SURGICAL AIRWAY SECUREMENT

A REPORT ANALYSING RESPONSES TO A SURVEY, FOCUS GROUPS AND FREEDOM OF INFORMATION REQUESTS

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Pentland Medical
Innovators Not Imitators

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FOREWORD

In October 2023, Pentland Medical and Dawn Stott Associates, formed a working relationship to raise awareness of the hazards and patient safety risks associated with securing a patient airway device in the theatre environments, ICU and emergency care settings.

It is important to state that this project is funded by and has received input from Pentland Medical, who have a commercial interest in this area through their work launching the LEAFix airway securing device in the UK and global markets. A Commercial Impact Assessment has been developed in support of the project, which includes a cost analysis. It should be noted that LEAFix does not standardise the securement of the airway device; it does, however, provide a solution to standardise the equipment used for the task but not the methodology.

Following an inaugural round table discussion meeting it was agreed that a 'cross sector' Short Life Working Group (SLWG) would be formed to facilitate a consultation on the way an airway device is currently secured when a patient is undergoing a surgical intervention. The group's goals were acknowledged as identifying systemic barriers to the standardisation of airway management and to develop guidance to support a more robust and consistent way of securing the airway device.

Initially the group's mission has been to review current policy, guidance and legislation; to help interpret and apply them to daily anaesthetic practice; to support healthcare facilities and personnel with materials and resources on airway management; to help ensure compliance with policy to establish an environment where standardisation of approach is accepted and guidance is available to support healthcare professionals ensure the patient for whom they are advocating, is safe.

This report contains key findings from a survey of healthcare professionals who work within the perioperative setting, ITU and emergency care environments, along with focus group findings and freedom of information responses.

When research first started on the area of airway securement it was astonishing to find that no guidance existed from any recognised bodies in the UK and only a brief mention of the subject could be found. The airway is one of the most vital pieces of equipment in any general anaesthetic, and the Difficult Airway Society (DAS) are generally regarded as the leading authority on anything airway related, not just in the UK but are also internationally recognised. However, the DAS guidance states nothing beyond the fact that healthcare professionals should secure the airway device, with no advice on best techniques or materials that should be used. It also became evident that there were a multitude of practices that had never been risk assessed.

It is acknowledged, however, that until now there has not been any solution designed and risk assessed, to secure an airway device in the theatre environment, leaving a vacuum where healthcare professionals worldwide are forced to improvise by developing their own techniques and by using off-label generic materials such as tape and ties. There are also a huge number of varying circumstances encountered involving the use of different airway products and surgical positions which further complicates matters when it comes to a standardised approach to airway device securement.

The goal of this project has been to shine a light on existing practices and highlight the harm that is being caused to patients through lack of guidance and to show that better solutions and guidance are needed. It is our opinion that this report provides compelling evidence that urgent review is required of existing practices and for guidelines to be established, supporting the requirement for dedicated medical devices to perform airway device securement.

Statement of limitations regarding the Study

Despite its contributions, this study is not without limitations. First, the sample size and demographic diversity may not fully represent the broader population within the given environment, limiting the generalisability of the findings. Secondly, the study design, whether cross-sectional, longitudinal, or experimental, may introduce biases or limit casual inferences. Data collection methods, such as self-reported surveys or interviews, could lead to potential inaccuracies due to recall bias or social desirability bias. Furthermore, external factors not accounted for in the analysis, such as environmental or cultural differences, could have influenced the outcomes.

Future research would address these limitations by incorporating larger and more diverse samples, refining methodology, and exploring additional variables. However, the outputs do highlight the issue that we are championing for change.

Whilst this report is sponsored by Pentland Medical it is designed to highlight the issues required to drive safety improvement for better and safer patient outcomes.

SUMMARY OF FINDINGS

Facial harm, infections and more serious incidents are entirely preventable, yet the absence of national guidelines has resulted in an inconsistent approach to securing an airway device within UK hospitals.

A survey of healthcare practitioners was developed to explore whether there is a standardised approach to securing an airway device in their hospital. The intention was to use the findings to support ongoing work around safer patient care and better clinical outcomes.

The responses collected have been dealt with in line with the Data Protection Act 2018. All personal information has been kept confidential.

In the survey the following questions were posed:

1. ***Are you aware of any incidents of poor patient care resulting from current airway securement techniques? If so, please provide details below.***

   Of the responses received 23% of the people surveyed were aware of incidents of poor patient care resulting from their airway securement techniques.

   Some respondents also left comments as follows:

- As all our patients go to ICU post op we have had some patients with pressure area issues around the corners of their mouths due to a tube tie being too tightly secured.
- Tube tied too tight resulting in indentation and redness of neck/cheek areas.
- Red marks on face when prone and from ties around the neck on 'head down' cases
- Yes, but unable to share details.
- Last week a doctor doing an anaesthetic lost the patients airway didn't know what to do so we called for help.
- Yes, occasionally ties are too tight and can cause pressures issues around the mouth
- The use of cotton tapes/ties to secure airway, resulting in PU damage.
- Not personally, but I understand that some patients can have skin reactions to adhesive tapes and that if all practicable measures aren't taken it may be easy for the airway to dislodge.
- ET tubes not secured at the correct length. Corner of mouth sore.
- Accidental extubation in the prone position.
- Occlusion of cuff port with tube tie.
- If use tracheal tie then position patients in Trendelenberg for prolonged periods of time, the tie can cut into the patient's skin.
- Maybe I can't consider this as poor patient care, but it definitely requires some attention. I am referring to the ties used to secure airway adjuncts. Though they are necessary, careful attention is required. If tied too tight it leaves a mark on the patient.
- Pressure sores at the lip corner
- Potential for the accidental displacement/removal of tube (these used to be a problem in the past; however, since the practice changed, no more)
- Yes, 'Igel' was tied too tightly so couldn't pass a suction catheter down the hole
- *Yes. Incident happened in 2016. Patient suffered cardiac arrest post undetected oesophageal intubation.**
- Damage in the corners of the mouth from a poorly tied tube tie,

- *Yes, accidental de cannulation of crit care patient.**
- Yes. Misplaced device, injury to lips and perioral skin.
- Cuts.
- Pressure sores.

* *These two points were actual feedback, but we feel that the responders may have misunderstood the question and do not feel that these responses accurately reflect the patient incident. We have assumed that the first patient suffered anoxia, which is the reason for the cardiac arrest. With the second patient we feel that the practitioner lost venous access and were unable to administer the correct medication to re-intubate. However, as the survey was anonymous there isn't a way of checking this. We felt that the information provided should be included in the report.*

2. ***How do you currently secure an airway***

- Tapes and Ties = 57.3% used this method of securing
- Elastoplast or Similar = 20.16% used this method of securing
- Fit for Purpose Device (not specified) = 4.3%
- Mixture of all or another method = 8.7% used a mixture of methods depending on procedure
- No response = 9.4%

3. ***Is there a standardised approach to securing an airway in your theatre?***

Yes = 72%
No = 21%
Unsure = 7%
Of those surveyed and answered 'Yes' to the above question considered tapes and ties as a standardised approach to securing the airway.

The comments showed that the decision regarding the method of securing the airway was generally consultant led, however, in 90% of the cases, the ODP or Anaesthetic Nurse would be responsible for securing the airway device.

4. ***Are you aware of the infection prevention risks when using adhesive tape to secure an airway?***

Yes = 56.5%
No = 43.5%

The results show that 56.5% of the respondents were aware of the infection risks associated with using tapes. However, they continued to use this as a method of securing the airway device even though it is an unlicenced and unhygienic way of managing the securement.

5. ***Are you aware that the airway may migrate during an intervention, and this could cause harm to the patient?***

The survey results showed that 95.7% of the respondents were aware that the

airway may migrate during the intervention and could cause serious harm to the patient but continued to use the same methods of securement.

6. ***Would you or a colleague be interested in joining a focus group to discuss standardisation further?***

   Yes = 35.29%
   No = 36.97%
   Maybe = 27.74%

   From the response received to this answer it was agreed that a series of focus groups would be arranged to discuss standardisation and culture within the theatre/anaesthetic department.

The above responses show that there is a need to provide nationally recognised guidance and training by employing organisations. For agency practitioners who make up part of the theatre team, this guidance should form part of their induction and possibly part of their requirement to work through a recruitment agency.

FOCUS GROUPS

The purpose of the focus groups was not to determine actionable recommendations but to provide insight into how things are currently being undertaken and take these ideas, thoughts and suggestions to the SLWG. As a result of five focus groups the following key findings emerged relating to the ways that airways are managed and secured in different hospitals.

Continual Professional Development (CPD) hours were accredited to the meetings and a certificate provided to those who attended.

The questions shown below were broken down into subsections:

Patient Safety:

Q1 Who is responsible for safe patient care in the anaesthetic room?
Q2 Who would be held responsible if something untoward happened to a patient?
Q3 Are you aware of any incidents of poor patient care within the anaesthetic department or any area where the airway device is secured?

Incidents of poor practice – infection control issues and patient harm:

Q1 Are you aware of any incidents of poor patient care within your department?
Q2 Are you aware of any infection incidents affecting patients when using tape to secure an airway?
Q3 Do you test the tape for infection/bacteria prior to using?

Communication:

Q1 How good is communication within your department?
Q2 How would you describe the culture within your department?
Q3 How effectively are changes etc., communicated within your hospital?
Q4 Is your reporting process effective and does it support a good patient safety culture?
Q5 What role should employees play in suggesting improvements to processes?

Current Practices:

Q1 How do you currently secure an airway device?

Standardisation:

Q1 Is there a standardised way of securing an airway device in your hospital?
Q2 How would you define a standardised approach – can you share an example of processes that should be standardised.
Q3 In your opinion, which processes work well in your department and which could benefit from standardisation?
Q4 What advantages do you see in standardising processes and what challenges/drawbacks do you foresee?
Q5 If you wanted to change a process how involved would you feel in the decision making related to the standardisation process?
Q6 Do you feel that you should have a say in the process of change?
Q7 How do you think the success of standardising a process should be measured?
Q8 What channels or mechanisms would you suggest for collecting ongoing feedback from colleagues about the standardised processes?

Focus Group Key Findings:

- Patients were being harmed because of the methods currently in place to secure an airway device and whilst some were considered minor incidents there were mentions of more serious patient outcomes, including cardiac arrest, oesophageal tear, resulting in the death of the patient.
- Running the focus groups has strongly highlighted the difficulties around standardisation of the airway securement process.
- The consensus across the focus group discussions was that everyone in the environment had a responsibility for the patient in the anaesthetic room and that their safety was paramount.
- The anaesthetist generally took responsibility for choosing how the airway device was fixed, however, it was unlikely that they would secure the device.
- Communications within the environment was mixed and practitioners did not always feel they received two-way communication following an incident or if new initiatives were being implemented into the department.
- Culture often prevented professionals speaking up and speaking out when there were incidents about to occur or if new initiatives were not right for the environment.
- There is still a culture of hierarchy within the environment which can prevent individuals from feeling able to share their ideas.
- Most delegates felt they should have a say in change processes but didn't feel that they did. Changes happen without collaboration with those people who are going to be using the equipment or undertaking the new processes.
- Most people who joined the focus groups used tapes and ties to secure the airway. Does this amount to standardisation?
- There was little understanding about the infection risks associated with the use of tapes. There was greater understanding about the possibility of facial harm when using ties, tapes, and Elastoplast.

A full report of the discussions is available upon request.

Complex construct of a safety culture

Throughout the report we mention a safety culture, which is a complex construct culture as it is characterised by intricate and multifaceted systems of beliefs, practices, social structures and technologies. Such cultures typically emerge in groups that have developed significant specialisations and interconnectedness within their ideological frameworks i.e. around patient safety.

Within this report the complex construct is intended as a generalisation and should not be interpreted as applying to specific cases or individual circumstances.

FREEDOM OF INFORMATION REQUESTS

The final element of the triangle of information gathering was through Freedom of Information (FOI) requests to UK NHS Foundation Trusts. The information requested was for the period between the 1 January 2020 to 31 December 2023.

Responses from FOI requests to NHS England Foundation Trusts have shown that a substantial number of trusts have experienced inadequate patient outcomes because of poor airway management. It has also highlighted that many trusts do not report the incidents of patient harm. Sometimes this is due to the normalisation of the process and that the incidents are so 'small' it is not felt necessary to report them. The FOI requests were designed to define how patient safety is delineated around securing an airway device and how standardisation can be improved to ensure the reduction of current incidents of failure and infection to patients.

We requested an understanding of the number of reported incidences within the NHS of patient harm or even death because of poor airway management. As well as the questions shown below, we stated that when securing an airway device an optimal endotracheal tube (ETT) securing device should provide maximum stability to prevent inadvertent movement or extubation, optimal ventilation, whilst maintaining patient comfort.

Requests were sent to 148 Foundation Trusts with the following responses:

Mental health only	9
Not a surgical unit	10
Not in the desired format	3
Wanted paying for the information as not in desired format	8
Would not provide under Section 12 of the act	1
No direct email	12
No response (to date)	33

Total responses to the FOI questions

Damage to a patient's skin when removing the surgical tape used to hold the airway device in place.	552
Skin damage i.e. pressure sores because of using cotton ties to secure the airway	351

Death of, or harm to a patient because of inadvertent airway adjunct movement (displacement) or extubation whilst maintaining patient comfort.	0
Death or cardiac arrests of patient due to undetected oesophageal intubation	0
Hospital acquired infection because of using tapes that are non-sterile.	1

Five hospitals were unable to provide the information in the format requested but responded as follows:

Hospital 1: 69 in total but no breakdown
Hospital 2: 17 in total – 5 back of neck and 12 mouth
Hospital 3: 44 in total under the category of airway management. No breakdown
Hospital 4: Five incidents in total under airway and respiratory problems and intubation problems
Hospital 5: 81 incidents in total, 1 x severe harm; 10 x moderate harm and 71 low harm. Of the 59 incidents of skin damage there was one incident of severe harm

CONCLUSION

The summary findings from the survey, focus groups and FOI requests identify that there are risks to the patients associated with undergoing an anaesthetic intervention. They highlight the cultural barriers and failings with communication. It does show that there are standardised approaches, however, they are not consistent with every specialty working in the same way in the same trust.

If we are to continue improving healthcare services, then developing cultural change in healthcare is crucial. Improving the quality of care, reducing medical errors and ultimately enhancing patient outcomes is essential for the future. Transforming the culture within healthcare organisations requires a comprehensive approach that involves leadership commitment, employee engagement, continuous/ongoing education and a focus on patient-centered care.

A lack of guidelines and inadequate preventative measures, a lack of effective management strategies (including risk assessments) and a general absence of specific perioperative education and training are the main barriers to safer airway device management within the anaesthetic environment.

New regulatory systems and sometimes political unawareness can cause pressures on the industry due to their often single minded need to cut headline costs. Only recently the Association for British Healthcare Industries have announced that £50k worth of registration projects have been withdrawn due to the costs associated with compliance. This will have a catastrophic impact on much needed healthcare innovation.

Reuters have identified in their article in 2022 that many industry partners are no longer taking their product to market due to the high costs involved in the process. It is scandalous to think that some of these products are being designed to support patient safety and will now not be entered into the medical device arena, but we continue to use unlicensed products to secure an airway device.

From an infection prevention perspective, the National Infection Prevention and Control Manual, Chapter one, Standard Infection Control Precautions (SICPs) states that care equipment can be easily contaminated with blood and other bodily fluids and infectious agents. They classify care equipment as either:

- **Single use** – equipment which is used once on a single patient then discarded. Must never be reused even on the same patient.
- **Single patient use** – equipment which can be reused on the same patient.
- **Reusable invasive equipment** – used once then decontaminated e.g. surgical instruments.
- **Reuseable non-invasive equipment (often referred to as communal equipment)** – reused on more than one patient following decontamination e.g. commode, patient transfer trolley.

Multi-patient rolls of tape are by definition classified as ‘non-invasive re-usable equipment’, which by reason of the SICPs above, must be decontaminated to adhere to the National

Infection Control Standards. This is clearly not happening as rolls of tape, by their structure cannot be decontaminated.

Healthcare is a high-risk industry, and professionals should follow guidance developed from the best available evidence (NICE 2024) rather than traditional and ritualistic practice. If the airline or chemical industries just did what they thought on the day, depending on the professional managing their safety it would be deemed unacceptable.

NEXT STEPS

Moving forward, the project's key focus will be on:

- Collaboration to establish strategic guidance, standards, and recommendations for healthcare professionals working in the anaesthetic environment, when securing an airway device.
- Support practitioners with education and learning around change management to create a common language and framework that fosters collaboration and efficiencies when driving improvements in secure airway management.
- Advocate for all incidences related to secure airway management to be reported to ensure poor practice isn't normalised.
- Develop and facilitate consultations with government to identify barriers to the reduction of harm to inform the development of national guidance on secure airway management.
- Advocate for national guidance on secure airway management to be included in local and national policy.
- Advocate for all methods of securing the airway to be risk assessed and used under license.

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All the results shared in this document are up to and including the 10 October 2024.

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