risk is highly dependent upon the context within which the scopes are to be used, as illustrated in the models presented. This report, using a model which has been calibrated using queuing theory, has shown that a number of factors will influence the cost-saving potential of single-use scopes. Important contextual features are: the risk profile of the case load, the number of intubations performed, the number of re-usable scopes available, and the efficiency of their use and management. An additional factor that is difficult to allow for in a model is that variations within accepted clinical practice could have an impact on the input parameters utilised. From our discussions with experts, it is clear that even between similar units, the clinical experience of clinicians as well as their preferences will affect the opportunity identified for single-use scopes. In particular, in settings where there is a strong preference for scope availability ‘just in case’, the value of single-use scopes may be high.

REFERENCES

Aldawood, A. S., Arabi, Y. M., & Haddad, S. 2008, "Safety of percutaneous tracheostomy in obese critically ill patients: a prospective cohort study", *Anaesthesia & Intensive Care*, vol. 36, no. 1, pp. 69-73.

Auroy, Y., Benhamou, D., Pequignot, F., Bovet, M., Jougla, E., & Lienhart, A. 2009, "Mortality related to anaesthesia in France: analysis of deaths related to airway complications", *Anaesthesia*, vol. 64, no. 4, pp. 366-370.

Bair, A. E., Filbin, M. R., Kulkarni, R. G., & Walls, R. M. 2002, "The failed intubation attempt in the Emergency Department: analysis of prevalence, rescue techniques, and personnel", *The Journal of Emergency Medicine*, vol. 23, no. 2, pp. 131-140.

Barbetti, J. K., Nichol, A. D., Choate, K. R., Bailey, M. J., Lee, G. A., & Cooper, D. J. 2009, "Prospective observational study of postoperative complications after percutaneous dilatational or surgical tracheostomy in critically ill patients", *Critical care and resuscitation : journal of the Australasian Academy of Critical Care Medicine*, vol. 11, no. 4, p. Dec.

Beecham, J., Perkins, M., Snell, T., & Knapp, M. 2009, "Treatment paths and costs for young adults with acquired brain injury in the United Kingdom", *Brain Injury*, vol. 23, no. 1, pp. 30-38.

Beiderlinden, M., Walz, M. K., Sander, A., Groeben, H., & Peters, J. 2002, "Complications of bronchoscopically guided percutaneous dilational tracheostomy: Beyond the learning curve", *Intensive Care Medicine*, vol. 28, no. 1, p. 2002.

Beltrame, F., Zussino, M., Martinez, B., Dibartolomeo, S., Saltarini, M., Vetrugno, L., & Giordano, F. 2008, "Percutaneous versus surgical bedside tracheostomy in the intensive care unit: a cohort study", *Minerva Anestesiologica*, vol. 74, no. 10, pp. 529-535.

Bhattacharya, P., Chakraborty, A., & Agarwal, P. 2007, "Comparison of outcome of self-extubation and accidental extubation in ICU", *Indian Journal of Critical Care Medicine*, vol. 11, no. 3, p. 01.

Bhatti, N., Mirski, M., Tatlipinar, A., Koch, W. M., & Goldenberg, D. 2007, "Reduction of complication rate in percutaneous dilation tracheostomies", *Laryngoscope*, vol. 117, no. 1, p. January.

Cobas, M. A., De la Pena, M. A., Manning, R., Candiotti, K., & Varon, A. J. 2009, "Prehospital intubations and mortality: a level 1 trauma center perspective", *Anesthesia & Analgesia*, vol. 109, no. 2, pp. 489-493.

Cook, T. M., Scott, S., & Mihai, R. 2010, "Litigation related to airway and respiratory complications of anaesthesia: an analysis of claims against the NHS in England 1995–2007", *Anaesthesia*, vol. 65, no. 6, pp. 556-563.

Cook, T. M., Woodall, N., & Frerk, C. 2011, "Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1: anaesthesia", *British Journal of Anaesthesia*, vol. 106, no. 5, pp. 617-631.

Cook, T. M., Woodall, N., Harper, J., & Benger, J. 2011, "Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 2: intensive care and emergency departments", *British Journal of Anaesthesia*, vol. 106, no. 5, pp. 632-642.

Department of Health. 2011. *National Schedule of Reference Costs 2010-11 for NHS Trusts.* [Data File] Retrieved from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_131140

Djabatey, E. A. & Barclay, P. M. 2009, "Difficult and failed intubation in 3430 obstetric general anaesthetics", *Anaesthesia*, vol. 64, no. 11, pp. 1168-1171.

El Solh, A. A. & Jaafar, W. 2007, "A comparative study of the complications of surgical tracheostomy in morbidly obese critically ill patients", *Critical Care (London, England)*, vol. 11, no. 1, p. 2007.

Fischler, L., Erhart, S., Kleger, G.-R., & Frutiger, A. 2000, "Prevalence of tracheostomy in ICU patients. A nation-wide survey in Switzerland", *Intensive Care Med*, vol. 26, no. 10, pp. 1428-1433.

Glossop, A. J., Meekings, T. C., Hutchinson, S. P., & Webber, S. J. 2011, "Complications following tracheostomy insertion in critically ill patients - experience from a large teaching hospital", *Journal of the Intensive Care Society*, vol. 12, no. 4, pp. 301-306.

Harris, B., Andrews, P., Murray, G., Forbes, J., & Moseley, O. 2012, "Systematic review of head cooling in adults after traumatic brain injury and stroke. 2012;**16**(45).", *Health Technology Assessment*, vol. 16, no. 45.

HES. 2011. *HESonline. Primary diagnosis: 4 character 2010-11 [Freely available inpatient data].* [Data File] Retrieved from: http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=214

Heuer, J. F., Barwing, T. A., Barwing, J., Russo, S. G., Bleckmann, E., Quintel, M., & Morer, O. 2012, "Incidence of difficult intubation in intensive care patients: analysis of contributing factors", *Anaesthesia & Intensive Care*, vol. 40, no. 1, pp. 120-127.

Hill, B. B., Zweng, T. N., Maley, R. H., Charash, W. E., Toursarkissian, B., & Kearney, P. A. 1996, "Percutaneous Dilational Tracheostomy: Report of 356 Cases", *The Journal of Trauma and Acute Care Surgery*, vol. 41, no. 2.

Jaber, S., Amraoui, J., Lefrant, J. Y., Arich, C., Cohendy, R., Landreau, L., Calvet, Y., Capdevila, X., Mahamat, A., & Eledjam, J. J. 2006, "Clinical practice and risk factors for immediate complications of endotracheal intubation in the intensive care unit: A prospective, multiple-center study", *Critical Care Medicine*, vol. 34, no. 9.

Jabre, P., Avenel, A., Combes, X., Kulstad, E., Mazariegos, I., Bertrand, L., Lapostolle, F., & Adnet, F. 2011, "Morbidity related to emergency endotracheal intubation--a substudy of the KETAmine SEDation trial", *Resuscitation*, vol. 82, no. 5, pp. 517-522.

Kearney, P. A., Griffen, M. M., Ochoa, J. B., Boulanger, B. R., Tseui, B. J., & Mentzer Jr, R. M. 2000, "A single-center 8-year experience with percutaneous dilational tracheostomy", *Annals of Surgery*, vol. 231, no. 5, p. 701.

Mayo, P. H., Hegde, A., Eisen, L. A., Kory, P., & Doelken, P. 2011, "A program to improve the quality of emergency endotracheal intubation", *Journal of Intensive Care Medicine*, vol. 26, no. 1, pp. 50-56.

McDonnell, N. J., Paech, M. J., Clavisi, O. M., & Scott, K. L. 2008, "Difficult and failed intubation in obstetric anaesthesia: an observational study of airway management and complications associated with general anaesthesia for caesarean section", *International Journal of Obstetric Anesthesia*, vol. 17, no. 4, pp. 292-297.

McGrath, B. A. & Thomas, A. N. 2010, "Patient safety incidents associated with tracheostomies occurring in hospital wards: A review of reports to the UK National Patient Safety Agency", *Postgraduate Medical Journal*, vol. 86, no. 1019, p. September.

McKeen, D., George, R., O'Connell, C., Allen, V., Yazer, M., Wilson, M., & Phu, T. 2011, "Difficult and failed intubation: Incident rates and maternal, obstetrical, and anesthetic predictors", *Can J Anesth/J Can Anesth*, vol. 58, no. 6, pp. 514-524.

Mort, T. C. 2004, "Emergency tracheal intubation: complications associated with repeated laryngoscopic attempts", *Anesthesia & Analgesia*, vol. 99, no. 2, pp. 607-613.

NAP4 2011, *Major complications of airway management in the United Kingdom: Report and findings. 4th National Audit Project of The Royal College of Anaesthetists and The Difficult Airway Society* 4.

ONS, 2011. *Office for National Statistics Interim Life Tables.* [online] Available at: http://www.ons.gov.uk/ons/taxonomy/index.html?nscl=Interim+Life+Tables [Accessed October 28 2011]

Oreadi, D. & Carlson, E. R. 2012, "Morbidity and mortality associated with tracheotomy procedure in a university medical centre", *International Journal of Oral and Maxillofacial Surgery*, vol. 41, no. 8, p. August.

PSSRU 2011, *Unit Costs of Health and Social Care 2011*.

Quinn, A. C., Milne, D., Columb, M., Gorton, H., & Knight, M. 2013, "Failed tracheal intubation in obstetric anaesthesia: 2 yr national case-control study in the UK", *British Journal of Anaesthesia*, vol. 110, no. 1, pp. 74-80.

Rose, D. K. & Cohen, M. 1994, "The airway: problems and predictions in 18,500 patients", *Can J Anaesth*, vol. 41, no. 5, pp. 372-383.

Sakles, J. C., Laurin, E. G., Rantapaa, A. A., & Panacek, E. A. Airway management in the emergency department: a one-year study of 610 tracheal intubations. Annals of Emergency Medicine 31[3], 325-332. 1998.
Ref Type: Abstract

Schwartz, D. E., Matthay, M. A., & Cohen, N. H. 1995, "Death and Other Complications of Emergency Airway Management in Critically Ill Adults: A Prospective Investigation of 297 Tracheal Intubations", *Anesthesiology*, vol. 82, no. 2.

Shavelle, R., Strauss, D., Day, A., & Ojdana, K. 2007, "Life Expectancy," in *Brain Injury Medicine: Principles and Practice*, N. Zasler, K. Douglas, & D. Zafonte, eds., Demos Medical Publishing, New York, pp. 247-261.

Shiga, T., Wajima, Z., Inoue, T., & Sakamoto, A. 2005, "Predicting difficult intubation in apparently normal patients: a meta-analysis of bedside screening test performance", *Anesthesiology*, vol. 103, no. 2, pp. 429-437.

Thomas, A. N. & McGrath, B. A. 2009, "Patient safety incidents associated with airway devices in critical care: a review of reports to the UK National Patient Safety Agency", *Anaesthesia*, vol. 64, no. 4, pp. 358-365.

Thompson, E. C., Fernandez, L. G., Norwood, S., Wilkins, H., III, & Vallina, V. L. 2001, "Percutaneous dilatational tracheostomy in a community hospital setting", *Southern Medical Journal*, vol. 94, no. 2, pp. 208-211.

Tvede, M., Kristensen, M., & Nyhus-Andreasen, M. 2012, "A cost analysis of reusable and disposable flexible optical scopes for intubation", *Acta Aneasthesiologica Scandinavica*, vol. 56, no. 5, pp. 577-584.

Ventura, T., Harrison-Felix, C., Carlson, N., Diguiseppi, C., Gabella, B., Brown, A., Devivo, M., & Whiteneck, G. 2010, "Mortality after discharge from acute care hospitalization with traumatic brain injury: a population-based study", *Archives Of Physical Medicine And Rehabilitation*, vol. 91, no. 1, pp. 20-29.

Walz, M. K., Peitgen, K., Th++rauf, N., Trost, H. A., Wolfhard, U., Sander, A., Ahmadi, C., & Eigler, F. W. 1998, "Percutaneous dilatational tracheostomyΓÇöearly results and long-term outcome of 326 critically ill patients", *Intensive Care Medicine*, vol. 24, no. 7, pp. 685-690.

Wang, H. E., Cook, L. J., Chang, C. C., Yealy, D. M., & Lave, J. R. 2009, "Outcomes after out-of-hospital endotracheal intubation errors", *Resuscitation*, vol. 80, no. 1, pp. 50-55.

APPENDIX A: QUESTIONNAIRE SENT TO EXPERTS

Questionnaire to obtain information to inform health economic models of the Ambu aScope2 single-use intubating scope with re-usable intubating fibrescopes

Based on your own experience of intubating fibrescopes:

For use in endotracheal intubation (OT / ITU):

Please describe the setting in which you work (e.g. OT - general surgical/obstetric/ mixed; ITU; other e.g. A&E):

How many general anaesthetics are conducted in this setting? *Per day___ Per week___ Per month___*

What percentage of these involve endotracheal intubation?

What percentage of these involve use of an intubating fibrescope?

What percentage of these intubations are 'difficult' (i.e. involve more than one attempt to intubate)?

For what percentage of the difficult intubations was the difficulty not expected?

In your clinical setting:

How many re-usable intubating fibrescopes do you have?

Are single-use intubating fibrescopes currently available in this setting?

In your experience, in what percentage of unexpected difficult intubations do you find re-usable scopes to be unavailable when required? (due to repair, use in another part of the hospital or sterilisation for example)

For use in repositioning displaced tracheostomy (ITU setting):

How many beds does this ITU have?

How often does a displaced tracheostomy require repositioning using an intubating fibrescope?

Per number of patients? ___Per day? ___ Per week? ___ Comments:

In your expert opinion:	Operating theatre environment				
	General operating theatre	A&E	Eye surgery	Obstetrics	IVF
What percentage of general anaesthetics are associated with intubation?					
Are re-usable fibre optic scopes normally used in current practice?	Yes/No/ Don't know	Yes/No/ Don't know	Yes/No/ Don't know	Yes/No/ Don't know	Yes/No/ Don't know
In what percentage of					

patients does the initial attempt to intubate fail?					
In what percentage of patients does intubation completely fail if a fibrescope is not available?					
In what percentage of patients does intubation with the aid of a fibrescope fail?					
Please comment on variations in availability and use of re-usable fibrescopes within different settings: i.e. type of surgery, size of hospital, theatre configuration, scope sterilisation service, physical location, etc.					

Outcomes of failed intubation:

Consider all intubations carried out across the country as part of general anaesthesia, in which difficulty with intubation was not anticipated.

This questionnaire concerns the probability of various outcomes for the patient given the intubation has failed. These probabilities consolidate all contexts over which such failure occurs, i.e. net of the different skill levels, levels of support, age of patient etc. Please feel free to use the figures below in formulating an answer. Please give your best guess and 95% credible limits (i.e. high and low estimates) on this best guess

Please comment on the probability of harm when intubation fails

- No harm ___ please explain _____
- Probability of the following outcomes (Numbers per million intubations):

	Best Guess	High	Low
a) Death	☐	☐	☐
b) Brain Damage	☐	☐	☐
c) Increased ITU length of stay	☐	☐	☐

Comments:

Do you have any comments on the estimates of intubation events and harm below?

Cook 2011 (NAP4)*	**Numerator**	**Denominator**	**Incidence**
Tracheal tube death/brain damage (combined)	10	1,102,900 (anaesthesia involving tracheal tube)	9.1 (95% CI 3.4 to 14.7) per million
Tracheal tube events**	91	1,102,900 (anaesthesia involving tracheal tube)	82.5 (95% CI 65.6 to 99.5) per million

* Cook T M, Woodall N, and Frerk C. Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1: Anaesthesia. British Journal of Anaesthesia 2011;106 (5): 617–31

**Tracheal tube events that led to: death, brain damage, the need for an emergency surgical airway, unanticipated ICU admission, or prolongation of ICU stay.

Auroy 2009* **	**Incidence of death**	**Note**
French national survey. Setting: GA procedures	Difficult intubation related annual death in general anaesthesia procedures employing tracheal intubation: • 1:46000 (95% CI 1:386000 to 1:13000) in 1978-1982 • 1 : 176 000 (95% CI 1 : 714 000 to 1 : 46 000) , i.e. **0.61 (95% CI 0.14–2.16 per 100 000) in 1999**	Reported are deaths in anaesthetic intubations, i.e. the denominator is intubations (rather than difficult or failed intubations).

***Auroy Y, Benhamou D, Pe´quignot F, Bovet M, Jougla E and Lienhart A. Mortality related to anaesthesia in France: analysis of deaths related to airway complications. Anaesthesia 2009,64:366–370

Indirect and rough estimation based on the above two studies:

- Tracheal tube **death** = 6.1 per million anaesthetic intubations (Auroy 2009);
- Tracheal tube event = 82.5 per million anaesthetic intubations (NAP4 report);
- Therefore, tracheal tube **death** in tracheal tube event = 6.1/82.5 = 7.39%.

- Tracheal tube **death/brain damage (combined**) = 9.1 per million anaesthetic intubations (NAP4 report);
- Tracheal tube **death** = 6.1 per million anaesthetic intubations (Auroy 2009);
- Therefore, tracheal tube **brain damage** = 9.1 - 6.1 = 3 per million anaesthetic intubations;
- Therefore, tracheal tube **brain damage** in tracheal tube events = 3/82. 5=3.63%

Comments:

Thank you

APPENDIX B: SUMMARY OF EXPERT OPINION ELICITED AS PART OF THIS WORK PACKAGE

Introduction

As published information to inform model parameters appeared to be sparse, information was sought from clinical experts. A number of different approaches to obtaining clinical opinion are available, including Bayesian elicitation of prior beliefs in order to obtain prior distributions rather than point estimates. This methodology presented a number of problems in this context: the timeframe for completion precluded design of an appropriate elicitation exercise to obtain prior distributions for the multiple parameters for which other estimates were missing or sparse; there are multiple NHS contexts in which fibreoptic endoscopes are used for intubation, and a greater understanding of this context was necessary to inform both the model under development and any later Bayesian elicitation exercise. We therefore chose to use an email survey to obtain opinions, supplemented by telephone interviews to explore these responses in a more qualitative manner in order to gain a better understanding of the context underlying the opinions offered.

Methods

A questionnaire (see Appendix A) covering the parameters where estimates from expert opinion were required and to elicit the context for the clinical experts' own practice and opinion was designed and sent via email to the clinical experts specified by and agreed with NICE. Replies were followed up with telephone interviews conducted by BBC EAC researchers (RJL, SB, AC, CC) with notes taken of answers which provided information, context or opinion additional to that in the questionnaire response. The questionnaire was sent to the clinical experts appointed for this technology assessment, MTEP committee members with relevant expertise and additionally two clinical experts in obstetric anaesthesia.

Results

1. Clinical experts' experience of intubating fibroscopes

The expertise of the clinical experts who responded to the questionnaire and the settings in which they worked are described in Box 1 below.

Box 1

Clinical Expert (numbered for anonymity)	Clinical expertise of responders
CE1	Anaesthetist in specialist NHS hospital doing ENT, maxillofacial and plastics including their care on ITU
CE2	ITU and respiratory medicine
CE3	General anesthesia and sedation practice, ICU consultant for 23 years until 4 years age. The hospital has every specialty except for neurosurgery and burns/plastics.
CE4	General surgical/ENT/ Max Fax/ occasional neurosurgery
CE5	50/50 ICU and Anaesthesia (including A&E attending emergencies, I am personally involved in around 300-400 Anaesthetics per year and probably 50 or so per year on the ICU (emergency induction of anaesthesia for the critically ill
CE6	Expertise in obstetric anaesthesia
CE7	Obstetrics

Numbers of anaesthetics, of intubations and of available fibrescopes

Clinical expert estimates of numbers of anaesthetics and difficult intubations are given in Table 1. The experts did not always find it easy to quantify anaesthetic workload or experience of intubation and used a number of metrics. They did not always provide the estimates requested.

Reported experience varied widely with setting. Some experts qualified their estimates on difficult intubation: they emphasised that "difficult" is a matter for clinical judgement; that trainees are less likely to intubate a patient on the first attempt; that practice regarding equipment varies; and that there was less time in the ICU setting to manage difficult airways safely. An obstetric anaesthesia expertise pointed out that *"regional anaesthesia techniques predominate (epidural anaesthesia), representing around 95% of elective anaesthesia in obstetrics in his experience. In an emergency setting, this may reduce to around 70-75%"* (CE6). He further explained that, in his hospital, around 2000 out of 8000, (one quarter) of deliveries will by Caesarean section, representing around 95% of obstetric anaesthesia in his experience. Around one quarter of these will involve GA, *all* of which will involve intubation. Due to the emergency nature of such procedures, all are conducted as a rapid sequence intubations. In this obstetric setting the medical team are conscious that all intubations have the potential to be difficult. However, due to the limited timeframe within which they can act, the patient is immediately woken up after just two attempts to intubate. This means

that in this particular location a fibreoptic endoscope has been used just once in the last three to four years. In his facility there was one re-usable fibrescope which, as indicated above, is used very rarely. Although the rate of failed intubation is much higher than in other settings, and the potential for harm is also very great, there is limited opportunity to use a fibrescope as best practice dictates that when intubation fails the patient should be woken up. This situation is unlikely to change in the near future (though with rising obesity in pregnant women, there is some chance that their use may be slightly more common in the future in elective caesarean sections).

One expert (CE4) did not offer an estimate of unexpected difficult intubations, but commented: *"This is a difficult question. Partly as an airway enthusiast I am more likely to anticipate difficulty and use a ramp or alternative device. Also difficulty may be expected "he looks like he has a bit of a short neck but based on my other assessments I think I will be able to intubate him" but no action taken. Or difficulty may be anticipated – "he has a BMI of 50", and action taken. "I will anesthetise him on the HELP pillow". Or difficulty may be anticipated "I know this person was difficult to intubate previously" but the anaesthetist may make a clinical judgement (which may or may not turn out to be valid) that airway management manoeuvres can be optimised or conducted differently so to facilitate easier airway management. Are there situations where I request a fibrescope for the just in case scenario- yes – these are different to the people I identify as requiring a fibreoptic intubation from the outset but require the same resource utilisation as if I actually performed a fibreoptic intubation even though the re-usable scope may not ever be touched."* He also commented: *"as an 'airway enthusiast' I am more likely to use additional pieces of apparatus to facilitate intubation or place more store in my pre-op assessments than other anaesthetists?"*

Another (CE5) commented*: "I would just have to quote standard figures here. I expect around 5% of all intubations to be difficult (take more than 1 attempt or require an alternative strategy). It is rare (<1% of all intubations) that these are unexpected, but that may be because of experience. It gets a bit complicated here, because I often supervise trainees who may take more than one attempt to intubate but I probably wouldn't have done (so be careful with your definitions!) although most would not then class and record this airway/intubation as 'difficult'. I do an emergency list where there is a proportionally higher number of broken jaws than most hospitals. Consequently we perform regular awake fibreoptic intubation (personally or supervise 1-2 per month) for these patients who have a perceived difficult airway. A 'difficult airway' on the ICU is again a little more complex. The patients may have an anatomically normal airway and if they were having a routine op, would not be considered as 'difficult' but if they get a bit swollen and become very oxygen dependant on the ICU, you have very little time in which to manage an airway. Consequently, these patients have difficult airways because plan A needs to work, otherwise you are very quickly in trouble. So I would say more airways are difficult in the ICU, but because they are different types of difficulty to the more standard anaesthetic difficult airways, a direct comparison is difficult. I usually bring all of the difficult airway kit to the patient's bedside on ICU if I am intubating them, as I expect more trouble".*

Clinical experts were asked what in their experience, was the percentage of unexpected difficult intubations did they find re-usable scopes to be unavailable when required (due to repair, use in another part of the hospital or sterilisation for example). Answers ranged from 0 through 30% to 60%:

- *In no instances* (CE1)
- *Approx. 30% of time a re-usable scope unlikely to be immediately available* (CE2)
- *Never because it is such a huge hospital with large resources* (CE3)
- *This depends on the storage capability of the hospital- units without a HEPA Cabinet are unlikely to have a scope sterilised and ready for use- scopes once clean are only 'sterile' even without use for 4 hours unless they are stored appropriately. I am also aware of times when if a loan scope cannot be sourced then for the repair of scope or failure of sterilisation apparatus we have had a very limited scope capability. I am also aware of local hospitals who have resorted to AScopes to overcome this issue*. (CE4)
- *We had a critical incident in 2012 on our ICU where the FOS was unavailable when needed unexpectedly during an intubation. We had 3 intubating fibrescopes and 3 bronchoscopes within 20 yards of the patient in a drying cabinet in an ante-room. 1 scope was missing (in decontamination), 1 had a flat recharge-able battery and the 3rd scope had a battery which was locked away, with a mains-powered light source that needed an adapter (which was present but the staff couldn't work this out acutely). The bronchoscopes all need a large 'stack' system (digital TV and mains powered light source) to work which would need a member of staff to bring to the bedside. The incident involved someone going to theatres to retrieve an (incompatible) light source and was resolved by using the disposable aScope which was located on the ICU. I have taken 1 aScope to A&E and 1 aScope to the wards during ICU emergency work as I know that they do not have a fibreoptic device immediately to hand. I have had 2 incidents in 2012 where I was waiting for a clean scope to come back from our decontamination unit. They can turn a scope around inside 1 hour but that requires someone to take it to them (5 min walk) and collect it. Usual 'down time' is 3-4 hours. If we use a scope after 6pm, there is no replacement until the following morning (3pm at weekends). I have used an aScope in these 2 situations purely because no alternative was available – once in theatre and once in ICU. These were both elective situations and the patient and surgical teams were assembled and waiting. Choice was a logistical one, not clinical emergency for these 2. For the unexpected difficult intubation then, from my figures (off the top of my head) for 2012, we are talking 3 in 3-400 all cases, or 3 in 15-20 of the difficult ones. We have a big hospital with lots of scopes and so one would expect a scope to be always available – not always the case.* (CE5)

<u>Intubating fibrescope use in repositioning displaced tracheostomy in ITU settings in which the clinical experts worked</u>

Clinical experts offered variable or no estimates of the frequency of use of intubating fibrescopes to reposition displaced tracheostomies in the ICU (Table 2). It was pointed out that fibrescopes were used to check if tracheostomies needed to be repositioned, were used in emergency intubations, but these did not always arise from displacement of tracheostomies.

CE5 further commented: "*Scopes are used for a variety of indications here – usually to inspect trachys that are suspected of being partially displaced. We had 6 trachy emergencies in 2012 recorded as critical incidents which all required a scope immediately. Not all of these were due to a*

blocked or displaced trachy and the scopes weren't used in all, but needed to be present in case the problem escalated."

Clinical expert opinion on intubation and the use of fibrescopes in the operating theatre environment

The questionnaire then went on to ask the clinician's expert' opinion rather than about their personal clinical experience. We asked about general operating theatres, and also about two high risk settings, the Accident and Emergency Department and in Obstetrics, and about two low risk settings, eye surgery and In vitro fertilisation (IVF).

The experts' answers varied markedly regarding the frequency of intubation where some uncertainty was expressed (Table 3). One expert (CE2) did not comment saying he was not an anaesthetist.

Another did not offer estimates in all scenarios above but commented:

"Re-usable scopes fail at two points, 1 the scope itself, 2 the sterilisation equipment. If either of these two points fail then the re-usable fibrescope service is severely curtailed (clearly at point 2 it will be completely disrupted). However scope availability is not the only issue: personnel must be present who can use the sterilisation equipment and process the scope appropriately (an advantage for the Ascope is that minimal training is required to render it ready for use. Finally, there must be an operator to use the scope (re-usable or aScope) as the skill of using the scope is fundamental to the success of the procedure- ie the scope itself does not facilitate tracheal intubation, rather the scope in the hands of an appropriately trained user allows tracheal intubation. Disposable scopes could allow every hospital to have a ready to use fibrescope available in an unanticipated difficult airway- however the A2Scope fails in the sense that it does not conform with present Difficult Airway Society guidelines that suggest the best thing to do for the 'average user' is a low skill fibreoptic intubation though a laryngeal mask with an Aintree catheter. The A2scope does not (although I understand that future versions may well do) fit through an Aintree catheter making this low skill technique impossible. Disposable fibreoptic technology is part of a spectrum of devices that may decrease the morbidity and mortality associated with airway management and general anaesthesia."

One expert (CE5) did not give estimates on percent of failed intubations where a fibroscope was or was not available but commented: *"I don't know the answer to this and you won't find it in the literature. A fibrescope is one of a variety of intubation aids that are available and each will have its merits in different situations. E.g. if intubation fails due to an obstructing laryngeal tumour, then a fibrescope probably won't be much use. Most anaesthetists would try a fibrescope in the failed intubation situation and would be pleased to have one to hand, but this is no guarantee of success – depending on experience and the patient."*

Table 1: Anaesthetics, intubations and intubating fibrescope availability in the settings in which the clinical experts worked

Setting	**N general anaesthetics**	**% involving endotracheal intubation**	**% involving use of intubating fibrescope**	**%'difficult' (i.e >1 attempt) intubations**	**% unexpected difficult intubations**	**N re-usable intubating fibrescopes available**	**N single-use intubating fibrescopes currently available**
Specialist NHS hospital: ENT, maxillofacial and plastics including care on ITU (CE1)	45 per day	40	-	15	<10	4	yes
ITU and respiratory medicine (CE2)	10 per week	100	-	4	<1	1 and access to 3 in adjacent departments	yes
Every specialty except for neurosurgery & burns/plastics, 22 theatres and 5-6 other places, ef cardiac catheter lab. Taking just the theatres into account: (CE3)	>100 per day	33	-		Don't know	6	Yes, one in isolated site
Hospital, *Excluding the ENT service which is at another site* (CE4)	Around 4000 per annum	-	-	5% but not as high as 10		3 or 4 depending upon department	Yes, primarily for infected cases, but have been used for the just-in case scenario (see comments)
In Breast Theatres	1200 per annum	20	-				
In Neurosurgical theatres	1500 per annum	90-95	-				
In general Theatres		75	-				

Setting	**N general anaesthetics**	**% involving endotracheal intubation**	**% involving use of intubating fibrescope**	**%'difficult' (i.e >1 attempt) intubations**	**% unexpected difficult intubations**	**N re-usable intubating fibrescopes available**	**N single-use intubating fibrescopes currently available**
(Colorectal and Urology)							
In ICU	700 admission per annum	70	-				
NHS Trust	about 40,000 surgical procedures per annum	Around 40% Trust wide. For the specific ops I tend to do, this is about the same (mixture of day case and bigger procedures)	-	5	<1	In each theatre suite (5) there are at least 2 scopes. In each ICU (2) there are at least 2. We also have bronchoscopes on the ICU (2 each) which could be used but aren't ideal.	Keep a stock of around 5-10
Obstetrics (CE7)	3 per week	100%	2	10	30	None	None

Table 2: Frequency of use of intubating fibrescope to reposition tracheostomies in the experts' ICUs

N ITU beds	How often does a displaced tracheostomy require repositioning using an intubating fibrescope?			Comments:
	Per n of patients?	Per day?	Per week?	
2-4 (CE1)	1 in 10 patients			CE1: Note that we are a specialist unit with a much higher than usual use of scopes because of our case load and position as a centre for teaching of airway management, particularly using flexible endoscopic intubation. ITU is burns so hence low turnover
17 (CE2)	100%		<1	It is my practice to confirm the repositioning of a displaced tracheosotmy, by fibreoptic endoscopy on all occasions
14 (CE3)		1		
23 (CE5)				We manage about 120 patients per year with a trachy – we perform 60 on ICU patients and the rest are done during head and neck surgical procedures.

Table 3: Clinical expert opinion on intubation and the use of fibrescopes.

In your expert opinion:	Operating theatre environment					
	General operating theatre	A&E	Eye surgery	Obstetrics	IVF	Comments
What percentage of general anaesthetics are associated with intubation?						
CE1	30	?	?30	100	?	
CE3	40	90	60	100	1	
CE7	60	100	40	100	20	
CE4	75	99	(Historical recollection) 10	No current obstetric practice- all GA Sections are routinely intubated	Cannot comment	
CE5	40	Nearly All	10	10	10	

Are re-usable fibre optic scopes normally used in current practice?						
CE1	Yes	Yes	Yes	Yes	Don't know	
CE3	Yes	Yes	Yes	Yes	No	
CE7	Yes	Don't know	Don't know	Yes	No	
CE4	Yes	-	Our eye hospital uses disposable to allow ease of access	-	Cannot comment	"normally available" is probably a better statement
CE5	Yes	No	Don't know (not on our site)	Yes	Don't know (not on our site)	
In what percentage of patients does the initial attempt to intubate fail?						
CE1	?10	??20	?10	?30		Reading initial "attempt" as first pass with laryngoscope, hence counting repositioned scope, external laryngeal pressure etc as subsequent attempts
CE3	25	25	25	40	1	
CE7	5	15	5	15	2	
CE4	-	-	-	-	-	
CE5	Around 5% of all intubations	Higher, perhaps 10-15%	I don't know – estimate 5%	Around 10% of intubations	I don't know mostly young fit women low	
In what percentage of patients does intubation completely fail if a fibrescope is not available?						
CE1	Excluding predicted difficult airway, perhaps <2%					
CE3	1	1	1	1	N/A	
CE7	2	3	2	5	0.5	
CE4	-	-	-	-	-	
CE5	See comment in text below					
In what percentage of patients does intubation with the aid of a fibrescope fail?						
CE1	@1% of <u>all</u> attempts					

	with a flexi scope					
CE3	0.1	0.1	0.1	0.1	N/A	
CE7	1	2	1	1	0	
CE4	-	-	-	-	-	
CE5	See comment in text below					

Clinical experts were asked to comment on variations in availability and use of re-usable fibrescopes within different settings: i.e. type of surgery, size of hospital, theatre configuration, scope sterilisation service, physical location, etc. Further comments were as follows:

- *Numbers above are purely my impressions based on personal experience, figures are not really available that can be applied to general populations, various papers will give these numbers though not necessarily applicable to all populations/practices/ current times or presented as you ask. Particularly you must be careful not to confuse different definitions of difficult intubation/laryngoscopy etc.*

  Availability of scopes across hospitals is highly variable in terms of physical presence but also more importantly in how well maintained they are, the quality of image generated, the amount of time needed to find individual components of the kit, which staff now how to put equipment together etc. Large NHS hospitals will be much better equipped than small private hospitals (with 2 to 4 operating theatres) which generally still at best have one poor quality and poorly maintained fibrescope, which then is unavailable for protracted periods following use. (CE1)

- *All of this depends on the experience of the anaesthetist mainly*. (CE3)
- *Great variability between units and specialties, often with little or no sound economic basis*. (CE7)

  High volume areas have re-usable scopes. We have about 10 drying/storage cabinets in our Trust and about 140 scopes in total. Scopes can be stored for 72 hrs then resterilised. 1 central decontamination suite. We now have fibreoptic disposable scopes on ENT wards, wards where trachys are managed, day case theatre and obstetric theatre (fairly remote sites) so we have the immediate availability in case of emergency. (CE5)

2. Clinical expert opinion on outcome probabilities

Not all of the experts answered this section of the questionnaire. Clinical experts were asked to consider all intubations carried out across the country as part of general anaesthesia, in which difficulty with intubation was not anticipated. One expert commented that "*Difficulty with intubation was not anticipated*" was a "*significant qualifier*" and that his answers hence related to

this specific scenario (CE1). He further commented "*I have to confess to having seriously struggled to find any accepted figures upon which to base the answers to these questions*".

The experts were told "*This questionnaire concerns the probability of various outcomes for the patient given the intubation has failed. These probabilities consolidate all contexts over which such failure occurs, i.e. net of the different skill levels, levels of support, age of patient etc. Please feel free to use the figures below in formulating an answer. Please give your best guess and 95% credible limits (i.e. high and low estimates) on this best guess*". Clinical experts were also asked to comment on the probability of harm when intubation fails (Table 4).

Clinical experts were asked to provide their own estimates of the probabilities of harm in the tabular format below (Table 5). Estimates varied widely.

Not all however felt able to provide this without qualification. One clinical expert's (CE1) views were as follows:

Death: *individual and even combined figures for death and brain damage resulting when intubation is attempted – as part of a general anaesthetic where there was no anticipated difficulty – and subsequently fails is very low and unknown. In NAP4 of 70 tracheal tube related adverse events in the operating theatre 2/3 had an anticipated "difficult airway" and "all 12 who experienced unexpected failed intubation in theatre survived neurologically intact" (NAP4 Summary Booklet page 16). I would put the order of magnitude of the combined figure at definitely less than 1 in 100 and perhaps as low 1 in 1,000 000.*

Brain Damage vs increased ITU length of stay: *We may assume 5% of all airways are awkward (Rose, D.K. & Cohen, M.M., 1994, The airway: problems and predictions in 18,500 patients, Canadian journal of anaesthesia = Journal Canadien d'Anesthésie, 41(5 Pt 1), pp. 372-83.), i.e. need at least more than 1 attempt with a laryngoscope or more specialised technique (up to and including tracheostomy under local anaesthesia). In NAP4 12 patients were recorded as adverse airway events related to tracheal tubes as above under a), these will therefore have been patients having unplanned tracheostomy or ITU admission which can be counted as increased ITU length of stay, however it is not known in NAP4 how many patients with unanticipated difficult intubation were managed without any tracheostomy or ITU admission and hence no denominator is available.*

Table 4: Expert opinion on the probability of no harm.

Estimate of no harm	Explanation
>80%	Most routine intubations (e.g. For elective surgery as most intubations are) will not result in significant harm if they fail (significant harm = more serious than broken teeth or temporary arterial desaturation), as oxygenation will be achievable by other means, this is particularly so where difficulty with intubation is not anticipated as this would likely indicate absence of significant anatomical abnormality. (CE1)
0	Failed intubation will always result in some form of harm in context of unexpected difficulty with intubation. (CE2)
95%	The skill set of anaesthetists and the current situation where trainees almost never work alone. (CE3)

Table 5: Clinical expert opinion on outcomes of failed intubation where given

Probability of outcome (Numbers per million intubations)									
Death			Brain damage			Increased ITU length of stay			
Best guess	High	Low	Best guess	High	Low	Best guess	High	Low	Expert
See above						1 in 100	1 in 5	1 in 1000	CE1
5	10	2	10	20	2	100	150	50	CE2
5	9	3	5	9	3	15	30	9	CE7
1	1	1	2	3	1	5	10	3	CE3

Other expert comments were:

- *My main experience lies in ICU patients. I would anticipate that the probability of death or brain damage or increased length of stay following failed intubation due to unexpected difficult airway in an ICU setting or emergency operation, than in a more elective operating theatre setting. In ICU setting I suspect length of stay likely to be increased in at least 50% of cases, brain damage likely in up to 30% of cases and death in 10% of cases.*
- *I think it is impossible for me to better guess the NAP4 data. However I am aware that the NAP4 report itself admits that there may have been underreporting of events by up to 75%- i.e. there should have been 532 anaesthesia events not 133. I am also aware that the anticipation of a difficult airway in NAP4 is much lower than that found in the most recent studies and meta-analysis 2.2% versus 5.8% (T Shiga et al). Of the 2.2 only 10% had an awake fibreoptic intubation. Whether this was due to a lack of equipment or expertise is not stated, however the report concludes that fibreoptic intubation was not attempted often enough. Also, the NAP4 inclusion criteria were necessarily strict and may not have captured all the harm associated with a failed or traumatic intubation- subglottic stenosis can be a result of atraumatic intubation but clearly could not be accounted for in a snapshot study. There was also no possible record of cases having to be delayed because of a prolonged intubation attempt- did this have an impact on other patient's treatment etc.* (CE4)
- *I cannot put a figure on this I'm afraid. It would be a complete guess. There are so many factors involved. You can take a normal looking patient to a theatre with the most experienced anaesthetist and all the kit and it can all go wrong (Elaine Bromily case in NAP4). When there is a problem and hypoxia occurs, the outcomes are usually bad. Fortunately (for the patients and not for this study!) this is rare.* (CE5)

Clinical expert views on estimates of intubation events and harm in the medical literature

Clinical experts were asked to comment on the estimates from the medical literature given in Box 2 below.

Comments on NAP4 were as follows:

- *Tracheal tube death/brain injury: Because of data collection method likely to be small underestimate.* (CE1)

- *Tracheal tube events: Only refers to serious effects of failure, many, many failed first attempts at intubation will not show here. The figure should actually be 70 for anaesthesia involving a tracheal tube, other cases are from ITU and Accident and Emergency and again no denominator is available for those figures.* (CE1)

Comments on our indirect and rough estimates were as follows:

- *The figures including yours derived above are the best estimates available of serious adverse events. Note that failed first attempts at intubation (your major question in preceding pages) are innumerable, and hence incidence and consequences of (e.g. cost or minor harm) from failed first attempts at intubation cannot be derived here. The hope is that more ready availability of flexible endoscopic intubation will push down numbers of serious harm and diminish the unquantified numbers of minor harm to no harm.* (CE1)
- *As above the estimates take into account all general anaesthesia procedures. I am of the view that the risks differ in different clinical environments with ICU and procedures undertaken outside of an operating theatre environment (A&E) as the highest risk.* (CE2)
- *I have no argument with the figures which as far as I am aware are obtained from surveys and will therefore be better than my guesses.* (CE3)
- *I think trying to tease absolute numbers out of the two studies is unhelpful- given the wide ranging confidence intervals*. (CE4)
- *For the UK, NAP4 is probably our best guess. They comment in the intro that not all incidents will have been reported to NAP4. We know from critical incident work that probably around 1 in 10 incidents are reported. It probably wasn't as bad for NAP4, but this is an underestimate. To get 'into' NAP4, you needed to have a significant sequalae from your failed airway management. That means that there are many more (unknown) numbers of difficult or even failed intubations that were successfully managed. What we don't know is how many of the successful ones went well because the clinical areas were better equipped. NAP4 does highlight some of the equipment problems involved in some of the cases. The French numbers seem reasonable but I am not as familiar with this report.*

  I think the theme for me with these incidents is that these airway events are rare but also unpredictable. When they do happen, they can go very wrong quickly and those managing the airway need all the kit asap. My own view is that fibrescopes need to be available as part of the equipment (and they are on the difficult airway society list http://www.das.uk.com/equipmentlistjuly2005.htm) *and providing appropriate scopes in remote areas or ones where provision of a drying cabinet and the associated infrastructure is too expensive.*

  There are clinical areas and situations where one might expect a higher rate of complications – ICUs, ENT units, hospitals that are trauma centres or have large head and neck units. Here, a scope should be immediately available. This may be possible through conventional scopes but may be reasonably provided by these disposable ones.

  I think it will be difficult to find an acceptable model but appreciate why you wish to do so. Whatever you come up with will undoubtedly be criticised! From an individual patient point

of view, if there is a death from a failed intubation and essential equipment is not nearby (when it can easily be provided) then whatever the odds, this is a tragedy. (CE5)

Box 2: Relevant estimates from or based upon the medical literature

Cook 2011 (NAP4)*	Numerator	Denominator	Incidence
Tracheal tube death/brain damage (combined)	10	1,102,900 (anaesthesia involving tracheal tube)	9.1 (95% CI 3.4 to 14.7) per million
Tracheal tube events**	91	1,102,900 (anaesthesia involving tracheal tube)	82.5 (95% CI 65.6 to 99.5) per million

* Cook T M, Woodall N, and Frerk C. Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1: Anaesthesia. British Journal of Anaesthesia 2011;106 (5): 617–31
**Tracheal tube events that led to: death, brain damage, the need for an emergency surgical airway, unanticipated ICU admission, or prolongation of ICU stay.

Auroy 2009***	Incidence of death	Note
French national survey. Setting: GA procedures	Difficult intubation related annual death in general anaesthesia procedures employing tracheal intubation: • 1:46000 (95% CI 1:386000 to 1:13000) in 1978-1982 • 1 : 176 000 (95% CI 1 : 714 000 to 1 : 46 000) , i.e. **0.61 (95% CI 0.14–2.16 per 100 000) in 1999**	Reported are deaths in anaesthetic intubations, i.e. the denominator is intubations (rather than difficult or failed intubations).

***Auroy Y, Benhamou D, Pe´quignot F, Bovet M, Jougla E and Lienhart A. Mortality related to anaesthesia in France: analysis of deaths related to airway complications. Anaesthesia 2009,64:366–370

Indirect and rough estimation based on the above two studies:

- Tracheal tube **death** = 6.1 per million anaesthetic intubations (Auroy 2009);
- Tracheal tube event = 82.5 per million anaesthetic intubations (NAP4 report);
- Therefore, tracheal tube **death** in tracheal tube event = 6.1/82.5 = 7.39%.

- Tracheal tube **death/brain damage (combined**) = 9.1 per million anaesthetic intubations (NAP4 report);
- Tracheal tube **death** = 6.1 per million anaesthetic intubations (Auroy 2009);
- Therefore, tracheal tube **brain damage** = 9.1 - 6.1 = 3 per million anaesthetic intubations;
- Therefore, tracheal tube **brain damage** in tracheal tube events = 3/82. 5=3.63%

Summary Clinical experts worked or had worked in a variety of settings with varying numbers of anaesthetics and intubation rates that varied according to case-mix. Between zero and six re-usable intubating fibrescopes were available and in all but one obstetric setting single-use fibrescopes were available.

Repositioning of displaced tracheostomies using an intubating fibrescope in the ITU was reported by different experts to occur once a day or once a week and in 100% or 10% of patients.

When the experts were asked for their clinical expert opinion on percentages of anaesthetics requiring intubation in different settings, a wide range was quoted for each setting.

Fibreoptic scopes were reported to be: in normal use in general operating theatres and eye surgery (use of single-use scopes also reported); not to be in normal use in IVF, but there were inconsistent views on this in the A and E and obstetric settings and a number of “don’t know” answers.

A range of estimates of rates of failed intubation were given, with some qualifications and uncertainty.

Estimates of no harm resulting from failed intubation ranged from zero to more than 80%, but higher rates of harm were quoted in the ICU setting. There were extremely divergent views on rates of death, brain damage and increased ITU stay following failed intubation.

While clinical experts gave some support to the estimates proposed by the EAC, there were multiple caveats, including that event rates would vary with setting and that the confidence intervals around the point estimates would be wide.

APPENDIX C: ADDITIONAL INFORMATION ABOUT PARAMETER ESTIMATES

1. Published incidence rates of harm resulted from failed tracheal intubation

To identify the published incidence rates of brain damage, ITU (or ICU or CCU) admission and death which resulted from a failed, difficult or delayed tracheal intubation (incidence rate of each type of harm given separately), literature searches for relevant studies were conducted on MEDLINE and EMBASE from 2008 to present. Key words were used such as death, brain damage, ITU (or ICU or CCU) admission, and failed (or delayed or difficult) intubation. Relevant MESH terms were also used. See **Appendix C1** below for the search strategy.

A number of relevant studies were identified that directly reported applicable incidence rates. The studies varied in terms of location, setting, patient population, outcome measurement, etc. Also, the majority of these studies were single centred and small in terms of sample size. Hence, the reported incidence rates varied considerably across the studies.

A large study by Auroy et al(Auroy et al. 2009) was identified that reported tracheal intubation related death in general anaesthesia procedures using the French national mortality database. The study reviewed death certificates from the French national mortality database for the calendar year 1999 to analyse cases in which airway complications had contributed to peri-operative death. However, the incidence of death reported in the study was death in general anaesthesia procedures employing tracheal intubation, rather than death in difficult intubations or failed intubations. **Table 10** below presents the annual incidence of difficult intubation related death in general anaesthesia procedures reported in this study.

Table 10. Annual incidence of difficult intubation related death in general anaesthesia procedures in France

Auroy 2009(Auroy et al. 2009)	**Incidence of death**	**Note**
French national survey. Setting: general anaesthesia procedures	Difficult intubation related annual death in general anaesthesia procedures employing tracheal intubation: • 1:46000 (95% CI 1:386000 to 1:13000) in 1978 – 1982 • 1:176 000 (95% CI 1:714 000 to 1:46 000) , i.e. **0.61 (95% CI 0.14 – 2.16 per 100 000) in 1999**	Reported are difficult intubation related per death in the total number of tracheal intubations in general anaesthesia procedures. The denominator relates to intubations rather than difficult intubations.

Another search for publications was also conducted on MEDLINE and EMBASE from 2008 to present, using keywords with less refined but broader concept, i.e. “airway management” and “major complications”, with the attempt to indirectly estimate relevant incidence rates from more representative and generalisable data source such as the Auroy study(Auroy et al. 2009). For search strategy see **Appendix C2**.

From this search, the UK NAP4,(Cook, Woodall, & Frerk 2011;Cook, Woodall, Harper, & Benger 2011) was identified to be the most informative. The NAP4 is a report of the major complications of airway management in the UK (results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society). Based on data collected from all the UK’s National Health Service hospitals from 1st September 2008 to 31st August 2009, the NAP4 reported complications of airway management that led to death, brain damage, the need for an emergency surgical airway, unanticipated ICU admission, or prolongation of ICU stay. **Table 11** below presents the incidence of total tracheal tube events and the combined incidence of death and brain damage related to tracheal tube.

Table 11. Annual tracheal tube related death/brain damage and total annual tracheal tube events in the UK

Cook 2011 (NAP4)(Cook, Woodall, & Frerk 2011;Cook, Woodall, Harper, & Benger 2011)	**Numerator**	**Denominator**	**Incidence**
Tracheal tube events	91	1,102,900 (anaesthesia involving tracheal tube)	82.5 (95% CI 65.6 to 99.5) per million
Death/brain damage resulted from tracheal tube events	10	1,102,900 (anaesthesia involving tracheal tube)	9.1 (95% CI 3.4 to 14.7) per million

Note: the reported tracheal tube events are not all the tracheal tube events but only those that led to death, brain damage, the need for an emergency surgical airway, unanticipated ICU admission, or prolongation of ICU stay.

Using data from the Auroy study(Auroy et al. 2009) and the NAP4 report,(Cook, Woodall, & Frerk 2011) the incidence of intubation related death and incidence of intubation related brain damage can therefore be indirectly and approximately estimated as follows.

Incidence of death in tracheal tube events:

- Tracheal tube **death** = 6.1 per million **anaesthetic intubations** (Auroy 2009(Auroy et al. 2009))

- Tracheal tube events = 82.5 per million anaesthetic intubations (NAP4 2011);
- Therefore, tracheal tube **death** in **tracheal tube events** = 6.1/82.5 = **7.39%**;

Incidence of brain damage in tracheal tube events:

- Combined tracheal tube **death/brain damage** = 9.1 per million **anaesthetic intubations** (NAP4);
- Tracheal tube **death** = 6.1 per million **anaesthetic intubations** (Auroy 2009(Auroy et al. 2009))
- Tracheal tube **brain damage** = 9.1 – 6.1 = 3 per million **anaesthetic intubations**;
- Therefore, tracheal tube **brain damage** in **tracheal tube events** = 3/82. 5 = **3.63%**

Directly reported incidence rates of harm from published studies which were identified from the two searches of electronic databases mentioned above, the reference lists of the sponsor's submission and key studies, and those indentified through hand search of papers and through experts in this field, were also summarised in **Appendix C3**.

Appendix C4 presents additional data on the incidence of failed or difficult intubation that were from studies identified from the above sources.

Appendix C5 presents additional information on some of the incidence rates reported in the NAP4 that are not directly relevant but may be informative.

2. Published incidence rates of displacement of tracheostomy

For published evidence on the risks of displacement of tracheostomy and harms which resulted from displaced tracheostomy, MEDLINE and EMBASE were searched (see **Appendix C6** for search strategy). Studies were excluded if they were: on paediatric tracheostomy; with mixed patients of adults and yang children (age <6 years) but results were not reported separately for adults and children; conference proceedings; with less than 200 patients or tracheostomies. A number of relevant studies were identified. Outline of the findings was summarised in the **Appendix C7**. Unsurprisingly, the studies varied in terms of location, setting, year in which the study was conducted, patient population, outcome measurement, etc, and the reported incidence of displaced

tracheostomy varied considerably across the studies. Few studies reported harms which were directly resulted from tracheostomy displacement.

Appendix C1. Search strategy – published incidence rates of harm which resulted from problematic tracheal intubation

1 (death* or mortalit*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

2 exp brain damage, chronic/ or exp brain death/ or exp hypoxia-ischemia, brain/

3 (ICU or ITU or intensive care or critical care).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

4 admission*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

5 3 and 4

6 1 or 2 or 5

7 exp intubation, intratracheal/ or exp tracheostomy/

8 (delay* or fail* or difficult*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

9 7 and 8

10 6 and 9

11 limit 10 to humans

12 limit 11 to english language

Appendix C2. Search strategy for indirect estimation of risk of harm which resulted from problematic tracheal intubation

1 major complication*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

2 airway management*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

3 1 and 2

Appendix C3. Published incidence rates of harm resulted from tracheal intubation

Table A. Risk of brain damage resulted from problematic intubation (reported as patient with brain damage in patient intubated)

Study	Brain damage	Severe hypoxemia	Note
Mort 2004(Mort 2004) Single centre, USA. Emergency intubation in out-of-theatre	-	1.9% (in those requiring ≤ 2 intubation attempts) 18% (in those requiring >2 intubation attempts)	Intubation: conventional laryngoscopy intubation; in critically-ill patients (n=2833) Airway unexpected to be difficult: not specified.
Sakles 1998(Sakles, Laurin, Rantapaa, & Panacek 1998) Single centre, Canada Emergency department	0%	0%	Any adverse event was 0 in 610 intubated patients, in 7 of which intubation was failed. Intubation: conventional laryngoscope Airway unexpected to be difficult: not specified
Quinn 2012(Quinn et al. 2013) UK Obstetric Surveillance System (UKOSS) data; Apr 2008 – Mar 2011 GA obstetric.	0%	-	There was no hypoxic brain injuries (57 failed intubations) Intubation: no case used a fibrescope to aid intubation. Airway unexpected to be difficult: not specified.
Jaber 2006(Jaber et al. 2006) Multicentre, France; Jan 2003 – Jun 2003 ICU	-	40%	Intubation: conventional laryngoscopy for initial intubation Airway unexpected to be difficult: not specified
Thomas 2009(Thomas & McGrath 2009) UK National Patient Safety Agency database. CCU, ICU, or at the time of admission to the unit.	≤18.31%	-	Reported 26/142 (18.31%) "more than temporary harm" associated with delayed/failed intubation in adults and children (excluding babies less than 18 months old). The authors stated that of the 1085 airway incidents "Eighty-eight intubation incidents were associated with equipment problems." Intubation: not specified whether fiberoptic. Airway unexpected to be difficult: the study focused on 'unexpected or unintended airway incident".

ED: emergency department. GA: general anaesthesia. ICU: intensive care unit. CCU: critical care unit.

Table B. Risk of ICU (or ITU or CCU) admission resulted from problematic intubation (reported as admission in patient)

Study	ICU (or ITU or CCU) admission	Note
Quinn 2012(Quinn et al. 2013) UK Obstetric Surveillance System (UKOSS) data; Apr 2008 – Mar 2011 GA obstetric.	0%	No case was admitted to ICU purely for airway management as a result of failed intubation (57 failed intubations). Intubation: no case used a fibrescope to aid intubation. Airway unexpected to be difficult: not specified.
Rose 1994(Rose & Cohen 1994) Single centre, Canada Setting: operating room, GA, excluding obstetric	1.8%	The risk was unexpected ICU admission rate following difficult intubation by direct laryngoscopy either from the operating room or the Post Anaesthetic Care Unit (PACU). Intubation: for initial tracheal intubation some used DL and the other used alternative approaches (including any method to intubate the trachea in a patient without general anaesthesia, and/or those involving fibreoptic, lightwand, retrograde placement and/or tracheostomy). Airway unexpected to be difficult: abnormal airway was determined in some patients, but it was unclear of the patients based on which the risk was calculated, how many patients were with unexpected abnormal airway.
Sakles 1998(Sakles, Laurin, Rantapaa, & Panacek 1998) Single centre, Canada Setting: ED	0%	Any adverse event: 0 in 610 intubated patients in 7 of which the intubation was failed. Intubation: conventional laryngoscope Airway unexpected to be difficult: not specified

ED: emergency department. GA: general anaesthesia. ICU: intensive care unit. ITU: intensive treatment unit. CCU: critical care unit. DL: direct laryngoscopy.

Table C. Risk of death resulted from problematic intubation (reported as death in problematic intubation except in two studies Jaber 2006(Jaber et al. 2006) and Heuer 2012(Heuer et al. 2012))

Study	Incidence of death (denominator in parentheses)	Note
Quinn 2012(Quinn et al. 2013) UK Obstetric Surveillance System (UKOSS) data; Apr 2008 – Mar 2011 Obstetric GA	0% (failed intubation)	There were no deaths reported in 57 failed intubations Intubation: no case used a fibrescope Airway unexpected to be difficult: not specified
Djabatey 2009(Djabatey & Barclay 2009) UK sources including Meditech electronic patient record system etc; Jan 2000 – Dec 2007 Setting: Obstetric GA	48.5% (failed intubation)	"Failed maternal intubation is the most frequent cause of death directly attributed to anaesthesia, accounting for 50 out of 103 deaths reported in Confidential Enquiries from 1976 to 2005." Intubation: not specified Airway unexpected to be difficult: not specified; it was generic obstetric general anaesthetics
McKeen 2011(McKeen et al. 2011) Single centre, Canada; 1984 –2003 Setting: Obstetric GA	0% (difficult and failed intubation)	0 death in 123 difficult intubations and 2 failed intubations Intubation: either direct laryngoscopy or alternative intubating equipment Airway unexpected to be difficult: not specified; it was generic obstetric general anaesthetics
Schwartz 1995(Schwartz, Matthay, & Cohen 1995) Single centre, USA Setting: out-of-theatre emergency intubation (including ICU, cardiac care unit, acute care hospital floors, etc)	16% (difficult intubation + esophageal intubation)	In 297 intubations the problematic intubations: difficult intubation was 8% and esophageal intubation 8%. "Intubation associated death", defined as death that occurred during or within 30mins of the procedure, was 7 in 270 intubations (2.59%) in patients with an obtainable systolic blood pressure. Therefore, difficult intubations and esophgeal intubations in the 270 intubation was 16% x 270 = 43, thus death in difficult intubation and esophageal intubation =7/43 (16%) Intubation: translaryngeal tracheal intubation Airway unexpected to be difficult: not specified
Jabre 2011(Jabre et al. 2011) (Retrospective review of a multi-centre trial, France; Apr 2007 - Feb 2008) Setting: emergency intubation in the out-of-hospital setting	Before reaching the hospital: 11% (difficult intubation) 28 days after the arrival: 36% (difficult intubation)	Death in difficult intubation group: 11% before reaching the hospital and 36% within 28 days after the arrival Unclear whether deaths were necessarily as a result of difficult intubation Intubation: not specified Airway unexpected to be difficult: not specified
Wang 2009(Wang et al. 2009) (Registry data, USA) Setting: out-of-hospital emergency intubation	▪ 3% (difficult intubation) ▪ 14% (failed intubation) ▪ 3% (tube misplacement or dislodgement)	The risks were reported as death in: multiple intubation attempts 3%, failed intubation 14%, and tube misplacement or dislodgement 3%. Intubation: laryngoscopy Unexpected difficult airway: not specified
Cobas 2009(Cobas et al. 2009)	71% (failed/delayed intubation)	Of the patients requiring pre-hospital intubation, 63 were either with an intubation in the

Single centre prospective observational study, USA Setting: pre-hospital intubation		esophagus or with alternative airway device in place due to failed intubation on arrival. All were eventually intubated in the hospital. Eighteen of the 63 survived to discharge and the remaining 45 died Unclear whether deaths were necessarily as a result of difficult/delayed intubation Intubation: variety of approaches including ETI, laryngeal mask airway, and Combitube and/or cricothyroidotomy Unexpected difficult airway: not specified
Sakles 1998(Sakles, Laurin, Rantapaa, & Panacek 1998) Single centre, Canada; 1995 –1996 Setting: emergency department	0% (patient with failed intubation)	Any adverse event 0 (in 610 intubated patients in which 7 were failed) Intubation: conventional laryngoscope Airway unexpected to be difficult: not specified
Jaber 2006(Jaber et al. 2006) Multicentre, France; Jan 2003 – Jun 2003 Setting: ICU	0.8% (**intubation**)	*"During 247 intubations performed two (0.8%) met the definition of intubation-associated mortality."* Intubation: conventional laryngoscopy for initial intubation Airway unexpected to be difficult: not specified
Heuer 2012(Heuer et al. 2012) Single centre, Germany; Aug 2007 – Aug 2008 Setting: ICU anaesthesia	10.4% (**intubated patient**)	Reported as of patients intubated in the ICU those who died in the ICU. Intubation: initial attempt included DL (n=173), flexible fibrescope (n=8) and blind nasal technique (n=17) Airway unexpected to be difficult: not specified

ED: emergency department. GA: general anaesthesia. ICU: intensive care unit.

Appendix C4. Incidence of failed or difficult intubation

Incidence of problematic intubation

Study	Intubation event rate	Note
Reported as problematic intubation in total intubation		
Quinn 2012(Quinn et al. 2013) UK national study using the UK Obstetric Surveillance System data Apr 2008 – Mar 2011	Failed: 0.45%	Reported as 1 failed in 224 intubations Intubation: no case used a fibrescope to aid intubation Airway unexpected to be difficult: not specified
Bair 2002(Bair, Filbin, Kulkarni, & Walls 2002) The National Emergency Airway Registry data Jan 1998 – Feb 2001 Setting: emergency department	Failed: 2.68%	207 failed in 7,712 intubations = 2.68% Intubation: fiberoptic and other non-fiberoptic Unexpected difficult airway: not specified
Mayo 2011(Mayo et al. 2011) (single centre, USA; 2003 –2005) Setting: emergency endotracheal intubation in ICU	Difficult: 20%	Difficult emergency endotracheal intubation (>3 attempts): 20% Intubation: standard laryngoscopy. Unexpected difficult airway: not specified
Heuer 2012(Heuer et al. 2012) (Single centre, Germany; Aug 2007 – Aug 2008) Setting: ICU anaesthesia	Difficult: 23%	Intubation: initial attempt included DL (n=173), flexible fibrescope (n=8) and blind nasal technique (n=17) Unexpected difficult airway: not specified. The authors stated that "*Every intubation in the ICU setting should be considered potentially difficult*"
Jaber 2006(Jaber et al. 2006) Multicentre, France; Jan 2003 – Jun 2003 Setting: ICU	Difficult: 12% Esophageal: 5%	Intubation: conventional laryngoscopy for initial intubation Airway unexpected to be difficult: not specified
Reported as patient with problematic intubation in total patient intubated		
McDonnell 2008(McDonnell, Paech, Clavisi, & Scott 2008) Multicentre, Australia. Obstetric GA	Failed: 0.4% (95% CI 0.01-0.9%) Difficult: 3.3% (95% CI 2.3-4.5%)	Failed intubation occurred in 4 of 1095 patients (1 in 274), i.e. 0.4% (95% CI 0.01-0.9%) Difficult intubation in 36 of 1095 patients (1 in 30), i.e. 3.3% (95% CI 2.3-4.5%) Intubation: laryngoscope Airway unexpected to be difficult: tracheal intubation was planned
Jabre 2011(Jabre et al. 2011) (Retrospective review of a multi-centre trial, France; Apr 2007 - Feb 2008) Setting: emergency intubation in the out-of-hospital setting	Difficult: 11% Impossible intubation: 0	Difficult intubation (intubation difficulty scale >5) was in 73 patients out of 650 intubated = 11% Intubation: not specified Airway unexpected to be difficult: not specified
Sakles 1998(Sakles, Laurin, Rantapaa, & Panacek 1998)	Failed: 1.1% Oesophageal: 5.4%	Could not be intubated in 7 patients out of 610 intubated patients = 1.1% Oesophageal intubations in 33 patients out of 610 intubated patients = 5.4%

Single centre, Canada Setting: emergency department		Intubation: conventional laryngoscope Airway unexpected to be difficult: not specified
Rose 1994(Rose & Cohen 1994) Single centre, Canada Setting: operating room, GA, excluding obstetric	Risk of patient with problematic intubation using DL: • difficult: 1.8% (326/18205) • awkward: 2.5% (448/18205) **In patients with difficult intubation the risk of failed intubation using DL: 16.56% (54/326)** Risk of patient with failed intubation: • failure using DL: 0.3% (54/18205) • failure using alternative approach: 3.1% (11/353) • **failure using fiberoptic: 0 (0/4)**	The risks were reported as patient with problematic initial intubation in patients with intubation attempt. For direct laryngoscopy, difficult intubation refers to > 2 laryngoscopies; awkward intubation refers to ≤ 2 laryngoscopies. Intubation: tracheal intubation was attempted in 18558 patients. For the initial tracheal intubation, in 18205 patients DL was used and in the other 353 patients alternative approaches were used (including any method to intubate the trachea in a patient without general anaesthesia, and/or those involving fiberoptic, lightwand, retrograde placement and/or tracheostomy). **Of the 353 patients used alternative approaches fiberoptic was used in 4 patients.** Airway unexpected to be difficult: normal airway was determined in 16702 and abnormal 1858 patients by preoperative assessment.
Shiga 2005(Shiga, Wajima, Inoue, & Sakamoto 2005) Systematic review and meta-analysis. Searches from 1980-2004; included 35 studies (50,760 patients). Setting: patients with no airway pathology	Difficult intubation: • overall patients population: 5.8% (95% CI 4.5-7.5%); • normal patients excluding obstetric and obese patients: 6.2% (95% CI, 4.6–8.3%); • obstetric patients: 3.1% (95% CI, 1.7–5.5%); • obese patients: 15.8% (95% CI, 14.3–17.5%)	Intubation methods were not stated

ED: emergency department. GA: general anaesthesia. ICU: intensive care unit.

Appendix C5. Additional information — some incidence rates reported in the NAP4 that are not directly relevant but might be informative

Death/brain damage resulted from **tracheal intubation problems** during anaesthesia

	Death/brain damage	**Intubation problems**	Rate of deaths
Cook 2011 (part 1)(Cook, Woodall, & Frerk 2011)	10	91	10/91 = 10.1%

Death resulted from **all** primary airway management complications

	Deaths	Airway management problem	Rate of deaths
Cook 2011 (part 1 & 2)(Cook, Woodall, & Frerk 2011;Cook, Woodall, Harper, & Benger 2011)			
Anaesthesia, ICU, and ED	38	184	38/184 = 21%
Anaesthesia	16	133*	16/133 = 12%
ICU	18	36	18/36 = 50%
ED	4	15	4/15 = 26.7%

Brain damage resulted from **all** primary airway management complications

	Brain damage	Airway management problem	Rate of brain damage
Cook 2011 (part 1 & 2)(Cook, Woodall, & Frerk 2011;Cook, Woodall, Harper, & Benger 2011)			
Anaesthesia, ICU, and ED	8	184	8/184 = 4.3%
Anaesthesia	3	133*	3/133 = 2.3%
ICU	4	36	4/36 = 9%
ED	1	15	1/15 = 6.7%

Emergency surgical airway resulted from **all** primary airway management complications

	Admission or prolongation	Airway management problem	Rate of admission or prolongation of stay
Cook 2011 (part 1 & 2)(Cook, Woodall, & Frerk 2011;Cook, Woodall, Harper, & Benger 2011)			
Anaesthesia, ICU, and ED	75	184	75/184 = 40.8%
Anaesthesia	54	133*	54/133 = 40.6%

Emergency surgical airway: any forms of emergency access to the upper trachea as part of airway management that did not form part of the primary airway management plan, and was taken into account where the primary airway management plan failed and a needle/cannula or a surgical airway was performed.

ICU admission (or prolongation of stay in case of patients already in ICU) resulted from **all** primary airway management complications

	Admission or prolongation	Airway management problem	Rate of admission or prolongation of stay
Cook 2011 (part 1 & 2)(Cook,			

Woodall, & Frerk 2011;Cook, Woodall, Harper, & Benger 2011)			
Anaesthesia, ICU, and ED	122	184	122/184 = 66.3%
Anaesthesia	100	133*	100/133 = 75.2%

* For the events the airway in use or intended for maintenance included: tracheal tube of any sort (n = 91), supraglottic airway device (n = 35), and facemask (n = 7). Therefore, tracheal tube related problems among all airway management problems during anaesthesia: 91/133 = 68.4%

Appendix C6. Search strategy for incidence of tracheostomy displacement

Databases: Ovid MEDLINE(R) (1946 to January Week 3 2013) and MEDLINE (1980 to January Week 3 2013)

1 (dislodge* or displace*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

2 (accidental removal or accidental extubation or accidental decannulation).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

3 1 or 2

4 tracheo*tom*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

5 (incidence or rate* or risk*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

6 3 and 4 and 5

7 limit 6 to (english language and humans)

Appendix C7. Risk of tracheostomy displacement and harm resulted from tracheostomy displacement

Study	Risk of tracheostomy displacement	Risk of brain damage, death, or ICU admission resulted from tracheostomy displacement	Note
Aldawood 2008(Aldawood, Arabi, & Haddad 2008) Single centre, ICU, Saudi Arabia. May 2004 – Oct 2005 Consecutive critically ill patients underwent PT, N =227 PT, including 50 in obese (BMI ≥ 30 kg/m^2) and 177 in non-obese patients	Accidental extubation: 1.76% (4/227) Paratrachcal insertion: 2.2% (5/227)	Death: 0 death in 227 PTs	N =227 consecutive percutaneous tracheostomy (PT) in critically ill patients, including 50 in obese (BMI ≥ 30 kg/m^2) and 177 in non-obese patients. In 45 obese patients PT was performed without bronchoscopic guidance
Barbetti 2009(Barbetti et al. 2009) Single centre, ICU and OT, Australia. Mar 2002 and Dec 2007 Critically ill patients, 913 patients underwent PDT at the bedside in the ICU, and 250 underwent ST in the OT	Displacement of ST: 4.8% (12/250) Unplanned decannulation of ST: 0.8% (2/250) Obstruction of ST: 3.6% (9/250) Damaged pilot tube: 0	-	Displacement: tube displaced from trachea into pre-tracheal soft tissue; Unplanned decannulation: accidental complete dislodgement of tube; Obstruction: blocked tube inhibiting free passage of air into or out of lungs
Beiderlinden 2002(Beiderlinden et al. 2002) Single centre, anaesthesiological ICU with mixed surgical and medical patients, Germany. Sep 1998 - Jan 2001 N= 136 consecutive PDTs under bronchoscopic guidance with stepwise dilation	Dislocation/accidental decannulation 0.74% (1/136)	Cannula-related death: 0 Cannula-related hypoxaemia (SaO2<80%): 1/136	-
Beltrame 2008(Beltrame et al. 2008)[*] Single centre, ICU, Italy. Jan – Dec 2002 N=528 patients including 367 underwent PDT (Jan 2003 – Dec 200) and 161 underwent ST	Accidental extubation: PDT 2.45% (9/367); ST 0/161; **total** (PDT+ST): 1.7% (9/528) Cannula dislodgment: PDT 0/367; ST 1.86% (3/161); **total** (PDT+ST): 0.57% (3/528)	Only minor complications were observed in both PDT and ST	Two general ICUs in a hospital, bedside tracheostomy, including 367 consecutive patients underwent PDT and historical cohort of 161 with ST
Bhattacharya 2007(Bhattacharya, Chakraborty, & Agarwal 2007)[*] Single centre, ICU, India. Nov 2004 – Oct 2005. N = 552 intubated patients	Unplanned extubation: 5.80 % (32/552 patients) • accidentally extubated: 1.09% (6/52); • patient self-extubated: (4.71% (26/552)	Prolonged hypoxia due to accidental extubation: 50% (3/6). Of the self-extubations: none led to any adverse event	Discrepancy in the study: it was stated that 32 incidents of unplanned extubation occurred in 29 patients. However, the author also stated that 'of them, 26 patients suffered self-extubation while the rest six patients were accidentally

			extubated." Of the 6 cases of accidental extubation: 3 had sequelae of prolonged hypoxia Of the self-extubations: none led to any adverse event
Bhatti 2007(Bhatti et al. 2007) Retrospective single centre, ICU, USA. Jul 2002- Jun 2005 Consecutive PDT (n=318) at an Otolaryngology-Head and Neck Surgery	Accidental decannulation or accidental extubation: 0.63% (2/318)	Death related to tracheotomy: 0	-
El Solh 2007(El Solh & Jaafar 2007) Single centre, ICU, USA. May 1999 – Sep 2005 Elective open tracheostomy in morbid obesity (BMI≥40kg/m2) (n = 89) and control (n = 338)	**Total** (morbid obesity + control): • extratracheal placement 0.7% (3/427) • tube obstruction 1.17% (5/427)	-	Tube obstruction: related to clot, mucus, tracheal wall leading respiratory arrest or to severe hypoxemia requiring reintubation Extratracheal placement: false passage or paratracheal placement of tracheostomy tube Early complications: during the first seven days after the procedure Late complications: after the seven day period until hospital discharge or death
Fischler 2000(Fischler, Erhart, Kleger, & Frutiger 2000)[*] National survey, ICU (48 of the 69 Swiss ICUs), Switzerland, in 1995 and 1996 N=90,412 patients.	Cannula displacement: 11% Paratracheal cannula malposition: 7%	-	-
Glossop 2011(Glossop, Meekings, Hutchinson, & Webber 2011) 4 ICUs in one UK NHS Trust over a period of 18 months (year not reported), n=200	Accidental decannulation: 4% Tube blockage: 6%	Of the blockages and displacements, 40% resulted in severe hypoxia and in two patients, cardiac arrest	Post-decannulation one patient (0.8%) required immediate recannulation
Hill 1995(Hill et al. 1996)[‡] Single centre, ICU (90% of PDTs in ICU), USA. 1995 356 patients underwent PDT	Premature extubation of the trans-laryngeal tube 1.7% (6/356) Paratracheal dilation: 1.7% (6/356)	-	-
Kearney 2000(Kearney et al. 2000)[*] Single centre; ICU, OT, and ED, USA. Sep 1990 – May 1998 829 consecutive PDTs in 824 patients (770 in ICU, 56 in OT, and 1 in ED)	Premature extubation: 1% (9/829 PDTs) Guidewire dislodgement: 0.5% (4/829 PDTs)	Death: 1 of the deaths occurred when the tracheostomy tube dislodged several hours after PDT and was most likely related to incorrect tracheostomy tube selection	829 PDTs were attempted and 827 were completed on 824 patients Five deaths directly related to PDT (0.6%)
McGrath 2010(McGrath &	Incidents of tracheostomy	More than temporary	It was not mentioned whether

Thomas 2010) UK NPSA data, hospital words. Oct 2005- Sep 2007 N=453 incidents where patients were directly affected	tube displacement: 32.5% (147/453) Incidents of tracheostomy tube blockage: 28.5% (129/453)	harm: • displaced tube 12.9% (19/147) • blocked tubes 36.4% (47/129/) patients	the patients included adults only all both adults and children Repeat incidents and any incidents involving critical care units were excluded
Oreadi 2012(Oreadi & Carlson 2012) Single centre, OT, USA. 2003 – 2010 192 consecutive ST (in 191 patients), including 187 elective tracheotomies and 5 emergent tracheotomies; all performed in the OT under GA	Dislodgement of tracheotomy tube: 0 Airway obstruction: 0.5% (1/192)	"No deaths were attributed to the tracheotomy procedure"	-
Thompson 2001(Thompson et al. 2001) Single centre, ICU, USA. Aug 1992 – Oct 1998 PDT in 300 consecutive critically ill patients (all intubated trauma patients were assessed at approximately day 7)	Dislodgement: 0.67% (2/300); Misplacement: 0	One death occurred which did not seem to directly relate to dislodgment of misplacement of tracheostomy	All PDTs were done in the ICU unless the patient was undergoing a simultaneous operation that required general anaesthesia
Walz 1998(Walz et al. 1998) ǂ Single centre, ICU, Germany. Jun 1992 – Jul 1994 337 PDTs in 326 patients (aged 11-95 years)	Misplacement of cannula: 0.613% (2/326); Premature decannulation: 1.84% (6/326)	Death: 2, both "procedure related", including 1 cardiac arrest and 1 cannula exchange; Hypoxia ($SaO_2 \leq 80$ %): 1 with bleeding and 1 cannula exchange	Unclear whether the harms were directly related to tracheostomy misplacement of cannula or premature decannulation

PDT: percutaneous dilator tracheostomy. ST: surgical tracheostomy. OT: operating theatre. NPSA: the National Patient Safety Agency. GA: general anaesthesia

* Identified from the internet. ǂ From the studies of which the results were presented and compared in the Thompson study (Thompson et al. 2001)