Preoxygenation Using **E**nd-Tidal **Ox**ygen for Rapid Sequence Intubation in the **E**mergency **D**epartment (The PREOXED Trial) - A Multicentre Stepped Wedge Cluster Randomised Control Trial

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CONTENTS

1. EXECUTIVE SUMMARY

Background	Rapid Sequence Intubation (RSI) is a high-risk procedure in the emergency department (ED). Hypoxia during intubation can lead to dysrhythmias, haemodynamic compromise, hypoxic brain injury and death and is therefore of primary concern during any intubation procedure. Patients are routinely preoxygenated prior to RSI to prevent desaturation. For many years anaesthetists have used end-tidal oxygen (ETO_2) levels to guide the effectiveness of preoxygenation and nitrogen washout. The ETO_2 gives an objective measurement of preoxygenation efficacy. Currently, it is not possible to measure the effectiveness of preoxygenation in the ED and the only method used to ensure adequate preoxygenation is to ensure that the patient receives > 3 minutes of preoxygenation. ETO_2 levels are not routinely used in EDs for RSI.
Aim	The aim of this study is to determine if the use of ETO_2 monitoring reduces episodes of oxygen desaturation for patients with or at risk of hypoxia undergoing RSI in the ED.
Primary outcomes	The primary objective of the study is the proportion of patients that desaturate (SpO_2 <93% or >10 % from baseline at the end of preoxygenation) during the peri-intubation period
Secondary outcomes	Lowest oxygen saturation (SpO_2) during the peri-intubation time
Exploratory outcomes	- Time from preoxygenation to endotracheal intubation - Incidence of severe or very severe oxygen desaturation - Changes in preoxygenation techniques between the control and intervention periods - Changes in pre-oxygenation in intervention arm based on the ETO_2 result - Number of re-oxygenation events - Cardiovascular complications during RSI: bradycardia, tachycardia, hypotension,, oesophageal intubation, aspiration, cardiac arrest
Design	This is an international, multicentre, stepped-wedge randomised control trial on the implementation of ETO_2 use in ED patients at risk of hypoxia requiring RSI
Population	All adult (≥18yrs) patients requiring rapid sequence intubation (RSI) in the ED with the first approach of oral intubation using a laryngoscope will be included in the study. Only patients deemed by the treating clinician to be at high risk of hypoxia and those who are spontaneously breathing during preoxygenation will be included. Patients will be excluded if they are <18yrs old or if circumstances of the case (e.g., procedural urgency) prevent preoxygenation.
Sample Size	A total of 1400 patients would be required to achieve a power of 80% with a significance of 0.05. This is based on the plan to recruit 8 hospital sites with 7 clusters and 8 steps, meaning that each site will recruit 25 patients/step.
Study treatments	The intervention in this clinical trial is the introduction of ETO_2 monitors into EDs at 8 hospital sites. All other clinical practices are uncontrolled and at the discretion of the treating clinician throughout the study period.

2. BACKGROUND AND INTRODUCTION

Rapid Sequence Intubation (RSI) is a common procedure in Emergency Departments (ED). However, it is a high-risk procedure and is associated with significant complications including hypoxia, failed intubation, hypotension, trauma and aspiration. (1-3) Specifically, hypoxia during intubation can lead to poor outcomes such as dysrhythmias, haemodynamic compromise, hypoxic brain injury and death and therefore oxygen desaturation is of primary concern during any intubation procedure. (4, 5) In order to prevent desaturation events during intubation, a number of steps are taken by clinicians. These include optimal patient positioning, adequate preoxygenation, assessment of airway anatomy and development of a detailed airway plan as well as the use of apnoeic oxygenation.(6)

Effective preoxygenation is vital to ensure that the patient does not develop hypoxia during the period between induction (administration of sedative and paralytic agents) and restoration of ventilation by successful endotracheal intubation or rescue breathing. Various methods of preoxygenation have been developed to wash the nitrogen out of the lungs (denitrogenation) which allows the functional residual capacity (FRC) to act as an oxygen reservoir during intubation, which prolongs safe apnoea time, therefore, preventing desaturation whilst an endotracheal tube (ETT) is placed.

Adequate preoxygenation is especially important for those patients at highest risk of hypoxia during the RSI. This patient group includes those with underlying lung pathology e.g. pneumonia, patients with increased metabolic demand e.g. sepsis, patients with an oxygen requirement prior to RSI, or patients with underlying conditions that predisposes to hypoxia e.g. obesity.

For many years anaesthetists have used end-tidal oxygen (ETO_2) levels to guide the effectiveness of preoxygenation. ETO_2 measures the exhaled oxygen concentration and is a marker of the oxygen concentration in the alveoli. Prior to induction, anaesthetists most commonly preoxygenate with a face-mask seal via either a circle circuit, Mapleson circuit, or bag valve mask. ETO_2 provides an objective measurement of preoxygenation efficacy. The Difficult Airway Society guidelines suggest aiming for an ETO_2 of ≥87% prior to commencing RSI.(7) ETO_2 levels are not routinely measured in Emergency Departments.

Currently, it is not possible to measure the effectiveness of preoxygenation in the ED. Pulse-wave oximetry reflects peripheral oxygen saturation and not the pulmonary oxygen concentration. Therefore, to attempt to optimize preoxygenation the emergency clinician currently can only use time as a surrogate. The typically recommended duration of preoxygenation is > 3 minutes.

Recently, we conducted two multi-site studies (Ethics identifier: 2019/ETH06644) that investigated the use of ETO_2 in the ED.(8, 9) The first study was conducted with clinicians blinded to the ETO_2 result (8). We demonstrated that preoxygenation was uniformly poor with only 26% of patients achieving the required target ETO_2 of ≥85%. We then completed a second study where clinicians had access to ETO_2 values and found that the proportion of patients reaching levels ≥85% was improved to 67% of patients. (9) The prevalence of hypoxemia (SpO_2<90%) in the group blinded to ETO_2 was 18% (n=18, 95% CI: 11% to 27%)

and was 8% in the group where ETO_2 was available (n = 8, 95% CI: 4% to 15%). These studies indicate that the use of ETO_2 may substantially improve preoxygenation in the ED and therefore reduce the risk of hypoxia.

These studies, however, were focused on preoxygenation practices and not patient-oriented outcomes (hypoxia) and were limited in design and resources. Consequently, it is still unclear whether the use of ETO_2 in the ED leads to improved clinical outcomes.

3. RATIONALE FOR PERFORMING THE STUDY

The aim of this study is to determine the effectiveness of ETO_2 monitoring on preventing desaturation for patients with a high risk of hypoxia undergoing RSI in ED.

4. HYPOTHESIS

We hypothesise that the use of ETO_2 monitoring leads to reduced rates of oxygen desaturation during the peri-intubation period compared to when it is not used.

5. STUDY OBJECTIVES

5.1 Primary outcome

The primary objective of the study is the proportion of patients that experience oxygenation desaturation (SpO_2 <93%, or >10% from baseline if SpO_2 <93% at the end of preoxygenation) during the peri-intubation period (the time when laryngoscope first enters the mouth to 2 minutes after the endotracheal tube [ETT] is confirmed on waveform capnography).

5.2 Secondary objectives

The secondary objective of the study is the lowest oxygen saturation (SpO_2) during the peri-intubation period.

5.3 Exploratory outcomes

- Time from preoxygenation to endotracheal intubation
- Incidence of severe oxygen desaturation (SpO2 <80%) between induction and 2 minutes post ETT confirmation
- Incidence of very severe oxygen desaturation (SpO2 <70%)between induction and 2 minutes post ETT confirmation
- Changes in pre-oxygenation techniques between the control and intervention periods
- Changes in pre-oxygenation in intervention arm based on the ETO_2 result
- Number of re-oxygenation events
- The affect of preoxygenation methods and apnoeic period events (ventilation or nasal prong O_2) on ETO_2 results up to 2mins post ETT confirmation
- Cardiovascular complications during RSI:

    - bradycardia (HR< 40 bpm)
    - tachycardia (HR> 120 bpm)
    - hypotension (SBP< 90 mm Hg or a 30mmHg reduction from baseline)
- Other complications during RSI:
    - Operator reported aspiration between induction and intubation
    - Oesophageal intubation recognised after the laryngoscope blade has been removed, detected by waveform ETCO2
    - Cardiac arrest occurred during RSI

5.4 Subgroup analyses

A predefined list of subgroup analyses will be published prior to the commencement of the trial (see details in section 7.4) that will include analysis of desaturation rates in the following subgroups:

- BMI: <35 vs. ≥35
- Final Preoxygenation method: NRB vs. BVM (+/- PEEP) vs. NIV vs HFNP
- SPO_2 levels after preoxygenation: SpO_2 >93% after preoxygenation vs. SpO_2 <93% after preoxygenation.
- Incidence of desaturation within various ETO_2 subgroups:
    - >85%
    - 70-85%
    - 50-69%
    - <50%

5.5 Additional analyses

We also intend to analyse and report on differences in the primary outcome for the following groups (see details in section 7.4):

- Time to intubation (sedation to ETT confirmation): <180secs vs. ≥180secs
- Apneoic period: Ventilations vs. apneoic oxygenation
- Number of attempts: Single vs. Multiple attempts

6. STUDY DESIGN

6.1 Setting

This study will be conducted in several hospitals based in Sydney, Australia and several centres in the USA. All hospitals are tertiary level, university teaching hospitals with consultant/attending-level supervision of trainees and include the following:

- Australian sites:
    - Royal Prince Alfred Hospital
    - Royal North Shore Hospital
    - Westmead Hospital
    - Northern Beaches Hospital
    - The Alfred Hospital

- US Sites:
    - Lincoln medical center, NY
    - Hennepin County medical center, MN
    - University of New Mexico medical center, NM

6.2 Study Participants

All adult patients with a high risk of hypoxia requiring rapid sequence intubation (RSI) in the resuscitation bays of the ED will be included in the study. Patients with a high risk of hypoxia are defined as:

- Any patient requiring any form of oxygen therapy *before* preoxygenation.
- Any patient with respiratory pathology based on clinical or radiological findings. Including, but not limited to:
    - Pneumonia, pulmonary oedema, acute respiratory distress syndrome (ARDS), aspiration, pulmonary contusion from trauma, infective exacerbations of known lung disease (e.g. asthma, pulmonary fibrosis, emphysema) or pulmonary embolism (PE)
- Any patient with high oxygen consumption. Including, but not limited to:
    - Sepsis, Diabetic ketoacidosis, alcohol or drug withdrawal, seizures, thyrotoxicosis
- Any underlying patient condition that may predispose to hypoxemia. Including, but not limited to:
    - Obesity, pregnancy, underlying lung disease (e.g. asthma, pulmonary fibrosis, emphysema), severe injury- hypovolaemia/haemorrhage.
- or any other patient that the treating clinician has a high concern for hypoxemia during RSI.

Patients may be included in the study if there is another indication for RSI but with a high risk of hypoxia. For example, a patient with an overdose who has also suffered pulmonary aspiration. RSI is defined as the near-simultaneous administration of a sedative and paralytic agent to facilitate rapid tracheal intubation.(10)

6.2.1 Inclusion Criteria:

1. The patient is located in the ED resuscitation bay of the participating centre.
2. The planned procedure is orotracheal intubation using a laryngoscope and RSI technique with preoxygenation for patients who are spontaneously breathing.
3. The patient is deemed to be at a high risk of hypoxia during RSI as per the treating ED clinician, as defined in section 6.2.

6.2.2 Exclusion Criteria:

1. Patient is known to be less than 18 years old.
2. The patient has a supraglottic device in-situ e.g iGel or LMA.
3. The patient is known to be pregnant.

4. The patient is known to be a prisoner.
5. The patient was intubated in the prehospital environment.
6. Immediate need for tracheal intubation precludes preoxygenation i.e. the patient is in cardiac arrest.

6.3 Design

The trial will be an international, multicentre, stepped-wedge randomised control trial on the implementation of ETO_2 use in EDs for patients requiring RSI. A cluster will compose an individual hospital site and each site will serve as its own control with an implementation phase conducted at each site until all sites are recruited into the study period (Figure 1). To account for the differences in ED presentation rates at the various sites the cluster blocks will consist of patient numbers rather than a defined period of time. However, nearly all the sites will be recruiting at a similar rate, given that each site intubates 20-30 patients per month. During the interim analyses we will be monitoring the rate of recruitment at each site. The sites will be randomised using an online tool (https://www.random.org/lists/).

	Patient block								
Site	1	2	3	4	5	6	7	8	9
7									
6									
5									
4									
3									
2									
1									

= Control period

= Implementation and education period

= Study period

Figure 1- Trial design schema

6.4 Power calculation

To power this study, we utilised the assistance of a biostatistician (Ass. Prof. Kris Rodgers, Research Biostatistician). Utilising the calculations based on Hemming et al.(11) and based

on the plan to recruit 8 hospital sites with 7 clusters and 8 steps each site we calculated that 1232 (22 patients per step) patients would be required to achieve a power of 80% with a significance of 0.05 to detect an absolute difference of 10% in the rate of desaturation. Factoring in a missing data rate of approx. 14-15% this gives a total of 1400 patients required (25 patients per step). The intracluster correlation (ICC) was calculated at 0.01 given that we believe that the ICC is likely to be small based on our previous studies.(12) The proportion of patients in the control arm meeting the primary outcome (desaturation <93%) was calculated at 20%. This is based on current audit data from the Australia and New Zealand ED airway registry (ANZEDAR) demonstrating a desaturation rate of 20% for patients undergoing RSI with respiratory pathology.(13)
The proportion of patients in the intervention arm meeting the primary outcome was calculated at 10%, i.e. an absolute difference of 10% in desaturation rates between the control and intervention arms of the study. This was based on our previous study(9) demonstrating a desaturation rate of 10% in the intervention group and also based on a clinically meaningful difference of 10% between the two groups.

6.5 Control period

The control period includes a period whereby clinicians will not have access to ETO_2 monitoring and routine RSI practices will be documented including all study variables. At all institutions, RSI is performed in a similar manner, utilising an airway checklist. There is no 'standard operating procedure' for RSI in any of the EDs and methods, therefore, vary depending on clinician preference and the condition of the patient, however, each site is a tertiary-level, university teaching hospital and therefore clinical practice is up to date and evidence-based. Standard preoxygenation methods in the Emergency department often consist of a bag-valve mask, with or without a PEEP valve, set at 15L/min, or the use of non-invasive ventilation or a non-rebreather mask, with or without a nasal cannula, set at 15 L/min or flush rate oxygen (>40 L/min). These methods depend on clinician preference and practice varies widely within each institution. As described in our previous studies the US sites have access to high-flow (>30L/min) oxygen. This is the only difference in the preoxygenation method, and we have found no significant difference in the mode of preoxygenation to patient desaturation rates or ETO_2 levels among the different hospitals.

6.6 Implementation and education period

During the implementation and education period, the ETO_2 monitoring will be installed at the relevant hospitals and education will commence to clinicians. This will include all the nursing staff who work in the resuscitation bay and all medical staff including trainees (registrars/residents) and consultants/attendings. We will provide these clinicians with education on the study prior to commencement using several methods including

1. A virtual learning environment will be constructed including trial education video Departmental Meetings
2. Medical teaching sessions
3. Regular (daily) in-service for nursing staff
4. Weekly email departmental updates
5. On-the-floor reminders

6. Group emails

The education for the study will compose of a short presentation describing the study rationale and data collection. All clinicians will receive a short 10-minute lecture on the use of the ETO_2 monitor and the meaning of the result as well as the options available to improve the ETO_2 value.

6.7 Study period

For all patients involved in the study, the only intervention will be the use of ETO_2 to guide preoxygenation. All aspects of RSI will be at the discretion of the treating clinician including sedative/paralytic medications, positioning of the patient, preoxygenation method, intubation techniques and post-intubation sedation.

Clinicians will be encouraged to aim for the highest ETO_2 result possible with a goal of >85%. Clinicians will be able to view the ETO_2 values and can decide on any changes to the preoxygenation techniques if deemed necessary. These techniques may include improved patient positioning, improved face mask seal, increased oxygen flow, length of preoxygenation time, or altering the preoxygenation device.

Patients *in extremis* (e.g. cardiac arrest) will be excluded from the study, defined as those who need immediate tracheal intubation without a preoxygenation period.

The use of ETO_2 in clinical practice should only have a neutral or positive effect for the patient. Altering preoxygenation methods or times to improve the ETO_2 value should decrease the risk of subsequent hypoxemia. There are no foreseen risks to the use of ETO_2 monitoring and the clinician always has the ability to act in any way necessary to provide the best care for the patient.

6.8 Clinical practices during the trial

To ensure consistency during the trial period, and therefore mitigate any changing clinical practices in RSI that may influence outcomes of the study, we implemented a number of steps including:

- Utilisation of airway checklists in the institutions involved
- Documenting education and training to clinical staff during the two periods of the trial
- Advising the site PIs that education and training should be similar during the two periods of the trial
- Collecting data on RSI practices in the control period and study period to ensure similarity
- Perform a planned sub-group analysis on preoxygenation methods

6.9 Equipment

For hospitals in Sydney, the only additional equipment required for this study is the Philips™ IntelliVue G7m Gas Analyser Module 866173. This provides a non-dispersive infrared measurement of respiratory gases and a paramagnetic measurement of oxygen. The

IntelliVue G7m Gas Analyser Module is designed to work with the IntelliVue patient monitors currently used in the EDs at the Sydney sites. At Lincoln Medical Center, the gas analyser used will be a Philips G5 gas analyser connected to a Philips Intellivue MP 70. At the University of New Mexico Medical Center, the Masimo root monitor is used.
The gas analysers produce display waves for O_2 and CO_2, together with numerics for end-tidal values for O_2 and CO_2 and to our knowledge, there are no differences in values between the various devices used.
The gas sampling occurs through a side-stream sampling tube at a rate of 200ml/min ±20 ml/min, which is either obtained from a nasal cannula in the spontaneously breathing patient or a sidestream line if connected to a BVM.

7. STATISTICAL CONSIDERATIONS

7.1 Statistical Analysis

Prior to the conclusion of enrollment, we will make publicly available a complete, final statistical analysis plan and study protocol. Analyses conducted in accordance with the statistical analysis plan will be identified as *a priori*. Any additional analyses requested by the investigators or reviewers will be identified as *post hoc*. We intend to perform interim analyses every 500 patients that are enrolled.

7.2 Primary Analysis

The primary analysis will be an unadjusted, intention-to-treat comparison of patients who received ETO_2 use during the study period in comparison with the group of patients not receiving ETO_2 use during the control period regarding the primary outcome. The difference between the two study groups will be compared using a Generalised Linear Mixed Model to estimate the effect sizes for the binary outcomes.

7.3 Analysis of secondary and exploratory outcomes

We will perform intention-to-treat comparisons of secondary and exploratory outcomes. Continuous outcomes will be compared with the Wilcoxon Rank Sum test and categorical variables with the Chi-squared test. Data on patient characteristics will be summarised as number and proportion for categorical variables and as a median and interquartile range for continuous variables.

7.4 Effect Modification (Subgroup and Additional Analyses)

To evaluate whether pre-specified baseline variables modify the effect of study group assignment on the primary outcome, we will perform logistic regression modelling with the primary outcome as the dependent variable and independent variables of the study group, the proposed effect modifier, and the interaction between the two. Any interaction term with a p-value less than 0.1 will be considered to identify an effect modifier. To account for non-linear relationships, continuous variables will be analysed using restricted cubic splines

between 3 and 5 knots. Forest plots will be used to graphically display the adjusted analyses, and locally weighted regression or partial effects plots will be used to portray the association between continuous covariates and the outcome. A full list of prespecified subgroup analyses will be outlined in the detailed statistical analysis plan but will include:

- BMI (kg/m^2): <35 vs. ≥35. We hypothesise that body mass index will modify the effect of study group assignment on the primary outcome, with a greater incidence of desaturation in the control arm compared to the study arm of the trial for patients with higher body mass index as compared with patients with lower body mass index
- Preoxygenation method: NRB vs. BVM vs. NIV. We hypothesise that the patients preoxygenated with NRB will have the highest incidence of desaturation in the control arm in comparison to those in the study arm compared to patients preoxygenated with BVM or NIV
- Time to intubation (sedation to ETT placement): <180sec vs. ≥180 sec: We hypothesise that patients with more difficult airway anatomy may take longer to intubate and will modify the effect of study group assignment on the primary outcome, with a greater incidence of desaturation in the control arm compared to the study arm of the trial for patients with difficult airway anatomy as compared with patients with not difficult airway anatomy. This analysis will also be performed after excluding patients requiring a reoxygenation attempt.
- Incidence of desaturation within various ETO_2 subgroups: ≥85%, 70-85%, 50-69%, <50%. We hypothesise that patients with lower ETO_2 values at induction of <85% will modify the effect of study group assignment on the primary outcome, with a greater incidence of desaturation in patients with lower ETO_2 values (<85%) as compared with patients with ETO_2 values of ≥85%. This subgroup analysis will only be performed for the patients in the study arm of the trial as this is only when ETO_2 values will be available.
- Apnoeic period: Ventilations vs. apnoeic oxygenation. We hypothesise that patients who have positive pressure ventilations compared to apnoeic oxygenation through the apnoeic period will modify the effect of study group assignment on the primary outcome. Patients who receive positive pressure ventilations are hypothesised to have a lower incidence of desaturation in the study arm compared to the control arm of the trial.
- Intubation attempts: Single attempt vs. Multiple attempts. We hypothesise that patients requiring multiple intubation attempts will have a greater incidence of desaturation in the control arm of the study compared to the study arm of the trial.

7.5 Correction for Multiple Testing

We will analyse a single pre-specified primary outcome and a single pre-specified secondary outcome. Consistent with recommendations of the Food and Drug Administration and the European Medicines Association, each will be tested using a two-sided P value with a significance level of 0.05. For all other analyses, emphasis will be placed on the estimate of effect size with 95% confidence intervals, as recommended by the *International Committee of Medical Journal Editors*, and no corrections for multiple comparisons will be performed.

7.6 Handling of Missing Data

Oxygen saturation may be unavailable in some cases (equipment malfunction, observer error during a rapid, emergency procedure, or cardiac arrest). Missing data will not be imputed for the primary outcome or any of the secondary or exploratory outcomes. In adjusted analyses, missing data for baseline covariates will be imputed using multiple imputations.

8. DATA COLLECTION

8.1 Collection

Data will be collected prospectively in real-time using a case report form (CRF) by research staff when available. If the research staff are not available then data for the study will be available from three sources: [1] variables documented in the electronic medical record (EMR) as part of clinical care, [2] information recorded by clinical staff's bedside observation during the intubation procedure, and [3] variables reported by the operator immediately following the intubation procedure. It is infeasible to have research staff present during each emergency tracheal intubation. Therefore, clinical staff not participating in the tracheal intubation procedure will collect data elements relevant to outcomes of emergency tracheal intubation using a standardised CRF. These variables are readily available by bedside observation and do not require interaction with the patient but are not uniformly documented in the EMR (e.g., lowest oxygen saturation and lowest blood pressure from induction to two minutes after tracheal intubation). Immediately following the intubation procedure, the operators will record data elements known only to them (e.g., glottic view obtained during the procedure and visualization of gastric aspiration in the oropharynx). Operators and clinical staff observing the procedure at the bedside will not be considered key study personnel. Training will be provided to clinicians who may serve as operators or bedside observers. The activities of these clinicians will be limited to the reporting of data routinely reported as part of clinical care.

8.2 Variables

The variables collected are as follows:

The variables included in the study are shown on the Data Collection Sheet (Appendix 1) and will include the following:

Baseline:

- Age, gender, estimated weight and height
- Triage time- defined as when the patient is first registered on EMR
- Indication for RSI
    - Trauma - reduced LOC
    - Trauma - airway not patent
    - Trauma - neck/facial injury

    - Trauma - burn/inhalation
    - Trauma - drowning
    - Trauma - chest injury
    - Trauma - shock
    - Trauma - cardiac arrest
    - Medical - respiratory failure
    - Medical - airway obstruction
    - Medical - anaphylaxis
    - Medical - cardiac failure
    - Medical - Sepsis
    - Medical - GI bleed
    - Medical - Seizure
    - Medical - stroke/intracranial haemorrhage
    - Medical - altered level of consciousness (not overdose)
    - Medical - overdose/ingestion
    - Medical - cardiac arrest
    - Other
- Reason for high risk of hypoxia
    - Patient requiring any form of oxygen therapy before preoxygenation
    - Patient with respiratory pathology based on clinical or radiological findings. Including, but not limited to:
        - Pneumonia, pulmonary oedema, acute respiratory distress syndrome (ARDS), aspiration, pulmonary contusion from trauma, infective exacerbations of known lung disease (e.g. asthma, pulmonary fibrosis, emphysema) or pulmonary embolism (PE)
    - Patient with high oxygen consumption. Including, but not limited to:
        - Sepsis, Diabetic ketoacidosis, alcohol or drug withdrawal, seizures, thyrotoxicosis
    - Underlying patient condition that may predispose to hypoxia. Including, but not limited to:
        - Obesity, underlying lung disease (e.g. asthma, pulmonary fibrosis, emphysema)
    - or any other patient that the treating clinician has a high concern for hypoxia during RSI.
- Prediction of Intubation difficulty
    - limited mouth opening
    - limited anatomic neck mobility
    - cervical immobilization due to trauma
    - increased neck circumference
    - facial trauma
    - obesity
    - obstruction to view e.g. bleeding, epiglottitis, vomitus
- Observations at decision to intubate
    - GCS
    - RR
    - SBP
    - HR

- S_PO_2

Pre-RSI details:

- Preoxygenation start time
- Method of preoxygenation
  - Non-rebreather mask
  - Bag-valve-mask
  - Bag-valve-mask + PEEP
  - CPAP/BiPAP
- Oxygen flow rate with preoxygenation device (L/min): 15L/min or >40L/min
- Supplementary nasal prongs used – Y/N
- Oxygen flow rate with nasal prongs (L/min)
- Observations at the end of preoxygenation, which is the point of induction
  - RR
  - SBP
  - HR
  - S_PO_2
- Was ETO_2 was used – Y/N
- If so, what changes were made suring preoxygenation:
  - Change in preoxygenation technique:
    - Improved mask seal
    - Increased O2 flow rate
    - Increased Preoxygenation time
  - Change in preoxygenation method
    - BVM
    - BVM+PEEP
    - HFNP
    - NIV

RSI details (From first sedative medication until 2 minutes after ETT confirmation):

- Time of first sedative Induction medication
- Drug name and dose of first sedative induction medication
- Time of first paralytic medication
- Drug name and dose of first paralytic medication
- ETO_2 level at induction
- Lowest ETO_2 within 2 minutes after intubation
- Apnoeic oxygenation used?
- Method of apnoeic oxygenation
  - Nasal prongs
  - High-flow nasal prongs
- Head position: Flat, Elevated head of bed only, ramped
- Time of Endotracheal intubation confirmation via waveform capnography
- Method of intubation- Direct laryngoscopy, Video laryngoscopy (CMAC, McGrath, Glidescope), Hyperangulated blade (X-blade, D-blade)
- Number of re-oxygenation attempts- A re-oxygenation attempt is a failed first attempt at ETT placement followed by administration of an oxygen delivery device (BVM, NIV, supraglottic device) to maintain SpO_2 levels

- Observations up to 2 minutes after waveform capnography confirmation of endotracheal intubation
    - Lowest S_PO_2
    - Lowest SBP
    - Lowest and highest HR
- Intubation manoeuvres for failed first attempt- Free text
- Number of intubation attempts, defined as the number of laryngoscope blade insertion
- Complications during RSI
    - Operator reported aspiration between induction and intubation
    - Oesophageal intubation identified after the laryngoscope blade has been removed
    - Cardiac arrest occurred during RSI or within 2 minutes after ETT confirmation

The preoxygenation period is defined as the point at the decision for intubation and oxygenation commences for RSI to the injection of first sedative induction medication for RSI. The apnoeic period is from the first sedative induction medication to the time the laryngoscope first enters the mouth. The peri-intubation period is defined as the time the laryngoscope first enters the mouth to 2 minutes after endotracheal tube (ETT) confirmation on waveform capnography. The RSI time is the time from sedative administration until 2 minutes after ETT confirmation.

9. ETHICAL CONSIDERATIONS

9.1 Consent

Approval from human research ethics committees or institutional review boards (IRB) at each site will be confirmed prior to the commencement of the study.

We will request a waiver of informed consent because the study involves no or minimal risk and obtaining informed consent would be impracticable.

Participation in this study involves no or minimal incremental risk because:

- All patients eligible for the study are already undergoing tracheal intubation with preoxygenation as part of their clinical care
- All patients will be receiving the standard of care that is RSI. This study will have no direct impact or changes to RSI practices with the only intervention being an additional monitor (ETO_2) during RSI that is not routinely used in the ED. This adds to clinical information, is already considered standard of care in the operating theatre, and may lead to either no change or improved patient care. Therefore, there are no added risks to the patient. There are no foreseeable risks to the use of ETO_2 monitoring.
- The sole risk of the research is the loss of private health information. We will take strong measures to prevent this from happening (see Confidentiality and storage of data below).

Obtaining informed consent would be impracticable because

The expected critically ill medical condition of patients requiring emergency tracheal intubation in the ED. Based on prior trials in the same patient population and setting, nearly all of the patient's requiring RSI in the ED will have an altered mental status and lack the capacity to consent due to their critical illness. Further, family members or legally authorized representatives (LAR) are frequently unavailable when critically ill patients undergo intubation in the ED.

The time available for patients or LARs to consider participation will be insufficient. Even when a patient retains capacity or a LAR is immediately available, a meaningful informed consent process is precluded by the rapid clinical events leading up to emergency tracheal intubation. No published literature has quantified the time from clinicians' decision to perform emergency tracheal intubation (the inclusion criteria for PREOXED) until the initiation of the intubation procedure (completion of the PREOXED intervention). Obtaining informed consent for research requires study personnel to assess decisional capacity, identify a LAR when appropriate, review the informed consent document in a quiet setting, and provide sufficient time for the patient or LAR to process the information, assess the risks and benefits of participation, and ask questions. Meaningful informed consent cannot be executed in the brief time between the decision to perform emergency tracheal intubation and the initiation of the procedure. Emergency tracheal intubation of critically ill adults is a time-sensitive procedure for which every minute of delay increases the likelihood of hypoxemia, hypotension, and peri-procedural cardiac arrest. Delaying emergency tracheal intubation for a critically ill adult to attempt a meaningful informed consent process would be unsafe, impracticable, and unethical.

Because the study involves no or minimal incremental risk, the study would not adversely affect the welfare or privacy rights of the participant, and obtaining informed consent would be impracticable, we will request a waiver of informed consent. Numerous previous randomized trials comparing two standards of care for emergency intubation have been completed under a waiver of informed consent.(14-18)

As mentioned previously a similar study has been conducted at Royal Prince Alfred Hospital, Sydney (Ethics identifier: 2019/ETH06644) and Lincoln Medical Center, NY with a waiver of consent.

9.2 Risks and benefits

9.2.1 Risks of Tracheal Intubation in the ED

Patients eligible for this study will be experiencing risks associated with their medical condition. Patients who are severely ill enough to require emergency tracheal intubation in the ED as part of their clinical care are at high risk of complications. Many patients are undergoing intubation for altered conscious state, hypoxemia or hemodynamic instability. Hypoxemia or cardiovascular instability occurs in around 12% of intubations in the ED.(3)

Hypoxemia and hypotension during intubation are associated with an increased risk of cardiac arrest and death.(5, 19) Cardiac arrest occurs in 1% of cases of emergency tracheal intubation.(3)

Other complications during intubation may include aspiration (approximately 2.8% of cases), oesophagal intubation (1.3%) injury to oral or dental structures (0.2%), and pneumothorax (0.1%). The long-term consequences of complications occurring during emergency tracheal intubation are unclear. Neurologic recovery from traumatic brain injury may be worse after hypoxemia due to secondary ischemic insult.(20)

This study will not impact the rate of tracheal intubations occurring in the ED nor increase the risk of these complications.

9.2.2 Potential Risks of Participation in the PREOXED Trial

Participation in the PREOXED trial involves no or minimal incremental risk because all patients eligible for the study are already experiencing emergency tracheal intubation, with the accompanying risks, as part of their clinical care. This study will have no direct impact or changes to RSI practices with the only intervention being an additional monitor (ETO_2) during RSI that is not routinely used in the ED. This adds to clinical information and may lead to either no change or improved patient care. Therefore, there are no added risks to the patient.

9.2.3 Potential Benefits of Participation in the PREOXED Trial

Currently ETO_2 use is the gold standard for preoxygenation in the operating room. Limited evidence exists for the ED with the only evidence comparing ETO_2 use from our prior studies which demonstrated a benefit to patient care.(9) In this study we demonstrated that the use of ETO_2 in the ED was associated with a reduction in oxygenation desaturation rates from 18% without ETO_2 being available to 8% with ETO2 available.

9.2.4 Minimization of Risk

US Federal regulations 45 CFR 46.111(a)(1) require that risks to patients are minimized by using procedures which are consistent with sound research design. This trial meets this human subject's protection requirement by incorporating numerous design elements to minimize risk to patients.

9.2.5 Consumer engagement

Consumer engagement was not obtained during conceptualisation of the study, however we will seek feedback from a consumer engagement representative that is affiliated with the SLHD.

9.3 Confidentiality and storage of data

To limit the risks associated with the collection of protected health information (PHI), the minimum amount of PHI necessary for study conduct will be collected. Name, date of birth and medical record number will initially be required for this study to enable collection of all initial data via EMR. After data collection has been completed all data will be de-identified and the data will be stored in a secure online database (REDCap) only accessible to the investigators. No PHI details will be recorded on the Redcap database. To protect participant privacy, REDCap tools will be used to ensure that only deidentified data (i.e.no PHI) can be exported for use during analysis.
Hard copy data storage (CRF) at the Sydney sites will be stored safely in locked offices in secure cabinets as previously arranged for the ANZEDAR study.(3) The US sites have similar arrangements for data collected at that relevant institution.
The sharing of data for analysis purposes will be conducted as per the previous study (Ethics identifier: 2019/ETH06644). Please refer to the separate legal agreement. No PHI details will be shared between hospitals.

10. SAFETY MONITORING AND ADVERSE EVENTS

Assuring patient safety is an essential component of this protocol. The addition of the ETO_2 monitoring is anticipated to add to patient care, as per practices in the operating room and have no adverse events for the patient. However, any trial conducted during a high-risk, time-sensitive procedure like tracheal intubation of critically ill patients raises unique safety considerations. This protocol addresses these considerations through

- Prior conducted studies demonstrating a benefit to the patient population of interest
- No other changes to RSI practices
- Systematic collection of outcomes relevant to the use of ETO_2

10.1 Adverse Event Definitions

Adverse Event – An adverse event will be defined as any untoward or unfavourable medical occurrence in a human subject temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Any adverse event occurring during the research will be classified according to the following characteristics:

Seriousness – An adverse event will be considered "serious" if it:

- Results in death;
- Is life-threatening (defined as placing the patient at immediate risk of death);
- Results in inpatient hospitalization or prolongation of existing hospitalization;
- Results in a persistent or significant disability or incapacity;
- Results in a congenital anomaly or birth defect; or
- Based upon appropriate medical judgment, may jeopardize the patient's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Unexpectedness – An adverse event will be considered "unexpected" if the nature, severity, or frequency is neither consistent with

- The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in the protocol-related documents, such as the IRB-approved research protocol; nor
- The expected natural progression of any underlying disease, disorder, or condition of the subject experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

Relatedness – The strength of the relationship of an adverse event to a study intervention or study procedure will be defined as follows:

- Definitely Related: The adverse event follows (1) a reasonable, temporal sequence from a study procedure AND (2) cannot be explained by the known characteristics of the patient's clinical state or other therapies AND (3) evaluation of the patient's clinical state indicates to the investigator that the experience is definitely related to study procedures.
- Probably or Possibly Related: The adverse event meets some but not all of the above criteria for "Definitely Related".
- Probably Not Related: The adverse event occurred while the patient was on the study but can reasonably be explained by the known characteristics of the patient's clinical state or other therapies.
- Definitely Not Related: The adverse event is definitely produced by the patient's clinical state or by other modes of therapy administered to the patient.
- Uncertain Relationship: The adverse event does not fit in any of the above categories.

10.2 Monitoring for Adverse Events

For the following reasons we will not be monitoring for adverse events during this trial

- It is anticipated that there will be no adverse events for the patient related to the intervention of the trial
- The intervention of the trial (ETO_2 use) is considered standard of care for use in the operating room
- The pragmatic design of this stepped-wedge cluster randomised trial does not allow for interim analysis as an RCT normally would.

10.3 Compensation

If a participant suffers any injuries or complications as a result of the research project, they will be advised to contact the study team and will be assisted with arranging appropriate medical treatment. If participants are eligible for Medicare (Australia specific), they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. In addition, patients may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if their injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties

involved in the study (for example, the researcher, the hospital, or the treating doctor). Patients do not give up any legal rights to compensation by participating in this study.

11. AUDITS

We will permit study-related monitoring, audits, HREC review, and regulatory agency inspections and provide direct access to source documents.
A schedule of planned GCP audits is listed for annual review plus other relevant reviews.

Task	Person Responsible	Date
Study Staff GCP Certificates up to date	Radhika Seimon	Yearly
Protocol deviations and serious adverse events reported to HREC	Radhika Seimon	When required
Annual reports submitted to HREC	Radhika Seimon	Yearly
Communications with HREC and site governance	Radhika Seimon	When required

12. DATA USE

The data from this study will be analysed and may be presented at an International or National Conference meeting as well as published in a peer review journal in the speciality of Emergency Medicine.

13. CONFLICTS OF INTEREST

There are no conflicts of interest or financial disclosures for any of the researchers of this trial. Purchasing of equipment was supplied by funds from the Greenlight Institute for Emergency Care. A privately funded research group based within the Emergency Department at Royal Prince Alfred Hospital, Sydney Local health District.

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Appendix 1 – Case report form

PREOXYGENATION USING **E**ND-TIDAL **OX**YGEN FOR RAPID SEQUENCE INTUBATION IN THE **E**MERGENCY **D**EPARTMENT (The **PREOXED** Trial)

TO BE COMPLETED FOR ALL INTUBATIONS IN THE EMERGENCY DEPARTMENT

Name **Place Patient Sticker Here** Medical Record Number Age (year): Gender	**Data / time of arrival to ED** (Triage time) ☐☐/☐☐/☐☐☐☐ (24 hour format) Day Month Year HH MM **Weight:** kg **Height:** cm

Study Arm: Control (ETO2 not available) ☐ **Intervention (ETO2 Available)** ☐

INDICATION FOR INTUBATION – TICK ONE ONLY					
TRAUMA			**MEDICAL**		
Head injury – reduced LOC	☐	Respiratory failure	☐	Altered level of consciousness status (Not overdose)	☐
Head injury – airway not patent	☐	Airway obstruction	☐	Overdose / ingestion	☐
Neck / facial trauma	☐	Anaphylaxis	☐	Cardiac arrest	☐
Burn / inhalation	☐	Cardiac failure	☐	Other (please state):	
Drowning	☐	Sepsis	☐		
Chest trauma	☐	GI bleed	☐		
Shock	☐	Seizure	☐		
Traumatic cardiac arrest	☐	ICH / stroke	☐		

REASON FOR HIGH RISK OF HYPOXIA	
Patient requiring any form of oxygen therapy before preoxygenation	☐
Patient with respiratory pathology based on clinical or radiological findings e.g. Pneumonia	☐
Patient with high oxygen consumption e.g. DKA, Sepsis	☐
Underlying patient condition that may predispose to hypoxia e.g. Obesity	☐
Any other patient that the treating clinician has a high concern for hypoxia during RSI	☐

Was laryngoscopy predicted to be difficult? Yes ☐ No ☐ Unknown ☐	**Was a formal assessment made?** Yes ☐ No ☐ Unknown ☐
Why difficult? *e.g. "LEON" criteria See over*	

Observations at decision to intubate *"NR" if not recorded* *"UR" if unrecordable*	Time: ___ : ___ (HH:MM)	RR: _____	SBP: _____	HR: _____	SpO_2: _____	GCS: _____

PRE-INTUBATION							
Preoxygenation method* Time commenced: ___ : ___ (HH:MM)	NIL ☐	NP ☐	HFNP ☐	NRBM ☐	BVM ☐	BVM +PEEP ☐	CPAP /BiPAP ☐
Oxygen flow rate		L/min	L/min	L/min	L/min	L/min	L/min
Pressures if applicable						cmH_2O	cmH_2O

Observations at end of preoxygenation *"NR" if not recorded* *"UR" if unrecordable*	Time: ___ : ___ (HH:MM)	RR: _____	SBP: _____	HR: _____	SpO_2: _____

INTUBATION (FROM FIRST SEDATIVE MEDICATION TO 2 MINS AFTER ETT CONFIRMATION)			
First sedative medication	Time: ___ : ___ (HH:MM)	Drug: _____	Dose: _____
First paralytic medication	Time: ___ : ___ (HH:MM)	Drug: _____	Dose: _____

End-Tidal Oxygen	Was End-tidal Oxygen used?	Yes ☐	No ☐	ETO_2 at induction _____ %	

Change in <u>Preox technique</u> from ETO2 result?	Nil ☐	Improved Mask seal ☐	Increase in Flow Rate _____L/min ☐		Increased Preox time ☐	
Change in <u>Preox device</u> from ETO2 results?	Nil ☐	NP ☐	NRBM ☐	BVM ☐	BVM + PEEP ☐	NIV ☐

Apnoeic O_2 method†	NIL ☐	NP ☐	High Flow NP ☐
Oxygen flow rate		L/min	L/min
Pressures if applicable			

Was the patient ventilated through the apneoic period?	Yes ☐ No ☐		
If so, with what	BVM ☐	BVM+PEEP ☐	CPAP/BiPAP ☐
Oxygen flow rate	L/min	L/min	L/min
Pressures (if applicable)		cmH_2O	cmH_2O

Patient Position Tick **One** Only	Flat ☐	Elevated head of bed only ☐	Ramped ☐	

Time of ETT confirmation – with waveform capnography	Time: ___ : ___ (HH:MM)

Attempt	**Time**	**Specialty & Seniority** (e.g. ED Registrar)	**Laryngoscope**		**Reoxygenation attempt?** *Was there a failed attempt causing desaturation requiring intervention? (Y/N)*	**B** = Bougie **S** = Stylet **N** = Neither	**ETT size**
			Direct Video standard *(e.g. C-MAC)* **Video Hyper-angulated** *(e.g, D-Blade)*	**Size**			
1st							
2nd							
3rd							

Describe airway manoeuvres after failed first attempt. e.g. BVM, change position etc. **N/A if successful on first attempt**	

EVENTS DURING RSI (FROM FIRST SEDATIVE MEDICATION TO 2 MINS AFTER ETT CONFIRMATION)		
Actual lowest SpO_2		_____
Actual lowest HR		_____
Actual highest HR		_____
Actual lowest SBP		_____
Cardiac arrest	Asystole, bradycardia, or dysrhythmia with non- measurable MAP and/or CPR during or after intubation	☐
Aspiration	Visualization of newly regurgitated gastric contents below glottis contents as reported by intubator	☐
Oesophageal intubation	Oesophageal intubation after the laryngoscope blade has been removed	☐

*NRBM = Non re-breather Mask, BVM = Bag Valve Mask, BVM+PEEP = PEEP Valve attached to BVM, NIV = CPAP or BiPAP for preoxygenation

†NP = Nasal Prongs, BVM = *Active Ventilation* using BVM, CPAP/BiPAP = NIV after induction until laryngoscopy