OTEST

Oxford Track-&-Trigger Electronic System for Trauma.
A randomised stepped wedge trial comparing the effects of an integrated electronic "Track-and-Trigger" system and a paper-based "track-and-trigger" system.

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Study Synopsis

A randomised stepped wedge trial comparing the effects of an integrated electronic "Track-and-Trigger" system and a paper-based "track-and-trigger" system on hospital length of stay in adult trauma patients.

Control: a paper evidence-based "track-and-trigger" system on which physiological observations of blood pressure, pulse, oxygen saturation, temperature, urine output and conscious level are recorded. A score is manually assigned to each observed physiological value dependent on that value's position within the range of values seen in hospitalised patients. The scores for each physiological value are manually summed to provide a single (summary) measure of the patient's physiological status. The frequency of subsequent observations and the clinical response (see escalation algorithm, appendix 1) to a patient's physiological status are then set by following an algorithm based on the summary measure.

Intervention: physiological observations will be entered onto a tablet personal computer or personal digital assistant both integrated with a central display station. Scores will be automatically assigned and summed. The time of the next observation set and the appropriate clinical response will be automatically displayed according to the escalation algorithm. Visual warnings will be displayed if an observation set or clinical response is delayed.

Care in either group will commence on admission to the ward and continue until hospital discharge.

Study population: 1200 adult trauma patients.

Primary endpoint: time from admission to the trauma ward to "fit to discharge".

Secondary endpoints: hospital length of stay following ward admission, in-hospital mortality, 30 day mortality following ward admission, unplanned admissions to intensive care, cardiac arrest calls, appropriate escalation in frequency of observations, appropriate clinical escalation.

Background and Rationale

Deterioration in physiological observations has been repeatedly shown to precede adverse outcomes (1,2). However these physiological alterations commonly go unrecognised, resulting in treatment delay (3). Delays in appropriate treatment are known to worsen outcomes in critically ill patients (4,5). The National Institute for Clinical Excellence therefore recommends that all acute hospitals should implement a "track and trigger" system, which identifies abnormal observations and triggers alerts to appropriate medical staff using weighted scoring (6). However, "Track-and-Trigger" systems have not been shown to affect hospital length of stay or mortality (7).

Previous work has suggested that “track-and-trigger” systems may fail because scores are not correctly assigned, summary scores are not correctly calculated or because the appropriate observation rate and clinical escalations for a given summary score are not enacted (8-10). An electronically-based "Track-and-Trigger" system can be designed to automatically (correctly) assign scores to any physiological observation, compute the summary score (9) and prompt the actions designated as appropriate for the summary score, so improving system performance. The facility to display recent observations and summary scores on a central station may improve the ability of senior nursing staff to recognise patient deteriorations early.

Recognising these possibilities, the National Institute for Clinical Excellence made a research recommendation to "assess the clinical effectiveness of automated (electronic) monitoring systems compared with manual recording systems in identifying people at risk of clinical deterioration" (6).

Objectives

Primary objective: to assess whether the implementation of an integrated electronic “track-and-trigger” system improves relevant patient outcomes in comparison to an optimised paper-based system.

Secondary objective: to assess whether the implementation of an integrated electronic “track-and-trigger” system improves compliance with “track-and-trigger” algorithms in comparison to a paper-based system.

Study design

The study consists of three parts:

1. installation of system and checking (4 weeks)
2. Training of ward staff in the use of the new system (4 weeks)
3. A randomised stepped wedge trial of the clinical and compliance effects of the implementation of an integrated electronic “track-and-trigger” system. There are 12 zones across 2 wards (5 four-bed bays each comprising a zone, and 6 side-rooms on each ward, each group of 6 comprising a zone). The integrated

electronic “track-and-trigger” system will be introduced to incremental zones following random allocation.

Primary outcome measure: time from the first set of observations on the ward to “fit to discharge”. “Fit to discharge” is defined as either discharged from the ward to home or alternative care or accepted by social services as a “delayed discharge”.

Secondary outcome measures:

Patient outcome measures: hospital length of stay following ward admission, in-hospital mortality, unplanned admissions to intensive care, cardiac arrest calls.

Compliance measures: appropriate escalation in frequency of observations, appropriate clinical escalation.

Study participants:

Inclusion criteria: all patients > 16 years admitted to two trauma wards for an **eight** month period.

Exclusion criteria:

1. Patients whose treatment plan is palliative at admission to the trauma ward.
2. Patients with a learning disability.
3. Patients unable to speak English and without a suitable translator.

Study procedures:

The introduction of the integrated electronic “track-and-trigger” system will require all ward staff to be educated (by the trial nurses) in the data entry processes and the

interpretation of the displays on personal digital assistants, tablet personal computers and the central display station. Ward staff will be trained to educate subsequently appointed and temporary staff in the usage of the devices.

In the event of a system failure, patients will be returned to the paper-based system.

Informed consent:

An application to the National Information Governance board for a consent waiver will be made. The waiver is required to allow the trial to fully replicate the effects of an entire ward running an integrated electronic “track-and-trigger” system, and to allow complete zones to use the system.

Study assessments:

Study nurses will extract the following information from the patient’s notes and enter it into a trial specific data entry form.

1. The date and time of the first set of observations on the ward
2. In-hospital mortality
3. Unplanned admissions to Intensive Care – defined as any admission to the Intensive Care unit not occurring as a result of further surgery which was not planned at the commencement of therapy.
4. cardiac arrest calls

5. Appropriate escalation in the frequency of observations – defined as the next observation occurring within 1 hour of the time recommended in the escalation algorithm.

6. Appropriate clinical escalation – for those clinical escalations where clinical documentation should occur as a result of escalation – documentation of clinical escalation, or a consequence of clinical escalation within 1 hour of the time recommended in the escalation algorithm.

Separate research personnel, unaware of the allocation of the patient will document:

7. The date and time of discharge as recorded on the hospital admissions system.

8. If the patient is designated a “delayed discharge” by social services the “fit-to-discharge” point will be taken as 12:00 on the day of acceptance by social services as a “delayed discharge”.

Interventions

Physiological observations will be entered onto a tablet personal computer or personal digital assistant both integrated with a central display station, all inter-connected wirelessly. Scores will be automatically assigned and summed. The time of the next observation set and the appropriate clinical response will be automatically

displayed according to the escalation algorithm. Visual warnings will be displayed if an observation set or clinical response is delayed. Prompts and warnings will be displayed on the portable devices whenever a patient's chart is reviewed, and on a ward status view. Prompts and warnings will also be displayed on the central station. Warnings will be cleared for an observation set by completion of the required set of observations. Warnings will be cleared for a clinical response by the ward nursing staff documenting that the required response has occurred, or is no longer needed.

Safety reporting

In the event of any of the following occurring to any patient within the study, a Serious Adverse Events form will be completed by a member of the trial team:

1. Failure to document clinical observations leading to delay in diagnosis of a patient deterioration as a result of failure of the integrated electronic "track-and-trigger" system. The delay must be judged by the patient's consultant to have resulted in life-threatening consequences to the patient, or the patient's death. (Delays in recognition of deterioration as a consequence of system failure which do not meet these criteria will be separately reported).

2. Failure of the integrated electronic "track-and-trigger" system to correctly calculate the summary score leading to delayed escalation. The delay must be judged by the patient's consultant to have resulted in life-threatening consequences to the patient, or the patient's death. (Delays in recognition of deterioration as a consequence of system failure which do not meet these criteria will be separately reported).

3. Failure of the integrated electronic “track-and-trigger” system to correctly display the appropriate observation or clinical escalation, leading to delayed escalation. The delay must be judged by the patient’s consultant to have resulted in life-threatening consequences to the patient, or the patient’s death. (Delays in recognition of deterioration as a consequence of system failure which do not meet these criteria will be separately reported).

Any other events associated with the integrated electronic “track-and-trigger” system which are felt to have been deleterious to the patient will be separately reported, but will not be classified as a Serious Adverse Event unless deemed to meet published criteria by the Principal Investigator.

Serious Adverse Event forms will be available on the trial computer. The completed form should be faxed to the Principal Investigator (fax: 01865 857611). The Principal Investigator will report the event within 1 working day of becoming aware of the event to the Oxford Radcliffe Hospitals Research and Development Department (by fax: 01865 222648). The Research and Development Department will acknowledge receipt of the event documentation within two working days. The principal investigator will include an assessment as to whether the study can proceed; any changes necessary to the protocol should be included in this assessment.

In consultation with the Oxford Radcliffe Hospitals NHS Trust/University of Oxford Trial Safety group, Serious Adverse Events will be followed up until resolution.

Where, in the opinion of the Principal Investigator, the event was related (that is, resulted from the research procedures) and unexpected (that is, not listed in the protocol as an expected occurrence) the Principal Investigator will liaise with the

Research and Development department to ensure that the event is reported to the REC that gave a favourable opinion of the study within 15 calendar days of the Principal Investigator becoming aware of the event. The National Research Ethics Service serious adverse event form should be used (www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alld=311).

Statistics

Number of participants: 1200 patients will be enrolled into the study over an 8 month period to achieve equal number of patients in the treatment and control groups.

Analysis of endpoints: The primary endpoint will be assessed using survival analysis. A significance level of p=0.05 will be taken as indicating a difference between groups.

Ethics

A consent waiver will be requested for this study for the following reasons:

1. No additional procedure or observation will occur to the patients involved in the study.
2. The physiological data required is already collected and recorded on paper as part of the patient record.
3. Electronic “track-and-trigger” data entry is already part of standard practice in some United Kingdom hospitals.
4. To optimally test the intervention, patients need to be monitored immediately from their admission to the ward and not wait until a trial nurse becomes available.
5. The effect of the intervention across complete trial zones, and complete wards cannot be assessed without the inclusion of all patients within the zone/ward.

Confidentiality: patients will be assigned a trial number. All patient data will be connected to this number when stored electronically. Patient names or other identifiers will not be recorded electronically. All trial paperwork will be held in a locked file behind two locked doors. The trial computer, on which analysis of the anonymised data will take place will be password-protected and kept in a research-specific area behind two locked doors. The electronic "Track-and-Trigger" system will be protected by the Oxford Radcliffe NHS Trust electronic security system (see network security policy v2).

Trial funding

The trial is funded by the British Research Council.

Steering Committee

The trial is guided by a steering committee. The steering committee, in the development of this protocol and throughout the trial will take responsibility for:

1. The need to change the protocol for any reason
2. Monitoring and supervising the progress of the trial

Data Monitoring

The safety of the trial will be reviewed by an external data monitoring committee after 200 patients have received the intervention, and after each subsequent 200 patients. Dr Jacqueline Birks will provide data and statistical guidance to the committee.

The end of the trial

The trial will end following recruitment of 1200 patients. The trial will only be stopped prematurely by the Data Monitoring Committee following recommendation by the Data Monitor, or if mandated by the ethics committee or competent authority.

Publication Policy

The lead author for all papers will be Peter Watkinson**.** The authors have no vested interest in the results, which will be published regardless of outcome, in peer-reviewed journals. The final version will be agreed by the steering committee before submission.

Study Personnel

Principal Investigator: Dr Peter Watkinson

Co-investigators: Dr James Price, Professor Lionel Tarassenko, Dr Lauren Bailey, Sarah Webb.

Research Nurses: to be appointed

Trial Steering Committee: Dr Peter Watkinson, Dr David Clifton, Professor Lionel Tarassenko, Simon Noel, Sarah Webb, Dr Jacqueline Birks

Statistician: Dr Jacqueline Birks

References

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8. Smith AF, Oakley RJ. Incidence and significance of errors in a patient 'track and trigger' system during an epidemic of Legionnaires' disease: retrospective case note analysis. Anaesthesia 2006; 61: 222–8

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Appendix 1 – Track and Trigger algorithm