Study Protocol

SECURE

Service Evaluation of Cross-Specialty
UK Rapid Sequence Intubation Events

RAFT-5

Lead networks: RAFT and STAR

Collaborators: RRNs, TRIC, TERN, EMAR, SEARCH

Endorsed by: DAS, NIAA, RCoA, RCEM, SIVA

Version 4.0
December 2025

Project Summary

Title	**SECURE** – Service Evaluation of Cross-Specialty UK Rapid sequence intubation (RSI) Events
Chief investigator	Dr Jonathan Barnes, Consultant Anaesthetist (UHBW)
Sponsor Site	University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) – partnered with Bristol NHS Group
Study type	**Service evaluation** – UK-wide, multi-centre, prospective
Study setting	**NHS Trusts** in England, Wales, Scotland and Northern Ireland
Study sites	Single NHS hospitals
Eligibility	**NHS hospitals** with at least one of the following adult services: emergency medicine, critical care medicine and/or anaesthesia
Aims	To characterise in-hospital RSIs in adults across NHS hospitals
Objectives	• Describe the **availability of local resources** surrounding RSI events • Capture **contemporary clinical practice** around RSI events performed across all areas of the hospital by cross-specialty intubating teams • Describe and estimate the incidence of **immediate complications** of RSI events • To identify the **drivers of variation** in self-reported RSI practice across vignettes • Compare RSI events across the UK (resources, self-reported practice and observed practice) • Audit the findings against current recommendations
Data collection	Anonymised survey data will be collected using online forms and stored securely in a REDCap database hosted at the Sponsor Site (UHBW)

1. Site Survey	
Summary	Survey of **RSI resources: infrastructure, equipment and governance** – data will be entered by Site Leads
Study window	**One month** at all study sites: **1st – 31st March 2026**

2. Activity Survey	
Summary	Survey of **actual "user-defined" RSI events and "immediate complications"** – contemporaneous event data will be entered by each intubating team
Study window	**Continuous 14 days** *agreed by leads* at each site: **13th April – 25th May 2026**
Definitions	**User-defined**: any intubation deemed to be an RSI (or modified RSI) by the intubating team that meets the inclusion criteria **Immediate complications**: in the time period starting from induction and up to 30 minutes after the airway is secured
Inclusion criteria	**RSI events meeting ALL the following criteria:** • In-hospital (within NHS hospital grounds) • Patients ≥18 years (known or believed) • By anaesthetic, emergency medicine and/or critical care teams **Repeat RSIs in the same patient will be included as a new event**
Exclusion criteria	**RSIs events meeting ANY of the following criteria:** • Out-of-hospital (outside NHS hospital grounds) • Patients <18 years of age (known or believed) • Not by anaesthetics, emergency medicine or critical care teams **Patients with a functioning tracheostomy in-situ** **Intubations during cardiac arrest**

3. Vignette-based Practitioner Survey	
Summary	Survey of **individual self-reported RSI practice** – respondents must be airway trained (or competent) and involved in intubation decision-making
Study window	**One month** at all study sites: **1st – 30th June 2026**

Study Protocol

Version

SECURE (RAFT-5) Study Protocol Version 4.0
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Authors

Lead authors – Thomas Baumer, Swati Gupta, Thomas Davies
Other authors – Sara Tomassini, Callum Taylor, Carys Lim, Suzanne Harrogate, Jonathan Barnes
Contributors – Amelia Van Manen, Aravind Ramesh, Jessica Casey, Jessica Henry, Benjamin Milne, Roshan Ramasamy, Callum Taylor
Reviewers – all expert advisors as listed

List of abbreviations

Abbreviation	Definition
ASA	American Society of Anaesthesiologists
CPAP	Continuous positive airway pressure
DAS	Difficult Airway Society (UK)
EMAR	Emergency medicine airway registry
ED/EM	Emergency department / emergency medicine
ETT	Endotracheal tube
HFNO	High Flow Nasal Oxygen
HRA	(NHS) Health Research Authority
H_2RA	Histamine receptor antagonist
ICU/ICM	Intensive care unit / intensive care medicine
NAP	National Audit Projects in anaesthesia: NAP4-7
NGT	Nasogastric tube
NHS	National Health Service
NIV	Non-invasive ventilation

PPI	Proton pump inhibitor
PUMA	Project for Universal Management of Airways
RAFT	Research and audit federation of trainees
RCoA	Royal College of Anaesthetists
RCT	Randomised controlled trial
REDCap	Research electronic data capture
RRN	Resident doctor research network
RSI	Rapid Sequence Intubation
SCCM	Society of Critical Care Medicine
THRIVE	Trans-nasal humidified rapid insufflation ventilatory exchange
TCI	Target controlled infusion
TERN	Trainee emergency research network
TIVA	Total intravenous anaesthesia
TRIC	Trainee research in intensive care
USA	United States of America
UK	United Kingdom

Contents

1 Stakeholders

1.1 Sponsor Site

University Hospitals Bristol and Weston (UHBW) NHS Foundation Trust
– partnered with Bristol NHS Group
Clinical Audit and Effectiveness, Level 3, Education Centre
Upper Maudlin Street, Bristol, BS2 8AE

1.2 Delivery networks / endorsement

RAFT (Research and Audit Federation of anaesthetists in Training)
STAR (Severn Trainee Anaesthetic Research group)
RRNs (Resident Research Networks for UK anaesthetists)
TERN (Trainee Emergency Research Network)
TRIC (Trainee Research in Intensive Care)

1.3 Collaborator groups / endorsement

EMAR (Emergency Medicine Airway Registry)
South East Anaesthetic Research Chain (SEARCH)
SIVA (Society for Intravenous Anaesthesia)

1.4 Grant funding / endorsement

DAS UK (Difficult Airway Society) – direct application in September 2025 for small grant.

1.5 Investigation group

RAFT is the UK national resident anaesthetist research networks endorsed by the RCoA and NIAA. SECURE is the official 'RAFT-5 project', developed since November 2024 and will be delivered by resident doctors networks: RAFT, STAR (lead RRN), TRIC and TERN. The following members make up the **SECURE (RAFT-5) Investigation Group**:

SECURE (RAFT-5) Steering Committee:

- **Chief Investigator (CI):** Jonathan Barnes (Consultant Anaesthetist)
- **SECURE RAFT Chair:** Thomas Davies (RAFT)
- **SECURE STAR Chairs:** Thomas Baumer (STAR) and Swati Gupta (STAR)
- Sara Tomassini (RAFT)
- Amelia Van Manen (RAFT)
- Suzanne Harrogate (STAR)
- Aravind Ramesh (STAR)

SECURE (RAFT-5) Scientific Advisers:

- Professor Tim Cook – Anaesthetic and Intensive Care Consultant, Royal United Hospitals Bath NHS FT; Honorary Professor of Anaesthesia at University of Bristol

- Dr Sandeep Sudan – Anaesthetic Consultant, University Hospital Sussex NHS FT; RCoA Airway Lead; DAS Committee Member

- Professor Jonathan Benger – ED Consultant, UHBW NHS FT; Professor of Emergency Care at University of West England

- Dr Irene Grossi – Emergency medicine consultant, UHBW NHS FT; EMAR Lead

SECURE (RAFT-5) Subcommittee 'Working Groups':

STAR

- Thomas Baumer (STAR Executive Chair / STAR SECURE Lead)
- Swati Gupta (STAR Committee / STAR SECURE Lead)
- Aravind Ramesh (STAR Secretary)
- Suzanne Harrogate (STAR Anaesthetic Chair)
- Thomas Cloke (STAR ICM Chair)
- Carys Lim (STAR Treasurer)
- Jessica Casey (STAR Membership Secretary)
- Jessica Henry (STAR Liaison Lead)
- Maeve McLaughlin (STAR Liaison Lead)
- Oliver Barker (STAR Events Lead)
- Callum Taylor (STAR Website/IT Lead)

RAFT

- Thomas Davies (RAFT Chair)
- Benjamin Milne (RAFT ICM Vice-chair)
- John O'Rourke (RAFT Anaesthetic Vice-chair)
- David Ritchie (RAFT Treasurer)
- Inez Armstrong (RAFT Events Lead)
- Sara Tomassini (RAFT Secretary)
- Amelia Van Manen (RAFT IT/Education Lead)

TRIC/TERN/EMAR/No-THREAT

- Luke Flower (TRIC Co-chair)
- Adam Boulton (TRIC Co-chair)
- Benjamin Clarke (TERN Chair)
- Lauren Bose (EMAR Collaborator)
- Roshan Ramasamy (SEARCH)
- Todd Leckie (SEARCH)

2 Background

The RSI technique has changed significantly since its original description.

The Project for Universal Management of Airways (PUMA) defines an RSI as:
"…an intubation technique performed to reduce the risk and consequences of aspiration during tracheal intubation. The term 'rapid' refers to minimising the time interval between the pharmacologically induced loss of normal intrinsic airway protective reflexes and protection of the airway via correct placement of a tracheal tube such that an adequate seal with the tracheal wall is obtained (typically by inflation of the cuff). It does not refer to rushing to reduce the time between the decision to intubate and securing the airway" (1).

The traditional technique was described by Stept and Safar in 1970 (2). The paper suggested that 'performance requires an anaesthesiologist and at least one well instructed helper'. The 15-step process included insertion of a nasogastric tube (NGT) to empty the stomach, a two-minute period of oxygenation to denitrogenate the lungs followed by predetermined doses of thiopentone and succinylcholine, avoidance of ventilation during a period of apnoea, and securing of the airway with a cuffed endotracheal tube (ETT). Emphasis was made on the application of cricoid pressure from time of loss of consciousness till after inflation of the ETT cuff. The original description of the application of cricoid pressure to avoid aspiration was published by Sellick and predated this paper by almost a decade (3). Over the past 50 years, the technique has undergone steady and significant alterations, owing to continued advances in equipment and pharmacological agents.

There appear to be many variations of the 'modified' RSI and the available guidance reflects this heterogeneity.

The term 'modified RSI' is used to encompass a variety of technical components employed in various combinations and permutations during a single episode of airway management. Multiple interval surveys of RSI practice show great variation in practice (4-8). In the most recent UK-wide theatre-based RSI survey published in 2016 in the *British Journal of Anaesthesia* the authors proposed that there is wide controversy with regards to patient positioning, choice of drugs, preoxygenation techniques, ventilation during apnoea, and use of cricoid pressure (4). For example, in comparison to a previous national survey carried out in 2001, most respondents used propofol as an induction agent and only 18% used suxamethonium, 92% used cricoid pressure and 17% performed face mask ventilation during apnoea (4,5).

Recommendations continue to vary markedly by region and specialty. Some countries maintain regularly updated guidance; examples include the 2025 UK Difficult Airway Society (DAS) guidelines for the management of unanticipated difficult tracheal intubation and the 2018 DAS guidelines for tracheal intubation in critically ill patients, German recommendations for patients at risk of aspiration, and the Scandinavian emergency anaesthesia guideline (9-12). Beyond the UK and Europe, many other national guidelines exist, and the Society of Critical Care Medicine (SCCM) has also issued an ICU-focused RSI guideline (13-15). These differences have resulted in international harmonisation efforts such as PUMA (Figure 1) (1). The various components of an RSI are summarised in Table 1.

Figure 1. PUMA Universal Airway Guidelines on the Components of RSI

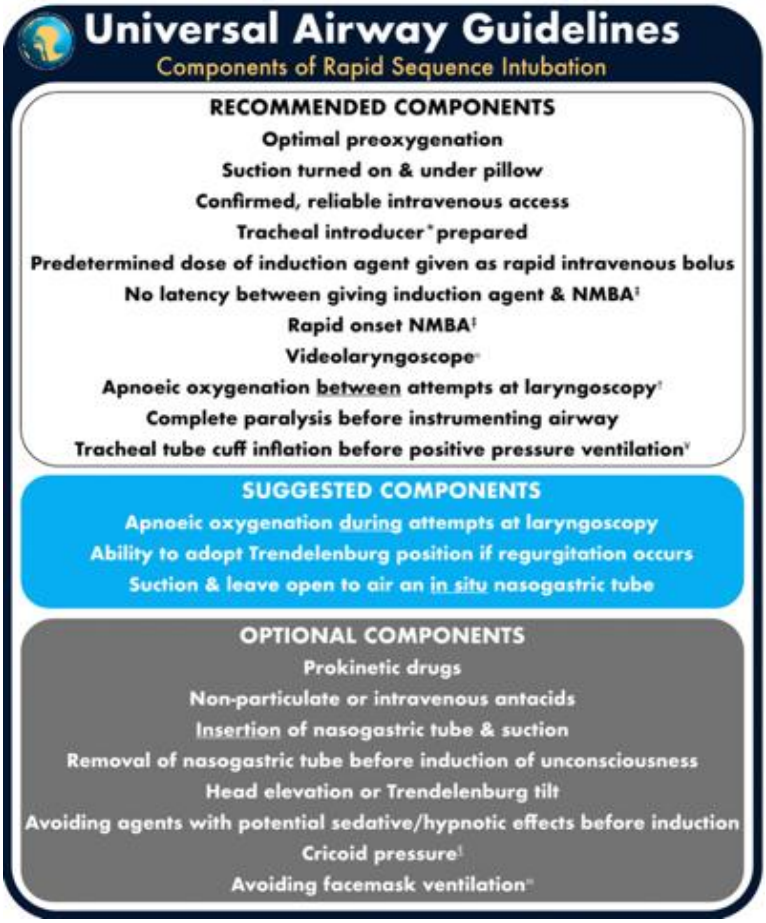


Table 1. Overview on evidence and guidance for the various components of an RSI

Optimal preoxygenation (strategies pre-induction)	There have been multiple studies comparing the effect of using high flow nasal oxygen delivery versus conventional use of a tight-fitting face mask. These have either found no difference in desaturation trends or suggest a possible increased safe apnoea time in the high flow nasal oxygen group (16-18). PREOXI is a 2024 American study that found a reduced incidence of hypoxaemia in emergency intubations carried out using a non-invasive ventilation (NIV) preoxygenation strategy, but this compared the use of NIV to a Hudson facemask pre-induction (19).
Apnoeic Oxygenation & Per-oxygenation (strategies post-induction)	The last decade has seen seminal papers investigating oxygenation including the use of THRIVE (20). Recommendations now support apnoeic oxygenation, via standard nasal cannula at 15 $L \cdot min^{-1}$ or high-flow nasal oxygen, during laryngoscopy or between attempts to mitigate desaturation (9). Positions on mask ventilation during RSI have moved from "no ventilation" towards physiology-guided, gentle ventilation, often with continuous positive airway pressure (CPAP) or NIV where hypoxaemia risk is high; this is most explicit in ICU-focused guidance (13). Where thresholds are stated, pressure-limited ventilation of ≤15–20 cmH_2O is advised to minimise gastric insufflation (10, 12).

Use of drugs to reduce risk of gastric aspiration	PUMA RSI guidance notes that these agents are optional, not recommended or suggested components, due to insufficient evidence for or against their routine use (1). Meta-analyses comparing histamine receptor antagonists (H_2RA) and proton pump inhibitors (PPI) in elective surgery—not RSI—show that H_2RAs are more effective when given as a single preoperative dose, with similar efficacy to PPIs when dosing is repeated or intravenous (21).
Use of NGT	There is no high-quality evidence directly supporting NGT placement, suctioning, or removal as strategies to reduce aspiration during RSI. Large prospective anaesthesia data found no benefit to routine gastric emptying, even in emergencies, except in suspected ileus or obstruction (22). A systematic review of routine NGT decompression post abdominal surgery found no reduction in pulmonary complications or aspiration (23). Guidance from PUMA lists NGT use as optional (1), and SCCM guidelines also recommend that its use be considered if appropriate (13).
Patient positioning	No systematic review or meta-analysis directly addresses patient positioning to reduce aspiration risk during RSI. Observational data in acute abdomen cases combining reverse Trendelenburg with NGT suctioning found no visible gastric content at intubation (24). Retrospective data from emergency intubations show a head-elevated "back-up" position reduces complication odds, including aspiration, by 53% compared with supine (25). PUMA RSI lists head elevation or Trendelenburg tilt as optional components due to insufficient supporting evidence (1). A planned systematic review aims to clarify how positioning affects RSI outcomes (26). DAS 2025 guidelines recommend a head up position for preoxygenation (9).
Use of gastric ultrasound	There is an emerging body of evidence to suggest that the quantitative assessment of gastric contents using ultrasound in patients at risk of pulmonary aspiration may help guide airway management strategies (27). The 2025 DAS guidelines for the management of unexpected difficult tracheal intubation suggest it will become a more widespread skill in this context (9).
Agents for induction and neuro-muscular blockade	There are no large randomised controlled trials comparing induction agents. A survey of UK anaesthetists in 2016 showed that 64% of respondents used propofol (4) and the international INTUBE study demonstrated that the most used agent in the critically ill was also propofol (28). A small single-centre RCT which showed propofol was superior to thiopentone for speed of onset and recovery from anaesthesia (29). A recent review aimed to evaluate the effect of different induction agents. Although they could not draw definitive conclusion based on the quality of the available evidence, they suggested that ketamine may be the most suitable induction agent in critically ill patients in view of the cardiovascular instability associated with propofol and increased risk of adrenal suppression shown with etomidate use (30). A Cochrane review published in 2015 showed that suxamethonium was superior to rocuronium to create optimal intubating conditions. However, this review included doses of rocuronium ranging from 0.6 mg/kg to 1 mg/kg. In subgroup analysis of higher dosages of rocuronium (0.9-1 mg/kg) there was no difference found between suxamethonium and rocuronium (31). The main perceived advantage of suxamethonium is the short duration of action: a recent study showed that reversal of rocuronium with sugammadex led to faster recovery from neuromuscular blockade compared to spontaneous recovery from suxamethonium (32).
Application of cricoid force	In the 4th National Audit Project (NAP4) of the Royal College of Anaesthetists (RCoA) the application of cricoid force was not associated with major airway complications (33). There has been other literature on this topic, including reviews (34-37). Given the lack of conclusive evidence that the application of cricoid force can prevent pulmonary aspiration or worsen laryngoscopy view, guidance on its use has been pragmatic and both the PUMA and 2025 DAS guidelines recommend it is an optional component that may be removed if it hinders laryngoscopy view or oxygenation (1, 9). Importantly it is nationally recommended in the UK that assistants receive regular training in the application of correct cricoid force (9).
Use of video-laryngoscopy and exhaled CO_2 monitoring	In recent years the RCoA has campaigned to raise the issue of undetected oesophageal intubation. Subsequently, there has been a publication and consensus guideline issued by PUMA and international airway societies and the recommendations have been reinforced by the 2025 RCoA endorsed DAS guidelines- these include the routine use of a video-laryngoscope alongside a double airway operator and airway assistant verbalisation of the achievement of sustained exhaled carbon dioxide (38).
Use of RSI checklists	There is evidence to suggest that the use of RSI checklists improves compliance and decreases complications (39). This is also commented upon in the 2025 DAS guidelines (9).

Indications for employing an RSI strategy are also evolving and difficult to delineate.

Although there are some educational articles which recommend specific indications for RSI, a nationally or internationally agreed list of indications does not exist (40). A 2022 *British Journal of Anaesthesia Education* article suggested that indications for RSIs include elective surgery patients with adequate fasting times and risk factors for aspiration, emergency surgery patients without adequate fasting times, emergency surgery patients with adequate fasting times and risk factors for aspiration, critically ill patients and obstetric patients (40). Perceived indications for employing an RSI strategy are of interest given its current use by airway operators from different specialties, the presence of an ageing and increasingly comorbid patient population and emerging technological developments such as the use of gastric ultrasound to determine stomach volume and novel drugs that delay gastric emptying (27, 41).

Meanwhile pulmonary aspiration and other complications from airway management remain an important cause of morbidity and mortality.

Aspiration still incurs significant morbidity and mortality both in theatre and outside of theatre. A US study identified that 5% of anaesthesia-related claims related to aspiration between 2000 and 2014, out of which 14% suffered permanent severe injury and 57% died (42). Within the UK the RCoA conducted the 4th National Audit Project (NAP4) between 2008-2009 looking at major complications of airway management. Aspiration accounted for 20% of airway incidents and approximately 50% of anaesthesia-related deaths – the single biggest cause overall. The estimated rate of fatal aspiration rate in NAP4 was 1 in 360,000. However, most incidents involved patients being inappropriately managed with supraglottic airways (33). More recently, the 7th National Audit Project 2021-2022 (NAP7) demonstrated that pulmonary aspiration remains the most common type of primary airway incident but that recommendations from NAP4 had been adopted and a review of the 25 cases of aspiration found that the patient profile had shifted: most aspiration events now occur in individuals with acute abdominal pathology that have been intubated using an RSI approach (43). This situation was sadly mirrored in a well-known 2024 coronial case of aspiration in a patient undergoing a modified RSI for bowel obstruction using a total intravenous anaesthesia approach (TIVA) (44). NAP7 analysis showed that aspiration accounted for 10% of the airway and respiratory causes of cardiac arrest in the perioperative period (43). The overall estimated incidence of aspiration or regurgitation was 1/670. During the COVID-19 pandemic, AEROCOMP collected data on elective and emergency anaesthesia over a 96-hour period in the UK (apart from Northern Ireland) and reported an aspiration incidence of 1 in 1476 theatre cases, all of which occurred during induction (45). Out of theatre, INTUBE (an international, prospective cohort study across 29 countries) reported an incidence of aspiration of 1 in 25 during all intubations in critically ill patients (28). Other smaller studies in the UK have reported similar rates of about 1 in 9 to 1 in 41 (46-47).

Airway management may also be accompanied by other complications as highlighted by a host of studies (28, 45-47). A spectrum of airway, respiratory, cardiovascular, and mechanical complications can occur. In the operating theatre NAP4 showed that major complications of airway management in theatre are very rare: in the order of 1/20000 anaesthetics (33). Studies in the emergency department and critical care settings report much higher overall complication rates between 10-45% (28, 47-51). The incidences of severe complication outcomes (cardiac arrest, aspiration, oesophageal intubation, airway or dental trauma, and emergency front of neck access) are all higher in studies which take place

out of theatre (28, 46-51). Recently the INTUBE study looked at peri-intubation complications in critically ill patients in emergency departments, wards and intensive care units across 29 countries. The study reported 42.6% of patients developed cardiovascular instability and 9.3% developed severe hypoxia, 5.6% of patients had oesophageal intubation and 4.7% had difficult intubation, 3.9% had aspiration of gastric contents (28). This can be compared to a cross-sectional observational study of elective surgical patients in 39 hospitals within London, UK. The incidences of complications were as follows: desaturation 1.87%, oesophageal intubation 0.11%, difficult intubation 0.85%, aspiration of gastric contents 0.05%. Few studies look specifically at the complications of RSI procedures (52). Adopting an RSI approach is associated with a higher incidence of failed tracheal intubation and an increased risk of accidental awareness under anaesthesia (33, 53).

Systematic identification, reporting and analysis of airway management complications are essential for improvement in clinical practice. However, audits and clinical studies of airway management are hindered by considerable heterogeneity in definitions, severity, grading, and criteria for reporting complications. This variability has driven a movement towards establishing a core outcome set in the recently published ATOM (Airway terminology and outcome measures) project, an international initiative which has developed consensus-based core outcomes and unified terminology for airway research (54). These standardised definitions are adopted where possible within the SECURE protocol.

SECURE aims to provide important insight into the current UK RSI practice to inform future research, education and guidelines.

RSI is a key component of emergency airway management and core skill for airway providers, but the challenges in defining the modern RSI and its components is reflected in both the PUMA guidelines as well as the newly released 2025 DAS guidelines for the management of unanticipated difficult intubation (1, 9). Although these allow for the application of professional judgement in a variety of settings, lack of standardised guidance may affect delivery of care. The Pamela Marking Prevention of Future Death coronial report suggested that the lack of standardised guidelines for the practice of RSI and for the use of TIVA during RSI may be compromising patient safety (44). A joint response from the RCoA, the Association of Anaesthetists, and DAS noted that certain elements of RSI remain controversial, and that high-quality evidence to support or refute individual components is lacking (55). Survey-based research into RSI practice, although able to highlight the great variability in its interpretation and conduct, has well-recognised limitations. When confronted with controversial or sensitive topics, respondents often provide answers they believe will be viewed favourably by others (56-57). This phenomenon, known as social desirability bias, leads to underreporting of undesirable behaviours and overreporting of desirable ones. The discrepancy between reported and actual behaviour (referred to as the say-do gap, or intention-behaviour gap) limits the validity of conclusions drawn from such research (58-59). Notably, there has been no UK-wide registry study examining RSI practice in the modern era and across all specialties.

As a cross-sectional service evaluation study, SECURE aims to characterise the actual variation in components of the modern RSI across all areas of practice and its complications in our contemporary patient population. This will supply a comprehensive snapshot of current national UK practice and will provide the basis for future research, education and guidelines.

3 Overview

3.1 Study type

SECURE is a UK-wide, multi-centre, prospective service evaluation.

3.2 Setting

SECURE will be conducted in **all eligible NHS hospitals across the UK** (England, Wales, Scotland and Northern Ireland).

Independent (private(hospitals without NHS governance structures are not included.

3.3 Hypothesis

We hypothesise that there will be wide variation in resources, team clinical practice and individual self-reported practice in relation to RSI events – in particular, between different clinical areas (theatres, ICU, ED, other remote areas), NHS hospitals and UK regions.

3.4 Aim

To **characterise in-hospital RSIs in adult patients across NHS hospitals in the UK**

3.5 Objectives

- Describe the **availability of local resources** surrounding RSI events
- Capture **contemporary clinical practice** around RSI events performed across all areas of the hospital by cross-specialty intubating teams
- Describe and estimate the incidence of **immediate complications** of RSI events
- To identify the **drivers of variation** in self-reported RSI practice across vignettes
- Compare RSI events across the UK (resources, self-reported practice and observed practice)
- Audit the findings against current recommendations

4 Structure

4.1 Regions

'SECURE regions' will include the same study sites as existing RRNs for anaesthesia (RAFT). ICM (TRIC) and EM (TERN) will ideally follow the same regions as closely as possible.

4.2 Sites

'Study sites' will be defined as single NHS hospitals.
As a study site is a single physical NHS hospital, data will always be collected at each study site. In some cases, it may be appropriate for two (or more) neighbouring study sites in the same Trust / (Health)board to share the same Site Leads / Local Investigators / Consultant Advocate(s). The SECURE Investigation Group will ask Regional Leads for finalised evidence of study site registration in their region in advance of SECURE data collection commencing.

4.3 Eligible hospitals

'Eligible hospitals' will be single NHS hospitals covered by <u>at least one</u> of the following adult speciality services:

- Anaesthesia – elective, urgent, scheduled, or emergency cases/procedures/lists
- EM – consultant-led major ED (A&Es) with full resuscitation facilities
- ICM – level 2 (high-dependency) and/or level 3 (ICU) critical care

4.4 Resident investigators

SECURE will be resident led and delivered by resident doctor investigators across all regions and study sites in the UK. A national recruitment drive will take place across all study sites for each specialty (according to service availability): anaesthetics (RRNs), ICM (TRIC), EM (TERN).

Resident investigators (collaborators) will be residents on anaesthetic/ICM/EM rotas:

- Resident doctors (F1-F2s, CT1-ST7 or equivalent)
- Clinical fellows (equivalent of F2 or above)
- SAS doctors (or locally employed doctors)
- Qualified ACCPs in ICM (or equivalent)
- Qualified Anaesthetic associates (or equivalent)
- Qualified physician associates in EM (or equivalent)

5 Participation

5.1 Investigator roles

All investigators and advocates will be provided with a certificate evidencing their role and will be listed as a collaborator in any publications relating to these roles:

1) **SECURE Regional Leads**
2) **SECURE Site Leads**
3) **SECURE Local Investigators**

} resident investigators (collaborators)

4) **SECURE Site Consultant Advocates**

RAFT is a national organisation that aims to overcome the issues faced by resident doctors with accessing research opportunities during rotational training. With this in mind, we aim for our projects to be resident-led.

Those applying to be Regional Leads and Site Leads will ideally be resident doctors where possible, allocated in collaboration with RRNs/RAFT//TRIC/TERN.

- Regional Leads (per region / specialty) have been recruited and agreed in every region UK – *there will be 1-2 residents per specialty per region*
- Site Leads required (per study site / specialty) will be decided by Regional Leads – *we recommend around 1-3 residents per study site per specialty (no strict upper limit)*
- Regional Leads and Site Leads are encouraged to stay in their role throughout the study
- Priority should be given to those Site Leads that are less likely to rotate during the study period (6 months: February – August 2026) – it is accepted that this may not always be possible
- Information relating to each role will be made available on the RAFT5 SECURE website

1) Regional Leads

Key tasks: regional publicity, Site Lead / Site Investigator recruitment, ongoing Site Lead support

Between 1-2 Regional Leads per specialty in every region:

- Anaesthetic Regional Leads – nominated from existing RRN committees or advertised
- ICU Regional Leads – recruited via TRIC (with support from anaesthetic RRNs)
- ED Regional Leads – recruited via TERN

2) Site Leads

Key tasks: local publicity, study registration with local information governance, Site Investigator recruitment/coverage; Consultant Advocate recruitment, facilitating study site data collection – please see Training, Promotion and Publicity section of this protocol for more detail

<u>At least one</u> Site Lead per (available) speciality in each study site:

- Anaesthetic Site Leads
- ICU Site Leads
- ED Site Leads

** Site Leads may cross-cover two or all three specialties in small study sites, and may cover two or more study sites within the same Trust / (Health)board if required*

3) Local Investigators

<u>Key tasks</u>: Activity Survey publicity, facilitating data collection during 14 day Activity Survey – please see Training, Promotion and Publicity section of this protocol for more detail

<u>Any number of</u> Local Investigators per (available) specialty in each study site:

- Anaesthetic Local Investigators
- ICU Local Investigators
- ED Local Investigators

** Local Investigators may cross-cover two or all three specialties in small study sites, and may cover two or more study sites within the same Trust / (Health)board if required*

4) Site Consultant Advocates

<u>Key tasks</u>: consultant name for information governance, local publicity and support – please see Training, Promotion and Publicity section of this protocol for more detail.

Site Consultant Advocates (or associate specialists) will be recruited by Site Leads – Airway Lead/Research Lead/Departmental Lead consultants are well suited to this role.

<u>At least one</u> Consultant Advocate per study site is <u>mandatory</u> (ie. at least one 'named' consultant) for information governance purposes, including study registration
– please consider having one Consultant Advocate per specialty for larger study sites (in smaller study sites it is acknowledged one for each specialty may not be possible):

- Anaesthetic Consultant Advocates
- ICU Consultant Advocates
- ED Consultant Advocates

** Consultant Advocates may cross-cover two or all three specialities if required, and may cover two or more study sites within the same Trust / (Health)board if required*

5.2 Training, promotion and publicity

This protocol, and information for leads, will be available on the RAFT5 SECURE website https://www.raftuk.org/raft-5-secure. The website will feature a recorded webinar in due course.

Alongside recruitment, an advertising campaign will before and throughout the study at a national, regional and local level. Promotional and survey materials will be provided to leads, including a generic poster (please to be printed out by investigators locally at each study site).

1) Regional Leads

Leads will be provided with promotional materials to disseminate to specialty colleagues in their region and information specific to regional leads will be put on the RAFT5 SECURE website.

2) Site Leads

Site leads will be given materials (promotional and survey posters) to disseminate within their department and information specific to site leads will be on the RAFT5 SECURE website.

3) Local Investigators

Under Site Lead guidance, Local Investigators will help distribute promotional material in the 6-8 weeks before the 14-day Activity Survey at their study site. Site Leads / Local Investigators will provided with survey posters (including the QR code survey link) to display during the Activity Survey across all theatres, ED and critical care.

4) Consultant Advocates

Site Leads are recommended to direct consultants to the RAFT5 SECURE website, where they can find the study protocol and other useful information about the study.

5.3 Investigator availability

In some hospitals, resident investigators may need to cover more than one specialty (particularly where anaesthetic / ICM rotas are 'cross-covered'). Site Leads should organise coverage across the three specialties in a way that works best locally. **The main role of local investigators will be to support intubating teams at their study site during the 14 days of the Activity Survey**:

- Data collection by intubating teams should be promoted using posters in key clinical areas
- Investigators should provide reminders at periodic intervals during the 14 days (e.g. hand-over, messages on work-team Whatsapp groups, checking-in regularly during shift, etc.)
- Availability for in-person troubleshooting should be maximised across theatres, ICU and ED
- Depending on investigator numbers, in-person support out-of-hours may be more limited
- Investigators may use formally agreed non-clinical time (e.g. study leave/EDT) – there is no expectation to use non-clinical time but it may help enhance capture, especially in theatre

5.4 Study registration

Site Leads will work together to complete mandatory Information Governance (IG) registration as outlined on the RAFT5 SECURE website in advance of initial data collection on 1st March 2026.

Any study sites experiencing difficulties registering the study, please inform the SECURE Investigation Group as soon as possible via Regional Leads.

During local study registration with IG departments, please see SECURE letter for study sites in the Appendix (section 10.2) – separate PDF copy downloadable on SECURE RAFT-5 website.

In accordance with good research practice, Site Leads will need to complete the following steps:

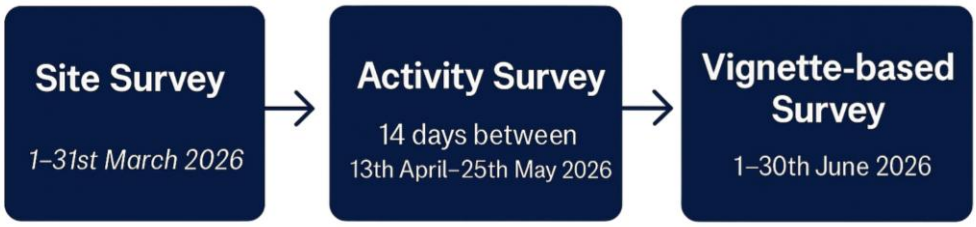
- ✓ **Strongly advised: inform departmental leads** – for each available specialty service (anaesthetics, ICU, ED) it is advisable to inform departmental leads about SECURE
- ✓ **Mandatory: at least one Consultant Advocate(s) per study site** (see instructions above) SECURE 'named' consultant(s) can be any interested consultant(s), or department lead, airway lead, research lead
- ✓ **Mandatory: study registration** – registration of the SECURE with the local Information Governance (i.e. audit / QI department or equivalent) is mandatory, listing Consultant Advocate(s) as the 'named' consultant(s). **The central study team will email Site Leads to ask for evidence of registration from all study sites, which should please be completed ideally by the 13th February 2026 – please inform your Regional Lead if there is a delay.**

  SECURE is a Service Evaluation and does not need to be registered with R&D departments (please speak to your Regional Leads if you experience any difficulty with registration because RLs can liaise with the central study team for further advice if necessary)
- ✓ **Optional: inform the Trust Caldicott Guardian (CG)** – Site Leads can inform their Trust CG if their Information Governance department or local consultants request them to do so

6 Method

6.1 Design

SECURE will consist of three separate surveys of different aspects of in-hospital RSI events in adults: study site resources, actual intubating team activity and individual perceptions. Each study site will collect data during a pre-defined study window for each survey:



6.2 Development

Each survey will be developed by subcommittee 'working groups', based on literature searches and current RSI recommendations (including RCoA, DAS and PUMA). All survey questions will be reviewed by cross-specialty SECURE Expert Advisers / statistician. Questions will be informed by:

- Current guidelines/recommendations relating to RSI
- Informal scoping of the literature
- Previous studies relating to emergency intubation/RSI
- Content of existing airway registries (such as EMAR)

6.3 Survey Completion

1) **Site Survey**
2) **Activity Survey**
3) **Vignette-based Survey**

SECURE study sites must partake in all three surveys to allow full completion of the study.

Before data collection can start on the 1st March 2026, SECURE must be registered at each study site with Information Governance (IG) – please see the Study Registration section 5.4 of this protocol for further details.

It is anticipated that Site Leads will submit full responses to the Site Survey and will target a high capture rate for the Activity Survey and Vignette-based Survey at their study site. During the 14-day Activity Survey, lower-volume hospitals may not capture any RSI events in certain clinical areas. This will be accepted on the presumption that all reasonable efforts have been made to promote the study and facilitate data entry by intubating teams during the 14 days.

1) Site Survey

Summary

This baseline survey will assess the **availability of resources surrounding RSI events**

Rationale

The Site Survey will be a service evaluation mapping out RSI-related resources. It will assess whether these dictate the pattern of clinical activity and decision making around actual observed practice in the Activity Survey. The survey will evaluate variation in resources across different clinical areas, study sites and regions of the UK.

Study window

One month at all study sites: **1st – 30th March 2026**

Completion of the site survey will predate and be a prerequisite for the Activity Survey

Participants

Site Leads will complete the Site Survey for all clinical areas covered by their specialty

Sampling

Site Survey electronic forms (via QR code or link): one form will be made available to Site Leads per clinical area – the form can be printed for subsequent electronic completion if needed

**** Survey entries will not be modifiable locally after submission by Site Leads– erroneous/duplicate entries (including region / study site / clinical area / date / estimated time) should be reported by email to the SECURE Investigation Group (email in section 8)****

Clinical areas

Site Leads will have multiple electronic forms available within a single Site Survey to allow **one electronic form to be filled per clinical area (as services available) – maximum of six forms**:

1) General theatres (non-obstetric) and recovery – *Anaesthetic Site Leads*
2) Obstetric theatres and recovery – *Anaesthetic Site Leads*
3) Remote anaesthesia areas (radiology, ECT, etc.) – *Anaesthetic Site Leads*
4) 'Hospital resuscitation team' areas: emergency resus bag (e.g. wards) – *ICM Site Leads*
5) Critical care areas (ICU, HDU, etc.) – *ICM Site Leads*
6) Emergency department – *EM Site Leads*

Domains

The Site Survey will cover four primary domains:

(i) **Demographics** – including study site type (e.g. tertiary vs. district general hospital), and availability of dedicated anaesthetic, ICM and EM services

(ii) **Infrastructure** – personnel availability and training to identify the presence of staff who routinely perform RSI (by specialty and grade), the training provided (e.g. simulation, airway courses), and the presence of dedicated airway leads

(iii) **Equipment** – availability of physical resources such as video-laryngoscopes, HFNO therapy, capnography, checklists and drugs including induction agents, muscle relaxants and emergency drugs (e.g. sugammadex)

(iv) **Clinical governance** – including debriefing practices, morbidity and mortality meetings, use of incident reporting systems (e.g. Datix), and presence of RSI-related audit or quality improvement processes

Questions

Survey responses will be designed to be categorical and quantitative in nature allowing the participants to select answers from predefined options. The questions will include nominal (e.g. equipment type), numerical (e.g. personnel numbers) and ordinal variables (e.g. availability).

2) Activity Survey

Summary

This survey will capture actual **"user-defined" RSI events and "immediate complications"**

Rationale

The Activity Survey will be a prospective service evaluation of RSI events: modern clinical practice by cross-specialty intubating teams in-hospital in adults. The survey will provide a snapshot across different clinical areas, study sites and regions of the UK. The survey will also describe and estimate the incidence of immediate complications following RSI.

Study window

Continuous 14 days as agreed by all Site leads to run in all clinical areas simultaneously at each study site: between **13th April – 25th May 2026**

Participants

In-hospital cross-specialty intubating teams – contemporaneous data on RSI events will be entered by a nominated member of each intubating team (entry will take less than 15 minutes)

Sampling

Activity Survey electronic form (via QR code or link) – will be available to all intubating teams

**** Survey entries will not be modifiable locally after submission by intubating teams– erroneous/duplicate entries (including region / study site / clinical area / date / estimated time) should be reported by email to the SECURE Investigation Group (email in section 8)****

Definitions

User-defined: any intubation deemed to be an RSI (or modified RSI) by the intubating team that meets inclusion criteria

Immediate complications: in the time-period starting from induction and up to 30 minutes after the airway has been secured

Inclusion criteria

RSI events meeting ALL the following criteria:

- In-hospital (within study site grounds)
- Patients ≥18 years (known or believed)
- Performed by anaesthetic, emergency medicine and/or critical care teams

Repeat RSIs in the same patient will be included as a new event

Exclusion criteria

RSIs events meeting ANY of the following criteria:

- Out-of-hospital (outside of study site grounds)
- Patients <18 years of age (known or believed)
- Not performed by anaesthetics, emergency medicine or critical care teams

Patients with a functioning tracheostomy in-situ

Intubations during cardiac arrest

Domains

The Activity Survey will capture four key domains relating to "user-defined" RSI events:

(i) **Situational aspects** – including location, timing, personnel, roles, grade

(ii) **Patient aspects** – including demographics, indications, aspiration risk

(iii) **Technical aspects** – including preparation, drug administration, airway management

(iv) **Immediate complications** – including airway, respiratory, cardiovascular complications

EMAR

EMAR is a voluntary registry for ED intubations - currently running in about 20-30 EDs around the UK, which routinely enter data into the EMAR database. During the SECURE Activity Survey, any study site that normally collects EMAR data will **temporarily pause EMAR for 14 days.**

The SECURE Investigation Group will transfer anonymised data across from REDCap into EMAR. **Following the 14 day Activity Survey at each study site, EMAR data collection will resume**. All study sites that are not currently part of EMAR will be invited to sign-up to EMAR long-term.

Questions

Consultation with airway experts in anaesthetics, ICM and EM will produce the final questions within the survey. Definitions for immediate complications will be designed to follow the ATOM study (Airway Terminology and Outcome Measures) as closely as possible where relevant (54).

Survey responses will be categorical and quantitative in nature as the questions will require participants to select answers from predefined options or to enter numbers. The option questions in generic terms will include both nominal (e.g. type of equipment) and ordinal variables (e.g. availability of equipment).

3) Vignette-based Practitioner Survey

Summary

This follow-up survey will be designed to identify **drivers of variation** in self-reported RSI practice across vignettes

Rationale

In contemporary practice, the term RSI, or "modified RSI", has evolved into variety of airway management components, some of which lack robust supporting evidence (see Section 2). A few components may be employed routinely, while many others may be used much more selectively. The Activity Survey will provide a contemporary snapshot of how frequently various components are employed by intubating teams in different types of patients and situations.

By contrast, the Vignette-based Survey will evaluate self-reported RSI practice by individual practitioners across iterative clinical scenarios with simplified factorial variation. We hypothesise that the presence of pulmonary aspiration risk, and other physiological challenges related to airway management (including respiratory function, haemodynamic status, neurological status and pregnancy), may drive some of the variation in modern RSI practice.

Study window

1-30th June 2026 (one month) at all study sites

Participants

Healthcare professionals working in anaesthetics/ICM/EM in the UK – respondents must be airway trained (or competent) to participate in intubation decision-making*

*(*Airway trained means post-IAC (or equivalent) for residents, and airway competent means on the GMC consultant specialist register (or equivalent) for anaesthetics/ICM/EM)*

Sampling

Vignette-based Practitioner Survey electronic form (via QR code or link) –
will be distributed cross-specialty across all study sites and regions of the UK throughout

Domains

- **Demographic data** – including speciality, grade and intubations performed
- **Clinical vignettes** – airway scenarios with selectable components of airway management

Questions

Consultation with airway experts in anaesthetics, ICM and EM will produce the final list of vignettes; these will reflect contemporary real-world dilemmas and controversies around RSIs that are relevant to each specialty as well as their perceived indications for RSI. Survey responses will be designed to be categorical in nature as the questions require participants to select answers from a predefined list of nominal variables (different components of RSI in each vignette). An expert in vignette design was consulted during the design process to ensure optimal validity.

6.4 Capture rate

- The Site Survey responses will be referenced against the overall number of study sites and available specialties at each study site – targeting an effective 100% response rate

- In the Activity Survey, there will be no pre-determined method for establishing denominator data. The capture rate will be estimated retrospectively using data on RSI numbers from previous similar single-centre and multi-centre studies, in particular NAP4 and NAP7 (43-44).

- Denominator data for the Vignette-based Survey will be based on the number of airway-trained (or competent) staff on anaesthetic, ICU and ED rotas throughout the UK – this denominator figure will be obtained from college estimates of clinician numbers

6.5 Statistical analysis

All three surveys will be analysed primarily using descriptive statistics. A statistician at the University of Bristol will be consulted to provide expert advice on each survey before national roll-out. The cost of statistical analysis will be in addition to the costings of the grant, funded as required from RAFT and STAR general research-related accounts.

For the Activity Survey we may conduct more detailed exploratory statistical analysis 'ad hoc' depending on the number of RSI events recorded. One key area of interest is around immediate complications and possible associated risk factors (situational, patient and technical factors), where a form of regression analysis may be appropriate to employ with statistician input.

Analysis of the Site Survey and Vignette-based Survey results will summarise participant responses, identify themes and consensus points, and explore differences in responses cross-specialty. This will be in the form of descriptive analysis and further sub-analyses.

7 Ethical / legal considerations

7.1 Service evaluation status

Having reviewed the NHS HRA toolkit, SECURE does not meet criteria for clinical research status. The **HRA has confirmed that SECURE will be considered a service evaluation** –see attached letter in appendix (for further information please contact the central study team).

7.2 Patient Carer and Public Involvement and Engagement (PCPIE)

The RCoA Centre for Research and Improvement (CR&I) has reviewed our proposal for SECURE with the Patient Carer and Public Involvement and Engagement (PCPIE) group. SECURE was reviewed at PCPIE meetings and members were invited to send written feedback.

Overall, the group were supportive of SECURE as a study concept and feedback was positive, including the potential to recruit a patient to review the design of the surveys – the full letter from the PCPIE group is attached to the appendices of this protocol.

7.3 Patient safety

The Activity Survey will not involve any intervention or change to the course of any patients' clinical care. **All individual patient data will be fully anonymised – no patient identifiable data will be collected**. Similarly, no pseudo-anonymised information will be accessible to study sites.

The Site Survey will not collect actual patient data and responses from individual study sites will be kept fully anonymised in the public arena, and only shared privately with study sites if requested.

The responses from individual practitioners in the Vignette-based Survey will be fully anonymised. The Vignette-based Survey will collect no data on actual patients and will run after the Activity Survey to prevent study bias or any influence on patient care.

7.4 Patient consent

On the basis of anonymity, **patient consent will not be required for the Activity Survey**. PCPIE group agree with this approach. The following processes have been followed for each nation:

- **England and Wales** – it has been confirmed through informal correspondence that Confidentiality Advisory Group (CAG) approval will not be required. SECURE does not meet the criteria for a CAG application and SECURE will proceed without needing CAG approval.

- **Scotland** – Public Health Scotland has confirmed PBPP approval will not be required and approval by individual local R&D departments in Scotland will only be needed if requested by

IG. If further information or advice is required, please discuss with the central study team (see email in Section 8)

- **Northern Ireland** – approval for SECURE to proceed in Northern Ireland has been sought and granted through NI-PAC (relevant data sharing agreements as requested by NI-PAC will be signed prior to the start of data collection in March 2026)

7.5 Data protection

All collaborators and the central SECURE Investigation Group will be required to comply with the Data Protection Act 2018 regarding the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

7.6 Data handling

All data will be stored securely in a REDCap database hosted at the NHS Sponsor Site.

The responses from all three surveys (including date, time, region, study site, clinical area) will be collected and stored centrally for safety reasons – this will allow the correction of any erroneous / duplicate data, which should be reported to the SECURE Investigation Group by email (Section 8).

7.7 Reporting and dissemination

We anticipate that the overall outcomes of SECURE will be presented at more than one national and/or international meetings and will be published in potentially multiple peer-reviewed paper(s). We will guarantee that results relating to specific regions and study sites will be fully anonymised and non-identifiable to regions/study sites when reported comparatively within the public arena.

After the results of each Survey have been reported, key findings of interest and relevance will be disseminated privately to study sites that wish to receive a summary report – interim review of results will not be possible. For Information Governance reasons, results will not be disseminated in a regional format.

7.8 Recognition and authorship

Study sites must take part in all three surveys across anaesthetics / ICM / ED (as available) at their site to complete the full study. We anticipate that it is possible, at a few smaller study sites, that zero RSI events will occur out-of-theatre during the 14 days – this will be accepted, on the basis that all reasonable efforts will be made by Site Leads to promote the Activity Survey.

Collaborator delivery networks and endorsing groups will be recognised as organisational 'authors' on relevant peer-reviewed journal publications, depending on their specific contribution. All resident leads, resident investigators and consultant advocates will be provided with a certificate evidencing their role and listed as individual collaborators in related peer-reviewed publications.

8 Project contacts

*If aware of any erroneous/duplicate data,
please email the SECURE Investigation Group as soon as possible
(and include region / study site / clinical area / date / estimated time)*

SECURE Investigation Group

Website: https://www.raftuk.org/raft-5-secure
Email: secure@das.uk.com
We will endeavour to respond to all emails within 7 days.

RAFT

Website: https://www.raftuk.org/
Email: committee@raftuk.org

STAR

Website: https://www.anaesthesiaresearch.org
Email: stargroupresearch@gmail.com

9 References

1. Project for the Universal Management of Airways Group. *Universal Principles for Rapid Sequence Intubation* [Internet]. 2019. Available from: https://www.universalairway.org. Accessed 16 March 2025.
2. Stept W J & Safar P. Rapid induction–intubation for prevention of gastric-content aspiration. *Anesth. Analg.* **49**, 633–636 (1970).
3. Sellick B A. Cricoid pressure to control regurgitation of stomach contents during induction of anaesthesia. *Lancet* **2**, 404–406 (1961).
4. Sajayan A, Wicker J, Ungureanu N, Mendonca C & Kimani P K. Current practice of rapid sequence induction of anaesthesia in the UK: a national survey. *Br. J. Anaesth.* **117**, i69–i74 (2016). doi: 10.1093/bja/aew017.
5. Morris J & Cook T M. Rapid sequence induction: a national survey of practice. *Anaesthesia* **56**, 1090–1097 (2001).
6. Rohsbach C, Wirth S, Lenz K & Priebe H. Survey on the current management of rapid sequence induction in Germany. *Minerva Anestesiol.* **79**, 716–726 (2013). doi:10.1007/s12630-013-0019-3.
7. Ehrenfeld J M, Cassedy E A, Forbes V E, Mercaldo N D & Sandberg W S. Modified rapid sequence induction and intubation: a survey of United States current practice. *Anesth. Analg.* **115**, 95–101 (2012).
8. Zdravković M, Berger-Estilita J, Sorbello M & Hagberg C A. An international survey about rapid sequence intubation of 10,003 anaesthetists and 16 airway experts. *Anaesthesia* **75**, 313–322 (2020). doi:10.1111/anae.14867.
9. Ahmad I, El-Boghdadly K, Iliff H, Dua G, Higgs A & Huntington M, et al. Difficult Airway Society 2025 guidelines for management of unanticipated difficult tracheal intubation in adults. *Br. J. Anaesth.* (2025) doi:10.1016/j.bja.2025.10.006.
10. Higgs A, McGrath B A, Goddard C, Rangasami J, Suntharalingam G & Gale R, et al. Guidelines for the management of tracheal intubation in critically ill adults. *Br. J. Anaesth.* **120**, 323–352 (2018).
11. Eichelsbacher C, Ilper H, Noppens R, Hinkelbein J & Loop T. Rapid sequence induction and intubation in patients with risk of aspiration: recommendations for practical anaesthetic management. *Anaesthesist* **67**, 568–583 (2018).
12. Jensen A G, Callesen T, Hagemo J S, Hreinsson K, Lund V & Nordmark J, et al. Scandinavian clinical practice guidelines on general anaesthesia for emergency situations. *Acta Anaesthesiol. Scand.* **54**, 922–950 (2010).
13. Acquisto N M, Mosier J M, Bittner E A, Patanwala A E, Hirsch K G & Hargwood P, et al. SCCM clinical practice guidelines for rapid sequence intubation in the critically ill adult patient. *Crit. Care Med.* **51**, 1411–1430 (2023).
14. Law J A, Broemling N, Cooper R M, Drolet P, Duggan L V & Griesdale D E, et al. The difficult airway—part 1: difficult tracheal intubation in an unconscious patient. *Can. J. Anaesth.* **60**, 1089–1118 (2013). doi:10.1007/s12630-013-0019-3.
15. Pawar D K, Doctor J R, Raveendra U S, Ramesh S, Shetty S R & Divatia J V, et al. All India Difficult Airway Association 2016 guidelines for the management of

unanticipated difficult tracheal intubation in paediatrics. *Indian J. Anaesth.* **60**, 906–914 (2016).
16. Sjöblom A, Broms J, Hedberg M, Lodenius Å, Furubacke A & Henningsson R, et al. Pre-oxygenation using high-flow nasal oxygen vs tight facemask during rapid sequence induction. *Anaesthesia* **76**, 1176–1183 (2021).
17. Lodenius Å, Piehl J, Östlund A, Ullman J, Jonsson Fagerlund M & [sixth author if exists], et al. THRIVE vs facemask pre-oxygenation for rapid sequence induction: a randomised trial. *Anaesthesia* **73**, 564–571 (2018).
18. Mir F, Patel A, Iqbal R, Cecconi M & Nouraei S A. THRIVE vs facemask pre-oxygenation: randomised controlled trial. *Anaesthesia* **72**, 439–443 (2017).
19. Gibbs K W, Semler M W, Driver B E, Seitz K P, Stempek S B & Taylor C, et al. Noninvasive ventilation for preoxygenation during emergency intubation. *N. Engl. J. Med.* **390**, 2165–2177 (2024).
20. Patel A & Nouraei S A. THRIVE: a physiological method of increasing apnoea time in difficult airways. *Anaesthesia* **70**, 323–329 (2015).
21. Puig I, Calzado S, Suárez D, Sánchez-Delgado J, López S & Calvet X. Meta-analysis: H2-receptor antagonists vs proton pump inhibitors for aspiration risk reduction. *Pharmacol. Res.* **65**, 480–490 (2012).
22. Mellin-Olsen J, Fasting S & Gisvold S E. Routine preoperative gastric emptying is seldom indicated. *Acta Anaesthesiol. Scand.* **40**, 1184–1188 (1996).
23. Nelson R, Tse B & Edwards S. Systematic review of prophylactic nasogastric decompression after abdominal surgery. *Br. J. Surg.* **92**, 673–678 (2005).
24. Ajmal M. Using nasogastric suction without cricoid pressure during rapid sequence induction: outcome in 224 acute abdomen cases. *Surgery Rehabil.* **3**, 1–6 (2019). doi: 10.15761/SRJ.1000152.
25. Khandelwal N, Khorsand S, Mitchell S & Joffe A. Head-elevated positioning decreases complications of emergent tracheal intubation. *Anesth. Analg.* **122**, 1101-1107 (2016). doi: 10.1213/ANE.0000000000001184.
26. Sivajohan A, Krause S C, Hegazy A, et al. Protocol for a systematic review on effective patient positioning for rapid sequence intubation. *BMJ Open* **12**, e062988 (2022).
27. Baettig S J, Filipovic M G, Hebeisen M, Meierhans R & Ganter M T. Preoperative gastric ultrasound in aspiration-risk patients. *Anaesthesia* **78**, 1327–1337 (2023).
28. Russotto V, Myatra S N, Laffey J G, Tassistro E, Antolini L & Bauer P, et al. INTUBE Study Investigators. Intubation practices and adverse events in 29 countries. *JAMA* **325**, 1164–1172 (2021).
29. Yousuf A, Wani S U, Mir S A, Ali T, Jan I & Bader S, et al. Comparative study of thiopentone vs propofol for induction. *Perioper. Care Oper. Room Manag.* **40**, 100513 (2025).
30. Kotani Y & Russotto V. Induction agents for tracheal intubation in critically ill patients. *Crit. Care Med.* **53**, e173–e181 (2025).
31. Tran D T, Newton E K, Mount V A, Lee J S, Wells G A & Perry J J. Rocuronium vs succinylcholine for RSI intubation. *Cochrane Database Syst. Rev.* 2015(10), CD002788 (2015).

32. Chambers D, Paulden M, Paton F, Heirs M, Duffy S & Hunter J, et al. Sugammadex for reversal of neuromuscular block: systematic review. *Br. J. Anaesth.* **105**, 568–575 (2010).
33. Royal College of Anaesthetists; Difficult Airway Society. *4th National Audit Project: Major complications of airway management in the United Kingdom*. London: RCoA; 2011.
34. Ellis D Y, Harris T & Zideman D. Cricoid pressure in ED rapid sequence intubation: risk-benefit analysis. *Ann. Emerg. Med.* **50**, 653–665 (2007).
35. Tessarolo E, Alkhouri H, Lelos N, Sarrami P & McCarthy S. Effectiveness and risks of cricoid pressure: systematic review. *Emerg. Med. Australas.* **34**, 484–491 (2022).
36. Hung K C, Hung C T, Poon Y Y, Wu S C, Chen K H & Chen J Y, et al. Effect of cricoid pressure on intubation: meta-analysis. *Can. J. Anaesth.* **68**, 137–147 (2021).
37. White L, Thang C, Hodsdon A, Melhuish T & Vlok R. Cricoid pressure during intubation: systematic review of RCTs. *Heart Lung* **49**, 175–180 (2020).
38. Chrimes N, Higgs A, Hagberg C A, Baker P A, Cooper R M & Greif R, et al. Preventing unrecognised oesophageal intubation: consensus guideline. *Anaesthesia* **77**, 1395–1415 (2022).
39. Zeuchner J, Graf J, Elander L, Frisk J, Fredrikson M & Chew M S. RSI checklist: effect on compliance and complications. *Acta Anaesthesiol. Scand.* **65**, 1205–1212 (2021).
40. Collins J, et al. Rapid sequence induction and intubation. *BJA Educ.* **22**, 484–490 (2022).
41. El-Boghdadly K, et al. Elective peri-operative management of adults taking GLP-1, GIP, SGLT-2 therapies. *Anaesthesia* **80**, 412–424 (2025).
42. Warner M A, Meyerhoff K L, Warner M E, et al. Pulmonary aspiration of gastric contents: closed claims analysis. *Anesthesiology* **135**, 284–291 (2021).
43. Cook T M, Oglesby F, Kane A D, Armstrong R A, Kursumovic E & Soar J. Airway and respiratory complications: NAP7 report. *Anaesthesia* **79**, 368–379 (2024).
44. Henderson K. Pamela Marking: Prevention of Future Deaths Report. Surrey Coroner Court (2025) [Internet]. Available from: https://www.judiciary.uk/prevention-of-future-death-reports/.
45. Potter T, Cronin J N, Kua J, Nurmi E, Wong D J N & Ahmad I, et al. Aerosol precautions and airway complications. *Anaesthesia* **78**, 23–35 (2023).
46. Gibson J, Leckie T, Hayward J, Hodgson L, et al. South East Anaesthetic Research Chain. Non-theatre emergency airway management. *Anaesthesia* **78**, 1338–1346 (2023).
47. Bowles T M, et al. Out-of-theatre tracheal intubation: multicentre study. *Br. J. Anaesth.* **107**, 687–692 (2011).
48. Sakles J C, Laurin E G, Rantapaa A A & Panacek E A. Airway management in the ED: 610 intubations. *Ann. Emerg. Med.* **31**, 325–332 (1998).
49. Jaber S, Amraoui J, Lefrant J Y, Arich C, Cohendy R & Landreau L, et al. Immediate complications of intubation in ICU: prospective multicentre study. *Crit. Care Med.* **34**, 2355–2361 (2006)
50. Griesdale D E, Bosma T L, Kurth T, Isac G & Chittock D R. Complications of intubation in the critically ill. *Intensive Care Med.* **34**, 1835–1842 (2008).

51. Simpson G D, Ross M J, McKeown D W & Ray D C. Tracheal intubation in the critically ill: national study. *Br. J. Anaesth.* **108**, 792–799 (2012).
52. Shaw M, Waiting J, Barraclough L, Ting K, Jeans J, Black B, et al. Airway events in obese vs non-obese elective surgical patients: a cross-sectional observational study. *Anaesthesia* **76**, 1585–1592 (2021). doi:10.1111/anae.15513.
53. Pandit J J, Andrade J, Bogod D G, Hitchman J M, Jonker W R & Lucas N, et al. NAP5 accidental awareness during anaesthesia. *Br. J. Anaesth.* **113**, 549–559 (2014).
54. Hansel J, Fuchs A, Cornwell B, Haynes K, Tanna V & Mohamed A, et al. Core outcome set for airway management research. *Anaesthesia* (2025) doi:10.1111/anae.70026.
55. Association of Anaesthetists, Royal College of Anaesthetists, Difficult Airway Society. Response to Prevention of Future Deaths report [Internet]. 16 April 2025. Available from: https://www.judiciary.uk/wp-content/uploads/2025/02/2025-0107-Response-from-Association-of-Anaesthetists-RCOA-Difficult-Airways-Society.pdf
56. King M F & Bruner G C. Social desirability bias: a neglected aspect of validity testing. *Psychol. Mark.* **17**, 79–103 (2000).
57. Grimm P. Social desirability bias [Internet]. In: Wiley International Encyclopedia of Marketing (2010) [cited 11 October 2023]. Available from: https://onlinelibrary.wiley.com/doi/10.1002/9781444316568.wiem02057.
58. Sheeran P. Intention–behaviour relations: conceptual and empirical review. *Eur. Rev. Soc. Psychol.* **12**, 1–36 (2002).
59. Sheeran P & Webb T L. The intention–behaviour gap. *Soc. Personal Psychol. Compass* **10**, 503–518 (2016).

10 Appendix

10.1 Patient Carer and Public Involvement and Engagement (PCPIE)

RCoA Royal College of Anaesthetists | CR&I Centre for Research and Improvement

PCPIE Patient, Carer & Public Involvement & Engagement

7th Aug 2025

RE: SECURE

Dear Drs Barnes and Davies,

Many thanks for inviting the RCoA CR&I Patient Carer and Public Involvement and Engagement (PCPIE) group to review your proposal for the above study. As you will be aware, proposals (+/- supporting documentation) are reviewed and discussed at PCPIE meetings, and members are invited to send written feedback. I am writing with a summary of this feedback, which could be used to develop / refine your work, and / or support a case for funding or institutional support.

Overall, the group were supportive of your proposal, and one member commented that "this comprehensive look at the problem [of variation in RSI techniques]is very welcome and has the opportunity to reduce tragic events". In general, they were positive about the plain English summary and were complimentary about its logical structure and concise language. However, one member would have liked some more information, as per the background / justification section.

The group considered the fact that patients would not be directly involved for consent purposes and were comfortable that this is appropriate for this low-risk and non-invasive study. They noted the intention to recruit a patient co-investigator and involve PPI representation in the design of the CRF and were positive about this approach.

We hope that you find this feedback useful, and wish you the very best with progressing the work. Please let us know if you need any more support from us, and we would be very grateful if you would provide us with an update regarding the project as it moves from design to implementation.

Yours Sincerely,

Cliff Shelton
Co-chairperson, PCPIE

10.2 SECURE Letter to study sites

Letter is downloadable as a separate PDF from the SECURE RAFT-5 website: https://www.raftuk.org/raft-5-secure

SECURE

Service Evaluation of Cross-Specialty UK Rapid Sequence Intubation Events

NHS
University Hospitals Bristol and Weston
NHS Foundation Trust

Dr Jonathan Barnes
Department of Anaesthesia
Bristol Royal Infirmary
Upper Maudlin St
Bristol
BS2 8HW

24th November 2025

To whomever this may concern,

Re: SECURE – Service Evaluation of Cross-Specialty UK Rapid sequence intubation (RSI) Events

I would like to confirm that SECURE as a project has been designed, registered and will be delivered as a service evaluation.

Overview

The SECURE service evaluation will be running across the UK in 2026. The study aim is to characterise in-hospital RSIs in adults across NHS hospitals (study sites). SECURE will consist of three distinct elements: a Site Survey (March) of RSI-related resources, an Activity Survey (14 days in April-May) of actual observed RSI practice by intubating teams, and a Vignettes-based Survey (June) of self-reported RSI practice by individual practitioners across a variety of hypothetical clinical scenarios.

Collaborators

SECURE is a resident-delivered project, led by RAFT (Research and Audit Federation of Anaesthetists in Training) in collaboration with Severn Trainee Anaesthetic Research (STAR) group, endorsed by the Royal College of Anaesthetists (RCOA), Royal College of Emergency Medicine (RCEM), National Institute of Academic Anaesthesia (NIAA), the Difficult Airway Society (DAS), and Society for Intravenous Anaesthesia. The project is

being delivered in collaboration with the Emergency Medicine Airway Registry (EMAR) and Emergency Medicine / Intensive Care resident research networks (TERN / TRIC).

Design

This project is designed and designated as a service evaluation on the recommendation of the NHS Health Research Authority (HRA) – ethical approval is not required. No patient identifiable data will be collected (as per HRA definitions), and there will be no direct patient contact or change to patient care in any way. No patient consent will be sought as this is a service evaluation. The design of each survey has been carefully considered to ensure it meets all criteria as a service evaluation.

Delivery

Patient data captured will be entered directly into an electronic data capture form and will not be traceable back to any patient. Data will be entered electronically by local teams of resident doctors and stored on a secure central server. Local data entry teams will not have access to data once it has been submitted. Any Trust-related service data will be kept fully non-identifiable when/if reported in the public arena.

Approvals

Based on the Confidentiality Advisory Group (CAG) online tool, the project does not require CAG approval (England and Wales). We have discussed SECURE with the eDRIS Team at Public Health Scotland, who have confirmed that the project does not require Public Benefit and Privacy Panel (PBPP) approval in Scotland. In Northern Ireland, the Privacy Advisory Committee (PAC) has agreed that the project can proceed following the sign-off of a data sharing agreement.

Registration

The study sponsor site is University Hospitals Bristol and Weston (UHBW) NHS Trust, and SECURE has received Information Governance department approval from the Sponsor Site. Approval from the Caldicott Guardian at the sponsor site was obtained. This project does not require R&D review, but evidence of registration with the audit or

service evaluation departments at all study sites will be required prior to commencing the project.

Delivery

All elements of delivery are designed to ensure clinical and information governance policies are strictly adhered to. This includes mandating that sites do not share any patient-identifiable information, and no patient related data is stored locally.

Summary

This is a service evaluation that does not require registration with R&D, but does require registration with departmental audit/clinical governance/service evaluation departments.

Please do not hesitate to contact the central study team should you require any further information (secure@das.uk.com).

Dr Jonathan Barnes

SECURE Consultant Lead, on behalf of SECURE Investigation Group

Consultant in Cardiac Anaesthesia and Critical Care, Bristol Heart Institute
Honorary Senior Lecturer, University of Bristol
National Executive Committee and Research Committee, ACTACC