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**Emergency Front of Neck Airway Registry**

**Final Version 1.0**

**21 December 2023**

**Short title:** Emergency Front of Neck Airway Registry

**Acronym:** eFONAR

**IRAS Project ID:** 330418

**Study Sponsor:** University of Nottingham

**Sponsor reference:** 23047

**Funding Source:** Royal College of Anaesthetists / Difficult Airway SocietySTUDY PERSONNEL AND CONTACT DETAILS

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# SYNOPSIS

|  |  |
| --- | --- |
| Title | Emergency Front of Neck Airway Registry |
| Acronym | eFONAR |
| Short title | Emergency Front of Neck Airway Registry |
| Chief Investigator | Professor Iain Moppett |
| Objectives | PRIMARY OBJECTIVETo provide a systems-based analysis of events and decision-making in the process of eFONA SECONDARY OBJECTIVESTo examine the qualitative relationships between eFONA and:* Patient characteristics
* The planned operation or procedure
* Pre-anaesthetic assessment and investigation of the airway
* Human factors
* Equipment selection and techniques used
* Guideline compliance and effectiveness.

To provide quantitative descriptions of the populations, techniques and processes reportedTo provide evidence-based recommendations for practice at national, hospital and individual levels |
| Study Configuration | National registry of anonymously reported, anonymous case reports of Emergency Front of Neck Airway events, with systems-based expert review |
| Setting | Secondary care |
| Number of participants | Estimated number of cases entered over three years: 300 |
| Eligibility criteria | All cases where an eFONA procedure has been attempted or performed, whether successfully of unsuccessfully, will be eligible for inclusionAll patients can be included regardless of age (number of cases involving children expected to be exceedingly small) |
| Description of interventions | Reporting of events around the time of eFONA event. No direct participation of patients. No interventions will be performed. |
| Duration of study | Three years. Up to 2 hours of data collation and completion of registry by reporter. |
| Methods of analysis  | Review of cases individually and collectively by the panel using SEIPS 2.0 systems-based framework. |

# ABBREVIATIONS

CAG Confidentiality Advisory Group

CI Chief Investigator overall

CRF Case Report Form

CR&I Centre for Research & Improvement

DAS Difficult Airway Society

eFONA emergency Front of Neck Airway

GCP Good Clinical Practice

HSC-PBPP NHS Scotland Public Benefit and Privacy Panel for Health and Social Care

NAP National Audit Project of the Royal College of Anaesthetists

NHS National Health Service

RCoA Royal College of Anaesthetists

REC Research Ethics Committee

REDCap Research Electronic Data Capture (a secure web application for building and managing online surveys and databases)

R&D Research and Development department

SEIPS 2.0 System Engineering Initiative for Patient Safety (analysis framework)

UoN University of Nottingham

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# STUDY BACKGROUND INFORMATION AND RATIONALE

During an operation or a period in intensive care, patients may need help with their breathing to provide adequate oxygenation. Once a patient is anaesthetised, one key role of the anaesthetist is to ‘manage their airway’. For most, this process is routine and straightforward. Very occasionally, successful airway management is much more challenging, and there is a risk of potential severe patient harm, including brain damage, cardiac arrest, and death. When anaesthetic teams encounter these ‘difficult airways’, they use guidelines to act decisively to deliver oxygen effectively in a timely manner. If these steps fail, the final option is to deliver oxygen directly into a patient’s windpipe (trachea) through the front of the neck. This procedure is called an emergency front-of-neck airway (eFONA) and can be lifesaving.

Emergency front-of-neck airways are very rarely required, however, collecting information about and learning from these events is difficult given their rarity.

The 4th National Audit Project (NAP4) of the Royal College of Anaesthetists and the Difficult Airway Society was a pan-UK service evaluation of adverse events in airway management. [[1]](#endnote-1)

It included 58 cases of eFONA out of approximately 3 million surgical episodes. However, the authors concluded, “Further research focused at identifying the success rates and optimal techniques of cannula cricothyroidotomy is required.” A randomized controlled trial in this area will never be possible due to ethical implications, therefore a national registry may offer an opportunity to safely gather this information.

**Why is this registry needed?**

An anaesthetic is not a treatment but rather it facilitates surgery to an affected organ or limb; mechanical ventilation of a critically ill patient; or the emergency management of a sick or injured patient in the emergency department. Whilst the need for the creation of an emergency front of neck airway is rare the potential for an adverse outcome (brain damage or death) is significant should this occur.

The creation of an emergency front-of-neck airway is recognised as the final step in attempting to provide enough oxygen to a patient under general anaesthetic. Fortunately, it is needed rarely, but this means that experience is gathered on individual case reports of success and failure. Multiple factors are thought to impact on the need for and success of eFONA. These include patient characteristics (e.g. age, body habitus); the context (e.g. emergency situations); the operator (e.g. seniority, training); the preceding events (e.g. airway assessment and management); techniques used (type of eFONA equipment), team-work and human factors. A registry will allow these cases to be examined fully and systematically to identify significant themes common to some or all cases, areas of good and inadequate practice and make recommendations that will allow doctors working in anaesthesia, intensive care and emergency medicine to save more lives in the future.

Collecting data from a cohort of cases will allow practice in this field to be improved and save lives, resulting in decreasing the risk of harm to patients by maximising the success rate of this rare but high-stake event therefore allowing more patients access to surgery safely for its primary purpose.

# STUDY OBJECTIVES AND PURPOSE

## PURPOSE

1. To improve care and outcomes for patients who require eFONA
2. To reduce the risk of patients needing eFONA in the first instance by improving care and outcomes

## PRIMARY OBJECTIVE

To provide a systems-based analysis of events, decision-making and patient outcomes in the process of eFONA.

## SECONDARY OBJECTIVES

To examine the qualitative relationships between eFONA and:

* Patient characteristics
* The planned operation or procedure
* Pre-anaesthetic assessment and investigation of the airway
* Human factors
* Equipment selection and techniques used
* Guideline compliance and effectiveness

To provide quantitative descriptions of the populations, techniques and processes reported.

To provide evidence-based recommendations for practice at national, hospital and individual levels.

# STUDY DESIGN

## STUDY CONFIGURATION

The registry will collect details of voluntary, anonymously reported, de-identified cases of emergency front of neck airway, a rare, life-threatening event. Data will be reported by clinicians from hospitals within the UK. These reports will then be reviewed by a review panel that will generate a systems-based analysis of events and decision-making in the process of eFONA. This systems-based analysis will be used to inform generation of evidence-based recommendations for practice at national, hospital and individual level.

## STUDY MANAGEMENT

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

There will be a study management group consisting of:

Dr Alastair McNarry, co-lead, former Royal College of Anaesthetists National Airway Lead.

Dr Parineeta Ghosh, eFONA fellow, Centre for Research & Improvement, RCoA

PPI representative (to be appointed)

Ms Laura Cortes, Research Co-ordinator, Centre for Research & Improvement, RCoA

## DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration:

Three years of data collection. Two years to analyse and publish data.

### End of the Study

The end of the study will be the last case reported.

## SELECTION AND WITHDRAWAL OF PARTICIPANTS

### Recruitment

The project will be based on voluntary reporting of NHS and non-NHS hospital-based events/cases by clinicians. The project will not directly contact clinicians to submit cases/ participate. The Registry will instead be advertised through the Royal College of Anaesthetists Airway Leads Network, through journal articles of the Royal College of Anaesthetists and the Difficult Airway Society Newsletter and presentations/ reminders at national meetings where clinicians involved in airway management will be present.

### Eligibility criteria

### Inclusion criteria

All cases where an eFONA procedure has been attempted or performed, whether successfully or unsuccessfully, will be eligible for inclusion.

All patients can be included regardless of age (although we expect the number of cases involving children to be small).

### Exclusion criteria

Non-emergency front of neck airway (this is sometimes performed as a planned procedure)

### Expected duration of participant participation

There is no direct contact with or active participation by patients involved in the study. Consent will not be sought from study participants (see below).

### Participant Withdrawal

Hospitals and health professionals record when a patient or parent/guardian does not want their / their child’s notes to be used for research. Patients/parents/guardians can inform the clinical teams if they do not wish their medical notes to be used for research. Should dissent be noted for the use of data in research we will not use it. Reporters will be explicitly asked to confirm that they are not aware of such dissent.

The data are anonymous with no link back from data entry to the clinician or the involved patient. It will be impossible to withdraw data as there is no method to accurately identify an individual even if they believe they have been included.

### Informed consent

Due to the eFONA reporting methodology, no explicit patient consent is sought. The registry will not receive or transfer any patient-identifiable data from reporting clinicians. No unique patient identifiers (e.g. name, date of birth, postcode, NHS number) will be recorded at any stage. Although direct identifiers are not being collected, the rarity of events, and the collection of some case characteristics (e.g. sex, ethnicity) means that we would seek approval from relevant panels (e.g. Confidentiality Advisory Group (CAG) in England and Wales / NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP)/ HSC Privacy Advisory Committee (NI).

## STUDY REGIMEN

The study closely follows the processes used by the Royal College of Anaesthetists in its UK-wide service evaluations – National Audit Projects (NAPs) 4-7.1 [[2]](#endnote-2) [[3]](#endnote-3) [[4]](#endnote-4) [[5]](#endnote-5) [[6]](#endnote-6) [[7]](#endnote-7) Cases are submitted anonymously by reporters about specific events and the cases are individually and collectively analysed by the panel to derive learning and recommendations from these findings can help in improving patient care and outcomes.

**Case Registry**

Data will be voluntarily uploaded by a participating clinician to REDCap servers hosted by the University of Nottingham. The project will not directly contact clinicians to submit cases/ participate. The Registry will instead be advertised through the Royal College of Anaesthetists Airway Leads Network, through journal articles of the Royal College of Anaesthetists and the Difficult Airway Society Newsletter and presentations/ reminders at national meetings where clinicians involved in airway management will be present.

Reporters will enter data directly into a secure research database, REDCap. The database portal will be accessed using a password issued to a clinician who may or may not be the reporting clinician by emailing or telephoning the administrative team at the Royal College of Anaesthetists. There is no mechanism to allow the central team to identify whether a request for a password translates to submission of case details.

The broad domains of data collected are as below, there will be mandatory fields and forms cannot be submitted without their completion.

|  |  |
| --- | --- |
| Screening | Ensuring cases meet inclusion criteria |
| Patient | Details about the patient |
| Settings and Timing | Times of day, where (e.g. Operating theatres, emergency department) |
| Preparation | Planning, assessment, and preparation |
| Personnel | Who was present |
| Checklist | Checklists and guidelines used |
| Plan | Primary and back up plans for airway management |
| Preoxygenation | Process of delivering oxygen / removing nitrogen from the lungs |
| Process | What happened, in what order etc. |
| Airway Problems | How were the initial airway problems managed? |
| eFONA | How was the eFONA managed? |
| Outcome | What were the outcomes? |

**Systems analysis**

Periodically (depending on the frequency of reporting, but 3 monthly is indicative) during the three-year case reporting period, the review group will meet to review the data using a structured, systems-based approach (SEIPS 2.0 – see below).

The panel consists of a group of clinicians and lay member with varied experience and expertise in planned and emergency airway management. This will include difficult airway experts and anaesthetists of varying grades (experienced and less experienced individuals) to ensure diversity and to encourage a variety of perspectives and backgrounds, with the aim of reducing the risk of groupthink. The panel will be provided specific training on the SEIPS approach by an expert in this methodology.

There will be no data linkage to other databases or sharing.

### Criteria for terminating the study

Basic descriptive statistics to examine the number of cases in the registry will be monitored throughout the study. As no intervention is taking place, the research team do not anticipate any untoward incidents occurring because of the registry. Study progress will be reviewed at least annually by the Royal College of Anaesthetists Centre for Research & Improvement, and the Difficult Airway Society research committee. Poor recruitment despite every attempt to improve the situation may also lead to a discontinuation of the registry.

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals; safety; or any other administrative reasons.

# ANALYSES

### Methods

**Quantitative**

Simple descriptive statistics will be used to summarise the characteristics of submitted cases numerically (e.g. means, median, modes, counts) and visually (e.g. box plots) with due regard for suppression of small case numbers.

**Qualitative**

Periodically (depending on the frequency of reporting, but 3 monthly is indicative) during the three-year case reporting period, an expert review group will meet and review the uploaded cases to identify themes around patient factors, equipment factors, technique used and human factors in the performance of eFONA.

The panels will use the SEIPS 2.0 framework to integrate these aspects, using the concepts of the work system, processes, and outcomes.



Figure 1. SEIPS 2.0 conceptual diagram (from Holden et al[[8]](#endnote-8)).

The panels will review each case as a small group (3-4 members). The whole panel will then review all the cases within the (three-month) period together to compare and contrast across cases, and to seek consensus on key themes within and between the systems and subsystems for individual/groups of cases. As an iterative process, the factors and themes are likely to develop during the time of the registry. Indicative domains, based on the SEIPS 2.0 methodology and combined with the experience of NAP4, subsequent NAPs, and expert opinion, include:

* Persons(s): *Clinicians involved, patient and context information: (age category, gender, operative speciality (includes critical care), presence or absence of airway assessment, previously recorded airway difficulties) and patient outcome* (to explore if any inferences can be drawn between those with successful and unsuccessful outcomes including death or disability (as far as known at time of reporting)
* Tasks: *Cycle of events information/sequence of events - to determine the effectiveness of the rescue strategies employed and whether they followed nationally recognised guidelines.*
* Tools and technologies: *eFONA technique employed including medical equipment used/*effective functioning of available emergency equipment*.* This information can be analysed for to assess usability, accessibility, familiarity, and functionality.
* Organisation: Time of event, location, resources available e.g. availability of senior personnel, training of the team
* Internal environment: Physical environment e.g. noise, lighting, physical layout
* External environment: National guidelines

### Sample size and justification

We estimate that there will be around 100 eligible cases per / year across the UK, but the precise number is unknown. We have therefore taken a pragmatic approach to our registry duration, balancing the need to collect data with the possibility of participant fatigue. A three-year period in the first instance allows one year after the registry shuts for analysis and publication and keeps us within a 5-year window.

# ADVERSE EVENTS

The occurrence of an adverse event because of participation in this study is not expected and no adverse event data will be collected.

# ETHICAL AND REGULATORY ASPECTS

## ETHICS COMMITTEE AND REGULATORY APPROVALS

Explicit patient consent is not sought through the eFONA / NAP reporting methodology. NAPs are undertaken without seeking individual consent and use limited identifiable data to protect confidentiality. Confidentiality Advisory Group (CAG) in England and Wales / NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP)/HSC Privacy Advisory Committee (HSC PAC) in NI) support will be obtained for access to patient identifiable information without consent.

The study will not be initiated before the protocol has received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider’s Research & Development (R&D) department, and the Health Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice and the UK Department of Health Policy Framework for Health and Social Care, 2017.

## INFORMED CONSENT AND PARTICIPANT INFORMATION

Due to eFONA reporting methodology, no explicit patient consent will be sought. Previous NAPs have been undertaken without seeking individual consent and use limited potentially identifiable data to protect confidentiality. The study team and expert review panel will not receive any directly identifiable patient data from reporting clinicians.

Voluntary and anonymous reporting is a recognised limitation of the registry. However, previous experience is that it improves reporting, creates a ‘safe’ environment for reporters and creates a complete firewall between reporters and the central review team ensuring that reporters, their institutions, and the cases (patients) cannot be identified.

Seeking consent from individuals involved risks creating bias in the registry,[[9]](#endnote-9) as well as allowing identification of the reporter. Similar issues have been recognised in other rare case registries and a waived consent approach i.e. approval via Confidentiality Advisory Group (CAG) / NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP)/HSC Privacy Advisory Committee (HSC PAC) in NI has been used in similar studies in the perioperative period in the UK[[10]](#endnote-10) and internationally,[[11]](#endnote-11) [[12]](#endnote-12) where the risk of selection bias is well recognised.

## RECORDS

### Case Report Forms

Each individual case will be reported by an anaesthetist using the REDCap electronic weblink reporting system. This report will not contain any patient directly identifiable data. No information concerning the place or date of the case will be recorded. These data will be reviewed in REDCap and any identifiable data that has been erroneously added will be removed by the eFONA project team before any further processing.

Data is stored in the UoN data centre on the locally hosted REDCap instance at the University of Nottingham King’s Meadow campus data centre where access is restricted.

All REDCap data will be treated as confidential and held securely in accordance with regulations. Access to REDCap shall be restricted to those personnel approved by the Chief or local Investigator and recorded as such in the study records.

The REDCap database includes a full audit trail.

Case reviews will be completed outside of REDCap. These will contain no potentially identifiable data and will be stored securely on University of Nottingham servers.

### Source documents

Only study staff shall have access to study documentation other than the regulatory requirements listed below.

### Direct access to source data / documents

The REDCap database shall made be available at all times for review by the Chief Investigator, Sponsor’s designee and inspection by relevant regulatory authorities.

## DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study’s participants to privacy and will adhere to the Data Protection Act, 2018. The REDCap instruments will only collect the minimum required information for the purposes of the study. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer-held data including the study database will be held securely and password-protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method).

Electronic data will be backed up every 24 hours to both local and remote media in an encrypted format.

# QUALITY ASSURANCE & AUDIT

## INSURANCE AND INDEMNITY

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects.

## STUDY CONDUCT

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria); accountability of study materials.

The Study Coordinator or where required, a nominated designee of the Sponsor, shall carry out a site systems audit at least yearly and an audit report shall be made.

## STUDY DATA

Monitoring of study data shall include data storage and data transfer procedures, local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Where corrections to the REDCap data have been made these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

## RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all study databases and associated meta-data encryption codes.

## DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

## STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Data generated as a result of this study will be available for inspection on request by the University of Nottingham representatives, the REC and the regulatory authorities.

# PUBLICATION AND DISSEMINATION POLICY

An interim summary will be produced annually and published in an appropriate format such as peer-reviewed scientific publications, conference presentations, on the Royal College of Anaesthetists Centre for Research & Innovation and Difficult Airway Society webpages.

A final summary report will be produced and similarly disseminated. Alongside this, recommendations will be made for institutions, training bodes, and departments and disseminated through appropriate channels.

All data will be reviewed before dissemination to ensure that no individual can be identified as being one of fewer than five people in each of several categories.

# USER AND PUBLIC INVOLVEMENT

Patient and Public Involvement/Engagement (PPI/E) has been and will continue to be embedded within the project. The Difficult Airway Society Lay representative has been involved in several years of discussions around the proposal for the eFONA Registry.

This project proposal was discussed at Patient, Carer & Public Involvement and Engagement (PCPIE) - Centre for Research and Innovation PCPIE group. Feedback from the group highlighted the strengths and need of this project as the formation of an emergency front-of-neck airway (eFONA) is a major complication of anaesthesia with significant implications for both the patient and the healthcare team. Because of the rarity of eFONA, learning at the individual or local level is likely to be very limited. A registry would address the difficulties of gaining meaningful information through other research methods. Most of the group members felt that the severity of eFONA and the recognised need for learning justifies the proposal to collect data without explicit consent from the patient (or consultation with a close friend or family member).

A lay representative will be specifically recruited to the expert review panel. In addition, they will be integral to the publication of the results and to make the results accessible and interpretable to the general public. The Centre for Research & Improvement (CR&I) of the Royal College of Anaesthetists (RCoA) also includes formal lay representation on its Board, where all projects (including eFONA) are reviewed on a regular basis.

### Topic selection

The broad study question was identified as necessary following the publication of the NAP4 report by both the Royal College of Anaesthetists and the Difficult Airway Society where there is significant lay input.

A lay representative will be an integral part of the expert analysis group ensuring that the themes identified are relevant to patients directly

### Undertaking the research

We do not anticipate asking lay representatives to be involved in numerical data analysis, but once the data is collated their opinion will be actively sought. Lay representatives will not have access to any patient-identifiable information, nor will they directly access the REDCap database.

### Dissemination of the research

Lay members of the expert panel will be involved in the dissemination and presentation of results as they wish. In addition, they will be involved in ensuring that the results are expressed in a digestible format for the general public.

# STUDY FINANCES

### Funding source

This study is funded by the Royal College of Anaesthetists and the Difficult Airway Society

### Participant stipends and payments

Participants will not be paid to participate in the study.

# SIGNATURE PAGES

Signatories to Protocol:

**Chief Investigator:** (name) IAIN MOPPETT



Signature:

Date: 21/12/23

# REFERENCES

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