

Research Report

Staff experiences of percutaneous tracheostomy in intensive care: challenges, complications and potential solutions

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Summary

Tracheostomies are performed in 10–13% of UK intensive care admissions. While the percutaneous technique is well established, accurate needle insertion can be difficult in patients with obesity or neck swelling. These challenges increase the risk of bleeding, airway loss and injury to neck structures. In anatomically complex cases, patients are referred for surgical tracheostomy, causing delays and additional healthcare costs. Semi-structured interviews and focus groups were conducted with 32 staff across three intensive care units. Participants included consultants, resident doctors, nurses, advanced practitioners and auxiliary staff. Interviews were recorded, transcribed and analysed using inductive thematic analysis. Six themes were identified. Tracheostomy was seen as a skilled, high-risk procedure best learned through supervised practice. Teamwork, equipment and the environment were considered vital to safety. Staff reported varied approaches to planning and performing the procedure, alongside strategies to prevent and manage complications. Participants reflected on how a guidance device might improve accuracy, drawing on experiences of the benefits and challenges of introducing new technologies into complex clinical settings. This study provides insights into tracheostomy practices, safety strategies and the potential role of guidance devices. Our study also presents a comprehensive end-user co-development model for future medical device design.

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Accepted: 13 November 2025

Keywords: critical care; equipment design; patient safety; qualitative research; tracheostomy

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Introduction

Between 15,000 and 20,000 new tracheostomies are inserted annually in National Health Service (NHS) hospitals [1], with two-thirds performed in the intensive care unit (ICU), accounting for 10–13% of all UK ICU admissions [2, 3].

Depending on a patient's anatomy, stage of illness and insertion indication, a tracheostomy will be performed by one of two techniques: surgical or percutaneous. The surgical method requires dissection of complex tissues, allows ligation of vessels and

directly visualises the trachea [4]; patients are usually transferred to operating theatres with an experienced surgical and anaesthetic team. Coordinating a window of patient, surgeon and operating theatre availability can lead to significant delays; ICU patients typically wait 3–4.5 days for this procedure [3, 5, 6]. Delays are compounded by prolonged sedation burdens, delayed physical and laryngeal rehabilitation and increased exposure to risk (delirium, infection and thromboembolism), adding significant financial and logistical costs to the healthcare system [7–9].

Percutaneous dilatational tracheostomy (PDT), the most common ICU tracheostomy technique, is usually performed at the bedside by ICU physicians [10]. The first critical step requires accurate needle placement into the trachea. Precise insertion can be challenging due to physiological instability and obesity in up to 30% of cases [11]. Needle misplacement can lead to catastrophic bleeding, damage to neck structures and airway loss [12]. While outcomes are similar between techniques [13], PDT is more cost-effective, can be performed at the bedside without theatre scheduling delays and may reduce wound infection rates, bleeding and mortality [14, 15].

Despite improvements in the quality of care following tracheostomy [5, 16], little progress has been made to increase the safety of PDT since the technique was first described in 1985 [10]. Bronchoscopic visualisation is routinely used in many centres, but this only confirms eventual tracheal puncture (or not) and, importantly, does not guide needle insertion through the tissues of the anterior neck.

We are currently involved in a project which aims to design a prototype medical device to precisely guide initial needle insertion during PDT, with the goal of improving procedural safety and the confidence of clinicians. To explore this concept and inform the design process, we conducted a study to investigate staff experiences with ICU tracheostomy and consider the potential role of a PDT guidance system in terms of user needs, technical requirements and workflow integration.

Methods

Following ethical and Health Research Authority approval (IRAS-ID-344825), orientation visits occurred at each of the three participating ICUs. Clinical tracheostomy leads identified potential participants. Purposive sampling [17] recruited staff from a range of roles including consultants, senior residents, staff nurses, advanced critical care practitioners (ACCPs) and ancillary staff with an equipment role.

Davis's Technology Acceptance Model was used to design and inform our interview and focus group schedules, focusing on 'usability' and 'ease of use' [18]. Semi-structured face-to-face or virtual semi-structured interviews and focus groups were conducted (by MM, AG, BM and CS) following a standardised topic guide (Appendices 1 and 2). Images showing the typical ICU set-up and prototype guidance device were presented to participants to help facilitate discussion (Fig. 1). Sample size was determined based on 'information power' as described by Malterud [19].

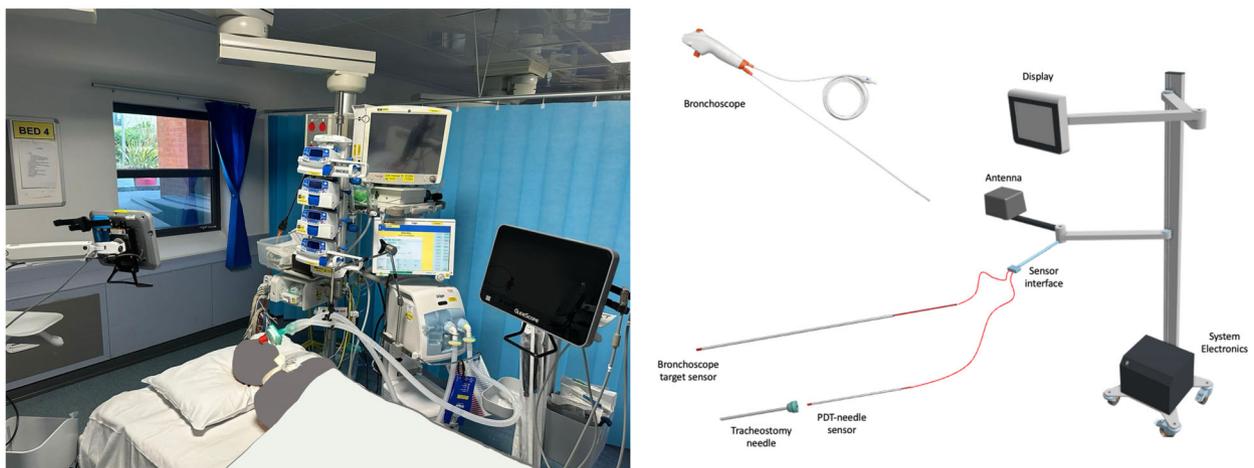


Figure 1 Images used in participant discussions. Left: typical 'set-up' for an ICU tracheostomy. Right: an image panel of the prototype device. PDT, percutaneous dilatational tracheostomy.

All sessions were recorded and transcribed via videoconferencing (Teams, Microsoft, Redmond, WA, USA) and analysed using an inductive thematic analysis approach, as described by Braun and Clarke [20]. Transcripts were coded by one researcher (MM) with continual discussion with other team members (AG, CS and BM). A written codebook was maintained together with reflective notes, and this contributed to a continually updated coding spreadsheet; codes were then coalesced into themes, and illustrative excerpts of dialogue were recorded for each theme.

As practising clinicians with various roles in tracheostomy practice, we were aware of our potential impact on data analysis: BM is an ICU consultant and tracheostomy lead at ICU-1; CS is an anaesthetic consultant at one of the hospital sites and BM and CS have current or previous experience working with some participants; MM and AG are resident doctors at ICU-3. To ensure the analysis was grounded in the data, we maintained a reflexive approach through the use of the diary and team discussions.

This study follows the standards for reporting qualitative research [21, 22].

Results

Thirty-two participants representing a range of multi-disciplinary roles attended 26 interviews and two focus groups across three diverse ICUs between September 2024 and February 2025 (Table 1).

Thematic analysis identified six key themes (Table 2), described below with representative quotes.

The first theme describes *gaining skills and keeping them*. Residents played an active role in PDT, with senior staff emphasising their supervisory responsibility and the educational value of the procedure:

OK, well, this is an educational opportunity potentially; who's around, who might benefit. Sometimes it becomes a discussion around who will benefit the most.

–Excerpt-1: ICU-1, Interview-10, Consultant-5

However, the degree of supervision required was dependent on the learner's experience and confidence level in PDT. As it is deemed a high-risk procedure, there is an element of conditional trust between supervisors and residents based on their experience:

If it's somebody who's not done particularly many, you'll be in with them because that's the sort of reassurance they will need. Those that have done quite a few, you'll be outside the curtain, outside the room in that sense and to be called if they need some help.

–Excerpt-2: ICU-3, Interview-5, Consultant-3

While residents were welcomed into PDT learning, opportunities had to be balanced against procedural efficiency and patient safety. Educational value was weighed against potential risk and some described reaching a limit when procedures became prolonged or unstable:

Everybody's got to learn, and so it's important that we involve our ICM [intensive care medicine] trainees in this process. But sometimes it takes too long, and the patient's ventilation is like a complete disaster, and you just feel like saying, "Come on, we just need to get on with it now".

–Excerpt-3: ICU-3, Interview-6, ACCP-1

Table 1 Details of participants.

Site	Role					
	Consultant	Speciality doctor	Resident doctor	ACCP	Nurse	Auxiliary staff
ICU-1	5	1	3	2	2	0
ICU-2	6	0	0	0	2	0
ICU-3	5	1	2	1	1	1
Total (%)	16 (50%)	2 (6%)	5 (16%)	3 (9%)	5 (16%)	1 (3%)

ACCP, advanced critical care practitioners; ECMO, extracorporeal membrane oxygenation; ICU, intensive care unit.

ICU-1: 17-bed general acute ICU accepting medical, surgical and burns patients at both intensive care and high-dependency levels. ICU-2: 44-bed cardiothoracic intensive care unit which accepts cardiac, thoracic and transplant surgical patients and hosts a specialised ECMO service. ICU-3: 12-bed district general hospital accepting medical and surgical patients and offering tertiary services to infectious disease patients.

Table 2 Description of themes and subthemes generated from interviews and focus group data.

Theme	Subthemes	Description
Gaining skills and keeping them	Training Continuing professional development	Describes how clinicians develop skills and knowledge relevant to the practice of tracheostomy insertion and maintain them in their clinical roles. It includes the interaction between learners and teachers, the importance of 'learning by doing', the transition from novice to expert and how technologies can enhance or inhibit learning. It acknowledges the variability of techniques and preferences in senior staff and the challenges this can present to learners
How people, equipment and the environment interact to keep patients safe	Leadership Human factors Ergonomics MDT	This theme incorporates human factors, ergonomics and teamwork. It includes the tension between 'leaders' managing the airway and the procedure itself, the importance of experience and expertise, how health professionals from different disciplines interact and how the set-up of the clinical environment helps and hinders individual and team performance
The dangers of tracheostomy insertion and how to prevent them	Complications and challenges of tracheostomy insertion Complications and challenges of airway management Governance/QI	Describes the challenges and complications of tracheostomy insertion and the airway management that is required to complete the procedure. This includes direct injury to important anatomical structures, the misplacement of airway devices and the dangers of performing a demanding procedure on an unstable patient. It also includes the risks of inaction and delay. Good governance structures and cognitive aids, such as checklists, help mitigate these issues
Variations in how to plan and do a tracheostomy	Pre-procedural planning Procedural techniques	Describes the similarities and differences in how clinicians plan and execute the tracheostomy procedure. It includes the decision-making process, family communication and logistical planning, as well as the specifics of the procedure itself
What assistive devices tell us and how	Device information Device interface	Draws on respondents' reflections on what an assistive device should display and how it should display it. It includes the types of information which could be important in reducing the uncertainties of needle location and the different options for effectively displaying or communicating this information during the tracheostomy procedure
The benefits and pitfalls of introducing new technologies in a complex environment	Introduction of new technology	Describes how changes in technology have influenced practice for better and for worse, considers how practice drives the development of technology and vice-versa. Respondents reflect on the dilemmas introduced by superior technologies which appear to be built to lower standards and how new technologies can introduce unintended consequences

MDT, multidisciplinary team; QI, quality improvement.

There was an acknowledgement, however, that exposure to tracheostomy was variable throughout training and whilst there is a paucity of formalised training to ensure a standardised approach is taught, there is also a unique opportunity in the variety that 'real world' experience brings:

I think during my training I got reasonable exposure to tracheostomies. But I don't know if that's true for everybody. I think you're often waiting for them to be performed, and I think going through different teaching parts, or learning on models for example, I don't think it produces the full picture of how it's performed.

–Excerpt-4: ICU-1, Interview-16, Consultant-7

As for any procedure, ongoing exposure and professional development help clinicians remain up to date. However, it was noted that particularly for consultants who are dual speciality trained (and hence work on the ICU relatively infrequently), they may go long periods without performing a PDT, affecting their confidence levels:

They might do at least one trachea a week, you know, and they'll be ... Whereas maybe some of the other consultants wouldn't do one for six months. And it's not a criticism because they'll tell you themselves – they feel rusty.

–Excerpt-5: ICU-3, Interview-6, ACCP-1

The second theme considers *how people, equipment and the environment interact to keep patients safe*. Focus groups emphasised the consultant's key leadership role in airway management and oversight in PDT, though this was not overtly stated:

CS: And you were pointing at [Consultant-6] while we were talking about a team leader. I mean, it strikes me that there might be team leadership that might get handed over.

ACCP-3: I think someone like [Consultant-6] walks in and you'd expect them to be leading, and it usually is and doing so well.

–Excerpt-6: ICU-1, Focus Group-1

A key concept was the idea of shared airway management, where the airway and needle operators work together to maintain oxygenation, ventilation and airway control during the procedure. The use of videolaryngoscopy and bronchoscopy, displayed on large monitors, was one approach to support this collaboration. Positioning of this screen was important and the view of the needle operator was deemed to be prioritised:

If I'm setting up the screens and I'm the airway person ... the main person who wants to have the best view of things, I think is the operator ... You're like the anaesthetist helping the surgeon essentially. So that's the person who needs to have the best view of everything.

–Excerpt-7: ICU-2, Interview-19, Consultant-10

Clinicians performing PDT were reliant on wider team support. The procedure involves multiple human factors, managed through non-technical skills, such as communication and oversight. To maintain situational awareness, a dedicated member of the team external to the procedure was often tasked with monitoring the patient's physiology. Typically, this was a member of the nursing team:

So, I take part of our role, and it's not team leading or anything, but we have that overview – we can run, overview, troubleshoot and keep an eye on the observations. There's much more of that role in a straightforward tracheostomy. There's no need for us to necessarily be hands on.

–Excerpt-8: ICU-1, Interview-11, Nurse-2

The third theme is *the dangers of tracheostomy insertion and how to prevent them*. Navigating the needle through the anterior neck and into the trachea was generally viewed as the riskiest part of the procedure:

The most important bit to me of this is being able to get your needle in the right place. And when you fail to do that, that's when complications come about.

–Excerpt-9: ICU-2, Interview-23, Consultant-12

When this went wrong, participants described complications ranging from minor to catastrophic, including bleeding, damage to adjacent structures in the neck, pneumothorax and surgical emphysema:

Insertion problems – they tend to be related to sticking needles in someone's neck. So, that tends to be damage to structures that you weren't intending to stick the needle in, pneumothorax would be the most obvious. Sticking a needle into a blood vessel ... Sticking the needle into the oesophagus or damaging the recurrent laryngeal nerve.

–Excerpt-10: ICU-1, Interview-10, Consultant-5

These complications were observed more often in cases where patients had variances in anatomy or individual risk factors for difficult tracheostomy insertion. This included situations where it was difficult to palpate the trachea, such as obesity or having a short neck:

I mean in the really big patients, either getting right into the centre of the trachea or getting into the right position . . . sometimes you end up between first and second ring. Sometimes you can end up even higher. And I find in [patients living with obesity] with short necks that can be an issue.

–Excerpt-11: ICU-2, Interview-19, Consultant-10

Key safety practices in PDT included frequent use of checklists, such as pre-procedural briefings, Local Safety Standards for Invasive Procedures (LocSIPPS) and a local clinical practice outline. Respondents stated that these checklists were generally adhered to more consistently in PDT than in other pre-procedural checklists due to the higher degree of perceived risk:

And while I think you have things like central lines and stuff like that where LocSIPPs aren't necessarily working that way, I think for something like traches . . . The vision of risk with traches is probably enough that . . . It's more on people's minds to play things by the book and to go through that proper process.

–Excerpt-12: ICU-2, Interview-19, Consultant-10

Data collection and reporting underpin policies, guidelines and checklists. However, one participant noted a lack of tracheostomy data, illustrating that system improvements are yet to be made in some aspects of tracheostomy care:

But where's that data for traches? . . . if an individual struggles or the needle is offline . . . I don't always think that incident forms are produced. It's just put down to the individual patient or the anatomy on the day. I am not aware of any data sets, even nationally with how many perc traches get done a year.

–Excerpt-13: ICU-1, Interview-11, Nurse-2

The fourth theme is *variations in how to plan and do a tracheostomy*. Participants generally stated a preference for PDT rather than a surgical tracheostomy, citing surgical delays and a view that PDT was the less invasive method:

If you would ask me, I would be always an advocate of the least invasive procedure, which is the percutaneous tracheostomy.

–Excerpt-14: ICU-3, Interview-3, Consultant-2

For more difficult patient anatomy, the decision for a tracheostomy was deemed to be clinician-dependent, contingent on confidence and skill level:

There're some patients you look at and you think that they're never going to get perc type thing, short stubby necks. But then I guess there's an in-between group and that's very much down to an experience of the clinician whether it's gonna go well or not.

–Excerpt-15: ICU-1, Interview-11, Nurse-2

Participants provided detailed preparatory steps for tracheostomy, including the routine ultrasound to assess the neck for vascular structures. The presence of vessels at the intended needle insertion site was generally a contraindication for PDT, with such cases typically referred for surgical tracheostomy in theatre. However, staff from ICU-2 (a cardiothoracic unit with an extracorporeal membrane oxygenation (ECMO) service) had more of a drive for percutaneous insertion and had a different perception of bleeding risk:

I think I'm at the end of the scale of people who are more keen to do a perc trache if we can. And therefore, if there are some vessels around, if they're veins and I think they're avoidable . . . then I tend to go ahead . . . I am conscious that a trache is not getting done either over a weekend or because they might end up needing to go on a surgical list and it doesn't get done for two or three days.

–Excerpt-16: ICU-2, Interview-23, Consultant-12

This perception of risk was attributed to departmental research and audit data indicating that bleeding rates between surgical and percutaneous tracheostomies were equivocal:

We audited the bleeding after trache in the ECMO patients . . . there was no difference in the bleeding rates. And people tend to think that it might be easier to do a surgical trache – I don't think that's necessarily easier.

–Excerpt-17: ICU-2, Interview-23, Consultant-12

Participants described the detailed PDT technique; however, they also identified inaccuracies in current practice – notably that insertion was without direct vision, leading to a discrepancy of actual and perceived needle location:

If you're not sure where that needle is and it hasn't appeared where you thought it was going to appear – the risks are the same as before, even though you've scanned the neck and you're prepared, you still can't identify where that needle is.

–Excerpt-18: ICU-1, Interview-15, ACCP-2

As a result, there was a perceived inaccuracy in needle placement, with several expressing limited confidence in the exact location of their needle:

There are some inaccuracies, so I don't know – in the average patient 70-80% confidence in the right spot.

–Excerpt-19: ICU-1, Interview-17, Consultant-8

The fifth theme relates to *what assistive devices tell us and how*. Interviewees expressed positive views on a guidance device for tracheostomy, recognising its potential to reduce uncertainty in needle positioning and minimise related complications:

So, the big thing really is identifying your midlines and I suppose it's like with anything, if you're having difficulty with it, you're probably not quite in the right place . . . if it was something that could give you an accurate assessment of exactly where your midline was, or certainly a safe insertion point was, that would be really useful.

–Excerpt-20: ICU-1, Interview-12, Resident Doctor-2

Participants discussed how the interface of a guidance system could be presented and integrated into ICU practice. They generally preferred a user interface showing the bronchoscope image and guidance imaging side by side, as it felt more intuitive.

Participants stressed the importance of user-friendly design adapted to ICU space constraints, with attention to cost and availability:

User friendly. Ease of access to the device itself . . . So if it's space saver, that would be great, if it doesn't take a huge space around it. Cost, obviously, don't want an expensive device that will just cost me a fortune and efficient.

–Excerpt-21: ICU-3, Interview-7, Consultant-4

The final theme describes *the benefits and pitfalls of introducing new technologies in a complex environment*. Participants described evolving practices, such as the shift to ultrasound for central venous access and the adoption of videolaryngoscopy for tracheal intubation. These innovations gained acceptance when supported by evidence or were perceived to improve patient safety:

When I first started central lines, it was all landmark based. Then ultrasound came along . . . And then data emerged to show it was safer and now you wouldn't dream of putting in a central line without ultrasound.

–Excerpt-22: ICU-1, Interview-10, Consultant-5

And I guess the major one has probably been videolaryngoscopes . . . they've integrated very well . . . building on an already familiar technique. In my opinion, making it a bit safer, a bit easier.

–Excerpt-23: ICU-2, Interview-19, Consultant-10

Similarly, participants also reflected on unsuccessful integration, including some cardiac output monitoring devices. These were considered labour-intensive and offered limited perceived patient benefit:

There are cardiac output monitors that have come and gone . . . again it was a huge fuff left to the nursing staff predominantly and ultimately not terribly helpful. So that was an example of something that we decided not to renew.

–Excerpt-24: ICU-1, Interview-10, Consultant-5

Participants acknowledged the need to adjust to new systems, and expressed confidence in their ability to do so, drawing on prior experience with ICU technologies. This sense of implicit trust in technology was evident:

If there was some familiarity with the technology and you'd done it with the same a bunch of times and it had gotten your confidence then I don't think any of us have got the ego to think that we have a monopoly of knowledge . . . I would tend to go with the technology.

–Excerpt-25: ICU-1, Interview-17, Consultant-8

Discussion

Our interviews and focus groups captured and synthesised current views of tracheostomy insertion from a diverse staff group working in varied clinical settings. Identified themes are relevant to many high-risk, technically complex procedures.

Percutaneous dilatational tracheostomy presents a useful, supervised learning opportunity for resident doctors in the ICU, offering 'real world experience'. Consultants generally recognised their role as supervisors in continuing education, noting that this responsibility relies heavily on a foundation of trust and a strong working relationship with the resident. The importance of this trust aligns with Ten Cate's four key variables that influence entrustment decisions: attributes of the trainee, attributes of the supervisors, context and the nature of entrustable professional activity [23]. Data from excerpts 2 and 3 illustrate how residents often require 'reassurance', which must be balanced with the need to 'get on with it'. These dynamics influence how supervisors assess residents' trustworthiness in the high-stakes ICU environment.

Experiential learning is required to master procedural skills. The 2021 Royal College of Anaesthetists stage 3 curriculum identifies PDT as a potential supervised learning event for residents with a special interest in intensive care medicine, as does the Faculty of Intensive Care Medicine (FICM) curriculum [24, 25]. However, formal objectives are lacking and structured tracheostomy training remains limited, with residents often 'waiting' for opportunities. Training was described as opportunistic and largely dependent on the ICU in which residents were rotating.

Our results demonstrated the important interplay of human factors and non-technical skills in PDT insertion. Unlike in the theatre setting, where roles are clearly delineated with the anaesthetist often maintaining oversight of the patient's physiology, the ICU environment demands greater adaptability. As shown in excerpt-8, nursing staff often assume an 'overview' role during bedside PDT, while ICU doctors focus on airway management and needle insertion. This redistribution of responsibility underscores the interprofessional nature of PDT and suggests that improving team communication and coordination could further improve procedural safety. Reassuringly, these findings support existing guidance from the Difficult Airway Society and the Association of Anaesthetists, which advocates integrating human factors into training and device design [26].

Needle insertion into the trachea was described as 'the most important bit' of the procedure and particularly challenging in patients living with obesity or with shorter necks. This aligns with existing evidence linking difficult anatomy to greater procedural complications [12, 27]. These patients fall into an 'in between' group where the tracheostomy insertion method (PDT or surgical) may vary by clinician preference. Participants' openness to guidance technology suggests a potential for more PDTs in such cases where a surgical approach may otherwise be taken, helping to reduce delays and system costs.

Mechanisms for safety in tracheostomy insertion are well outlined by FICM guidance using checklists, such as pre-procedural briefing and LocSIPSS. These were reported as routinely used across all ICU sites. However, a lack of robust data reporting was noted, acting as a barrier to quality improvement. This reflects national findings that as few as 25% of airway incidents are formally reported [3], underscoring the need for improved data collection and feedback systems to drive safety improvements.

One interesting finding in our analysis was how patient risk factors influenced clinicians' decisions to proceed with PDT. In ICU-2 (a cardiac and ECMO unit), bleeding was considered an expected part of the procedure. As a result, PDT was performed even in patients with bleeding risks, including those on therapeutic anticoagulation. A recent study comparing surgical and percutaneous tracheostomy in ECMO patients found no significant correlation between bleeding events and tracheostomy method [28]. However, a systematic review on anticoagulation and tracheostomy insertion recommended withholding dual antiplatelet therapy or therapeutic anticoagulation to minimise bleeding risk [29]. These findings highlight the need for a nuanced, individualised approach to PDT, balancing risks and benefits based on each patient's clinical status.

Literature shows that many ICU environments lack consistent design solutions to support patient care [30], with equipment and layout often cited as barriers to effective technology adoption [31]. New devices must align with ICU workflow requirements. By exploring staff insights, our data have emphasised the need for technology to be 'user-friendly' with 'ease of access'. Respondents generally welcomed assistive guidance tools and demonstrated familiarity with integrating new technologies within the ICU, as seen in the successful adoption of ultrasound and videolaryngoscopy. This is encouraging, given that previous

research highlights how steep learning curves can hinder the adoption of technology [32]. By capturing qualitative insights, we gained a deeper understanding of the PDT process and the practical needs for a fit-for-purpose device design in the ICU setting. This approach may offer a replicable model for the development of future medical devices and technologies.

There are several limitations in our study. While a qualitative approach enabled in-depth exploration of perspectives on PDT practice, it does not provide quantifiable weight to findings. All interviewees in our study had experience in ICU settings and had previously or currently worked alongside some participants. This may have influenced how openly participants reflected on their own practice, particularly where interviewees were more junior than the interviewers. Although we adopted a reflexive approach to data analysis, including regular team discussion to minimise bias, the interpretation of qualitative data may reflect researcher perspectives.

As far as we are aware, our study is the first to explore staff perceptions of tracheostomy in UK ICUs. Our qualitative interviews, focus groups and subsequent thematic analysis identified challenges in tracheostomy training, explored the multi-disciplinary dynamics of tracheostomy care, recognised key complications and discussed how an assistive device could be integrated to facilitate safer PDT insertion. We consider this detailed examination of the perceived problems and usefulness of an assistive device an essential first step when designing and developing a medical device.

Acknowledgements

This research is funded by the National Institute for Health and Care Research (NIHR) Invention for Innovation (i4i) programme (Guided Insertion For Tracheostomy; NIHR-206447) and supported by the NIHR HealthTech Research Centre in Emergency and Acute Care. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care. Authors AW, CJ, BM and CS are co-applicants on the NIHR i4i award, and the study presented is the first work package of this project, which aims to produce a prototype medical device to guide PDT needle placement. CS is an Editor of *Anaesthesia*, and the former Executive Editor of *Anaesthesia Reports*.

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Appendix 1

Topic guide: 'Key informant' interview

The purpose of these interviews is to gain insights into how *the respondent* perceives the procedure of ICU tracheostomy, including the potential pitfalls and challenges, and how an assistive device might improve the procedure, including considerations related to the introduction of a new technology into a well-established procedural workflow.

An image of a typical 'set-up' for an ICU tracheostomy will be displayed throughout the interview, for purposes of elicitation, and as a 'prop' that the respondent may wish to use to help explain aspects of the procedure. For the final section of the interview, an image panel of the prototype device will also be displayed.

This is a topic guide – questions will not be asked verbatim, but will be integrated into the conversation in an unintrusive fashion. The order in which topic areas are discussed will be determined by the development of the conversation, except for showing the image of the prototype device, which *must* be at the end of the interview after the other topics have been discussed. Topic areas plus additional cues offered by the participant will be explored and expanded through open questioning.

- 1** Open with introductions, ensure the participant's name and position recorded. Ask about their personal role in ICU tracheostomy (clinical, organisational, technical, support, research, etc.)
- 2** Explain the purpose of the photograph of the ICU tracheostomy 'set up'.
- 3** Ask the participant to explain the steps in an ICU tracheostomy from their perspective. This should focus on their own role, rather than that of others.
 - If the participant mentions any challenges or pitfalls, make a note of these and come back to them for more information at an appropriate point.



- 4 Ask if they follow a particular method/approach for ICU tracheostomy. Find out how they do this (protocol, guidelines, education). If literature is available, ask if it can be seen. How was the policy arrived-at? Does everyone comply with institutional policy? If not, why?
- 5 Discuss risks and problems encountered in ICU tracheostomy – does the institution do anything to make the procedure safer? Has it been successful?
 - Pick up on the challenges and pitfalls, if mentioned earlier.
- 6 Ask about problems with needle location/direction – have they ever encountered this issue? Are they aware of any complications as a result?
 - Ask about whether a device that assists with the location and direction of needle insertion would be valuable.
 - Ask what the device would need to do to be useful.
 - Ask about how the device might integrate with other technologies (in the broadest sense).
- 7 Ask about experiences of the introduction of new technologies – can they give examples of times this has been done well and/or poorly?
 - Ask about integration into existing tasks.
- 8 Show the participant the image panel of the prototype device – ask them for their opinions.

Appendix 2

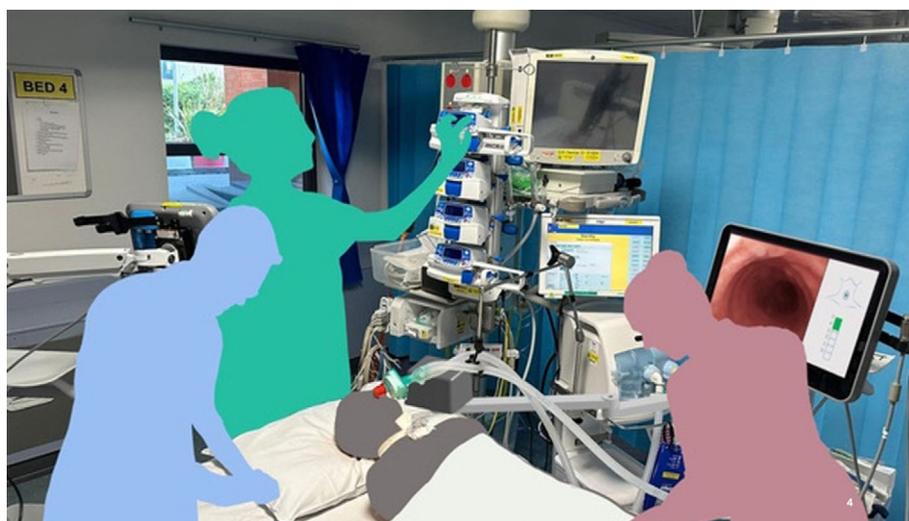
Topic guide: focus group

The purpose of these focus groups is to gain insights into how *healthcare teams* perceive the procedure of ICU tracheostomy, including the potential pitfalls and challenges, and how an assistive device might improve the procedure, including considerations related to the introduction of a new technology into a well-established procedural workflow.

Focus groups should involve interactions between participants – the facilitator should introduce the areas of focus, moderate the group, and move the discussion on at appropriate times.

An image of a typical 'set-up' for an ICU tracheostomy will be displayed throughout the focus group, for purposes of elicitation, and as a 'prop' that the participants may wish to use to help explain aspects of the procedure. For the final section of the focus group, an image panel of the prototype device will also be displayed.

This is a topic guide – questions will not be asked verbatim, but will be integrated into the conversation in an unintrusive fashion. The order in which topic areas are discussed will be determined by the development of the conversation, except for showing the image of the prototype device, which *must* be at the end of the focus group after the other topics have been discussed. Topic areas plus additional cues offered by the participants will be explored and expanded through open questioning.



- 1** Open with introductions, ensure participants' names and positions recorded. Ask about their roles in ICU tracheostomy (clinical, organisational, technical, support, research, etc.)
- 2** Explain the purpose of the photograph of the ICU tracheostomy 'set up'.
- 3** Ask the participants to verbally 'walk through' the steps in an ICU tracheostomy as a team. Take care to ensure that all participants get to participate, to build up a picture of how the teams work together.
 - If the participants mention any challenges or pitfalls, make a note of these and come back to them for more information at an appropriate point.
- 4** Discuss risks and problems encountered in ICU tracheostomy – does the institution do anything to make the procedure safer? Has it been successful?
 - Pick up on the challenges and pitfalls, if mentioned earlier.
- 5** Ask about problems with needle location/direction – have they ever encountered this issue? Are they aware of any complications as a result?
 - Ask about whether a device that assists with the location and direction of needle insertion would be valuable.
 - Ask what the device would need to do to be useful.
 - Ask about how the device might integrate with other technologies (in the broadest sense).
- 6** Ask about experiences of the introduction of new technologies – can they give examples of times this has been done well and/or poorly?
 - Ask about integration into existing tasks.
- 7** Show the participants the image panel of the prototype device – ask them for their opinions.