The Australia and New Zealand Emergency Department Airway Registry

Study Protocol

Version 1.1

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Introduction

Advanced airway management is an accepted core skill of Emergency Physicians in Australasia. RSI is, however, a high-risk procedure that has been shown to have an increased rate of severe complications – such as failed intubation, hypoxia, hypotension or surgical airway – when it takes place in the Emergency Department (ED) in comparison to the operating theatre. The recently published Fourth National Audit of Major Complications of Airway Management in the UK reviewed severe complications associated with airway management in the Emergency Department (ED). The authors found that a large proportion of events occurred out of hours, without consultant supervision, or without the operators following standard airway management algorithms and "failing to plan for failure."

Several studies have been published that describe the performance of intubation in the EDs of North America, UK, Korea and Japan, but to date, only a single centre study has been published from an Australian ED. This study, carried out at the Royal North Shore Hospital, prompted significant changes in the practice of intubation in that ED, along with an increased educational focus on the subject, in order to improve clinical management.

This project is being led by Dr. Toby Fogg and Dr. John Vassiliadis from the Royal North Shore Hospital ED, as a collaborative research venture with other EDs across Australasia and the Emergency Care Institute in NSW. It is a surveillance study to acquire data on the practice of intubation in the ED in order to improve the quality of care associated with this procedure.

Objectives

Primary Objectives

1. This project will provide each participating department the data that they will require for audit of their practice, with the hope that departments will highlight areas of potential process improvement and then enact change.

2. Pooled data will be used for a descriptive study of the practice of intubation in Australasian EDs, with particular emphasis on the indication, staff seniority, techniques (eg induction drugs or type of laryngoscope), number of attempts at laryngoscopy required and the rate of complications. We will compare tertiary, urban district and regional EDs, as well as FACEM/Registrar/CMOs (or equivalent), with regard to the above metrics.

Secondary Objectives

Due to the large database this project will create, it will allow us to investigate more specific research questions, including:

1. Can ED physicians predict difficulty of laryngoscopy?

2. Identify behaviours towards failed intubation at different experience levels – eg SRMO/REG/CMO/Specialist

3. Complication rates with reference to pre-oxygenation techniques, drugs and patient positioning

4. Comparison of different video laryngoscopes

5. Impact of manual in-line stabilisation/cricoid pressure/bougie on success

6. Use of a pre-RSI checklist

7. Drug choices for RSI

It should be noted that this list is not exhaustive and other areas of interest may arise as data collection and surveillance continues. See Supplementary File 1 – ANZEDAR Research Proposals - for a more detailed proposal of current research questions. See Page 9 for the policy on authorship.

Methods

This will be a prospective observational study of all intubations carried out within participating EDs.

Sample Size

A convenience sample will be used of all patients intubated in participating EDs over a 12-month period. Experience at three tertiary EDs in Sydney suggests an average rate of 170 per year per ED. This equates to 2.6 intubations per 1000 presentations (actual values = 1.73, 2.33, 3.81). Indications for intubation due to trauma at these hospitals – all major trauma centres – comprised approximately 30% of the total. At an urban district hospital ED in Sydney, 35 intubations were recorded in one year – this institution has an annual census of 24,000. This yields an intubation rate of 1.5 per 1000 presentations.

Data Collection

The team leader or the intubator will complete a data collection form – (Supplementary File 2 – ANZEDA Registry) as close to the time of intubation as possible. Any missing data will be established through interview with the staff involved and/or from the medical record.

"Clinical Champions", also known as Principal Investigators, will be required in all centres, with the responsibility of driving the project and ensuring data quality. Some episodes of intubation will be missed unless there is a checking process in place. Possible procedures include checking the resus patient registry books that are compiled by some departments or via review of the controlled drugs register, or equivalent, to identify patients who were administered thiopentone, propofol or ketamine for example. Each site will report the methods they use to ensure data accuracy, as this information will be described in the paper to discuss limitations and bias. A data compliance rate of at least 90% should be achieved.

The Clinical Champion should have regular discussions with staff in order to ensure accuracy and completeness of data. This will also allow for case directed teaching to occur if required. Feedback sessions have been found to be beneficial. Data can be presented every 3-4 months to the clinicians and this will highlight some of the significance of the project and help to hardwire the practice of data collection.

Data Forms

Data is initially recorded on a paper data collection form, ideally as close to the time of intubation as possible. It is later transcribed into an Excel file at each participating site by the Clinical Champion or their delegate (see below).

Much thought has been given to primary data entry directly into an online database but considerations with this include:

- Cost in proportion to the size and scale of the project
- Practicalities of IT solutions in a busy ED: a paper form provides a recognised basis for collating items of clinical information
- Needing to navigate through hospital firewalls across states and countries
- Speed of data entry – all trialled software options were slower than paper
- Providing a mechanism whereby users can easily return to partially completed forms and complete or amend them
- Paper provides ease of review for educational purposes and ensuring data integrity

The data forms are designed to be printed double sided and in colour and should be kept in a folder in the resuscitation area. Graphics for the folder and reminders for staff are available in Supplementary File 3 - Promotional Material.

Data Management and Security

The completed paper data collection forms will remain at the local sites. They will contain the patients name and MRN as this ensures the medical record can be reviewed, if necessary, to verify that the data is complete and accurate. They should be stored in a secure location managed by the Clinical Champion e.g. project file in a locked filing cabinet. These forms should be stored for a period of time as dictated by local ethics committees.

For collation, each site will have its own copy of a customised Excel spreadsheet into which data is entered. The data entry will be undertaken by the Clinical Champion or designated administrator assigned by the Clinical Champion with responsibility for data quality. The spreadsheet provides a copy of the form's data fields with fixed dropdown list response fields. This will help ensure consistent data entry.

To ensure a significant degree of anonymity in the spreadsheet, the Excel file will not contain the patients' MRN, name or date of birth. For data quality purposes, however, in order to trace an excel entry back to the paper form, the entry code from the relevant Excel line (eg RNSH 1, RNSH 2) will be copied on to the paper form at the time of data transcription. This allows records to be traced but ensures the individual is unable to be identified without access to the both the paper form and the medical record.

File Naming Convention

Blank Excel files will be downloaded each month from the ECI website and named according to the following protocol:

The Excel file name should be of the following structure:

Ordernumber_sitename_year_monthend_issue number.xls (or.xlsx)
Eg: **1_RoyalNorthShore_2014_Feb_2.xls**

Note the use of under-scores between the fields – with no spaces please. The following explains each element:

1) The Order number is the number of data sheets sent up until now (i.e. the first data sheet is 1, the second datasheet is 2 etc). It helps every one keep a track of where we are.

2) Please can each site choose their own brief name? (e.g. 'RoyalNorthShore' and 'StVicentSyd' is preferable to 'RNHS' or SVH).

3) The year and month end are those of the most recent case in the datasheet. If the cases span 2-3 months or over a year, just state the year and month for the last case.

If there are a few old cases from way back in the data (e.g. from a lost form) it does not matter. They get sorted out in the database. The file name should include the year then month so the files all order correctly in file manager when sorted/ordered.

4) An issue number can be omitted, but needs to be added if a data set is resent for some reason (e.g. an error in the data is corrected, or updated data with new information about cases is found etc.). It distinguishes the updated excel file from the older one.

Once a month's data is completed, the excel file is to be sent to this dedicated email address: AirwayRegistry@aci.health.nsw.gov.au.

In the event that more than 30 entries are required to be entered in a month, another excel sheet is to be downloaded and named as per the previous file sent but with the next order number in the sequence.

The data will be stored on Ministry of Health servers, within secure premises managed by HSS (the NSW Ministry of Health's IT provider). According to the monthly cycle, the project's central project manager will collate and quality-check the data (e.g. reviewing completeness of data fields, erroneous data entries etc).
After a period of 10 years, the data will be securely erased from the servers.

Data Analysis

Dashboard Style Reports

After upload, the data file will be analysed and a report will be generated and sent back to the site. This report will show:

1. Demographics, eg patient age, sex, indication for intubation
2. Time of day that intubations are occurring
3. Number of patients predicted to have difficult laryngoscopy
4. Degree of physiological derangement (eg number who presented hypotensive or hypoxic) before RSI was commenced
5. Patient positioning for RSI
6. Use of pre RSI checklists
7. Drugs used for sedation and paralysis
8. Seniority and experience of intubator
9. Number of attempts required, what is first pass success rate
10. Devices/blades used and Cormack and Lehane grades of laryngeal view obtained
11. Use of airway adjuncts, laryngeal manipulation and cricoid pressure
12. Use of capnography
13. Incidence of airway manoeuvres and complications

The report will also compare local performance with all the data to enable benchmarking. Site-specific data will not be revealed to other sites.

Study Questions

All data will be entered into Microsoft Excel 2010 (Microsoft, Redmond, WA, USA) and analysed using SPSS PASW version 18.0 (SPSS, Inc., Chicago, IL, USA). Descriptive statistics will include median and inter- quartile range (IQR from the 25th to the 75th percentile). χ^2-test or, as appropriate, exact tests will be used to compare groups of categorical data and to test for trends. Logistic regression analysis using the direct method will be used to calculate the odds of success of intubation on first attempt. For all analyses, actual *P*-values will be reported and all tests will be two-tailed. Statistically significant differences will be considered at the $P < 0.05$ level, and 95% confidence intervals (CI) will be presented where possible.

Definitions

This list is reproduced as a single page for the purpose of printing in Supplementary File 4 – Definitions.

- **Every** intubation in the E.D is to be included, not just RSIs. If no drugs are administered, these patients do not have a time of induction entered, only a time of intubation.
- **Team Leader**. This is the person in overall charge of patient management i.e. the most senior clinician present. For example, if an ED Registrar is acting as team leader, but an ED Specialist is present, the Specialist is the team leader.
- **Indication for Intubation.** Only tick one indication for intubation - occasionally "other" may need to be used and this should be clarified below.
- **Difficult laryngoscopy.** Was laryngoscopy predicted to be difficult and if so, elaborate in the comments section on what basis? The question regarding a formal airway assessment refers to the use of any standardised tool, eg the LEON (described on page 2 of the data form) or LEMON criteria.
- **Observations.** These are taken at the time of the decision to intubate and immediately after intubation is achieved.
- **Preoxygenation.** Indicate which mask is the one used prior to intubation, eg if the non re-breather mask is taken off and a BVM used, indicate only BVM.
- **Apnoeic Oxygenation.** Indicates oxygen delivery (usually Nasal Prongs) once the patient is rendered apnoeic by the induction drugs. If the patient receives active bag-valve-mask ventilations from this point until attempts at laryngoscopy are made, BVM should be ticked. Tick both NP and BVM if both are used.
- **Patient Position.** Tick the one that applies at the time of induction.

    - **Flat –** the patient is lying flat in the bed
    - **Bed tilted head up** – the whole bed is tilted 20-30 degrees head up, ie reverse Trendelenburg
    - **Pillow or Pad** – there is a pillow or small pad under the occiput
    - **Ramped or head up** – Patient's head /neck / shoulders elevated
- **Drugs.** If multiple doses of induction agent are given for repeated attempts at a prolonged intubation, state the first dose only. If a top up follows the first dose because it was inadequate, write down the total dose.
- **Attempts**. An attempt at intubation is defined as the passage of the laryngoscope blade into the mouth.
- **Prior experience.** This is somewhat arbitrary, as no clear definitions of novice or expert exist in the emergency literature. Intubators rarely know if they have performed 90 or 110 but they will likely perceive themselves to be an "expert ED intubator", i.e. mark the form as >100.
- **Blade types.** If an ED has more than one video laryngoscope available the specific type used will need to be specified. If not, "V" only can be marked.
- **External Laryngeal Manipulation** = bimanual laryngoscopy.
- **Capnography.** Tick the device used for immediate ETT position confirmation
- **Complications.** To be included, complications should occur within 10 minutes of completion of the RSI even if they are recognised after this time. For example, a reduction in the BP requiring a fluid bolus after 5 minutes is included as is a mainstem bronchial intubation identified when the CXR was reviewed after 20 mins.
- **Desaturation.** Include all patients whose oxygen saturation (SaO_2) dropped <93%, even if the SaO_2 was below this level when the first attempt commenced.
- **Hypotension**. Transient, mild hypotension that does **not** prompt either a fluid bolus or a dose of pressor/inotrope does **not** need to be recorded.

Project Timeline

Data collection has already commenced at some sites in Australia and New Zealand.

- These sites will transfer to the new data collection sheet by end of May 2013.
- Their data will be transcribed on to the new Excel file by the end of June 2013.

New sites will come on line over the next few months as ethics approvals are achieved. Once sites have their ethics approval, they will start data collection and continue for a 12-month period. All the 12-month blocks of data will be pooled and analysed with regards to the primary objective.

Data collection may continue beyond 12 months for ongoing site-specific audit and for answering secondary objectives.

Study Authorship and Database Access

The principal authors of the study are listed below.
Site Investigators will have their contribution acknowledged in the descriptive papers but will not be listed as authors unless they contribute to data analysis or writing a manuscript.

The database will be held securely at the ECI on password-protected servers owned by the Ministry of Health. A researcher may make a written application to the ECI to access the database in order to research a specific question and a committee comprising the investigators listed below will review their proposal. Authorship of subsequent papers will include the investigators listed below. Ethics approval for such a secondary study will need to be obtained.

Ethics Approval

RNSH HREC has granted ethics approval: (Study no. LNR/12/HAWKE/306)
Site-specific approval still needs to be obtained for each new ED in NSW.

Ethics approval has also been granted for sites in Victoria, Queensland and Tasmania, Western Australia and New Zealand.

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