York Health Economics Consortium

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

Providing consultancy and research in health economics for the NHS, pharmaceutical and health care industries since 1986

# Ambu aScope2 for Use in Unexpected Difficult Airways

## Final Report

## Updated Costing Model

## Produced by NUTH and YHEC External Assessment Centre

JOYCE CRAIG, Associate Project Director (YHEC)
MICHELLE JENKS, Project Director (YHEC)
JOE MOSS, Statistician (YHEC)

10 May 2019

**Project Name:** **Ambu aScope2 for Use in Unexpected Difficult Airways**
**Project Number:** **MTG14**
**Start Date:** **30 April 2018**
**Output Date:** **17 May 2018 initially and revised to 18 March 2019**

Correspondence to: Joyce Craig
York Health Economics Consortium (YHEC)
Enterprise House
Innovation Way
University of York
YORK
YO10 5NQ
Tel: +44 (0)7758 057856

**Declared interests of the authors: None**

Sections highlighted [redacted] summarise evidence presented by the sponsor as 'Academic in Confidence'.

The views expressed in this report are those of the author and not those of NICE. Any errors are the responsibility of the author.

# Contents

# Executive Summary

This costing study updates the costs informing the economic model on the Ambu aScope2 device. Its aim is to provide evidence to inform the review of the device which the National Institute for Health and Care Excellence (NICE) has started.

This project has updated all the cost parameters used by Birmingham and Brunel External Assessment Centre (BB EAC) in its 'Additional work' on the device. This work informed the Medical Technologies Advisory Committee's recommendations for Ambu aScope2. The new and original values, for each clinical setting, are presented in Table 1.

**Table 1: Cost parameters and sources used in costing update compared with BB EAC values**

| Parameter | Point estimate and source in cost update (2017/18 prices) | | | | Value in BB model (2010/11 prices) | % change |
|---|---|---|---|---|---|---|
| | Setting with no scope | Operating theatre | ICU | Obstetrics | | |
| Cost of Ambu aScope4 | **£199.80** (Ambu Ltd) | | | | £179 | 12% |
| Cost of monitor | **£1,699.00** (Ambu Ltd) | | | | £799 | 113% |
| Cost of litigation due to harm from intubation failure | **£214,756** | | | | £134,000 | 60.3% |
| Mean length of stay due to intubation failure | **3.4 days** (HES 2016/7 Code T88.4) | | | | 2 days | 70% |
| Length of stay in intensive care & general ward | **50/50** (Assumption by NY EAC) | | | | 100% ICU | -50% |
| Mean cost per day | **£980** (NHS Reference costs 2016/17) | | | | £1,213 | -19.2% |
| Brain damage cost per year | **£72,711** (Turner-Stokes et al, 2016) | | | | £36,320 | 100% |
| Life expectancy of brain damaged patients | **13.0 years** (HES 2016/7, ONS 2017 Shavelle, et al., 2007)* | | | **27.7 years** (same sources) | 12.5 and 26.4 years | 4% to 5% |

* Estimates were not directly retrieved from the literature sources provided and are explained in text.

The main changes are:

- The device currently marketed is the Ambu® aScope™ 4 Broncho (henceforth referred to as the Ambu aScope4). The cost of the device and monitor have increased by 12% and 113% respectively
- A 5-year life for the monitor is used, consistent with that advised by the sponsor. This is shorter than the 10 years used by BB EAC. The shelf life of the Ambu aScope4, the fourth-generation scope will be 36 months from the 1st of June 2018, compared

with the current 18 months. The BB EAC assumed 3 years in its analysis so this is not a change for costing purposes

- To increase the cost of successful litigation from intubation failure to £214,756 (2017/18 prices), compared with £134,000 (2010/11 prices) adopted by BB EAC, an increase of 60%
- To increase the mean annual cost to manage people with brain damage due to incubation failure to £72,711 (2017/18 prices) compared with £36,320 (2010/11 prices) adopted by BB EAC, an increase of 100%

Other changes included updating the mean length of stay due to intubation failure and tracheostomy displacement, updating the per diem cost and updating the life expectancy of people with brain damage or tracheostomy displacement.

The model developed by B&B has been re-run for:

- Hospital units without current reusable fibrescope provision
- Intensive care units (ICU)

It could not be re-run for a general operating theatre setting, obstetrics units or for managing patients with displaced tracheostomy in an ICU setting.

In all settings the expected cost of harm, given an intubation failure, is now estimated at £12,327. This compares to £6,607, reported in the BB EAC costing report, equivalent to an 87% increase.

The clinical experts advising the BB EAC agreed that using an Ambu aScope2 would reduce the probability of a failed unexpected difficult intubation by 70%, from 16.6% to 5.0%.

Applying this factor to the new cost parameters gives an estimated annual cost saving from purchasing a 5 scope Ambu aScope2 package[1] for a hospital setting without current reusable fibrescope provision of £1,638, excluding the cost of the monitor and £1,433, after deducting the cost of the monitor. In comparison, the BB EAC costing report estimated savings of £749 before deducting the cost of the monitor and £653 after deducting the cost of the monitor. Thus, net savings have more than doubled with the updated cost estimates, primarily because the expected cost of an intubation failure has increased in absolute terms by materially more than the cost a monitor. The Ambu aScope2, including cost of the monitor, is now forecast to be cost saving at a threshold of around 85 intubations per year. This is lower than the threshold of 110 reported by B&B EAC.

Applying these new parameters gives an estimated annual cost saving from purchasing a 5 scope package in an ICU setting with 2 reusable fibrescopes of £6,632, excluding the cost of the monitor and £6,428, after deducting the cost of the monitor. In comparison, the BB EAC costing report estimated savings of £3,128 before deducting the cost of the monitor and £3,031 after deducting the cost of the monitor. Thus, net savings have also more than doubled with

[1] The scopes are purchased in packs of 5 and cannot be purchased individually.

the updated cost estimates in this setting. The reason is the same; the expected cost of an intubation failure has increased in absolute terms by materially more than the cost a monitor.

The BB EAC report concluded the Ambu aScope2 was also cost saving:

- In settings with 2 multiple-use scopes at a threshold of 1,250-1,350 intubations per year
- In an ICU with 2 multiple-use scopes, at a threshold of 50-300 intubations per year
- For repositioning displaced tracheostomies in ICU for units at a threshold of 70 tracheostomies per year

Moreover, it noted that these thresholds would reduce if settings tried to ensure that all Ambu aScope2s are used before their expiry date.

Due to the limitations with the re-running the B&B model, none of these thresholds can be updated. However, we can advise that with the new cost parameters the Ambu aScope4 will be cost saving in these settings at lower thresholds.

The B&B model also reported probabilistic sensitivity analysis (PSA) results but the code could not be re-run. Hence no updated PSA results can be presented.

The results from applying the updated cost parameters do not conflict with the Committee's original recommendations:

> '6.2 *The Committee concluded that, although some cost model parameters were uncertain, the availability of the Ambu aScope2 in isolated hospital units, obstetric units, operating theatre units and intensive care units is likely to be cost saving.*
>
> *6.3 The Committee considered that use of the Ambu aScope2 has particular advantages for replacing dislodged tracheostomy tubes in intensive care units, with potential for significant cost savings in this setting*.'

# Abbreviations

| | |
|---|---|
| BB | Birmingham and Brunel |
| EAC | External Assessment Centre |
| ICU | Intensive care unit |
| MTAC | Medical Technologies Advisory Committee |
| NICE | National Institute for Health and Care Excellence |
| NY | Newcastle and York |
| PSA | Probabilistic sensitivity analysis |
| UKROC | UK Rehabilitation Outcomes Collaborative |
| VAT | Value added tax |

# Acknowledgements

Rasmus Vinther Russell, Corporate Health Economist, Ambu provided original articles and responded to questions from the EAC.  No experts were contacted in this costing update.

# Section 1: Introduction

## 1.1 INTRODUCTION

This document describes the methodology and results from a costing study update of the costs informing the economic evidence on the Ambu aScope2 device. The update was undertaken by the Newcastle and York (NY) External Assessment Centre (EAC). Its aim is to provide evidence to inform the review of the device which the National Institute for Health and Care Excellence (NICE) has started.

## 1.2 BACKGROUND

In July 2013, NICE published guidance on the Ambu aScope2 device (NICE, 2013). The Committee made 4 conclusions, 2 of which related to costs:

> '6.2 *The Committee concluded that, although some cost model parameters were uncertain, the availability of the Ambu aScope2 in isolated hospital units, obstetric units, operating theatre units and intensive care units is likely to be cost saving.*
>
> *6.3 The Committee considered that use of the Ambu aScope2 has particular advantages for replacing dislodged tracheostomy tubes in intensive care units, with potential for significant cost savings in this setting*.'

These recommendations were informed by additional modelling conducted by Birmingham and Brunel (BB) EAC at the request of the Medical Technologies Advisory Committee (MTAC).

The original submission by the sponsor, critiqued by the BB EAC in its assessment report, and presented at the first MTAC meeting on this device considered the incremental cost-savings per fibreoptic intubation from replacing all multiple-use scopes in a unit with disposable scopes. MTAC considered this to be unrealistic because multiple-use 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 multiple-use scope is available. As Ambu aScope2's immediate availability may be of particular value in emergency airways management in clinical settings where multiple-use scopes are not currently available, MTAC also requested that BB EAC consider scenarios where multiple-use fibrescopes are not available.

BB EAC developed 2 health economic models to evaluate the cost savings of purchasing Ambu aScope2:

- In small hospital units with no access to any fibrescope for unexpected difficult airways management
- To supplement the existing stock of multiple-use scopes in operating theatres and intensive care units (ICU) for unexpected difficult intubations and displaced tracheostomies

In all cases, the potential cost savings from purchasing the Ambu aScope2 were from using the disposable scope to avoid costly harm, especially brain damage, in the event of an unexpected difficult airway and no available multiple-use scope. These cost savings were compared to the cost of buying the scopes and using these within their 3-year shelf life.

Staffing levels were assumed to be the same for each type of device and no benefit was attributed to any potential reduced risk of infection or death from the single use Ambu aScope2 device. These assumptions are retained in this updated costing work.

### 1.3 SUMMARY OF NEW WORK BY NY EAC

NICE project staff provided the NY EAC with a copy of the model developed by the BB EAC. NY EAC reviewed the model. Due to difficulties in running the model, it only produces reliable results for settings with no existing reusable scopes and for an ICU with 2 existing reusable scopes. This report contains results from the model with updated costs for these settings. It replaces a previous report dated 6 March 2019 which only had updated results for using the disposable scope in settings with no reusable scopes.

The sponsor, Ambu, responded to an information request by NICE to inform the review of the 2013 guidance. The response identified technical developments made to the device and monitor in the intervening period, advised that the current model on the market is the Ambu® aScope™ 4 Broncho and summarised new clinical and health economics evidence, published since its original submission in 2012. The new health economics evidence consisted of 11 published and 2 unpublished studies plus a new economic model. The model compared Ambu aScope4 with multiple-use devices assuming the former replace the latter. It is also for a wider indication than the existing guidance (unexpected difficult airways).

The NY EAC requested copies of all publications and reviewed each in case any contained information relevant to updating the BB EAC model. None was found. A summary of this evidence, setting it within the context of the original scope was undertaken. The EAC also reviewed the cost assumptions in the new sponsor's model but none are relevant to this costing update.

## 1.4 REPORT LAYOUT

This report contains the following sections:

- Section 2 describes the BB EAC model and settings.
- Section 3 provides the original BB EAC and updated cost parameters.
- Section 4 provides the results of the original BB EAC model and those using the updated cost parameters.
- Section 5 discusses the limitations and conclusions informed by this work.

A summary of the economic studies provided by the sponsor is provided at Appendix A.

# Section 2: BB EAC Model and Settings

## 2.1 DESCRIPTION OF BB EAC MODEL

The details in this section have been extracted from the report "Additional work by the EAC for MTAC" (BB EAC, 2013). The model was designed to answer 3 questions from MTAC. These were to establish the potential cost savings with Ambu aScope2 compared with multiple-use scopes to manage patients with unexpected difficult intubation:

- In a clinical setting with no multiple-use scopes.
- In a clinical setting with one or more multiple-use scopes, noting these may not be available when needed, e.g. because they are in use or being cleaned.
- In an ICU setting with one or more multiple-use scopes with uses including to manage patients with displaced tracheostomy.

The model calculated the expected net cost savings per use of the Ambu aScope2 for management of an unexpected difficult airway. This was a function of the reduction in the probability of intubation failure with the Ambu aScope2 and the cost of failure (expected benefit) compared with the costs of providing the Ambu aScope2.

It also calculated the probability that the Ambu aScope2 scope was used before it expired. This depended on the incidence of unexpected difficult intubation, the availability of multiple-use scopes and the shelf life of Ambu aScope2 devices. This informed the expected cost savings from purchasing the Ambu aScope2 scope over its lifetime.

The model does not include the cost impact of incidence of contamination or cross-infection with multi-use scopes compared with Ambu aScope2 because during the initial development of the model no evidence on this was identified. Further, no evidence from clinical studies was identified on this during the update of the guidance.

## 2.2 SETTINGS AND SCENARIOS

Results were reported for 5 settings being:

- A hospital unit with no multiple-use fibrescopes;
- Settings with multiple-use fibrescopes available such as:
  - Operating theatres;
  - ICU;
  - Obstetrics wards;
- Use of Ambu aScope2 in ICU for displaced tracheostomy.

The figures provided by BB EAC are re-produced at Figure 2.1 and Figure 2.2. Figure 2.1 shows the decision tree associated with settings with no multiple-use scopes, whilst Figure 2.2 describes settings with multiple-use scopes available and hence included the need to calculate the probability of a multiple-use scope not being available when a patient with an unexpected difficult airway presents.

**Figure 2.1: Decision tree for isolated unit**

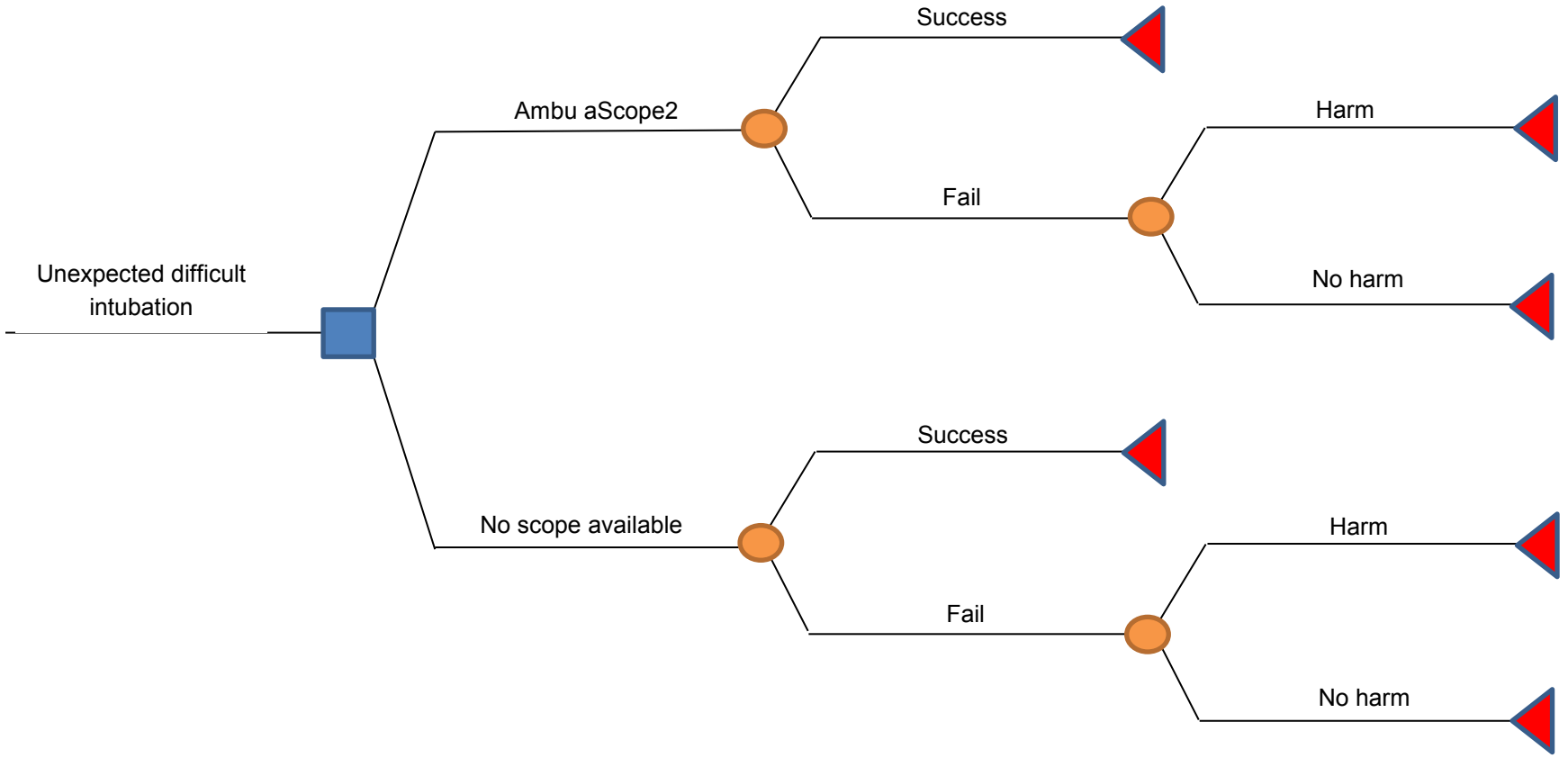
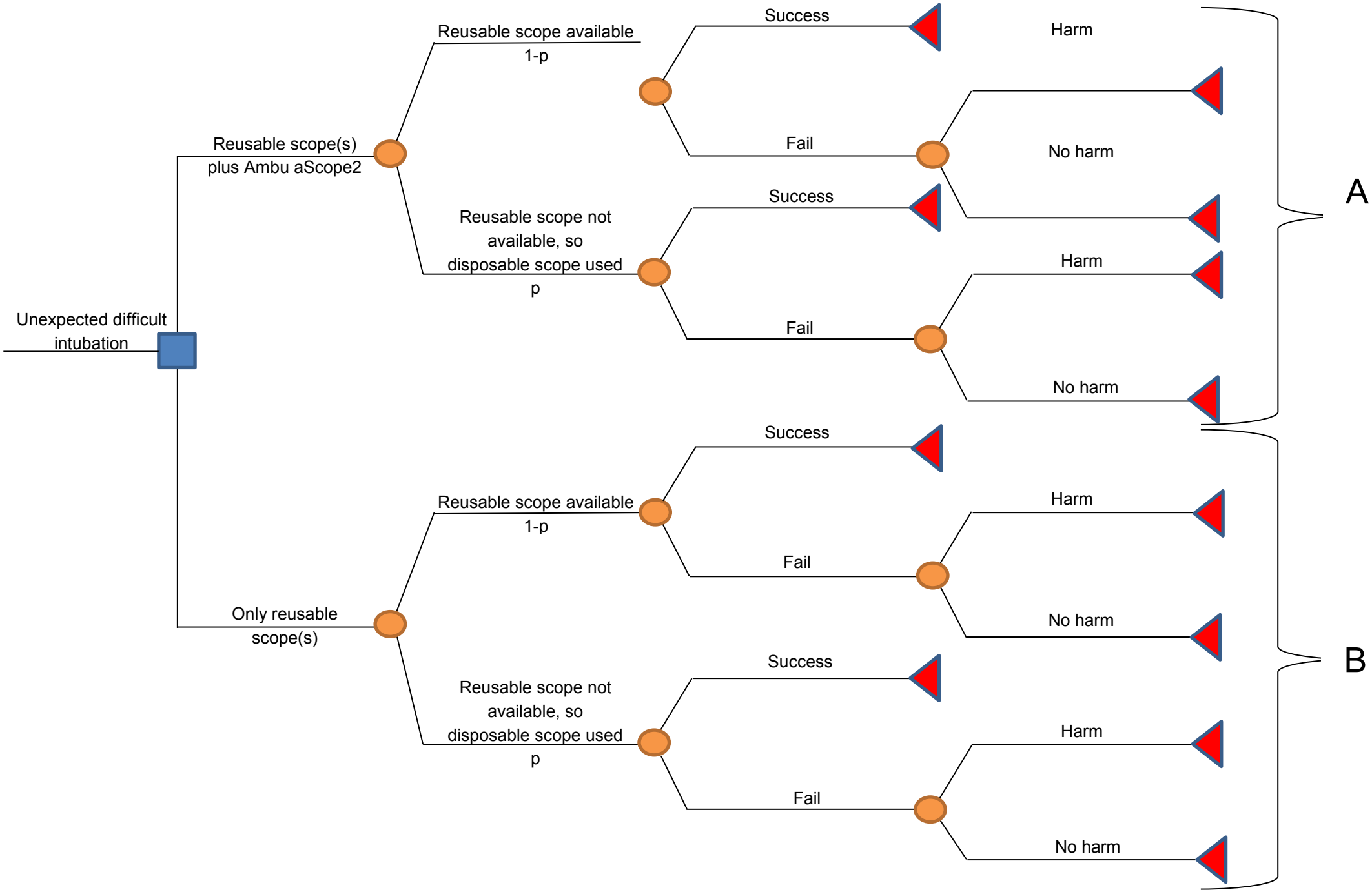


**Figure 2.2: Decision tree for unit containing one or more reusable scopes**



# Section 3: Costs Parameters

## 3.1 COST ASSUMPTIONS USED IN BB EAC MODEL AND COSTING UPDATE

Table 3.1 summarises the cost parameters used in this costing update and compares these to those adopted by the BB EAC in its original model for all parameters other than those applying tracheostomy displacement. These are reported in Table 3.2. The rationale underpinning the values used for each parameter is provided in the subsequent text.

**Table 3.1: Cost parameters and sources used in costing update compared with BB EAC values**

| Parameter | Point estimate and source in cost update (2017/18 prices) | | | | Value in BB model (2010/11 prices) | % change |
|---|---|---|---|---|---|---|
| | Setting with no scope | Operating theatre | ICU | Obstetrics | | |
| Cost of Ambu aScope4 | **£199.80** (Ambu Ltd) | | | | £179 | 12% |
| Cost of monitor | **£1,699.00** (Ambu Ltd) | | | | £799 | 113% |
| Cost of litigation due to harm from intubation failure | **£214,756** | | | | £134,000 | 60.3% |
| Mean length of stay due to intubation failure | **3.4 days** (HES 2016/7 Code T88.4) | | | | 2 days | 70% |
| Length of stay in ICU & general ward | **50/50** (Assumption by NY EAC) | | | | 100% ICU | -50% |
| Mean cost per day | **£980** (NHS Reference costs 2016/17) | | | | £1,213 | -19.2% |
| Brain damage cost per year | **£72,711** (Turner-Stokes et al, 2016) | | | | £36,320 | 100% |
| Life expectancy of brain damaged patients | **13.0 years** (HES 2016/7, ONS 2017 Shavelle, et al., 2007)* | | | **27.7 years** (same sources) | 12.5 and 26.4 years | 4% to 5% |

* Estimates were not directly retrieved from the literature sources provided and are explained in text.

### 3.1.1 Cost of Ambu aScope4 and Monitor and Life of Each

In its response to NICE, the sponsor advised that the list price of an Ambu aScope 3 or 4 is £999.00 (excluding VAT) for a box of 5 (£199.80 each). This is the minimum order quantity. In separate emails dated 3rd and 11th May 2018, the sponsor advised the list price of a monitor is £1,699 (excluding VAT). If a client orders 20 Ambu aScope4s, a monitor is provided free as a special start-up service. This special practice is only conducted at the initial orders after converting to Ambu® aScope™. This pricing practice is not considered in the analysis as it may not endure and only applies to a limited market sector.

These prices represent a 12% increase on the prices used by the BB EAC for the Ambu aScopes and a 113% increase for monitors.

The sponsor advised that, following stability tests approved by the Food and Drug Administration and for CE marking purposes, it expects to implement a 36 months shelf life by the 1st of June 2018. Currently, if an NHS hospital buys 5 scopes the "date of use" will be approximately 18 months hence. Sites will be informed about the extended shelf life when it is fully implemented. BB EAC assumed 3 years in its analysis so this is not a change for costing purposes.

The sponsor advised (email 4 May 2018) that it adopts a 5-year life to amortise monitors over. This is shorter than the 10 years used by BB EAC. The base case will use 5 years. Using 10 years would increase cost savings/reduce incremental costs by about £170 per year. The shorter life is adopted because the monitors have been subject to major technological development to enhance their image quality (see sponsor's submission for details) and such innovation is assumed to continue.

### 3.1.2 Cost of Litigation Due to Harm from Intubation Failure

This costing review has adopted a cost of litigation from intubation failure of £214,756 (2017/18 prices), compared with £134,000 (2010/11 prices) adopted by BB EAC, an increase of 60%.

The £134,000 came for a study of non-dental airway litigation claims paid and their average cost to settle. It was undertaken to inform the Major Complications of Airways Management Report conduct by the Royal College of Anaesthetists. The study examined all airways claims over 12 years from 1995 to 2006. The mean claim reported was updated by BB EAC to 2010/11 prices.

For the costing update a structured literature search was undertaken to identify any more recent evidence on the cost of such litigation. None was identified. Thus, the EAC updated the 2010/11 value of settlements for relevant changes in the values of claims paid since 2010/11. The change in the unit cost of payments made by NHS Resolution, the operating name of NHS Litigation Authority, under the Clinical Negligence Scheme for Trusts, was identified from the Annual Accounts of the Authority. The information required was first published in the 2012/13 accounts. In the 4 years to 2016/17, the average claim increased from £127,100 to £172,210, an average of 7.9% per year. This rate was assumed to apply over the 6 years from 2010/11 to 2016/17. An increase of 1.6% was applied from 2016/17 to 2017/18. This is the average inflation rate for the NHS over the most recent 2 years reported by Curtis and Burns (2017). If the higher rate of 7.9% is applied for this last year, the value of claims would be 6% higher at £228,168.

### 3.1.3 Mean Length of Stay Due to Intubation Failure and Cost

This costing review has adopted a mean length of stay due to intubation failure of 3.4 days, compared with 2 days adopted by BB EAC, an increase of 70%. The value was taken from Hospital Episode Statistics, HES 2016/7, code T88.4 for 'Failed or difficult intubation'.

In this costing update 50% of the stay is assumed to be in ICU and 50% on a general ward. In the initial costing report all days were assumed to be in ICU. The change was made because it is judged unlikely that patients would be discharged from ICU directly home.

The cost per stay in ICU was £1,328 and was extracted from NHS Reference Costs 2016/17. The cost of a general ward bed was estimated at £601 and was extracted from the same source. This is the average cost per length of stay for elective and non-elective admissions and includes excess bed-days. Both costs were increased by 1.6% (Curtis and Burns [2017]) to 2017/18 prices.

The average cost per incubation failure adopted in this costing update was £3,347 (2017/18 prices) compared with £2,426 (2010/11 prices) used in the initial costing work undertaken by BB EAC.

### 3.1.4 Brain Damage Cost per Year

This costing review has adopted a mean annual cost of £72,711 (2017/18 prices) to manage people with brain damage due to incubation failure, compared with £36,320 (2010/11 prices) adopted by BB EAC, an increase of 100%.

The BB EAC value was taken from a study by Beecham et al. who described the cost to manage young adults with acquired brain injury in the United Kingdom. The patient group with failed or difficult intubation as reported by, HES 2016/7, code T88.4 are much older (mean age 58 years) and hence these costs may not generalise to the population of interest. The EAC undertook a structured literature search to identify relevant sources. The search found a literature review of the costs of traumatic brain injury which concluded there was very little research on the economic costs associated with brain injury (Humphreys et al., 2013). The search terms were widened to include rehabilitation related studies. This wider search identified one relevant study by Turner-Stokes et al. (2016).

This study was an analysis of prospectively collected clinical data from the UK Rehabilitation Outcomes Collaborative (UKROC) national clinical database, 2010 to 2015. All 62 specialist rehabilitation services in England contributed to the database (n= 5,739), mean age of participants was 47 years, with 73% having acquired brain injury. This reported the annual costs to manage people with low (n= 699), medium (n= 1,607) and high (n= 3,433) dependencies. These were: £15,956, £26,958 and £70,341 respectively. Given the definition of brain damage used by the BB EAC being '*permanent low conscious level, neuro-behavioural deficit, or persistent vegetative state*' the annual costs for high dependency patients was used in the costing update. This value of £70,341 was updated from 2015/16 prices to 2017/18 using the indices from Curtis and Brown (2017).

### 3.1.5 Life Expectancy of Brain Damaged Patients

The life expectancy of brain damaged patients is required in the model to calculate the expected life time costs of a person with brain damage. This updated report has assumed 13.0 years for all patients other than pregnant women, for whom 27.7 years of remaining life was used. In comparison the BB EAC adopted 12.5 years and 26.4 years respectively.

The updated report has adopted the same methodology as the BB EAC applied in its initial costing work. This assumed that patients who acquire a brain injury will remain in such a state for approximately 50% of the life expectancy of other people alive at the same age. This is informed by a study by Shavelle, et al., (2007). HES data reported that the mean age of patients experiencing a failed or difficult intubation as 58 years (code T88.4) and 29 years for pregnant women (code O29.6) (HES 2016/7). The Office of National Statistics (ONS 2017) reported that the mean life expectancy for men and women, weighted by their proportions as reported in HES, alive at these time points as 25.9 years and 55.4 years. Applying a 50% early mortality as a consequence of the intubation event gave forecast life expectancies of 13.0 years and 27.7 years respectively.

## 3.2 COST OF DISPLACED TRACHEOSTOMY DISPLACEMENT

Table 3.2 presents the costs for tracheostomy displacement for the updated and initial cost review.

**Table 3.2: Cost parameters for tracheostomy displacement**

| | Cost update | Value in BB EAC model | % change |
|---|---|---|---|
| Mean length of stay for tracheostomy displacement | **6.1 days** (HES 2016/17) [code J95.0] | **6.7 days** | **-9.0%** |
| Life expectancy | **16.7 years** **Mean age 49.95 years** (HES 2016/17; ONS 2017; Shavelle et al., 2007)* | **15.6 years** | **7.1%** |

* Estimates were not directly retrieved from the literature sources provided and are explained in text.

The mean length of stay for tracheostomy malfunction (HES code J95.0) in 2016/17 was 6.1 days, 9% lower than the 6.7 days reported in 2010/11. The mean age for patients with such a displacement was 50 years. Applying the same logic as described in Section 3.1.5, gave a remaining life expectancy of 16.7 years, 7% higher than that calculated by the BB EAC in 2010/11 of 15.6 years.

## 3.3 OTHER PARAMETERS

Table 3.3 presents the key other parameters used in the model. These are taken directly from the Additional work by the BB External Assessment Centre. These have not been reviewed as part of the update work.

**Table 3.3: Key other parameters used in the BB EAC model**

| Parameter | Unit with no scope | Operating theatre | ICU | Obstetric |
|---|---|---|---|---|
| Probability of expected difficult intubation (i.e. use of reusable scope planned) | N/A | 2.2% | N/A | Uncertain |
| Probability of unexpected difficult intubation | 0.6% | 0.6% | 20% | 0.6% |
| Probability of failure given unexpected difficult intubation (no scope) | 16.6% | | | |
| Percentage reduction in failure rate with scope | 70% | | | |
| Probability of death given intubation failure | 2% | 2% | 14% | 2% |
| Probability of brain damage given intubation failure | 1% | 1% | 4% | 1% |
| Probability of other 'more than temporary harm' given intubation failure | 25% | 25% | 10% | 25% |
| Probability that harm results in successful litigation case against NHS | 4.5% | | | |
| Reusable scope downtime (days) | N/A | 1 | 1.5 | 1.5 |
| Probability reusable scope needs routine repair | N/A | 0.2 | | |
| Down-time with routine repair (days) | N/A | 4 | 5.5 | 5.5 |
| Probability reusable 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 |

N/A = Not applicable.

# Section 4: Results

This section describes the base-case results using the updated cost parameters and compares these to the results reported by the BB EAC from its original model.

## 4.1 SETTING WITH NO BRONCHOSCOPES AVAILABLE

The BB EAC assumed that, in a clinical setting with no bronchoscopes conducting 300 intubations per year, an unexpected difficult airway arises on average twice a year, leading to an intubation failure once every 3 to 4 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 now estimated at £12,327. This compares to £6,607, reported in the BB EAC costing report, equivalent to an 87% increase.

The clinical experts advising the BB EAC agreed that using an Ambu aScope2 would reduce the probability of a failed unexpected difficult intubation by 70%, from 16% to 5%. Applying this factor to the new cost parameters gives an estimated annual cost saving from purchasing a 5 scope Ambu aScope2 package for a hospital setting without current reusable fibrescope provision of £1,638, excluding the cost of the monitor and £1,433, after deducting the cost of the monitor. In comparison, the BB EAC costing report estimated savings of £749 before deducting the cost of the monitor and £653 after deducting the cost of the monitor. Thus, net savings have more than doubled with the updated cost estimates, primarily because the expected cost of an intubation failure has increased in absolute terms by materially more than the cost a monitor.

The BB EAC estimated that if such settings conduct 95-115 intubations per year, then purchasing a bundle of Ambu aScope2s may be cost saving. With the new costs applied, the break-even number of intubations is now 65 to 85.

No PSA results are reported because the B&B code could not be re-run.

## 4.2 INTENSIVE CARE UNIT

In the BB EAC base-case of 700 intubations per annum and 2 multiple-use scopes, annualised cost savings from purchasing a bundle of 5 scopes ranged from £3,128 to £3,219 (without monitor) and £3,031 to £3,123 (with monitor).

Applying the new cost parameters gives an estimated annual cost saving from purchasing a 5 scope package in an ICU setting with 2 reusable fibrescopes of £6,632, excluding the cost of the monitor and £6,428, after deducting the cost of the monitor. Thus, net savings have also more than doubled with the updated cost estimates in this setting. The reason is the same; the expected cost of an intubation failure has increased in absolute terms by materially more than the cost a monitor.

## 4.3 OPERATING THEATRE, OBSTETRICS AND DISPLACED TRACHEOSTOMY IN AN ICU SETTING

The BB EAC report concluded the Ambu aScope2 was also cost saving:

- In settings such as an operating theatre with 2 multiple-use scopes at a threshold of 1,250-1,350 intubations per year
- In an ICU with 2 multiple-use scopes, at a threshold of 50-300 intubations per year
- In Obstetrics units with 400 intubations and nil scopes but with a reusable scope present, purchasing a bundle of disposable scopes was cost-incurring
- For repositioning displaced tracheostomies in ICU for units at a threshold of 70 tracheostomies per year

Moreover, it noted that these thresholds would reduce if settings tried to ensure that all Ambu aScope2s are used before their expiry date.

Due to the limitations with the re-running the B&B model, none of these thresholds can be updated. However, we can advise that with the new cost parameters the Ambu aScope4 will be cost saving in these settings at lower thresholds.

# Section 5: Discussion and Conclusions

The BB EAC noted several limitations with its model and uncertainty on the values used to populate it but none related specifically to the cost inputs. These limitations have been magnified in the costing update because the BB EAC model provided by NICE was not fully executable. It could only be run for settings with no existing multiple-use scopes and in ICU.

The updated cost parameters have increased the savings from avoiding failed intubation in patients with difficult airways. The additional savings arise because of the increased costs of harms, specifically in the costs of:

- Managing patients with brain damage;
- Settling claims in relation to harm caused by intubation failure.

The cost of managing patients in the community with acquired brain injury was taken from a prospectively collected national clinical database, UKROC, from 2010 to 2015 and is judged to have internal and external validity.

In contrast, the assumption that the costs of settling claims for failed intubations have risen in line with the increase in unit costs for all claims in the period from 2010 to 11 cannot be tested without a detailed review of the relevant claims paid over several years. This is the main new uncertainty introduced by the costing update.

The BB EAC concluded the Ambu aScope2 was cost saving:

- In settings with no multiple-use scope provision at a threshold of around 100 intubations per year.
- In settings such as operating theatres with 2 multiple-use scopes at a threshold of 1,250 to 1,350 intubations per year.
- In an ICU with 2 multiple-use scopes, at a threshold of 50-300 intubations per year.
- For repositioning displaced tracheostomies in ICU for units at a threshold of 70 tracheostomies per year.

Moreover, it noted that these thresholds would reduce if settings substituted soon to expire Ambu aScope2 scopes for others, to try to ensure that all are used before expiry.

Due to the limitations with the model these thresholds cannot be updated. However, we can advise that with the updated cost parameters, purchasing a pack of 5 Ambu aScope2s will be cost saving in these settings at lower thresholds.

The limited analyses we can re-run produced results which doubled the estimated cost savings from purchasing a pack of 5 Ambu aScope2s in those settings with no reusable scopes and for use in ICU.

The results from applying the updated cost parameters do not conflict with the Committee's original recommendations:

> '6.2 *The Committee concluded that, although some* ***cost model parameters were uncertain,*** *the availability of the Ambu aScope2 in isolated hospital units, obstetric units, operating theatre units and intensive care units* ***is likely to be cost saving[2]****.*
>
> *6.3 The Committee considered that use of the Ambu aScope2 has particular advantages for replacing dislodged tracheostomy tubes in intensive care units,* ***with potential for significant cost savings in this setting***.[1]'

[2] Italics inserted by EAC

# References


- 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. Minerva Anestesiologica, vol. 74, no. 10, pp. 529-535.

- Birmingham and Brunel. Ambu aScope2 in unexpected difficult airways management: Additional work by External Assessment Centre for the Medical Technologies Advisory Committee. 2013. Available at https://www.nice.org.uk/guidance/mtg14/history.

- Curtis L and Burns A. Unit Costs of Health and Social Care 2017. Available at https://www.pssru.ac.uk/pub/uc/uc2017/sources-of-information.pdf.

- Humphreys I, Wood RL, Phillips CJ, Macey S.The costs of traumatic brain injury: a literature review.ClinicoEconomics and Outcomes Research, vol 5 autumn 2013. Available at https://www.dovepress.com/clinicoeconomics-and-outcomes-research-archive29-v612.

- NAP4. 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. Available at https://www.rcoa.ac.uk/document-store/nap4-executive-summary.

- NICE. Ambu aScope2 for use in unexpected difficult airways. Medical technologies guidance [MTG14] Published date: July 2013. Available at https://www.nice.org.uk/guidance/mtg14.

- NHS Digital, Hospital Episode Statistics for England. Admitted Patient Care statistics, 2016-17. Available at https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2016-17.

- NHS Improvement. National Schedule of Reference Costs, 2016-17 Available at https://improvement.nhs.uk/resources/reference-costs/.

- Office of National Statistics. Past and projected expectations of life (ex) from the 2016-based life tables. 2017 Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/bulletins/pastandprojecteddatafromtheperiodandcohortlifetables/2016baseduk1981to2066.

- 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.

- Turner-Stokes L, Williams H, Bill A, Bassett P, Sephton K. Cost-efficiency of specialist inpatient rehabilitation for working-aged adults with complex neurological disabilities: a multicentre cohort analysis of a national clinical data set. BMJ Open. 2016 Feb 24;6(2):e010238. doi: 10.1136/bmjopen-2015-010238. Available at https://www.ncbi.nlm.nih.gov/pubmed/26911586.

# Appendix A: Summary of Economic Studies Submitted by Sponsor

**Summary of economic studies provided by sponsor**

In its response to the NICE Information request, the sponsor identified 13 new health economic studies, 11 of which are published and 2 are unpublished. The EAC requested copies of all papers and received all except one (Sorli et al., 2015); and one reference was incorrect (Mankikian et al., 2014). The EAC has reviewed each paper received to identify any relevant information to update the B&B costing model. No such data were identified. For completeness, the EAC has summarised the studies where these pertain to indications relevant to the scope.

**Percutaneous dilatational tracheostomy**

Only one study specifically addressed patients undergoing a percutaneous dilatational tracheostomy (PDT). Sohrt et al., (submitted for publication) undertook a cost minimisation study comparing single-use with multiple-use bronchoscopes in these patients. A questionnaire regarding repair rates and costs for multiple-use bronchoscopes was sent to 366 hospitals in the US, UK and Germany to identify costs which supplemented those identified by a systematic literature search. Eleven studies met the inclusion criteria, and ninety-nine sites responded to the questionnaire.

Combining data from the literature and the questionnaires gave an average cost of $US406 for reusable bronchoscopes and $US249 for single-use bronchoscopes per PDT procedure, giving an incremental cost per use of a multiple-use bronchoscope compared to a single-use bronchoscope of $US157.

Two authors are employed by Ambu and a third declared receiving research support from Ambu.

**Patients with difficult airways**

No studies reported results for patients with unexpectedly difficult airways. One reported on patients with difficult airways (Aïssoua et al., 2013). The authors undertook a retrospective cost-comparison study, of multiple-use able- to single-use bronchoscopes in a general surgical department of a French university hospital from 2006 to 2012, with a total number of 270 bronchoscopy procedures. The costs were very similar being €206 per multiple-use scope and €200 for a single-use fibrescope.

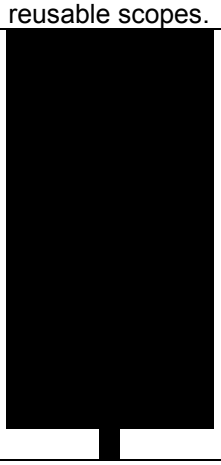
**Other studies**

The majority of the remaining studies were cost comparisons based on patient throughputs, primarily in intensive care settings, at the investigating hospitals. One of these was set in an English teaching hospital (Queens Medical Centre, Nottingham). This study, by McCahon et al. (2015), compared reusable devices from Olympus, Acutronic and Karl Storz and single-use (Ambu_ aScopeTM) fibrescopes, between 1 January 2009 and 31 March 2014. The total annual cost of fibreoptic intubation with multiple-use fibrescopes was £329 per use, compared with £200 to use a single-use fibrescope. Breakeven analysis identified it was cheaper to use single-use fibrescopes in locations undertaking fewer than 200 fibreoptic intubations per year.

The other studies that provide comparative cost information are tabulated in Table A1. Taken together they show that in high volume centres multiple-use scopes are likely to be cheaper than single use scopes. However, in settings where the number of bronchoscopies conducted annually are low, and there is no clarity as to that threshold, single use scopes may be cheaper. Moreover, in these settings the logistics of using a single use are easier and safety may be improved as the procedure can be conducted in a timelier manner. The individual studies are not discussed further as these have not been quality assured and are for wider indications than that defined for this cost update.

**Table A1: Summary of other comparative health economics studies**

| Authors and publication | Study type | Setting and comparators | Results | Conflict of interest and comments |
|---|---|---|---|---|
| Wojcik et al., 2015. Poster. | Retrospective micro costing study of 427 bronchoscopies performed in 2014. | French general hospital and all bronchoscopies. Single use versus reusable bronchoscopes. | Single use 251€: reusable 275 € | Nil conflicts. Authors note single use has a lower image definition than the reusable which could be a drawback for accurate diagnosis. |
| Perbet et al., 2017. Published article. | Prospective cost-comparison study of 518 airway management bronchoscopy undertaken between 2009 to 2014. | 16 bed ICU in French university hospital. Single use (aScope 2 & 3) versus reusable (Olympus and Pentax) bronchoscopes. Used for bronchoalveolar lavage (BAL), intubation, airway suctioning, and PT. | The costs per PT for reusable scopes 1 and 2 and single-use scopes were 1614€, 410€ and 204€ respectively. The costs per BAL for reusable scopes were 186€ and 189€ (no single use used for BAL). Breakeven was at 55 procedures per year, with costs of single and | Nil conflicts. Cost of reusable scopes depends on frequency of use and can vary widely. |

| Authors and publication | Study type | Setting and comparators | Results | Conflict of interest and comments |
|---|---|---|---|---|
| | | | reusable scopes equivalent | |
| Marshall et al., 2017. Published article. | Retrospective review of medical records of 93 patients undergoing flexible bronchoscopy in ICU in the year 2015. | Tertiary hospital in Singapore. Single-use bronchoscope aScope 3 versus reusable ((Olympus). Indications PT, BAL, and bronchial washing (BW). | Cost per procedure using single use Singapore dollars (SGD) 450. Cost per reusable scope: SGD 472. Single use had shorter start-up to end times and required fewer staff as no need to wheel in equipment. | Nil conflicts. ICUs without dedicated reusable equipment should adopt single use as logistically saves time and avoids delays. |
| Videau et al., 2017. Published article but only abstract in English. | Retrospective cost-comparison study, comparing cost of reusable- to single-use bronchoscopes over five years. | French hospital. Number of bronchoscopes not stated. Single-use bronchoscope aScope 3 versus reusable bronchoscopes but supplier not specified. | Total cost of reusable fibrescopes was 62,511€ compared with 79,200€ for single use. In settings with low usage, (15 incubations per year) single use was cheaper at 13,075€ versus 19,800€ for reusable scopes. | Nil conflicts. Single use better option at nights and weekends. |
| Mouritsen et al. (unpublished and academic-in-confidence) |  |  |  |  |

The other studies referenced by the company have not been included as one reported the cost of reprocessing endoscopes (Ofstead et al. 2017) and two were only available in French (Bertrand et al., 2014; Debraine et al., 2016).

**References for this appendix**


- Aïssou, M., Coroir, M., Debes, C., Camus, T., Hadri, N., Gutton, C., & Beaussier, M. (2013). Analyse de coût comparant les fibroscopes à usage unique (Ambu®aScopeTM) et les fibroscopes réutilisables pour l'intubation difficile. Annales Francaises d'Anesthesie et de Reanimation, 32(5), 291–295. https://doi.org/10.1016/j.annfar.2013.01.014.
- Bertrand, A., Lefrançois, A., & Saurel, N. (2014). Etude de cout en faveur du fibroscope á usage unique. Europharmat, 8–11.
- Debraine, C., Foy, G., Touratier, S., Faure, P., & Levert, H. (2016). Fibroscope réutilisable versus usage unique : analyse de coûts en réanimation. Congres National de local authorities Societe Francasie d"hygiene Hospitalier, 2016.
- Mankikian, J., Ehrmann, S., Guilleminault, L., Le Fol, T., Barc, C., Ferrandière, M., Guillon, A. (2014). An evaluation of a new single-use flexible bronchoscope with a large suction channel: Reliability of bronchoalveolar lavage in ventilated piglets and initial clinical experience. Anaesthesia, 69(7), 701–706. https://doi.org/10.1111/anae.12641.
- Marshall, D. C., Dagaonkar, R. S., Yeow, C., Peters, A. T., Tan, S. K., Tai, D. Y. H., Verma, A. (2017). Experience with the Use of Single-Use Disposable Bronchoscope in the ICU in a Tertiary Referral Center of Singapore. Journal of Bronchology and Interventional Pulmonology, 24(2), 136–143. https://doi.org/10.1097/LBR.0000000000000335.
- McCahon, R. A., & Whynes, D. K. (2015). Cost comparison of re-usable and single-use fibrescopes in a large English teaching hospital. Anaesthesia, 70(6), 699–706. https://doi.org/10.1111/anae.13011.
- Mouritsen JM, EhlersL. Cost-effectiveness of Ambu® aScope™ 4 Broncho compared to reusable bronchoscopes (Submitted as academic-in-confidence).
- Ofstead, C. L., Quick, M. R., Eiland, J. E., & Adams, S. J. (2017). A Glimpse At The True Cost Of Reprocessing Endoscopes: Results Of A Pilot Project. www.bostonscientific.com.
- Perbet, S., Blanquet, M., Mourgues, C., Delmas, J., Bertran, S., Longère, B, Constantin, J. M. (2017). Cost analysis of single-use (Ambu®aScopeTM) and 33 of 43 reusable bronchoscopes in the ICU. Annals of Intensive Care, 7(1). https://doi.org/10.1186/s13613-016-0228-3.
- Sohrt A, Ehlers L, Udsen FW, Mærkedahl, A, McGrath BA. Cost comparison of single-use vs. reusable bronchoscopes used for percutaneous dilatational tracheostomy. Submitted to PharmacoEconomics – Open for publication.
- Sorli, S. C., C, D. F. F., Thiveaud, D., Pecani, D., Pôle, C. H. U. T., & Logipharma, P. (2015). Etude de coût des fibroscopes réutilisables vs jetables en réanimation. Europharmat, 2015.
- Videau, M., Rghioui, K., Mottet, B., Sainfort, A., & Lefort, I. (2017). Analyse comparative de coût entre les fibroscopes bronchiques à usage unique et réutilisables : le fibroscope à usage unique, est-ce que ça vaut le coût ? Annales Pharmaceutiques Françaises, 75(6), 473–479. https://doi.org/10.1016/j.pharma.2017.07.004.
- Wojcik, A., Tywoniuk, M., Vella, I., & Luyckx, M. (2014). Medico-economic benefit from replacing reusable bronchoscopes with single-use versions: A microcosting evaluation, 314. 16th World Sterilization Conference. October 2015.