RESEARCH PROTOCOL

Title

Prospective data collection for procedural sedation performed in the Emergency Department

**Investigative team**

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**Introduction**

Emergency Department Procedural Sedation is performed many times each day in Emergency Departments around the country. It is becoming an increasingly important skill in the practice of Emergency Medicine. It allows the performance of procedures (including reduction of fractures and dislocations, suturing of wounds, draining of abscesses etc) which in the absence of sedation would be painful and distressing for patients and or technically more difficult or impossible for Doctors. This sedation is increasingly valuable in health systems which demand more efficient use of resources. Effective, safe procedural sedation offers this by saving operating theatres (which are resource intensive) for more complicated procedures. This study aims to add to the current knowledge base by ongoing data collection on procedural sedation done in the Emergency Department. The actual episode of care or procedural sedation method for the patients in the study period will not be influenced by this study. This study will simply be an observational study in order to document techniques and outcomes of sedation which is done in the normal practice of Emergency Medicine at our Hospitals.

**Aim/Objectives**

1. To audit/document the technique (drug choice, doses, routes etc) used in our practice of procedural sedation in our Departments.
2. To audit/document the safety/efficacy of these sedations
3. To audit/document the outcomes from the procedures for which these sedations are being done

**Method**

**Type of research** - Clinical audit

**Research design** – Prospective chart review

**Process** - All procedural sedations performed in our Emergency Department are currently documented with our standard sedation documentation paperwork (previously submitted). The study aims to review this paperwork in order to collate and document the procedure success rates, procedure side effects/complications and to follow up with a telephone call to patients to document patient outcomes and patient perceptions of the sedation.

**Population of interest** – All patients who receive procedural sedation as part of the care in the Emergency Department.

**Interventions/Procedures** – All patients who are included in this study will not have any change to the care that they receive by being included in the study. Their selection for sedation, sedation technique, and procedure are at discretion of the treating Emergency Physician – this study seeks to just document and record the outcomes of this sedation and procedure.

**Outcomes/Endpoints** – As included in the study data collection document, there are multiple data points collected, including patient demographic data and medical history, the indication for the sedation, the method/drug choice/doses for the sedation, the vital signs during the sedation, any complications of the sedation, and the outcomes of the sedation and the procedure.

**Statistical methodology** - The current database of our sedations over the past 10 years is in excess of 4000 patient sedation events. Due to the rare rates of certain complications in anaesthesia and sedation we aim to eventually have a database of 10000 patient sedation events to be able to draw inferences about their incidence with reasonable statistical confidence

**Data collection techniques** – Our study will review the sedation paperwork to document procedure success rates, procedure side effects/complications and will follow up with a telephone call to patients to document patient outcomes and patient perceptions of the sedation.

**Participant tasks** - The only participants' task in this study will be a follow up phone call from investigators within 6 weeks of their sedation to ascertain the progress of their procedure (fracture reduction etc), any post procedure side effects and their experience/satisfaction with the sedation

**Data analysis** - Our study will review the sedation paperwork to document procedure success rates, procedure side effects/complication and will follow up with a telephone call to patients to document patient outcomes and patient perceptions of the sedation. Data will then be entered and analysed using microsoft excel software.

**Ethical Considerations**

This is clearly a Low/Negligible Risk study. There is no change to patient’s treatment as a result of this observational study, and therefore there are no clinical risks to the patient due to being included in the study. All patients’ consent is sought, and patients are included in the study if they so consent.

All data will be de-identified and analysed in aggregate. No individual patient sedation events will be reported let alone patients be identified. Data will be collected on pre­formatted worksheets. This will be then entered onto a spreadsheet. All spreadsheets and data will be password protected, and only stored on designated computers at Bundaberg Base Hospital. Preformatted data abstraction forms will be held in a locked office in the secure location of the Emergency Department Offices of Bundaberg Hospital Emergency Department, where swipe card access is required for entry. The lock office key will be held by the Chief researcher. The deidentified data will be kept for the period of the study in an electronic format. Preformatted data forms will be shredded before incineration, following standard Queensland Health processes for the destruction of secure documents. The individual patient data will go back to form part of their medical record.

**Financial/ Resource considerations**

There are no additional resource considerations – we plan to do this study using in kind resources – ie under the current available clinical and non clinical time of staff. All of the study data collection is done as part of the usual patient’s clinical care and documentation of the episode of sedation. Data entry into the database and analysis will be done as part of current resourcing, including non clinical time of staff as rostered.

**Study timeline**

Data collection is currently planned to continue until 2020, with extensions to be sought as needed. We plan to begin analysis and publishing of data late 2019.

**Dissemination of findings**

Results will be both presented locally at hospital meetings, and to the wider medical profession at local and national conferences, and published as journal papers.