|  |
| --- |
| Protocol  |
| TEMP-T |
| Protocol Number: 1Version: 7Date: 06/04/2015 |
|  |
| **Author/s:****Elliot Long****Michael Barrett** **Patrick Fitzpatrick****Sponsor/s:****N/A** |
| **CONFIDENTIAL**This document is confidential and the property of The Royal Children’s Hospital. No part of it may be transmitted, reproduced, published, or used without prior written authorization from the institution.**Statement of Compliance**This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95). |

# Table of Contents

Contents

[Table of Contents 2](#_Toc347235306)

**[1.](#_Toc347235307)****[Glossary of Abbreviations & Terms](#_Toc347235307)** [4](#_Toc347235307)

**[2.](#_Toc347235308)****[Study Sites](#_Toc347235308)** [4](#_Toc347235308)

[2.1 Study Location/s 4](#_Toc347235309)

**[3.](#_Toc347235310)****[Funding and Resources](#_Toc347235310)** [4](#_Toc347235310)

[3.1 Source/s of Funding 4](#_Toc347235311)

**[4.](#_Toc347235312)****[Introduction/Background Information](#_Toc347235312)** [4](#_Toc347235312)

[4.1 Lay Summary 4](#_Toc347235313)

[4.2 Introduction 5](#_Toc347235314)

[4.3 Background information 6](#_Toc347235315)

**[5.](#_Toc347235316)****[Study Objectives](#_Toc347235316)** [7](#_Toc347235316)

[5.1 Research Question 7](#_Toc347235317)

[5.2 Primary Objectives 7](#_Toc347235318)

[5.3 Secondary Objectives 7](#_Toc347235319)

[5.4 Outcome Measures 7](#_Toc347235320)

[**6.** **Study Design** 7](#_Toc347235321)

[6.1 Study Design Diagram 7](#_Toc347235322)

[6.2 Study Type & Design & Schedule 9](#_Toc347235323)

[6.3 Standard Care and Additional to Standard Care Procedures 10](#_Toc347235324)

[6.4 Randomisation 10](#_Toc347235325)

[6.5 Study methodology 11](#_Toc347235326)

[**7.** **Study Population** 11](#_Toc347235327)

[7.1 Recruitment Procedure 11](#_Toc347235328)

[7.2 Inclusion Criteria 11](#_Toc347235329)

[7.3 Exclusion Criteria 11](#_Toc347235330)

[7.4 Consent 11](#_Toc347235331)

[**8.** **Participant Safety and Withdrawal** 12](#_Toc347235332)

[8.1 Risk Management and Safety 12](#_Toc347235333)

[8.2 Adverse Event Reporting 12](#_Toc347235334)

[8.3 Handling of Withdrawals 12](#_Toc347235335)

[8.4 Replacements 12](#_Toc347235336)

[**9.** **Statistical Methods** 12](#_Toc347235337)

[9.1 Sample Size Estimation & Justification 12](#_Toc347235338)

[9.2 Power Calculations 12](#_Toc347235339)

[9.3 Statistical Methods To Be Undertaken 12](#_Toc347235340)

[**10.** **Storage of Blood and Tissue Samples** 13](#_Toc347235341)

[10.1 Details of where samples will be stored, and the type of consent for future use of samples 13](#_Toc347235342)

[**11.** **Data Security & Handling** 13](#_Toc347235343)

[11.1 Details of where records will be kept & How long will they be stored 13](#_Toc347235344)

[11.2 Confidentiality and Security 13](#_Toc347235345)

[11.3 Ancillary data 13](#_Toc347235346)

**[12.](#_Toc347235347)****[Appendix](#_Toc347235347)** [14](#_Toc347235347)

**[13.](#_Toc347235348)****[References](#_Toc347235348)** [15](#_Toc347235348)

## **Glossary of Abbreviations & Terms**

|  |  |
| --- | --- |
| **Abbreviation** | **Description (using lay language)** |
| ETT | Endotracheal tube |
| LMA | Laryngeal mask airway |
|  |  |

## **Study Sites**

### Study Location/s

[List all locations, their address & contact details this study or parts of the study will be conducted]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Site** | **Address** | **Contact Person** | **Phone** | **Email** |
| RCH ED | 52 Flemington Road Parkville 3052 | Dr Elliot Long | 9345-7901 | Elliot.long@rch.org.au |

## **Funding and Resources**

### Source/s of Funding

N/A

## **Introduction/Background Information**

### Lay Summary

The aim of this study is to help improve the safety of emergency intubation. Children intubated outside of the operating room are very sick and are at high risk of adverse events. As part of a hospital-wide initiative to improve the safety of intubations outside of the operating room, we have standardized the equipment available for use. Despite recommendations by governing bodies that this equipment be prepared in a standardized way, it remains unclear whether this happens in practice. Additionally, it remains unclear what interventions may make it easier to standardize intubation equipment preparation. This study will randomize clinicians to unaided airway equipment preparation, preparation with the help of a checklist, and preparation with the help of an airway template. We will compare whether any equipment was forgotten between these groups, as well as the accuracy of the set-up, the time it took to set the equipment up, and clinician confidence and satisfaction with their set-up. This will provide evidence for the use / non-use of checklists and templates for incorporation into daily clinical practice.

Participants in the study will be senior clinicians (doctors and nurses) who would be expected to have the skills to set up airway equipment as part of their job description. The study will take place in the Emergency Department resuscitation bays where intubations normally occur, and participants will have access to all resources they would have in day to day practice. Participants will be identified as working in the resuscitation bays, and the study will be performed during their clinical shift. After obtaining written informed consent, the participant will be read a short scenario and be instructed to set up airway equipment in preparation for planned intubation. The participant will notify the study investigator when he/she has finished setting up the airway equipment, and will then fill in a short questionnaire. The total time taken for the study will be less than 10 minutes. No sealed / sterile equipment will be opened. No sharp or dangerous equipment will be handled. The study investigator will be responsible for cleaning and putting away any equipment taken out for study purposes.

### Introduction

Emergency intubation is a high risk, low frequency procedure. In a published study from our department, 1 intubation was performed every 5 days, and the adverse event rate was almost 50% (1). As part of a hospital-wide initiative to improve the safety of emergency intubation, we have developed a guideline, standardized equipment trolleys, and multidisciplinary team training. Another initiative aimed at improving safety is standardization of intubation equipment. No data exists showing an association between standardized set-ups with improved patient outcome, but it is nonetheless recommended by multiple governing bodies and utilized by many pre-hospital and hospital services (2, 3). This has been compared to the pre-flight checklist used by pilots, or the standardized and well-rehearsed behavior observed in Formula One pits. This study will provide evidence to support or refute the use of checklists / templates in standardizing airway equipment set-up in the non-operating room setting.

This study has been designed to test the omission rate of critically important airway equipment by clinicians using no aids, using an airway checklist, and using an airway template. The “gold standard” airway equipment set-up will be that recommended by the Australian Resuscitation Council (3). The study will be conducted “in situ” (in the clinical area where intubations in the Emergency Department normally occur). This will allow clinicians access to all the resources they would normally use in daily practice. Additionally, they will have familiarity with the type and location of equipment available. A study team member will approach clinicians during a “resuscitation” shift (ie- when they are allocated to be working in the resuscitation area). Participants will be senior nursing or medical staff who would be expected to be familiar with airway equipment set-up. They will be asked to provide written informed consent. Subsequently, they will be provided with a short vignette, and will be asked to set up equipment for intubation of the mock patient. They will be randomized to unsupported set-up, set-up with the help of a checklist, or set-up with the help of an airway template. When the participant is satisfied that all required equipment has been prepared for intubation, the study investigator will record what equipment has been omitted compared to the “gold standard”. The study participant will then be given a short survey to complete to determine their satisfaction and confidence with equipment set-up.

### Background information

Multiple studies evaluating the safety of non-operating room intubations, both in adults and children, have shown that the adverse event rate is considerably higher than that observed in the operating room setting (4, 5). Reason’s postulated for this discrepancy include the degree of un-wellness of patients in non-operating room intubations (intubation is occurring as a component of the resuscitation of the whole patient, who may have compromise of multiple organ systems), the urgent nature of these intubations (precluding careful planning and preparation), the technical aspects of the procedure and the infrequency with which it is performed (making skill acquisition and maintenance difficult), and the non-technical aspects of the procedure (involving the combined efforts of multiple team members from different specialties and backgrounds). As such, no single intervention has been shown to improve patient centred outcomes for non-operating room intubations (6). Following an audit of Emergency Department intubations, The Royal Children’s Hospital Airway Special Interest Group has designed multiple interventions aimed at improving the safety of non-operating room intubations. These include a difficult intubation algorithm, clear pathways for airway escalation, standardized airway equipment housed in identical airway carts in all critical care areas hospital-wide, as well as multidisciplinary team training in the technical and non-technical aspects of airway management. Thus far, over 200 medical and nursing staff have undergone airway team training. The TEMP-T trial sits within the greater project of improving the safety of non-operating room intubations.

The reason to focus on standardized equipment preparation is several-fold. Unlike in the operating room setting, where failed airway management results in postponement of an elective surgical procedure, failed airway management in the non-operating room setting may lead to patient death. The option to wake the patient and defer intubation does not exist. The focus in the operating room setting is only on the airway, no physiological derangements in other organ systems exist, and indeed, no acute compromise of airway or breathing exists in elective surgical cases. In contrast, non-operating room intubations occur as part of the resuscitation of a whole patient, who may have derangements in multiple organ systems. The focus on the airway occurs in the context of focus on breathing, circulation, and disability as well. Non-operating room intubations are time critical. In the operating room setting, diligent planning, indeed in some cases pre-anaesthetic appointments, are possible as the procedure being performed is not time critical. In the non-operating room setting, preparation and planning are compressed into several minutes. This does not leave room for error. The equipment and staff in operating room intubations are familiar, often having worked in the same environment on a daily basis for years. In the non-operating room setting, staff and equipment are unfamiliar. The team managing the patient is almost never comprised of individuals who have rarely worked together before. The equipment and its location / layout are not familiar to those who do not regularly work in that non-operating room environment. In light of these differences, any intervention that can increase the intubator’s familiarity with airway equipment and location may help to cognitively unburden the operator, allow concentration on other critical aspects of the task at hand, and potentially help improve the safety of intubation.

An audit of all major complications of airway management in the UK was performed by the Royal College of Anaesthetists and the Difficult Airway Society and reported in the fourth National Audit Project (NAP4) (2). This audit recommended “standardisation of all airway equipment, including difficult airway and rescue devices, across a hospital or group of hospitals. A checklist should be used for all emergency department intubations. Such a checklist might usefully identify preparation of the patient, equipment/ drugs and team, and preparation for difficulty”.

The Australian Resuscitation Council (ARC) recommends specific intubation equipment be prepared for every paediatric non-operating room intubation (3). This equipment list is being used as the “gold standard” against which study interventions will be based. This is based on the International Liason Committee on Resuscitation (ILCOR) consensus guidelines last published in 2010 (7).

## **Study Objectives**

### Research Question

Does the use of an airway template or checklist decrease the equipment omission rate compared to non-use.

### Primary Objectives

Evaluation of airway cart equipment omission rate by un-aided clinician set-up, set-up aided by checklist, and set-up aided by airway template.

### Secondary Objectives

To evaluate the equipment error rate, preparation time, variability in equipment location, and clinician satisfaction comparing three cohorts- unaided airway cart set-up, set-up aided by checklist, and set-up aided by template.

### Outcome Measures

The primary outcome measure is the equipment omission comparing unaided airway cart set-up to that aided by checklist or airway template.

The secondary outcome measures will be:

1. Equipment error rate
2. Time to completion of airway cart set-up
3. Equipment location variability
4. Clinician confidence and satisfaction

# **Study Design**

### Study Design Diagram

### Study Type & Design & Schedule

The study is a prospective randomized controlled study.

The study is designed as a paper-based intervention of senior medical and nursing staff working in the resuscitation room environment in the Emergency Department of The Royal Childrens Hospital.

The study is single centred.

The study is designed to assess the utility of paper-based interventions (checklist or template) in standardizing airway trolley set-up compared to no intervention. As a randomized controlled study, the primary study objective should be free of bias.

Data collected will include the participant role (medical or nursing) and level of seniority. Additionally, study information will include the rate of omitted items from airway trolley set-up, the error rate in airway trolley set-up, the time taken to set up the airway trolley, and staff confidence and satisfaction with airway trolley set-up. A photo of the airway trolley set up will be recorded for blinded assessment of variability in equipment location. No identifiable information will be recorded at any stage of the investigation.

Data will be collected during the participant encounter for omission rate, error rate, and satisfaction / confidence survey. This data will be recorded on a standardized Clinician Report Form (CRF) (attachment 1). This will be stored in a locked study cabinet accessible only to the primary investigator. A photograph of the airway trolley set-up will be taken with a dedicated digital camera at the time of participant encounter for later analysis. This will be stored on a password protected external hard drive.

Study preparation and planning will take approximately 2 months. Participant recruitment, based on a total number of participants of 61 with 7 study investigators recruiting 3-5 participants per week, will take approximately 1 month. Data collection and analysis will take approximately 2-3 months.

The study does not require home visits.

The study is not being used as part of a student project.

**STUDY TABLE**

|  |  |  |
| --- | --- | --- |
| **Example procedures** | **Assessment/Procedure** | **Assessment 1** |
| **Informed Consent** | **x** |
| **Designation / seniority Information** | **x** |
| **Omission rate** | **x** |
| **Error rate** | **x** |
| **Time to complete set-up** | **x** |
| **Photograph of airway trolley** | **x** |
| **Confidence / satisfaction survey** | **x** |

### Standard Care and Additional to Standard Care Procedures

|  |  |  |
| --- | --- | --- |
| **Standard Care Procedures** |  | **Additional To Standard Care** |
| **Procedure** | **Time/Visit** | **Dosage/Volume** |  | **Procedure** | **Time/Visit** | **Dosage/Volume** |
| Un-aided Airway trolley set-up | Assessment 1 | - |  | Aided airway trolley set-up | Assessment 1 | - |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

### Randomisation

The principal investigator will allocate each study investigator with sealed envelopes containing computer randomised study participant allocation information. The participant groups will be senior medical (1/3), junior medical (1/3), and nursing (1/3). Each participant group will be allocated to equal numbers of the 3 study arms (control, checklist, and template). Study group will be concealed from the participant and study investigator until enrollment has taken place.

## Study methodology

A study team member will approach clinicians during a “resuscitation” shift (ie- when they are allocated to be working in the resuscitation area). Participants will be senior nursing or medical staff who would be expected to be familiar with airway equipment set-up. They will be asked to provide written informed consent (see Appendix 1- Participant Consent Form). Subsequently, they will be provided with a short vignette, and will be asked to set up equipment for intubation of the mock patient. They will be randomized to unsupported set-up, set-up with the help of a checklist, or set-up with the help of an airway template. When the participant is satisfied that all required equipment has been prepared for intubation, the study investigator will record what equipment has been omitted compared to the “gold standard” (see Appendix 2- Clinical Report Form). The study participant will then be given a short survey to complete to determine their satisfaction and confidence with equipment set-up (see Appendix 3- Participant Satisfaction Survey).

## **Study Population**

### Recruitment Procedure

Participants will be identified by the study investigators as clinical staff (medical and nursing) working in the resuscitation area of the Emergency Department of The Royal Children’s Hospital. They will be asked if they have previously participated in the study, and excluded if so. Included participants will be provided with a brief scripted oral description of the study and what participation will involve. They will then be asked for written informed consent prior to enrollment. Control and intervention groups will be randomized.

### Inclusion Criteria

Medical and nursing staff working in the resuscitation area of the Emergency Department of The Royal Children’s Hospital.

### Exclusion Criteria

Prior enrollment in the study.

### Consent

Informed written consent will be obtained prior to enrollment in the study to ensure confidentiality with study procedures and scenarios.

# **Participant Safety and Withdrawal**

### Risk Management and Safety

In the event of participant safety compromise, including psychological distress, the study will be terminated and study information collection terminated.

### Adverse Event Reporting

N/A

### Handling of Withdrawals

Participants who chose to withdraw from the study will have data collection terminated. The participant will be asked the reason for withdrawal and any adjustments in study protocol discussed. Data previously collected from participants who have withdrawn from the study will not be included in data analysis.

### Replacements

Participants who withdraw from the study will be replaced to ensure total included sample size remains unchanged.

# **Statistical Methods**

### Sample Size Estimation & Justification

Our sample size calculation is based upon the absolute omission rate. We estimate from observations of current practice that omission rate is 80% without any template/checklist usage. We estimate that introduction of the template or checklist will result in an improvement to a 20% omission rate. Using a superiority design, recruiting 21 participants per group delivers a power of 0.99 with an alpha of 0.05, therefore 63 participants will be recruited. This is recruitment is feasible with current staffing levels at RCH ED.

### Power Calculations

We estimate that the omission rate will improve from the 80% control rate to 20% using the template or the checklists. Using a superiority design, recruiting 21 participants per group delivers a power of 0.99 with an alpha of 0.05.

### Statistical Methods To Be Undertaken

Randomization will use block randomization using computer generated quasi-random numbers. Randomization will be stratified according to clinician seniority with equal distribution of strata (senior medical staff, junior medical staff and nursing staff) per arm. The statistical analysis will be by intention to treat. The primary outcome is dichotomous and effect sizes will be presented as proportions of intervention and control groups who have reduced their omission rate. Primary and secondary outcomes have non-Gaussian distributions. Odds ratios and 95% confidence intervals will be calculated. Primary outcome analysis will be the comparison of proportions of two independent samples using χ2 test.

# **Storage of Blood and Tissue Samples**

## Details of where samples will be stored, and the type of consent for future use of samples

No blood or tissue samples will be obtained for study purposes.

# **Data Security & Handling**

### Details of where records will be kept & How long will they be stored

Clinical report forms will be stored in a locked cabinet in a secure non-clinical area. Study records will be kept for a minimum of 7 years post study closure.

### Confidentiality and Security

No identifiable study data will be collected. Consent forms will be stored in a locked cabinet in a protected non-clinical area for a minimum of 7 years post study closure.

### Ancillary data

Photographs of airway trolley set-up will be stored on a password protected single-user hospital desktop computer and backed up to a password protected external hard drive. They will be stored for a minimum of 7 years post study closure. No photographs will include identifiable participant information.

# **Appendix**

**List of Attachments included:**

|  |  |  |
| --- | --- | --- |
| **Document Name** | **Version Number** | **Date (e.g., 18 January 2012)** |
| Participant Consent Form | 1 | 11/03/2015 |
| Clinical Report Form  | 3 | 11/03/2015 |
| Participant survey | 1 | 11/03/2015 |
| Intubation Checklist | 12 | 23/01/2015 |
| Airway template | 1 | 23/01/2015 |
| LNR Signed Application Form  | 1 | 11/03/2015 |
| TEMP-T participant sheet | 1 | 11/03/2015 |
| TEMP-T pre-amble and vignette | 3 | 11/03/2015 |
| TEMP-T pre-submission Peer Review | 1 | 11/03/2015 |
| TEMP-T protocol  | 6 | 11/03/2015 |

# **References**

1. Long E, Sabato S, Babl FE. Endotracheal intubation in the pediatric emergency department. Paediatr Anaesth. 2014;24(12):1204-11.

2. Cook TM, Woodall N, Harper J, Benger J. Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 2: intensive care and emergency departments. Br J Anaesth. 2011;106(5):632-42.

3. Advanced life support for infants and children diagnosis and management. ARC and NZRC Guideline 2010. Emerg Med Australas. 2011;23(4):400-2.

4. Kerrey BT, Rinderknecht AS, Geis GL, Nigrovic LE, Mittiga MR. Rapid sequence intubation for pediatric emergency patients: higher frequency of failed attempts and adverse effects found by video review. Annals of Emergency Medicine. 2012;60(3):251-9.

5. Nishisaki A, Ferry S, Colborn S, DeFalco C, Dominguez T, Brown CA, 3rd, et al. Characterization of tracheal intubation process of care and safety outcomes in a tertiary pediatric intensive care unit. Pediatric Critical Care Medicine. 2012;13(1):e5-10.

6. Kennedy CC, Cannon EK, Warner DO, Cook DA. Advanced airway management simulation training in medical education: a systematic review and meta-analysis. Crit Care Med. 2014;42(1):169-78.

7. Biarent D, Bingham R, Eich C, Lopez-Herce J, Maconochie I, Rodriguez-Nunez A, et al. European Resuscitation Council Guidelines for Resuscitation 2010 Section 6. Paediatric life support. Resuscitation. 2010;81(10):1364-88.