PROTOCOL TEMPLATE (for HREA)
V 2 – December 2017

This template has been designed for population health research utilising routinely collected health data held by the NSW Ministry of Health or the Cancer Institute NSW.

This research protocol template must be used in conjunction with, and complement, the HREA.

1. PROJECT TITLE

Prehospital code crimson activation - the initial experience from the Greater Sydney Area.

2. SHORT TITLE (IF ANY)

Prehospital Code Crimson review.

3. VERSION CONTROL

Version	Date	Amendment (brief description)	Amendment date (as per amendment form)
1.1	15 Feb 2020	Adjustment of aims and outcomes to be more explicit. Code crimson replaced with "prehospital code crimson". Feedback from ITIM included. Missing data updated.	15 Feb 2020

4. INVESTIGATORS AND PARTICIPATING INSTITUTIONS	
The order of the Investigators as listed must be consistent with the order of Investigators in the HREA.	
PRINCIPAL INVESTIGATOR 1	
Name & title	Christopher Partyka
Institution	NSW Ambulance Aeromedical Operations
Position	Staff Specialist
Access to unit record data (Y/N[1])	*Y If 'Y' name site NSW Aeromedical Operations, NSW Trauma Database*
CONTACT PERSON	
Name & title	Christopher Partyka
Institution	NSW Ambulance Aeromedical Operations
Position	Staff Specialist
Access to unit record data (Y/N[2])	*Y If 'Y' name site NSW Aeromedical Operations, NSW Trauma Database*
INVESTIGATOR / RESEARCHER	
Name & title	Matthew Miller
Institution	NSW Ambulance
Division	Aeromedical Operations
Position	Staff Specialist
Access to unit record data (Y/N[1])	*Y If 'Y' name site NSW Ambulance Aeromedical Operation, NSW Trauma Database, Careflight Database (for purpose of data linkage)*
Is this the contact person? Y / N	*N*
INVESTIGATOR / RESEARCHER	
Name & title	Brian Burns
Institution	NSW Ambulance
Division	Aeromedical Operations
Position	Director of Research
Access to unit record data (Y/N[1])	*N*
Is this the contact person? Y / N	*N*
INVESTIGATOR / RESEARCHER	
Name & title	Michael Dinh

Institution	Agency for Clinical Innovation
Division	NSW Institute of Trauma and Injury Management (ITIM)
Position	Clinical Director
Access to unit record data (Y/N[1])	*Y If 'Y' name site NSW Trauma Database*
Is this the contact person? Y / N	*N*
INVESTIGATOR / RESEARCHER	
Name & title	Kelly Dee
Institution	Agency for Clinical Innovation
Division	NSW Institute of Trauma and Injury Management (ITIM)
Position	Clinical Review Officer
Access to unit record data (Y/N[1])	*Y If 'Y' name site NSW Trauma Database*
Is this the contact person? Y / N	*N*
INVESTIGATOR / RESEARCHER	
Name & title	Pooria Sarrami
Institution	Agency for Clinical Innovation
Division	NSW Institute of Trauma and Injury Management (ITIM)
Position	Research Fellow
Access to unit record data (Y/N[1])	*Y If 'Y' name site NSW Trauma Database*
Is this the contact person? Y / N	*N*
INVESTIGATOR / RESEARCHER	
Name & title	Hardeep Singh
Institution	Agency for Clinical Innovation
Division	NSW Institute of Trauma and Injury Management (ITIM)
Position	Data Officer
Access to unit record data (Y/N[1])	*Y If 'Y' name site NSW Ambulance Aeromedical Operation, NSW Trauma Database, Careflight Database (for purpose of data linkage)*
Is this the contact person? Y / N	*N*
INVESTIGATOR / RESEARCHER	
Name & title	Toby Fogg
Institution	Careflight, NSW
Division	-
Position	Medical Director

Access to unit record data (Y/N[1])	*Y If 'Y' name site Careflight Database*
Is this the contact person? Y / N	*N*
INVESTIGATOR / RESEARCHER	
Name & title	Tamara Johnson
Institution	Northern Sydney Local Health District
Division	Northern Beaches Hospital
Position	Resident Medical Officer
Access to unit record data (Y/N[1])	*N*
Is this the contact person? Y / N	*N*

[1] **Access to tabulated results ONLY = N**

5. SUBMISSION CHECKLIST	
Required Documents	**Submitted**
Cover letter - listing all submitted documents with date and version numbers and signed by the Principal Investigator 1 (date and version numbers MUST be provided on all documents)	☐
Human Research Ethics Application (HREA)* – as submitted at www.ethicsform.org/au Signatures from ALL investigators are required. **OR Request for an Amendment to an Approved Research Project** form http://www.cancerinstitute.org.au/research-grants-and-funding/ethics/research-amendments *Please note: Unsigned forms will not be accepted*	☐
Research protocol* including appendices (*OR tracked protocol for an Amendment*) **OR Combined Protocol and CHeReL Application for Data*** *Please note: Protocols submitted without track-changes and appropriate version control will not be accepted*	☐
Data Linkage Flow Chart *(where applicable)*	☐
Data Variable list(s) for each data collection	☐
Data Custodian signoff for each data collection	☐
Centre for Health Record Linkage (CHeReL) Technical Feasibility Letter For projects involving data linkage through the CHeReL, please provide the signed CHeReL Technical Feasibility Letter *(refer to http://www.cherel.org.au)* *Please note: Applications without evidence of support from Data Custodians and/or the linkage provider WILL NOT be put forward to the HREC*	☐
NSW Privacy Form *	☐
Independent Peer Review Report * (refer to AIHW HREC Guidelines for best practice)	☐
CVs of all Principal Investigators (please confirm with the PHSREC Secretariat for researchers who have previously submitted applications to the PHSREC)	☐
All documentation relevant to the project, such as Participant Information and Consent form(s), survey tools, and questionnaires (*where applicable*)	☐
Correspondence with other HREC(s) in Australia (*where applicable*) *Please note: If your project is an extension or addendum to a project which already has approval from another HREC, ALL documentation reviewed by the original HREC must be provided (including HREC letter of approval).*	☐

**** Links to these forms can be found on the Cancer Institute NSW website:***
https://www.cancerinstitute.org.au/data-research/research-ethics/submissions

6. TABLE OF CONTENTS

7. BACKGROUND/RATIONALE

Provide an introduction to the study including a brief literature review, outline of knowledge gaps, how the study will address these, and the intended contribution to the field (750 - 1000 words).

Trauma is the fourth leading cause of mortality in Australia and New Zealand and leading cause of mortality in adults less than 40 years of age.[1] Second to death caused by central nervous system injury, haemorrhagic shock represents a leading cause of early death among the injured.[2] Haemorrhage is also responsible for the majority of preventable traumatic deaths with rates of up to 16% reported in the literature.[3,4] Delays to both haemorrhage control and the administration of blood products are likely causative factors leading to increased mortality.[5] The concept of Damage Control Resuscitation (DCR) aims to rapidly restore homeostasis in haemorrhaging patients through the replacement of blood products and early definitive care.[6,7] While the DCR approach was initially designed to address the issue of early mortality in combat casualties,[8] it has since been adopted in civilian prehospital medicine.[9,10]

Prehospital advanced trauma teams now provide sophisticated resuscitation in trauma patients by combining haemorrhage control techniques and blood product replacement to restore homeostasis. Haemorrhage control is undertaken by applying extremity tourniquets, pelvic binders and endovascular balloon occlusion of the aorta.[11,12] Many prehospital advanced trauma teams now carry blood products and as such can replace blood loss with red cells, plasma[13,14] and antifibrinolytics[15] whilst minimising crystalloid instillation.[9,13,16-18] There is still some debate about the optimum transfusion strategy in these patients,[17,19,20] and there can be challenges in seamlessly continuing blood product resuscitation on arrival at hospital.[5,21] However despite this, the advances in prehospital haemostatic resuscitation have led to dramatic reductions in prehospital and in-hospital mortality.[5,10]

The second component of damage control resuscitation is the early access to definitive haemorrhage control such as the operating theatre or interventional radiology as well as ongoing transfusion. To facilitate ongoing and timely trauma care on arrival at hospital, some systems have implemented designated protocols (Table 1) for prehospital recognition and notification of bleeding trauma patients requiring timely transfer to intervention[22-24] and swift access to a massive transfusion in the hospital.[25] Initially described in 2008,[26] the protocol to improve the prehospital and initial in hospital management of the actively bleeding trauma patient is known as the Trauma 'Code Crimson' Pathway. It has been implemented by NSW health[22] and Auckland City Hospital,[24] while the UK has a similar model,[23,27] and a French study[25] aims to implement a model focused only on the transfusion on arrival component. Due to the recent implementation of these protocols there is yet limited evidence of their effectiveness. However, the publications available[21,23,25] and cases reported[28] thus far indicate that "Code Crimson" protocols have a role in the reduction of mortality in haemorrhaging trauma patients.

In New South Wales, The Institute of Trauma and Injury Management (ITIM) Trauma 'prehospital Code Crimson' Pathway[22] was distributed to the NSW trauma services in October 2017, with each trauma service managing the implementation in their hospital. Currently, activation of the trauma 'Prehospital Code Crimson' pathway is indicated in patients with '*persistent haemodynamic instability despite standard trauma care, assessed as being secondary to ongoing haemorrhage in blunt or penetrating trauma, which is unresponsive to intravenous fluids and or blood transfusion*'.[22] Examples include a patient with a positive Focused Assessment with Sonography for Trauma (FAST) scan and ongoing shock requiring laparotomy or a patient with a penetrating chest injury and massive haemothorax or evidence of cardiac injury. The current protocol involves activation by a prehospital physician which results in both the mobilisation of in-hospital resources including massive transfusion protocol and operating theatre preparation. It also triggers

notification to specific interventionalists such as the trauma surgeon and other relevant specialist surgeons as well as the interventional radiologist. This is designed to facilitate a rapid decision, within ten minutes of a patient's arrival to hospital, as to whether an immediate interventional or operative is needed.

From our recent audit of prehospital code crimson patients, we identified that follow up of these patients is severely limited by our current review processes at New South Wales Ambulance Aeromedical Operations (NSW AO). Specifically, as we do not have an ongoing clinical contact with our patients, we are not permitted to obtain details from their clinical records that would allow us to correctly audit this pathway. Similarly, ITIM is not permitted to access prehospital details for these patients, beyond what is recorded in the inpatient data collections and passed onto the Collector database.

The purpose of this study is to join these two data sources (prehospital data from NSW State Wide Retrieval Database (SWRD) and Careflight's retrieval database with in-hospital data from the NSW Trauma database). This will allow us to describe in better detail the patient population in whom a trauma 'prehospital Code Crimson' pathway was activated, the rate of requirement for continued in-hospital transfusion of blood products, the need for and timing of early interventions to control haemorrhage following hospital arrival, and the coagulation profile of these patients. It will also aim to review the accuracy of prehospital physicians in determining whether or not their hemodynamically unstable patients will require either ongoing transfusion or interventional haemorrhage control. We would like to perform this study in two phases. The first phase will be a retrospective review combining those data already collected as part of our NSWA AO audit with the NSW Trauma database. This will also allow us to gain an insight into the data that is collected, what is missing and what else could be added to our data collection. The second phase will be an ongoing prospective data collection, with the aim to provide not only a larger sample size, but also continual quality improvement for our services.

Table 1: Existing protocols

	'Prehospital CODE CRIMSON'	'CODE CRIMSON'	'RED FLAG ALERT'	'CODE RED'
Country	Australia	New Zealand	France	England/Scotland
Developed by	ITIM & ACI NSW [22]	Auckland City Hospital [24]	Traumabase	TLSTG created a unified nationwide version for Scotland

Intent of protocol	Streamline patients with life-threatening haemorrhage that is refractory to resuscitation to definitive intervention, including an operating theatre or interventional radiology suite. [22]	To get all of the surgical decision makers and facilitators in the resuscitation room to facilitate rapid access to theatre or interventional radiology.[22]	Create a binary predictive model to expedite haemorrhage control response through quick access to massive transfusion protocol and/or immediate haemostatic procedures[25]	Reduce time to administration of blood products to patients at the earliest opportunity upon their arrival to hospital.
Validation /Reporting	Cases reported by Grabs et al[26] Hanley et al [28]	-	Validated by Hamada et al [25] Note: retrospective validation study, yet to be reported in use	Reported by Reed et al [23] Weaver et al [21] Morton et al [27]
Activation criteria	1. Persistent haemodynamic instability despite standard trauma care 2. Assessed as being secondary to ongoing haemorrhage from blunt or penetrating trauma 3. Unresponsive to intravenous fluids and or blood transfusion	1. Meet usual trauma call criteria AND 2. Two or more of: - Penetrating mechanism - SBP <90mmHg - Pulse rate >120 - Positive e-fast trauma ultrasound	1.Two or more of: - Shock index ≥1 - Unstable pelvis - Mean arterial BP ≤70mmHg - Pulse rate >120 - Point of care haemoglobin ≤13 g/dl - Pre-hospital intubation Note: Blunt trauma only and excludes penetrating injury and pre-hospital cardiac arrest	1. Suspicion or evidence of active haemorrhage 2. Systolic BP<90 mmHg 3. Failure of blood pressure to respond to an intravenous fluid bolus
Pre-Hospital Activation	Pre-hospital team to alert receiving ED via bat phone	Pre-hospital team to alert receiving ED	Pre-hospital team to alert receiving ED	Pre-hospital team to alert receiving ED
In-hospital Activation	1. Activate trauma team 2. ED fluid warmer and or rapid infuser primed with blood	1. Call a trauma code crimson via usual trauma call with ETA 2. Call in ED specialist if not on site	The Red Flag alert would be called through to the receiving ED indicating a patient is high risk for severe haemorrhage	1.Activate trauma team 2.Check there is 4u O-neg CRCs in ED fridge 3.Alert blood bank

Notify Surgical teams	Trauma surgeon & relevant subspecialty surgeons	Surgical registrar to notify on-call consultant		Notification of teams is done as part of the usual trauma call, but is not part of the "code red" protocol
Notify Anaesthetist		Anaesthetist on call		-
Notify Radiology	Radiographer in resus	Radiology registrar		-
Notify Theatre/IR	Operating theatre / IR room and check staff availability, mobilise additional as required	Notify level 8 (operating theatre/IR) nursing coordinator		-
Notify blood bank	Activate MTP	Notify		On alert blood bank prepares a "shock pack" of a further 4u PRBC, and thaws 4u FFP. Further packs are 1:1:1
On Arrival	1. Rapid decision (<10 minutes) for disposition 2. Surgeon to decide: OT/IR/CT	Not specified		Usually trauma management with the addition of a dedicated runner who brings the blood products

8. AIMS/OBJECTIVES

Provide a statement of primary and secondary aims/objectives, key research questions, and/or a clearly defined hypothesis (where appropriate). The aims/objectives should reflect the datasets and variables requested. **Please do not list variables here – attach a separate data variable list with justifications for individual variables in the context of the statistical analysis plan.**

Primary aim.

To describe the patients who had prehospital 'code crimson' activation initiated by a GSA-HEMS physician within the first 24 months of policy implementation.

Secondary aim(s).

To assess if data-linkage can help us identify;

1. Those inpatients who were treated by AO, and received care that would be consistent with a prehospital code crimson patient, but in who prehospital code crimson was not activated.
2. Those patients in who a prehospital code crimson was activated but did not receive inpatient care consistent with a prehospital code crimson patient.

To describe the key interventions and timings that a prehospital code crimson patient receives and see if these are consistent the aims of prehospital code crimson.

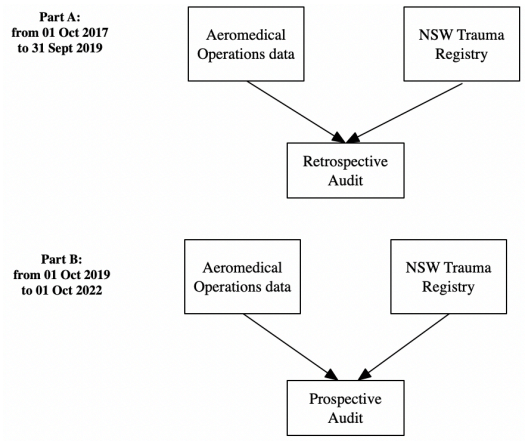
9. METHODS

STUDY DESIGN

Describe the type of study (e.g. retrospective cohort study, case control study).

This will be a two-part study. The first will be a retrospective review combining data from NSW AO, Careflight NSW and NSW Institute of Trauma Injury Management for the first 24 months of prehospital Code Crimson implementation. The second will be an ongoing prospective data collection (Figure 1) for a further three years.

Figure 1: Overview of study



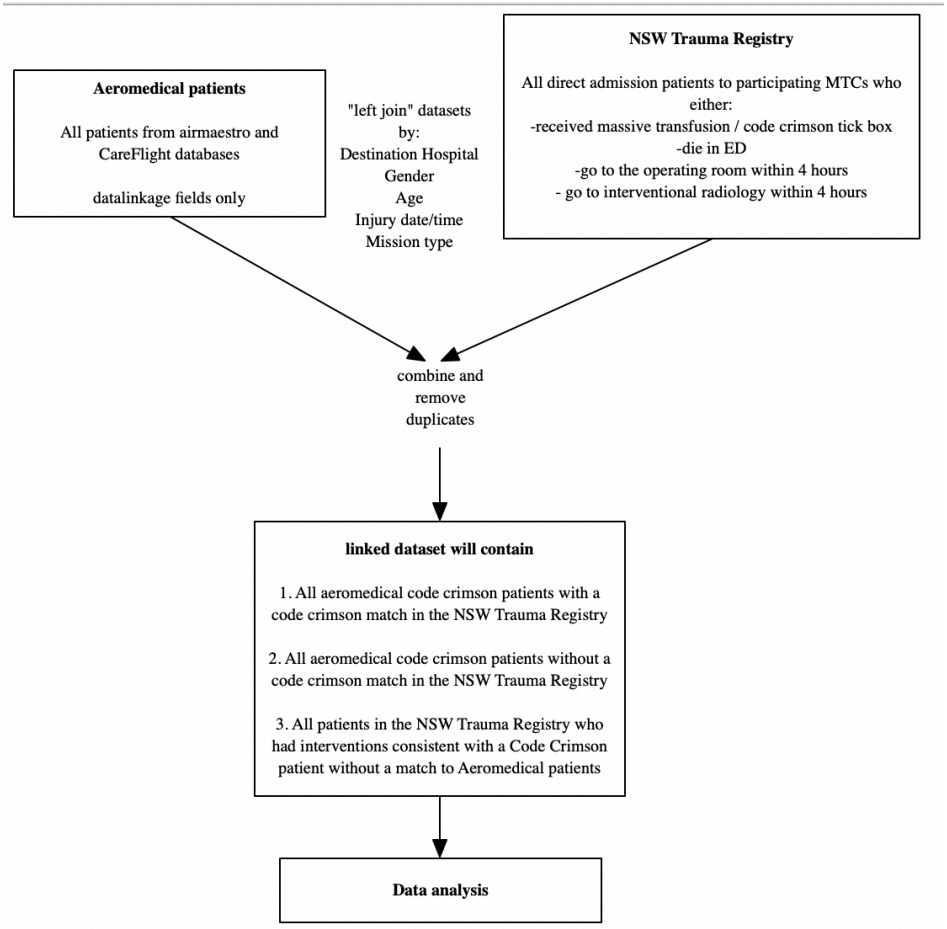
Study procedures

Figure 2 outlines the study procedure. Essentially, the study dataset will be created through joining of the Aeromedical Operations (AO) data with the NSW Trauma Registry. The dataset will be created by performing a 'left-join' of all AO prehospital patients with those in the NSW Trauma registry who are identified as meeting the in-hospital requirements for prehospital Code Crimson. To limit the amount of information gathered on patients, only the data required for the linkage will be extracted for the join (see Figure).

Following the join we will be able to identify the following patients:

i) Those Aeromedical prehospital Code Crimson patients who have a match with NSW Trauma Registry for patients identified as likely meeting code crimson criteria
ii) Those Aeromedical prehospital Code Crimson patients who do not have a match in the NSW Trauma Registry for patients identified as likely meeting prehospital code crimson criteria (represented by empty fields)
iii) Those NSW Trauma registry patients identified as likely meeting prehospital code crimson criteria but who do not have a match in the Aeromedical operations

Figure 2: Joining procedure between datasets



Patients identified in the three groups will then have the remainder of the data fields extracted.

The second part of the project will be an ongoing joining of datasets to regularly review these patients, so that we can assess the performance of the pathway and feedback to the Major Trauma Centres and Aeromedical Operations organisations. The interval of these joins will be determined by those looking after the data, but likely every two-months.

COHORT/STUDY POPULATION

Please describe your cohort/study population, specifying any inclusion /exclusion criteria.

Identification of participants

There will be two sources of participants, Aeromedical Operations (AO) and the NSW Trauma Registry. Aeromedical participants will be identified from an SWRD & Careflight database search. SWRD is the electronic, secure database kept by Greater Sydney Area Helicopter Emergency Medical Services (GSA-HEMS) where by all treated patients have a clinical record created. Careflight's Retrieval Database is also an electronic, secure database held for all their treated patients. Firstly, cases will be chosen by the selection of the 'Prehospital Code Crimson activation' tick box. Additional cases will be identified by freetext search in "Case details" box. Keywords will include 'prehospital Code Crimson', 'crimson' and common misspellings of crimson (eg crmson).

The participants from ITIM will be identified through a search of the NSW Trauma registry as detailed in the study procedures.

Inclusion criteria.

- Trauma patients retrieved by AO (tasked from Bankstown, Wollongong, Orange or Careflight bases) who triggered a prehospital code crimson activation
- ITIM patients who are identified as either prehospital Code Crimson activation/Massive Transfusion Protocol (MTP), or have a CT scan within one hour or procedure outlined in Table 2 within 6 hours or who die in the emergency department.
- Dates 01 Oct 2017 to 31 Sept 2019 for part A; 02 Oct 2019 to 01 Oct 2022 for part B.

Exclusion criteria.

- NSW Trauma Registry patients who do not meet the criteria of a prehospital code crimson response

Table 2. ICD-10-CM procedure codes to be used for NSW Trauma Registry criteria of interventional radiology or operating room procedure

ICD-10-PCS procedure code	Justification
Computerised Tomography within one hour	
56001-00 CT brain 56007-00 CT brain with contrast 57001-00 CT brain and chest 57007-00 CT brain and chest with contrast 56301-01 CT chest and abdomen 56307-01 CT chest and abdomen with contrast 57001-01 CT brain chest and abdomen 57007-01 CT brain chest abd with contrast 56301-00 CT chest 56307-00 CT chest with contrast 56801-00 CT chest abdomen and pelvis 56807-00 CT chest and pelvis with IV contrast 56407-00 CT abdomen 56407-00 CT abdomen with contrast 56501-00 CT abdomen and pelvis 56507-00 CT abdomen pelvis with contrast 56409-00 CT pelvis 56412-00 CT pelvis with contrast	
Procedures involving vessels/heart/lungs within 4 hours	

Heart/chest: 38450-00, 38447-00, 38727-00, 38727-01, 38456-00, 38653-00, 38550-00, 38559-00, 38568-00, 38514-00, 38440-01, 38438-00, 38438-01, 38438-02, 90173-00, 38418-00 Vessels: 34106-04, 34103-12, 34103-13, 90209-02, 33833-00, 33833-01, 33833-02, 33833-03, 33815-04, 32736-00, 90222-00, 35321-05, 35321-06, 30058-01, 90223-01	These codes should capture embolization procedures of the vessels and chest drains/thoracotomy	
Solid organ procedures within 4 hours		
Spleen:30596-00, 30597-00, 30566-00, 30565-00, 30515-03, 30515-05, Intestines: 32003-00, 32000-00, 32003-01, 32000-01, 32005-01, 32004-01, 32006-00, 32006-01, 32005-00, 32004-00, 32012-00, 32009-00 Liver: 30415-00, 30418-00, 30421-00, 90319-00, 30422-00, 30425-00 Pancreas 30593-00, 30583-00, 30593-01 Laparotomy 90375-00, 30373-00,30600-00, Kidney 36522-01, 36516-01	These codes should capture a patient going to theatre and having an emergency laparotomy.	

DATA COLLECTION

Please identify the nature of the data to be collected (multiple options may be selected).

☐ Primary data collection (e.g. original data from surveys, interviews, and/or focus groups etc.)

Please provide a description of primary data sources below.

Please <u>specify the names of the sites</u> for primary data collection.

☒ Secondary data collection (e.g. routinely collected data)

Please provide a description of the secondary data source(s) below.

Please specify the <u>names of the sites or agencies</u> for secondary data collection.

Please also complete Section 13 below.

New South Wales Ambulance Aeromedical Operations: State Wide Retrieval Database
Careflight NSW Database
Institute of Trauma Injury Management: NSW Trauma Database

The data fields to be collected are outlined in Table 3 Appendix A.

Agency Type for secondary data (tick all that apply)	☒ State / Territory	☐ Commonwealth	☒ Private Sector

CONSENT

*Briefly outline the consent process to be used in the study as indicated in the **HREA** and **NSW Privacy Form**. **Select one only:***

1. ***Request a waiver of consent – with strong justifications***

For both parts of the study a low-negligible risk application to the Human Research Ethics committee will be made seeking waiver of consent as this project is considered low to negligible risk, and it would be impracticable to obtain consent, and we have made reasonable attempts to protect patients privacy (as provided for under section 2.3.10 in the National Statement).

This data will not be changed or used in any other way than for the purpose of this study. No other data on the recruited patients will be collected in addition to that used in routine patient assessment and management. Identifiers will be used to collect data on demographics, prehospital and in-hospital investigations and outcomes; once these data are linked to the clinical data collected as part of routine assessment and management, the patient's data will be allocated a unique study number. The ability to re-identify patients from these data will then be very difficult.

There is no risk to the rights, privacy or professional reputation of carers, health professionals and/or institutions as the study solely concerns the impact of a single clinical intervention which is used ubiquitously, and has no intent to identify individual clinicians or carers, nor to use the data as commentary on the institutions concerned.

Safety considerations/participant safety

There is no specific participation required by participants. With patient data being grouped during the analysis there are no specific safety considerations to participants.

DATA GOVERNANCE

*Specify the data governance arrangements for the **entire data lifecycle** for the study. Where applicable, include information regarding:*

1. Data collection: specify all site(s) where data will be collected.
2. Data transfer & security: specify the processes to be used between sites and methods of encryption.
3. Data access, use and disclosure: specify the processes (including the use of a remote access facility).
4. Data storage: include all site(s) at which data will be stored.

5. Data retention: specify the period of retention of the data following completion of the project.
6. Data disposal: specify how the information will be destroyed and the methods to be used.

1 & 2. Data Collection, transfer and security. Data are routine administrative data sets collected by the participating organisations. These data will be transferred using the NSW Health secure file transfer service.

3. Data Access and use. At the time of writing the protocol, all transferred data will be downloaded to a NSW Health computer and then immediately uploaded and stored on the NSW Ambulance REDCap server. This server is firewalled and sits inside of the NSW Ambulance network. Access to the raw data will only be by Dr Matthew Miller (NSWA) and Mr Hareep Singh (ITIM) who will be performing the data-linkage and analysis. When data is accessed from REDCap for data analysis this will be done on password protected computers. Matthew Miller will use a NSW Ambulance computer that has R software installed on it, this way all data will be stored and analysed within the NSW Ambulance network.

4. Data Storage. REDCap is a server-based data collection and storage software hosted by NSW Ambulance on an internal server. It is not accessible to persons outside of the organisation.

5. Data retention. All data will be kept in raw format on RedCap for 7 years, and then destroyed securely.

6. Data disposal. All data will be compliant with NSW Health guidelines for the electronic storage of information and not maintained on any backup server. No paper records are intended to be created or kept.

NSW Ambulance is responsible for configuring and maintaining the computers used for the analysis.

Harris, P. A. et al. Research Electronic Data Capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support. Journal of biomedical informatics 42, 377–381 (2009).

10. ANALYSIS PLAN

OUTCOMES/EXPOSURES AND COVARIATES

Describe the study outcome measures (primary and secondary) and include information on study exposure/s, covariates, and other factors and how these are defined based on the data. Please provide sufficient detail (200 word minimum).

Study outcomes

Primary outcome

A descriptive analysis of patient demographics, mechanism and patterns of injuries plus outcomes including mortality (0-4 hours post-arrival, 4-24 hours post-arrival and >24 hours post-arrival).

Secondary outcome(s)

1. To identify the proportion of prehospital code crimson patients who received in-hospital massive transfusion (including product type and amount) within 4 hours of hospital arrival if data available.
2. To identify the proportion of prehospital code crimson patients who require interventional haemorrhage control (laparotomy, thoracotomy or angioembolisation) within 6 hours of hospital arrival.
3. To identify any missed prehospital code crimson patients
4. To estimate the accuracy of prehospital code crimson activation by prehospital medical teams
5. Key timing: Hospital arrival time to CT.
6. Key timing: Hospital arrival time to OT.
7. Mortality versus TRISS/RTS.

Hypothesis Statement

Hypotheses.

- Prehospital physicians accurately predict the need for ongoing in-hospital blood transfusion as measured by an under-triage rate of <5% and over triage rate of 10%
- Prehospital physicians accurately predict the need for in-hospital interventional haemorrhage control measured by an under-triage rate of <5% and over triage rate of 10%

STATISTICAL ANALYSIS

Provide a statistical analysis plan outlining how the aims/objectives will be met, the statistical methods to be used, and who will be carrying out the analysis. Please provide sufficient detail (200 word minimum).

These joins will be performed using the R package fuzzyjoin package which allows for the join to match patients based on a time-window. This will let us allow for differences in patient contact times. The data analysis will first present demographic and outcome data as descriptive variables. Demographic data will include age, gender, mechanism of injury, hospital disposition and injury pattern as described by the AIS codes. 95% CI will be created around any point estimate.

Statistical tests to be conducted.

We will create a 2x2 table of prehospital code crimson activation to in-hospital outcome to compare the sensitivity and specificity similar to a diagnostic test. Under triage rate will be defined as [prehospital code crimson patients in ITIM dataset not identified as code crimson by AO. Over triage rate will be will defined as [identified as prehospital code crimson by AO but not prehospital code crimson patient in ITIM dataset]. Table 5 presents how this will be constructed:

Table 5: Construction of the 2x2 table for data analysis.

		NSW Trauma Registry Either -received massive transfusion -go to the operating room within 4 hours - go to interventional radiology within 4 hours -die in ED	
		Present in dataset	Not present in dataset + sum of remainder of NSW trauma database
Aeromedical dataset	Code Crimson Activated	True Positive	False Positive
	Code Crimson not activated	False Negative	True Negative (missing cell to be calculated using capture-recapture methodology below)

False positive = Inappropriate prehospital code crimson activation (over triage)
False negative = Missed prehospital code crimson activation (under triage)

The missing data in the True Negative cell will be completed by a capture-recapture methodology[1]. Three methods will be used, the classical formula, the 'Nearly Unbiased Estimator'[2] which uses a simple formula to calculate the missing cell data, and a log-linear model approach using the R-package RCapture[3]. By using both methods we will be able to see if the estimates differ and this will let us see whether there is a violation of the assumption of independence of the databases.

Sample size and statistical power

As this is a quality improvement project, we will be using a convenience sample of NSW Trauma patients. The initial data summary (part A of the project) with then allow us to estimate ongoing sample sizes as required. For a recent internal audit of prehospital code crimson patients, we estimate there are approximately 35 prehospital code crimson activations per year, with a potential for a further prehospital 35

missed (false negative) cases. There are approximately 4000 cases reported in the NSW Trauma registry each year (ISS >12).

Missing data plan

Missing data will be reviewed and reported on. If less than 5% a complete case analysis will occur. Any missing data over 5% will be reviewed on a case by case basis. If it is a variable not related to an outcome, available case analysis may be used. If it is related to an outcome, consideration will be given to perform multiple imputation.

We are particularly interested in the missing data, as items that cannot be found by data-linkage mean it is difficult for the organisations to perform ongoing QAQI. Therefore the missing data will be reported back to each organisation for consideration of updating their datasets for future use.

11. REFERENCES

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Appendix A.

Variables to be collected (Table 3).

Table 3a.

Patient variables to be collected from NSW State Wide Retrieval Database.

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
1.	Study number	Ordinal	Text	Allocated study number/unique identifier
2.	Age	Continuous	YY/Unknown	Years rounded down
3.	Gender	Nominal	1= Male 2= Female 3= Unknown	Patient gender
4.	Weight	Continuous	Number/Unknown	Weight of patient in kg, as reported on case sheet.
5.	Mechanism	Nominal	1= Blunt trauma 2= Penetrating trauma 3= Unknown	Dominating mechanism of injury

Table 3b.

Prehospital mission variables to be collected from both NSW State Wide Retrieval Database.

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
6.	Case sheet number	Nominal	Number	Patient's retrieval case sheet number
7.	HEMS notification time	Continuous	(hh:mm)	Actual time that retrieval team first notified
8.	HEMS dispatched time	Continuous	(hh:mm)	Actual time that team dispatched
9.	Time at patient	Continuous	(hh:mm)	Actual time team arrives at patient
10.	Time departed scene	Continuous	(hh:mm)	Actual time retrieval team departs scene with patient
11.	Time at destination	Continuous	(hh:mm)	Actual time retrieval team arrives at receiving hospital

12.	Mode of transport	Nominal	1= Helicopter 2= Road ambulance 3= Fixed-wing	Primary mode of transport from scene to hospital
	Mission category	Nominal	1= Bush 2= Recreational 3= Cliff/Remove access 4= Farm 5= Road traffic accident 6= Snow 7= Water 8= Home 9= Industrial 10= Other 11= Pedal cyclist 12= Pedestrian 13= Recreation/sport 14= Shooting 15= Stabbing 16= Train 17= Assault 18= Fall 19= Horse	
	Code Crimson Activated	Nominal	1= Met criteria - notification made 2= Did not met criteria - notification made 3= Met criteria - notification not provided	As selected by Prehospital Physician
	Receiving hospital	Nominal	1= Canberra 2= John Hunter 3= Liverpool 4= Orange 5= Royal North Shore 6= Royal Prince Alfred 7= St George 8= St Vincents 9= Westmead 10= Children's Randwick 11= Children's Westmead	
	Observations at patient :: GCS	Continuous	Number	Range 3 to 15
	Observations at patient :: HR	Continuous	Number	Beats per minute
	Observations at patient :: RR	Continuous	Number	Respirations per minute
	Observations at patient :: SBP	Continuous	Number	mmHg

	Observations at patient :: Temperature	Continuous	Number	*C
	Observations at patient :: SaO2	Continuous	Number	percentage
	HEMS Intervention (Intubation)	Nominal	1= Yes 2= No	
	HEMS Intervention (Chest)	Nominal	1= Nil 2= Needle thoracostomy 3= Finger thoracostomy 4= Intercostal catheter	
	HEMS Intervention (Circulation/Haemorrhage)	Nominal	1= Transfusion 2= Trauma Line 3= IO Access 4= Fluid Warmer 5= Active Rewarming 6= Pelvic Splintage 7= Tourniquet 8= Max-Fax kit 9= Haemostatic Gauze 10= Thoracotomy 11= Other	
	Prehospital RBC transfusion	Continuous	Number	No. of units
	Prehospital Plasma transfusion	Continuous	Number	No. of units
	Prehospital Cryo transfusion	Continuous	Number	No. of units
	Prehospital Platelet transfusion	Continuous	Number	No. of units
	Prehospital MTP activated	Nominal	1= Yes 2= No 3= Not known	
	Receiving Hospital MTP Activated	Nominal	1= Yes 2= No 3= Not known	
	HEMS Intervention (Medications)	Nominal	1= TXA (or PATCH) 2= Inotropes (incl. adrenaline) 3= Hypertonic saline 4= Calcium	
	Prehospital ultrasound	Nominal	1= Pneumothorax 2= Haemothorax 3= Haemoperitoneum 4= Pericardial tamponade	

			5= Other findings	
	Prehospital US 'other' findings	Free text		
	Observations at destination :: GCS	Continuous	Number	Range 3 to 15
	Observations at destination :: HR	Continuous	Number	Beats per minute
	Observations at destination :: RR	Continuous	Number	Respirations per minute
	Observations at destination :: SBP	Continuous	Number	mmHg
	Observations at destination :: Temperature	Continuous	Number	*C
	Observations at destination :: SaO2	Continuous	Number	percentage
	Condition	Nominal	1= Stable throughout 2= stable then deteriorated 3= unstable improved with treatement 4= unstable did not improve 5= deceased prior to arrival 6= deceased post arrival	Patient condition during GSA-HEMS treatment & transport

Table 3c.				
NSW Trauma Registry variables to be collected.				
Data variable number	**Data variable name**	**Type of data**	**Data variable categories or values**	**Definition of data variable**
	Injury Date / Time	Continuous	D/M/Y, HH:MM	
	ED Arrival	Continuous	D/M/Y, HH:MM	Date/time the patient arrives to ED
	ED Departure	Continuous	D/M/Y, HH:MM	Date/time the patient departs ED
	Post ED Disposition	Nominal	1= Died 2= Discharged 3= HDU	Location patient is sent from ED

			4= ICU 5= OT 6= Interventional radiology 7= Transferred 8= Ward	
	Initial ED Vitals – Temperature	Continuous	Number	*C
	Initial ED Vitals – SaO2	Continuous	Number	percentage
	Initial ED Vitals – Pulse Rate	Continuous	Number	Beats per minute
	Initial ED Vitals – Respiration Rate	Continuous	Number	Respirations per minute
	Initial ED Vitals – SBP/DBP	Continuous	Number	mmHg
	Initial ED Vitals – GCS Eye	Nominal	1= None 2= To pain 3= To voice 4= Spontaneous	Eye opening response
	Initial ED Vitals – GCS Verbal	Nominal	1= None 2= Incomprehensible sounds 3= Inappropriate words 4= Confused 5= Oriented	Verbal response
	Initial ED Vitals – GCS Motor	Nominal	1= None 2= Abnormal extension 3= Abnormal flexion 4= Withdraws to pain 5= Localises pain 6= Obeys commands	/6
	Initial ED Vitals – GCS Total	Continuous	Number	/15
	Initial ED Vitals – Intubated	Nominal	1= Yes 2= No	Intubated by receiving hospital
	Procedure Name	List	ICD10AM codes	Any procedures performed on patient during their stay in hospital for this particular admission.
	Start Date/Time	Continuous	D/M/Y, HH:MM	Date/time procedure performed.
	AIS Code and body region	Continuous		Abbreviated Injury Score (AIS) Code and body region.

	Injury Severity Score (ISS)	Ordinal	1-75	Max = 75
	TRISS	Continuous	Number	Trauma and injury severity score is a combination index based on Trauma score(RTS), Injury severity Score (ISS), and patients age.
	Discharge Status	Nominal	1= Survived 2= Died 3= Not known	
	Discharge or Death Date/Time	Continuous	D/M/Y, HH:MM	The date/time the patient was discharged (from acute care services) or died
	Total ICU Days	Continuous	Number	Number of days the patient spent in ICU
	Total Ventilator Days	Continuous	Number	Number of days the patient has been ventilated
	Total Hospital Days	Continuous	Number	Total number of days the patient remained in this acute care facility
	Discharged To	Nominal	1= Deceased 2= Home 3= Rehabilitation 4= Other hospital	Disposition location
	Massive transfusion or Code Crimson	Nominal	1= Yes 2= No 3= Not known	

Table 3cd

Careflight NSW variables to be collected.

Data variable number	**Data variable name**	
1	Allocated study number	
	Patient Demographics	
2	calculate age for data linkage and demographics	
3	Gender	
4	Weight	
5	Mechanism	
	Prehospital Mission Variables	
6	OpsSmart number	

7	Notified (date time)	
8	Confirmed	
9	Met patient	
10	Commenced patient transport	
11	Arrived destination	
12	Patient transport	
13	Incident	
14	Interventions::management decisions:: Activate prehospital code crimson	
15	Diagnosis	
16	Hospital/clinic	
	Prehospital Patient Variables	
17	Observations::GCS	
18	Observations::HR	
19	Observations::RR	
20	Observations::SBP	
21	Observations::SpO2	
22	interventions::airway:: LMA, intubation, Surgical Airway	
23	Interventions::ventilation::open thoracostomy, intercostal catheter, needle thoracostomy	
24	Interventions::Circulatory support::Tranexamic acid, HTS, Touriniquet, haemeostatic dressings	
25	Interventions::Circulatory support::Red Cells 1-3 units and ::redcells >3 units	
26	Interventions::Circulatory support::FFP/Factors	
27	Interventions::Circulatory support::FFP/Factors	
28	Interventions::Circulatory support::Platelets	
29	Investigations::ultrasound-diagnotic	
30	Interventions::Anaesthesia	
31	Interventions::Pelvic Splint	
32	Interventions:: Femur splint	
33	Patient condition	