SYDNEY TRIAGE TO ADMISSION RISK TOOL (START) TRIAL

STUDY PROTOCOL

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VERSION CONTROL

Version	Date	Description and changes
1.0	October 2016	Original version to be submitted
1.1	October 2016	Current version – age criterion, start dates and times amended with corresponding NEAF submitted to RPA

STUDY TITLE

The Sydney Triage to Admission Risk Tool (START) trial: A randomised control trial evaluating the use of a risk prediction tool to improve Emergency Department patient flow and patient outcomes

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RATIONALE

ED overcrowding and increasing demand are ongoing problems in Australia. Novel solutions are required to improve patient flow in ED to minimise the adverse effects of overcrowding and improve patient experience and outcomes. The investigating team have previously derived and internally validated a risk score tool called the Sydney Triage to Admission Risk Tool (START) using state-wide ED data. This tool predicted patient disposition with an overall accuracy of around 80%. This study will be undertaken to implement and evaluate the utility of START in clinical practice and determine if the use of the tool translates into improved patient outcomes.

OBJECTIVES

Investigate whether use of the START score improves ED performance and decreases length of stay in ED

METHODS

Design – Randomised control trial with unit of randomisation being day of the week

Setting – The study will be conducted in the Emergency Departments of Royal Prince Alfred Hospital (around 75,000 ED presentations per year), Canterbury Hospital, and Concord Hospital (both around 40,000 ED presentations per year). All three hospitals are within the Sydney Local Health District.

Patient population – Eligible adult (age>16 years) patients will be consecutive patients presenting at these hospital Emergency Departments between 1000 and 1500. Exclude planned representations, immediately life-threatening presentations (trauma calls, stroke calls, LifeNet (acute myocardial infarction) and cardiac arrest

calls), transfers from other hospitals, expected admissions and those brought in by police

Intervention – The START score will be scored by a designated trained investigator at the point of triage. The investigator will observe each nursing triage encounter and enter relevant data fields (see START risk scoring sheet) that is being routinely collected by the triage nurse. The score will be calculated using a paper scoring checklist or mobile app calculator if available. Risk scores and probabilities were determined using a previous derivation and validation paper. The recommendation based on the score will range from very likely admission, likely admission, uncertain, likely discharge and very likely discharge. For patients allocated to the intervention group a copy of the paper START risk scoring checklist will be attached to the clinical notes and used by the Nurse Unit Manager or patient flow Navigator in ED together with the treating clinician to assist with disposition decisions. These decisions may include allocation of in-patient or short stay unit beds, or streaming to fast track units. The patient will not be interviewed, approached or contacted for any information and no specific patient information will be recorded on the scoring app.

Control – Presentations allocated to control group will receive standard management in ED by clinicians without the assistance of the risk score tool. The study investigator will still score the triage encounter using the risk tool but the results of the risk scoring will not be made known to the clinician or included in the clinical notes.

Group allocation - Consecutive days of the week (Monday to Friday) during the study interval will be randomly allocated by date using a computer generated number sequence in an opaque sealed envelope drawn at the start of the day by the study investigator.

Consent – Triage nurses and Nurse Unit Managers in ED will be asked to read a study information sheet and consent during regular weekly nursing in-service sessions. As the information does not directly affect patient care and will not involve direct interaction with ED patients, patient consent will not be obtained. Patients will be informed with signage at the triage office that a study investigator will be observing the triage process and collecting information that is being entered by the

triage nurses. Study investigators are clinically trained staff but will not interfere with normal clinical processes.

Primary Outcome – The primary outcomes are proportion of patients with length of stay less than four hours and total length of stay in ED. These are routinely collected using existing patient information systems (FirstNet, Cerner Millenium) and reported by the ED data manager Ms Sook Lee Chai.

Secondary Outcome – Disposition time, (time that admission ready or discharge ready icons were activated on patient information system) Representation within 3 days of initial presentations, did not wait and hospital length of stay. These are also routinely collected and reported by the ED data manager.

Other data variables collected

The following variables will be collected at time of patient departure from ED using the patient information system.

- Designation of first treating doctor
- First location of patient
- Admitting team
- Emergency short stay unit (EMU) admission
- Age and sex of patient

Statistical Analysis

The hypothesis will be that patients allocated to the intervention groups are associated with reduced length of stay in ED. Descriptive statistics will be used to compare proportions and means between groups and (multi-level modelling used to account for day of week randomisation??)

Specified subgroups

Pre specified subgroups will be admitted or discharged patients

Sample Size calculation

Based on length of stay in the derivation study, the mean (SD) for admitted patients was 7.2(12) and 3.3(16) for discharges. A 2 hour decrease is considered a clinically

meaningful and it is estimated that around 500 patients in each arm. A total of 1200 presentations will need to be analysed assuming exclusions are factored. This will provide enough power to detect a 10% improvement in proportion of patients staying in ED less than four hours with a power of 0.80 and a two tailed alpha of 0.05. Assuming around 5 presentations are allocated and studied each hour at each site, an estimated six months of active recruitment is required (two days a week at four hours a day).

Study period and timeline

- Ethics application September-November 2016
- Implementation study at RPA November-February 2017 – this study will implement the risk score tool for all triage encounters to assess processes and identify potential problems. This will likely take around three months
- Education and implementation across Sydney Local Health District April 2017
- Run in period May 2017
- Trial period – July-December 2017
- Analysis September to February-April 2018
- Presentations and publications – May to June 2018

Ethics

An application will be made to the NSW Population and Health Services Research Ethics Committee with RPA Ethics committee acting as the lead site for all three single site applications. The trial will also be submitted for registration in the ANZ Clinical Trials Registry

Data storage

All risk tool forms and data collection sheets will be stored in paper form in a locked cabinet with the offices of the ED Executive. Patient details contained on data collection sheets will not be used for data analysis.

LIMITATIONS

The study will be limited to patients presenting during the hours of 1000 to 1500 on weekdays. This is seen as a necessary step to ensure study protocols are met prior to wider implementation across all hours.

KEY STAKEHOLDERS AND APPROVALS

1. Emergency Department Directors and Nurse Managers and data managers at all three sites
2. Sydney Local Health District Emergency Clinical Director and Clinical Manager of ED clinical streams Sydney Local Health Districts
3. Emergency Care Institute Research Committee, NSW Agency for Clinical Innovation

POTENTIAL RISKS AND RISK MITIGATION STRATEGIES

- Absence of investigator staff – All investigators have been involved in study design phases, have collaborated extensively on previous projects and will be able to take over as CI in the event of leave or illness.
- Online system failure – The system will be backed up and managed by Web Services in Sydney Local Health District

KEY DELIVERABLES

START risk scoring app and scoring sheet

Data to further analyse disposition risk scores based on prospective data collection

ATTACHMENTS

1. Risk score tool and calculator app screenshot
2. Data collection sheet
3. Participant information sheet and consent form
4. Risk score derivation paper (submitted yet to be published)

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram