1. Protocol details

1.1 PROTOCOL TITLE:

Prevalence of airway complications and association with aerosol precautions – a prospective, multicentre, service evaluation (AeroComp)

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2 List of Abbreviations and Definitions

AC	Airway Complication
AE	Adverse Event
AP	Aerosol Precaution
AR	Adverse Reaction
ASR	Annual Safety Report
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
DMC	Data Monitoring Committee
e-CRF	Electronic Case Report Form
EC	European Commission
GAfREC	Governance Arrangements for NHS Research Ethics Committees
ICF	Informed Consent Form
MA	Marketing Authorisation
MS	Member State
PI	Principle Investigator
Participant	An individual who takes part in a clinical trial
PPE	Personal Protective Equipment
QA	Quality Assurance
QC	Quality Control
SAD	Supraglottic airway device
SAE	Serious Adverse Event
SDV	Source Document Verification
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TMG	Trial Management Group
TSC	Trial Steering Committee

3 Summary/Synopsis

Title	Prevalence of airway complications and association with aerosol precautions – a prospective multicentre service evaluation
Protocol Short Title/Acronym	AeroComp
Protocol Version number and Date	v1.2 (13/10/2021)
Study Duration	5 days
Lead Site	Guy's and St. Thomas' NHS Foundation Trust
Chief Investigator	Dr Kariem El-Boghdadly
Medical condition or disease under investigation	Perioperative airway complications
Purpose of service evaluation	Identify current usage of aerosol precautions and incidence of airway complications in patients undergoing general anaesthesia.
Primary objective	Identify current rate of airway complications (defined as a composite of multiple individual components) in patients undergoing general anaesthesia for elective and emergency procedures.
Secondary objective(s)	- Risk of the primary outcome stratified by each individual component of the aerosol precaution bundle - Individual complications that comprise the primary objective (airway trauma, aspiration, desaturation, difficult intubation, difficult ventilation, second intubator required, laryngospasm, failed intubation, emergency front-of-neck airway, oesophageal intubation). - Association between risk of airway complications and patient COVID-19 status.
Number of Subjects/Patients	~3600
Study Type	Service evaluation
Endpoints	*Primary Endpoint* ● Composite outcome of perioperative airway complications *Secondary Endpoints* ● Individual airway complications ● Components of the aerosol precaution bundle
Main Inclusion Criteria	Adult patients undergoing general anaesthesia for relevant procedures during the pre-defined study window (as defined by this study, see ***Section 7***) within hospitals affiliated with the Pan-London Perioperative Audit and Research Network (PLAN) and other regional trainee networks
Data collected/storage (if applicable)	Anonymised data will be stored on the PLAN REDCap secure data capture server.

4 Introduction

Although most airway management is uncomplicated, when complications occur they can be catastrophic resulting in significant morbidity and mortality [1]. The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) pandemic has resulted in significant changes to airway management [2] due to concern over transmission of aerosolised virus particles to healthcare professionals [3]. Initial reports suggest that patients infected with SARS-CoV-2 may be more at risk of airway complications including hypoxaemia [4], airway trauma [5], and airway oedema [6]. While it is possible SARS-CoV-2 itself may be a risk factor for airway complications, aerosol precautions, designed to reduce the transmission of virus particles to healthcare workers, may also contribute. These aerosol precautions include modified anaesthetic techniques, unfamiliar equipment, and personal protective equipment (PPE).

Anaesthetic management varies, in part, depending on the patient's coronavirus disease 2019 (COVID-19) status. Personal protective equipment for droplet precautions is advised for staff dealing with COVID-19 negative patients and comprises eye protection, gloves, and surgical facemasks at the minimum [7]. COVID-19 positive or COVID-19 unknown patients require staff to use a greater level of aerosol precaution PPE, comprising respirator masks (e.g. FFP3), long-sleeved gowns, gloves and eye protection. It is currently not known whether use of aerosol precaution PPE and other methods used to reduce viral transmission during airway interventions increases the risk of airway complications, but it may be a contributing factor to difficult intubations reported in COVID-19 patients [6, 8].

We aim to describe airway management and the different components of the bundle of aerosol precautions used to protect healthcare workers, and report the associated incidence of airway complications.

5 Trial objectives and purpose

Aims

1. To determine the incidence of airway complications in patients undergoing general anaesthesia during the COVID-19 pandemic.
2. To identify components of the aerosol precaution bundle (including PPE and anaesthetic techniques) which may be associated with a greater risk of airway complications.

6 Study design & Flowchart

6.1 Study Design

AeroComp is service evaluation exploring the incidence of airway complications amongst patients undergoing general anaesthesia for surgical procedures within NHS Trusts. All adult patients undergoing any surgical procedure (with the exception of obstetric procedures) with the primary method of anaesthesia planned to be general anaesthesia will be eligible for enrolment to this study. The study duration will encompass 5 days (patients being enrolled over a 96 hour consecutive window with a further day of follow-up data collection) with an estimated total of 3600 patients being included. Individual sites are free to choose their own data collection window between 1st November

2021 and 3rd December 2021 as long as the 96 hour window commences at 07:30 on a Monday and closes at 07:29 on a Friday.

Primary outcome:

- Incidence of airway complications at both induction and emergence, defined as a composite of: airway trauma, aspiration, dental/lip/mucosal injury, change of intubation device, desaturation, three or more laryngoscopy attempts, grade 3 or 4 laryngoscopy, difficult face mask ventilation, difficult supraglottic airway device (SAD) usage, emergency front-of-neck airway, failed tracheal intubation, laryngospasm, oesophageal intubation (immediate or delayed recognition), requirement of reintubation immediately after extubation, and need for second intubator.

Secondary outcomes:

- Risk of composite outcome of airway complications will be reported for each individual component of the aerosol precaution bundle.
- Individual complications that comprise the primary outcome.
- Subjective operator assessment of airway difficulty
- Unanticipated airway difficulties necessitating significant deviation from the original airway plan.
- Composite risk of airway complication and association with confirmed/suspected COVID-19 infection, known negative COVID-19 infection without any potential COVID-19 risks, and all other patients.

7 List selection

Operating lists from all participating NHS hospitals will be included, with patients from those lists being eligible. Both elective and emergency cases will be included. The centres and local investigators will be identified by the Pan-London Perioperative Audit and Research Network (PLAN) or other national trainee research networks.

Data will be collected over a continuous 96-hour period (07:30 Monday until 07:29 Friday). For all cases, the start time of the procedure will be the time point of the first set of observations on the anaesthetic chart and used to identify those patients to include.

7.1 Patient inclusion criteria

- Adult patients (≥ 18 years of age)
- Undergoing a surgical, radiological or cardiological procedure (interventional or diagnostic) with the primary method of anaesthesia planned to be general anaesthesia

7.2 Patient exclusion criteria

- Paediatric patients (< 18 years of age)
- Patients where the induction of general anaesthesia occurs in the emergency department (ED), critical care unit or general ward
- Patients in cardiac arrest at the time of airway intervention
- Patients having obstetric procedures (pregnant patients undergoing non-obstetric surgery will be included)

- Procedures planned to be performed under regional anaesthesia, local anaesthesia or sedation
- First set of observations outside the 96-hour study period
- Patients already with an airway device in place (e.g. ventilated patients transferred from ITU, tracheostomy)

8 Project procedures

8.1 Patient inclusion

Patients will be identified as eligible by local investigators using methods specific to the centre, however this will likely involve published operating lists and emergency theatre bookings. All eligible patients will be included if possible.

9 Data

9.1 Data to be collected

Data will be collected on all operating lists with patients who meet inclusion criteria in participating hospitals. Each hospital taking part will have nominated staff who will be responsible for data collection.

For each day of the study the local investigating team will determine the total number of patients eligible for inclusion.

For each included patient, the anaesthetist or anaesthetic assistant (e.g. operating department practitioner, anaesthetic nurse) will be asked to complete a paper case record form (CRF; ***Appendix 2***). Where more than one anaesthetist is involved, the most senior anaesthetist should be asked to complete the CRF.

Completed CRFs will be collected from the treating anaesthetic team. Local investigators will be responsible for ensuring accuracy and completeness of data. Where appropriate, this should include cross-checking with patient notes and other sources of information.

Completed CRFs will be stored in a secure location accessible by the local PI and other named members of the study team in accordance with NHS Information Governance standards. Information from each paper CRF, as well as the total number of eligible patients for each day of the project, will be entered via a secure web-based portal onto a secure database. The database will have data validation rules built-in to ensure accurate data entry (e.g. range checks, and field validation).

No patient-identifiable information will be uploaded to the secure database. Each site may elect to use a local ID upon the CRF to facilitate retrospective data capture within the immediate time frame of the project however this should be detached once the CRF is completed and will not form part of the dataset uploaded to the data capture server. Paper CRFs will be retained by the local study team in a locked, secure location in the hospital for a period of 6 months after the project ends to allow queries about study quality to be addressed during data cleaning and analysis. The local ID will not remain upon the CRF during this period.

Additionally, the lead for each site will submit, via the on-line REDCap system, the study week that site has selected (from one of weeks commencing 1st, 8th, 15th, 22nd or 29th November), the total number of eligible procedures for each 24 hour period of the study, and the list of all local investigators involved in the study (to enable production of certificates to demonstrate involvement as well as to allow naming of all collaborators on any manuscripts arising from the study). The site details data capture form is provided in ***Appendix 3***.

All investigators and any other individuals contributing to the study will be required to comply with the Data Protection Act 2018 and the NHS code of confidentiality.

Data to be collected:

- Site (automatically populated dependent upon the login credentials of the local investigator)
- Day of the study
- Age of patient (grouped into 18-39, 40-59, 60-79 and ≥ 80 years)
- Sex of patient
- American Society of Anesthesiologists (ASA) physical status
- Patient body mass index (BMI), grouped into underweight (< 18.5 kg/m^2), normal (18.5 – 24.9 kg/m^2), overweight (25.0 – 29.9 kg/m^2), class 1 obesity (30.0 – 34.9 kg/m^2), class 2 obesity (35.0 – 39.9 kg/m^2), class 3 obesity (>= 40.0 kg/m^2)
- Surgical urgency (elective; expedited; urgent; emergency)
- Start time of procedure (first set of observations entered into the anaesthetic record), grouped into daytime (07:30–17:59); evening (18:00–23:59); and overnight (00:00–07:29)
- Surgical specialty
- Surgical severity (minor; intermediate; major)
- Location of procedure: within or outside the main operating theatre complex (including stand-alone day surgery units), used to identify “remote-site anaesthesia”.
- Grade of anaesthetist managing airway (initial airway manager and second airway manager if required)
- PPE worn by anaesthetist managing airway:
  - Eye protection: visor; goggles; other
  - Respiratory protection: surgical mask; disposable FFP2/3 mask; re-usable FFP2/3 mask; powered air-purifying respirator; other
  - Body protection: plastic apron; long-sleeved gown; hazmat suit; other
  - Gloves: single pair; double pair; other
- Airway management technique- pre-oxygenation, mask ventilation, apnoeic oxygenation
- Airway equipment utilised to maintain oxygenation and facilitate anaesthesia, divided into:
  - Airway devices utilised: facemask, supraglottic airway device; tracheal tube; other (including rigid bronchoscope, jet ventilator and transnasal humidified rapid-insufflation ventilatory exchange)
  - Airway techniques including: direct laryngoscopy; videolaryngoscopy; use of a flexible bronchoscope over which a tracheal tube is passed, categorised into whether performed awake or asleep
  - Use of cricoid force?

- Adjunct equipment including: bougie; stylet; Oxford or HELP pillow; high and low-flow nasal cannulae; aerosol boxes or drapes; as well as a free text option for other potential equipment

- Patient COVID-19 status:
    - Positive: RT-PCR or lateral flow test positive for SARS-CoV-2; OR symptoms consistent with COVID-19 with no SARS-CoV-2 test available; OR recent exposure to SARS-CoV-2
    - Negative: RT-PCR or lateral flow test negative for SARS-CoV-2 infection; AND actively cohorted with other COVID-19 negative patients for the entirety of their hospital stay prior to this operation; AND self-isolated according to institutional guidelines.
    - Unclear: No SARS-CoV-2 result available with no risk factors; OR not self-isolated according to institutional guidelines; OR not in a COVID-19-free pathway.
- Whether anaesthesia was terminated at the end of the procedure with a plan to wake up the patient (emergence from anaesthesia).

Airway complications:

- Number of tracheal intubation attempts.
  An attempt is defined by the number of times the laryngoscopy device is inserted or re-inserted into the patient's airway.

- Best grade of laryngoscopy: modified Cormack and Lehane grading [9] into 1, 2a, 2b, 3 and 4.

- The following complications categorised into induction and emergence (defined as the period around the time of cessation of anaesthesia until hand over of patient to recovery/intensive care staff):
    - Airway trauma: evidence of airway bleeding or oedema.
    - Dental injury (arising solely from anaesthetic, rather than surgical, interventions)
    - Lip and mucosal injuries (arising solely from anaesthetic, rather than surgical, interventions)
    - Pulmonary aspiration: inhalation of oropharyngeal or gastric contents into the larynx and lower respiratory tract [10]
    - Change of intubation device: use of an additional airway device, e.g. change from supraglottic airway to tracheal tube, change from direct to videolaryngoscopy (or vice versa), use of bougie if not initially anticipated, change in type of laryngoscope e.g. McCoy vs Macintosh blade
    - Desaturation: reduction in oxygen saturations to ≤90% during airway management
    - Severe Desaturation: reduction in oxygen saturations to ≤80% during airway management
    - Difficult mask ventilation: need for two-person (or more) mask ventilation
    - Difficult SAD insertion: multiple insertion attempts; excessive leak; insufficient ventilation; change of SAD size/design

- Failed tracheal intubation even after intervention of a second airway manager, including:
  - If oxygenation and provision of anaesthesia was possible via SAD and a decision was made to continue with surgery
  - If a decision was made to wake the patient and abandon surgery
  - If this resulted in death this should be recorded separately, as above
- Laryngospasm: unwanted muscular response of the larynx that produces partial or complete obstruction of the laryngeal airway [11].
- Oesophageal intubation (recognised): tracheal tube placed in the oesophagus and recognised before delivery of the fourth ventilatory breath
- Oesophageal intubation (delayed recognition): tracheal tube placed in the oesophagus and 4 or more ventilatory breaths delivered.
- Reintubation within 30 minutes of the end of the procedure
- Second airway manager: initial airway manager either requests the assistance of a second individual to directly manage the airway or the supervising anaesthetist requests a second individual to take over management of the airway.
- Emergency front-of-neck airway
- Death due to hypoxia or other complication of airway management.
- Significant deviation from original airway plan
- Subjective assessment of ease of 1) mask ventilation, 2) SAD placement and use, and 3) tracheal intubation, using a 5-point Likert scale (1-5) with addition of "not attempted" for each question

9.2 Data handling and record keeping

All investigators and study staff will be required to comply with the requirements of the Data Protection Act 2018 with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Data will be collected onto paper CRFs by either local investigators or the anaesthetic team involved with the case. If local IT capabilities permit, data may be directly uploaded to the data capture service. Local investigators will also upload the total number of eligible patients for each 24 hour period of the study to identify capture rate.

Data will be uploaded by local investigators to the PLAN secure data capture server (https://www.planasm.org/redcap) which is hosted in a secure Tier 2 data centre in London Docklands with regular backup. The interface will use the REDCap v10.4.1 electronic CRF software. A REDCap ID for each patient included will be provided by the system for each new e-CRF uploaded. No uploaded data will contain patient-identifiable information.

All collected data will be anonymised. The following steps have been undertaken to ensure that patients cannot be reidentified from the collected data:
1) All ages are collected in bands.
2) No specific operation/procedure name is collected.
3) The date of surgery is not specifically collected, purely the day of the week upon which it took place in any one of five weeks within the data collection period.
4) No name, hospital number or NHS number is uploaded to the data collection server.

5) All sites are required to register the service evaluation with local Clinical Governance departments prior to recruitment to ensure any local issues are handled appropriately.
6) Caldicott Guardian approval at the lead site has been obtained (available to sites upon request)
7) Information Governance approval at the lead site has been obtained (available to sites upon request).

10 Statistical considerations

10.1 Sample size calculation (some pilot/feasibility studies may not require a formal sample size calculation)

Shaw *et al.* [12] reported an incidence of 91 airway complications in 1874 patients (~5%). Therefore, assuming an anticipated 5% incidence of our primary outcome in our study population, a desired error of +/-1% (absolute error) of our estimate for the incidence, and a 95% confidence level of achieving the desired estimate precision, we calculate the sample size required for our study to be ≥1822 patients (Appendix 4; [13]). For a conservative estimate, with 50 centres each performing 18 procedures a day, we expect 3600 patients to be included, allowing acceptable rates of detection of rare events.

10.2 Statistical analysis

Incidence of airway complications amongst the sampled population will be reported as a composite of airway complications as mentioned in **Section 9**.

Continuous data will be reported using means (standard deviation, SD) or medians (interquartile ranges [range]) where appropriate. Categorical data will be reported as numbers (percentages, %) with 95% confidence intervals (CI) calculated using an appropriate method, where applicable. A p value of < 0.05 will be considered as statistically significant. Relationships between categorical variables and outcome measures will be presented as univariate odds ratios with accompanying p-values (Pearson's Chi-square test with Yates' continuity correction). Univariable logistic regression models will be fitted to investigate potential associations between variables describing patient, operator or procedural characteristics and the primary outcome of incidence of airway complications. A multivariable logistic regression model will then be fitted to include all covariates to obtain adjusted association estimates. Variables included in the regression modelling will be selected based on scientific and clinical plausibility of affecting the outcome of airway management.

11 Ethical considerations

This study is designed as a service evaluation, and no ethical approval is expected to be required. As we are collecting routinely captured data with no patient identifiable data, and will not involve either direct patient contact or influence their care in any way, no patient consent will be required. Approval from the Caldicott Guardian at the lead site (Guy's and St. Thomas' NHS Foundation Trust, London, UK), and audit registration at all recruiting centres will be required prior to commencing the project. Participating hospitals will ensure that their local investigators will be appropriately trained, but no GCP certification will be required from investigating teams as this is a service evaluation. The local PI will ensure that no patient identifiable information will be stored during the study.

12 Financing and Insurance

No funding will be required for this study. All investigators will be NHS employees working in their respective trusts and standard NHS Indemnity will apply.

13 Reporting and dissemination

Where possible, we plan to present the results of the project in peer-reviewed journals or other conference presentations to communicate findings to the community and provide updates on potential best practices for personnel risk mitigation. The anonymised dataset will be made available to other researchers within the field upon reasonable request.

14 References

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15 Appendices

15.1 Appendix 1 - Protocol amendment / Revision history

Version Stage	Version No.	Version Date	Protocol updated & finalised by	Appendix No. Detail the reason(s) for the protocol update
	1.0	**17/09/2021**	**Dr Kariem El-Boghdadly** **Dr John Cronin** **Dr Tom Potter** **Dr Justin Kua** **Dr Eveliina Nurmi** **Dr Danny JN Wong** **Professor Tim Cook** **Dr Imran Ahmad**	**Subject to Final Approval**
	1.1	**30/09/2021**	**Dr Kariem El-Boghdadly** **Dr John Cronin** **Dr Tom Potter** **Dr Justin Kua** **Dr Eveliina Nurmi** **Dr Danny JN Wong** **Professor Tim Cook** **Dr Imran Ahmad**	**Changed layout of CRFs** **Split airway device usage into awake/asleep** **Defined surgical urgency** **Added non-binary sex option**
Current	**1.2**	**13/10/2021**	**Dr Kariem El-Boghdadly** **Dr John Cronin** **Dr Tom Potter** **Dr Justin Kua** **Dr Eveliina Nurmi** **Dr Danny JN Wong** **Professor Tim Cook** **Dr Imran Ahmad**	**Removed Research Questions section as this is a service evaluation, not research.** **Reworded use of local ID to make it explicit this is removed prior to storage of CRFs.** **Add section to Data Handling describing anonymised data.**

15.2 Appendix 2 – Sample Case Record Form (CRF)

AEROCOMP

Study Day[1]: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday

Study ID: _____

Hospital: _____

PATIENT DETAILS

Age: ☐ 18 to 39 ☐ 40 to 59 ☐ 60 to 79 ☐ 80 and over

Sex: ☐ Male ☐ Female ☐ Other

ASA Score: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

BMI (kg/m^2): ☐ < 18.5 ☐ 18.5 – 24.9 ☐ 25.0 – 29.9 ☐ 30.0 – 34.9 ☐ 35.0 – 39.9 ☐ ≥ 40.0

PATIENT COVID-19 STATUS

☐ Positive *(PCR/LFT positive; COVID-19 symptoms; recent exposure)*

☐ Negative *(PCR/LFT negative and self-isolated and cohorted in COVID-19 free pathway)*

☐ Unclear *(No test result available with no risk factors; not self-isolated; not cohorted in COVID-19-free pathway)*

SURGICAL DETAILS

Surgical urgency[2]: ☐ Elective ☐ Expedited ☐ Urgent ☐ Emergency

Severity[3]: ☐ Minor ☐ Intermediate ☐ Major

Specialty: ☐ Breast ☐ Bariatric ☐ Cardiac ☐ Cardiology ☐ Dental ☐ Other: _____ ☐ ENT ☐ General ☐ Gynaecology ☐ Max-Fax ☐ Neurosurgery ☐ Ophthalmology ☐ Ortho/Trauma ☐ Plastics ☐ Radiology ☐ Thoracic ☐ Transplant ☐ Urology ☐ Vascular

Procedure performed within main operating theatre complex: ☐ Yes ☐ No

ANAESTHETIC DETAILS

Start time[1,4]: ☐ 00:00 to 07:29 ☐ 07:30 to 17:59 ☐ 18:00 to 23:59

Grade of initial airway manager[5]: ☐ CT1-2 ☐ ST5-7 ☐ Consultant ☐ CT/ST3-4 ☐ SAS/SCF ☐ Other

Grade of second airway manager[5,6]: ☐ CT1-2 ☐ ST5-7 ☐ Consultant ☐ CT/ST3-4 ☐ SAS/SCF ☐ Other

PPE worn by anaesthetist managing airway: *(tick all that apply)*

Eye protection: ☐ Goggles or safety glasses ☐ Visor (or PAPR hood) ☐ Other _____

Body protection: ☐ Plastic apron ☐ Long-sleeved gown ☐ Hazmat suit ☐ Other _____

Respiratory protection: ☐ Surgical face mask ☐ Disposable FFP2/3 respirator ☐ Re-usable FFP2/3 respirator ☐ Powered air purifying respirator (PAPR) ☐ Other _____

Gloves: ☐ Single pair of gloves ☐ Double pair of gloves ☐ Other _____

AIRWAY MANAGEMENT (tick all that apply)

Induction: ☐ Inhalational ☐ Intravenous: non-RSI ☐ Intravenous: RSI/modified RSI

Oxygenation: ☐ Pre-oxygenation ☐ Post-induction mask ventilation ☐ Apnoeic oxygenation

Airway device: ☐ Face mask (as sole airway device) ☐ Supraglottic airway device ☐ Tracheal tube ☐ Other[7]

Equipment: ☐ Bougie ☐ Stylet ☐ Oxford pillow ☐ High-flow nasal cannulae ☐ Low-flow nasal cannulae ☐ Clear plastic 'aerosol' box ☐ Other: _____

Airway technique:	Awake	Asleep
Direct laryngoscopy	☐	☐
Video laryngoscopy	☐	☐
Flexible bronchoscope	☐	☐

Was there a significant deviation from the original airway plan? ☐ Yes ☐ No

Was cricoid force used? ☐ Yes ☐ No

Subjective ease of face mask ventilation: ☐ Not attempted ☐ 1 (Easy) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (Difficult)

Subjective ease of SAD insertion: ☐ Not attempted ☐ 1 (Easy) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (Difficult)

Subjective ease of tracheal intubation: ☐ Not attempted ☐ 1 (Easy) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (Difficult)

AIRWAY COMPLICATIONS (tick all that apply)

Tracheal intubation attempts[8]: ☐ 1 ☐ 2 ☐ 3 ☐ >3

Best grade of laryngoscopy[8]: ☐ 1 ☐ 2a ☐ 2b ☐ 3 ☐ 4

Was the patient woken up at the end of surgery?[9] ☐ Yes ☐ No

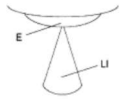
Airway complications: *(tick all that apply)*	Induction	Emergence[9]
Airway trauma	☐	☐
Aspiration	☐	☐
Change of intubation device	☐	☐
Death[10]	☐	☐
Dental injury	☐	☐
Desaturation (SpO_2 ≤90%)	☐	☐
Desaturation (SpO_2 ≤80%)	☐	☐
Difficult mask ventilation (2-person technique)	☐	☐
Difficult SAD (excessive leak, poor ventilation, hypoxia)	☐	☐
Emergency front-of-neck airway	☐	☐
Failed tracheal intubation – continue with SAD	☐	☐
Failed tracheal intubation – awaken patient	☐	☐
Laryngospasm not reversed with positive pressure	☐	☐
Lip/mucosal injury	☐	☐
Oesophageal intubation (recognised)[11]	☐	☐
Oesophageal intubation (delayed recognition)[11]	☐	☐
Reintubation immediately post-procedure[9]	☐	☐
Second airway manager required[6]	☐	☐

PLEASE DETACH THIS SECTION AND SECURELY DISCARD ONCE DATA COLLECTION IS COMPLETE

Local ID: _____

AeroComp Case Record Form v1.2 Notes

1) The study day is defined as the time period from 07:30 on the specified day until 07:29 the following morning. Thus, if an operation commences at 04:00 on Friday morning, the "Study Day" should be Thursday, and Start Time should be 00:00 to 07:29.
2) Surgical urgency is defined as per NCEPOD (https://www.ncepod.org.uk/classification.html)
    a. Immediate – Immediate life, limb or organ-saving intervention – resuscitation simultaneous with intervention. Normally within minutes of decision to operate.
    b. Urgent – Intervention for acute onset or clinical deterioration of potentially life-threatening conditions, for those conditions that may threaten the survival of limb or organ, for fixation of many fractures and for relief of pain or other distressing symptoms. Normally within hours of decision to operate.
    c. Expedited – Patient requiring early treatment where the condition is not an immediate threat to life, limb or organ survival. Normally within days of decision to operate.
    d. Elective – Intervention planned or booked in advance of routine admission to hospital. Timing to suit patient, hospital and staff.
3) Surgical severity is defined as per NICE guidance NG45 (https://www.nice.org.uk/guidance/ng45/chapter/recommendations). Examples include:
    a. Minor – Excising skin lesion, draining breast abscess.
    b. Intermediate – Primary repair of inguinal hernia, excising varicose veins in the leg, tonsillectomy or adenotonsillectomy, knee arthroscopy.
    c. Major – Total abdominal hysterectomy, endoscopic resection of prostate, lumbar discectomy, thyroidectomy, total joint replacement, lung operations, colonic resection, radical neck dissection.
4) Start time should be the time of the first set of observations upon the anaesthetic record.
5) SAS – specialty and associate specialist; SCF – senior clinical fellow. If no exact match is presented please choose the closest equivalent grade.
6) Second airway manager: if a second individual took over management of the airway following management by the initial airway manager their grade should be recorded here and "second airway manager required" ticked within the complication section. Leave blank if not applicable.
7) Other: this applies to, for example, rigid bronchoscopes, jet ventilators and transnasal humidified rapid-insufflation ventilatory exchange. This should be ticked only if it was the primary airway device following induction of anaesthesia. Typically this will be a planned technique involving pre- +/- per-oxygenation following discussion with the operating surgeon beforehand. Also select if the primary means of oxygenation during the procedure is via a surgically placed jet ventilator (e.g. laryngeal procedures) and no other airway device is placed prior or subsequently by the anaesthetist. The exact device used does not have to be specified.
8) Tracheal intubation attempts/laryngoscopy grade should be left blank if intubation is not attempted. The grade here refers to the Cormack and Lehane system as modified by Yentis and Lee, shown below.
9) If the patient was not woken up at the end of surgery, emergence complications should not be recorded. If the patient was woken up and then immediately reintubated, this should be recorded as: Woken up: Yes; Reintubation immediately post-procedure: On emergence.
10) Only death due to hypoxia or another complication of airway management should be recorded.
11) Recognised oesophageal intubation is detected after the first but before the fourth ventilatory breath has been delivered. Delayed recognition is when four or more ventilatory breaths have been delivered.

Original Cormack and Lehane system	1 Full view of the glottis	2 Partial view of the glottis or arytenoids		3 Only epiglottis visible	4 Neither glottis nor epiglottis visible
View at laryngoscopy					
Modified system	1 As for original Cormack and Lehane above	2a Partial view of the glottis	2b Arytenoids or posterior part of the vocal cords only just visible	3 As for original Cormack and Lehane above	4 As for original Cormack and Lehane above

E = epiglottis, LI = laryngeal inlet. From Yentis SM, Lee DJH. (1998) Grading of direct laryngoscopy. Anesthesia. 53:1041-4.

15.3 Appendix 3 – Site Details Data Capture Form

AeroComp Site Details Data Capture Form v1.2

Data to be submitted via REDCap prior to commencement of study:
https://planasm.org/redcap
Please use the "AeroComp – Site Details" project and the "BEFORE Study" eCRF

Site Name:

Trust:

Consultant Lead Investigator:

First Name(s): Last Name:

e-mail:

Trainee Lead Investigator:

First Name(s): Last Name:

e-mail:

Selected Study Week:

1st-5th November	
8th-12th November	
15th-19th November	
22nd-26th November	
29th November – 3rd December	

AeroComp Site Details Data Capture Form v1.2

Data to be submitted via REDCap following completion of data collection:
https://planasm.org/redcap
Please use the "AeroComp – Site Details" project and the "AFTER Study" eCRF

Total number of eligible patients for each 24-hour period (07:30 through to 07:29 the following day):

Monday	
Tuesday	
Wednesday	
Thursday	

List of all contributing investigators including their roles:
https://planasm.org/redcap
Please use the "AeroComp – Investigators List" project

Please ensure these are accurate as these details will be used to generate participation certificates and be used as the collaborator list for all publications arising from this study. Continue on a separate page if necessary.

First Name(s)	Last Name	e-mail	Role (please tick)		
			Lead Trainee	Lead Consultant	Local Investigator

15.4 Appendix 4 – Sample Size Calculation

Sample Size for Frequency in a Population

Population size(for finite population correction factor or fpc)(*N*):	1000000
Hypothesized % frequency of outcome factor in the population (*p*):	5%+/-1
Confidence limits as % of 100(absolute +/- %)(*d*):	1%
Design effect (for cluster surveys-*DEFF*):	1

Sample Size(*n*) for Various Confidence Levels

Confidence Level(%)	Sample Size
95%	1822
80%	780
90%	1284
97%	2232
99%	3142
99.9%	5117
99.99%	7142

Equation

Sample size n = **[DEFF*Np(1-p)]/ [(d^2/$Z^2_{1-\alpha/2}$*(N-1)+p*(1-p)]**

where

n = sample size

DEFF = design effect from clustered data

N = population size (assumed to be 1 million)

p = the estimated proportion

d = the desired absolute precision

1-α = the desired confidence level

Z = the Z-score for the corresponding confidence level (normally 1.96 for a 95% confidence level)