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Prehospital trauma death review in the State of Victoria, Australia: a study protocol

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TITLE

Prehospital trauma death review in the State of Victoria, Australia: a study protocol

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ABSTRACT

Introduction: Regionalised trauma systems have been shown to improve outcomes for trauma patients. However, the evaluation of these trauma systems has been oriented towards in-hospital care. Therefore, the epidemiology and care delivered to the injured patients who died in the prehospital setting remain poorly studied. This study aims to provide an overview of a methodological approach to reviewing trauma deaths in order to assess the preventability, identify areas for improvements in the system of care provided to these patients and evaluate the potential for novel interventions to improve outcomes for seriously injured trauma patients.

Methods and analysis: The planned study is a retrospective review of prehospital and early in-hospital (<24 hours) deaths following traumatic out-of-hospital cardiac arrest (OHCA) that were attended by Ambulance Victoria between 2008 and 2014. Eligible patients will be identified from the Victorian Ambulance Cardiac Arrest Registry (VACAR) and linked with the National Coronial Information System (NCIS). For patients who were transported to hospital, data will be linked the Victoria State Trauma Registry (VSTR). The project will be undertaken in four phases: 1) survivability assessment; 2) preventability assessment; 3) identification of potential areas for improvement; and 4) identification of potentially useful novel technologies. Survivability assessment will be based on predetermined anatomical injuries considered unsurvivable. For patients with potentially survivable injuries, multidisciplinary expert panel reviews will be conducted to assess the preventability as well as the identification of potential areas for improvement and the utility of novel technologies.

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3 **Ethics and dissemination:** The present study was approved by the Victorian
4 Department of Justice and Regulation HREC (CF/16/272) and the Monash University
5 HREC (CF16/532 – 2016000259). Results of the study will be published in peer-
6 reviewed journals and reports provided to Ambulance Victoria, the Victorian State
7 Trauma Committee and the Victorian State Government Department of Health and
8 Human Services.
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21 **KEYWORDS:**

22 Trauma, Prehospital trauma death, Traumatic injuries, Injury prevention, Survivability,
23 Outcome assessment, Quality assessment, Quality improvement, Medical errors
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30 **Strengths and limitations of this study:**

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- This study will be a population-based detailed review of prehospital and early in-hospital deaths following trauma.
 - This review will identify opportunities to improve each component of the acute continuum of care for severely injured patients.
 - Amid declining autopsy rates, the availability of full autopsies may limit the proportion of cases that can undergo detailed review.

BACKGROUND

The global burden of traumatic injuries is well established. Trauma remains the leading cause of death and disability in people aged between 1 and 44 years old.[1] However, temporal improvements in outcomes for trauma patients have been observed, which has been linked to the establishment of regionalised trauma systems.[2-5] Nevertheless, the focus of the evaluation of these trauma systems has been oriented towards in-hospital care. As a result, little is known about the epidemiology and care delivered to those patients that die in the prehospital setting.[6]

A recent systematic review including 27 studies on prehospital trauma death assessment highlighted the heterogeneity of methodology and terminology used in prehospital trauma death studies.[7] Furthermore, the heterogeneity and the lack of standardisation between the prehospital trauma death studies often precluded comparison between systems limiting potential improvements and translation from research to prehospital care.[7] Reviewing trauma death cases has been a core component of trauma research.[8] In addition to assessing the quality of clinical care delivered relative to a standard of care, reviewers may also assess preventability of death, and potential areas for improvement. Furthermore, deaths may be used as a performance indicator, measure of health service quality, help identify new strategies to improve the clinical care, injury prevention and implementation of novel technologies.[7] There is an urgent need for a consensus-based methodological approach and terminology standardisation to enable the current limitations of the prehospital death studies to continue the improvement of trauma patient care.

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5 Drawing upon existing literature, this study aims to provide an overview of a
6 methodological approach to reviewing trauma deaths in order to assess the survivability
7 and preventability, identify areas for improvements in the system of care provided to
8 these patients and evaluate the potential for novel interventions to improve outcomes for
9 seriously injured trauma patients.
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20 **METHODS**

21 **Study design**

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25 We will perform a retrospective review of prehospital and early in-hospital (<24 hours)
26 deaths following traumatic out-of-hospital cardiac arrest (OHCA) that were attended by
27 Ambulance Victoria during the period of 2008 to 2014. Paediatric (< 16 years old) and
28 adults (\geq 16 years old) will be assessed concomitantly but will be analysed separately.
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36 This manuscript does not differentiate between these two populations.
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40 Unlike previous prehospital trauma death studies, we decided to include early in-hospital
41 deaths because we believe they are likely to have been influenced by the prehospital
42 system and the care received. We believe focussing solely on prehospital deaths and
43 ignoring early in-hospital deaths may underestimate the scope for improvement in the
44 prehospital setting.
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51 **Data sources**

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55 Prehospital and in-hospital deaths following traumatic OHCA will be identified from the
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3 Victorian Ambulance Cardiac Arrest Registry (VACAR). To obtain causes of death and
4 detailed injury information, data will be linked with the National Coronial Information
5 System (NCIS). For patients who were transported to hospital, but subsequently died in-
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8 hospital, data will be linked the Victoria State Trauma Registry (VSTR).
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14 Victorian Ambulance Cardiac Arrest Registry

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17 The VACAR is a population-based registry of all OHCA events attended by emergency
18 medical services (EMS) in the state of Victoria, Australia. The registry captures in-field
19 treatment data electronically and a highly sensitive search filter is used to identify
20 potential cardiac arrest cases before manual review by registry personnel. The registry
21 methodology, including data capture and completeness, and quality assurance
22 processes have been described previously.[9] All deaths attended by paramedics are
23 collected in VACAR.
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35 National Coronial Information System

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37 All deaths directly or indirectly resulting from injury or non-natural causes are reported to
38 coroners. The NCIS is an Internet-based data storage and retrieval system for Australian
39 coronial cases (<http://www.ncis.org.au>) and includes every death reported to the coroner
40 since 2000. The NCIS contains coded data fields, including the intent, mechanism of
41 injury, and event location. In addition to these coded data fields, the NCIS contains full
42 text documents, including the police report on the circumstances of the death, the
43 autopsy report, and the forensic toxicology report.
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56 The coroner is responsible for making a determination about whether a full autopsy
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(complete internal and external examination) is required, or if an external examination only is sufficient to establish a cause of death. The senior next of kin has the right to object to an autopsy being performed.

To enable a robust evaluation of the system of care provided to each patient, there is a need to have complete coronial records. As a result, this study will exclude cases that do not have a full-autopsy. It is known that this can be limited by the unavailability of 'open' coronial cases.[10] Furthermore, autopsy rates are declining over time, [11] which may reduce the proportion of cases with full autopsies.

Victorian State Trauma Registry

The population-based VSTR collects data about all hospitalised major trauma patients in Victoria.[12] A case is included in VSTR if any of the following criteria are met: (1) death due to injury; (2) an Injury Severity Score (ISS) >12 [Abbreviated Injury Scale (AIS) 2005-2008 update]; (3) admission to an intensive care unit (ICU) for more than 24 hours; and (4) urgent surgery.[2] The VSTR collects AIS-coded injury information and data on the in-hospital management of major trauma patients.

Data linkage

Data linkage between VACAR and NCIS will be achieved using a combination of deterministic and probabilistic linkage methods. Identifiable information (full name, date of birth, event date, event address, residential address) is available in both VACAR and NCIS to enable linkage. Where the full name or date of birth is not available in VACAR, the event date and event address will be used for linkage.

Approach to the problem

During our prehospital trauma death study, the following phases will be undertaken and are detailed in this manuscript: 1) survivability assessment; 2) preventability assessment; 3) identification of potential areas for improvement; and 4) identification of potential novel technologies to improve the care of acutely injured patients.

REVIEWING TRAUMA DEATHS

The focus of this study will be on those cases that received attempted resuscitation from paramedics. This represents approximately 28% of trauma deaths attended by Ambulance Victoria.[13] It is acknowledged that there may be areas for improvement in the system of care provided to a subset of patients who did not receive attempted resuscitation, however, this is outside the scope of the current study.

Phase 1: Survivability assessment

It is anticipated that there will be greater than 700 prehospital and early in-hospital deaths following traumatic OHCA that received attempted resuscitation from paramedics over the 7-year study period. As a result, it is not feasible to use an expert panel review methodology on all of these cases. Previous studies have used a preliminary 'survivability' assessment as a filtration method to identify a specific subset of cases that have the potential for improved outcomes.[14] However, the methods used to define 'survivability' have been varied.[7] While some studies relied solely on expert clinical opinion, most previously published studies have used a consensus-based approach.

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3 However, the inter-rater reliability is known to be poor.[15] Recently, studies have
4 started to use strict predetermined criteria with the expectation that it would decrease
5 the subjectiveness regarding survivability assessment.[16]
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12 In this study, each case will undergo detailed review to determine whether the
13 anatomical injuries were 'survivable'; that is, cases in which the anatomical injuries were
14 potentially survivable in ideal situations, but the patient subsequently died. Two
15 clinicians with experience in trauma management generated a list of 13 injuries that
16 were deemed unsurvivable. This list was adapted from Davies et al. (2014).[16] (Table
17 1). Two clinicians will independently review each autopsy to determine whether the
18 anatomical injuries were survivable. All disagreement will be solved by consensus first,
19 then a third clinician will be involved if the disagreement remains unsolved. Despite
20 being frequently used in prehospital trauma death studies, we decided to avoid using
21 any survival prediction algorithms or validated scores such as the ISS because we
22 consider them potentially misleading. They have been associated with significant missed
23 opportunities for improvement when used for case selection in trauma quality
24 improvement programs.[17]
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44 **Phase 2: Preventability assessment**

45 Definition of preventability

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48 Drawing from classifications of preventability from the World Health Organisation's
49 (WHO) Guidelines for Trauma Quality Improvement Programs, Shackford et al.,[18]
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3 MacKenzie et al.,[15] Vioque et al.,[19] and Oliver and Walter[7], preventability will be
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5 classified using the following classification:
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10 *Not preventable:*

- 11 • System provided appropriate and timely care
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- 13 • Evaluation and management appropriate according to relevant clinical
- 14
- 15 guidelines at the time the death occurred
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22 *Potentially preventable:*

- 23 • System generally provided appropriate and timely care, although potential
- 24 for improvement
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- 26 • Evaluation and management generally appropriate
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- 29 • Some deviations from standard of care that may, directly or indirectly, have
- 30 been implicated in patient's death
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38 *Preventable:*

- 39 • Delivery of care was suboptimal
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- 41 • Avoidable error is judged to have directly caused the outcome
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47 Preventability assessment using an expert panel review methodology

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49 Assessment of the care delivered was frequently performed using a panel of experts in
50 previous studies on prehospital trauma death.[20] The underlying methods used have
51 evolved substantially over the years. The initial studies used small panels relying mainly
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3 on subjective impressions and implicit criteria leading to low reproducibility of implicit
4 judgments when they are made by different experts.[14] Recent studies have more
5 consistently used a standardized approach based on explicit criteria[20] leading to an
6 increase in the inter-rater reliability.[21-24] However, whilst most prehospital trauma
7 death studies use a panel at some point during their study, the review process and the
8 panel's objectives were widely divergent. Moreover, the panel composition has varied in
9 terms of member training levels and number of participants. While most studies included
10 at least one doctor with clinical experience in the care of injured patients (emergency
11 physician, trauma physician, general surgeon or others), the inclusion of a
12 multidisciplinary team involving members of the prehospital team was less frequent.[7]
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28 Multidisciplinary panels will be used to identify components of the system of care where
29 current best evidence care was not delivered. To ensure that the number of cases
30 reviewed by each panellist is manageable, we will use smaller sub-panels to
31 independently review cases. We plan to use four sub-panels that will comprise at least
32 one intensive care paramedic, one emergency physician / trauma surgeon and one
33 other (e.g. advanced life support paramedic, nurse, forensic pathologist, injury
34 epidemiologist).
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47 Two weeks prior to the review, panellists will be provided with all relevant data related to
48 each case, in de-identified form. This will include the full autopsy, police report,
49 toxicology data and the patient care records (PCRs) for each of the attending ambulance
50 crews. For patients who survived to hospital but subsequently died early (<24 hours) in
51 their hospital stay, data on all hospital interventions and timing of these interventions will
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3 be provided. Prior to the expert panel review, each panellist will make an independent
4 assessment of preventability which will be submitted to the research team. At the panel
5 review meeting, the case will be discussed in-depth and if 100% agreement is achieved
6 on preventability, this will be used as the final decision. If there is any disagreement,
7 these cases will go to a larger panel review subsequent to the small sub-panel reviews.
8 This wider panel review will comprise at least two intensive care paramedics, two
9 emergency physicians / trauma surgeons and one other.
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21 To measure the inter-panel reliability, a random selection of ~20 cases will undergo
22 review by two independent panels. Following these reviews, a percentage of agreement
23 and kappa coefficient will be measured.
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30 **Phase 3: Identification of potential areas for improvement**

31 Only a few studies have evaluated the potential areas for improvement during the
32 prehospital care of severely injured patients using a standardised approach.[25]
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40 To facilitate the identification of areas for improvement, we will use the Joint
41 Commission's (formerly the Joint Commission on Accreditation of Healthcare
42 Organisations) patient safety event taxonomy.[26] This has been recommended by the
43 WHO's Guidelines for Trauma Quality Improvement Programs[27] and is similar to that
44 used by McDermott *et al.*[28] This classification uses five interacting root nodes:
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51 1. Impact

- 52 • The impact or outcome/harm to the patient is death in all cases.
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2. Type (see below for a list of potential factors)

- Describes the implied or observed events/processes that failed or were faulty.
- These are categorised into factors that relate to:
 - *The system*: failure or insufficiency of the trauma system to deliver care appropriately and in a timely fashion.
 - *Diagnosis*: Injury not diagnosed because of misinterpretation, inadequacy or lack of clinical examination, or delay in diagnosis.
 - *Treatment/management*: therapeutic or diagnostic decision made contrary to available data/management plan and not in accordance with recommended optimal standards of care.

3. Domain

- Implies the setting in which the factor occurred (e.g. prehospital setting), the discipline of staff providers involved, as well as the target of the intervention (therapeutic or diagnostic).

4. Cause

- Refers to the factors and agents that led to the incident. This is commonly grouped into:
 - *System*: includes organisational (e.g. management, organisational culture, protocols/processes, training) and physical (e.g. facilities, equipment, infrastructure); and
 - *Human*: factors that involve direct contact with the patient. Grouped as:

- *Diagnostic factors*: data are incorrectly perceived, incorrect intention formulated and wrong action is performed
- *Intention factors*: data are correctly perceived, but incorrect intention is developed and wrong action is performed
- *Execution factors*: data are correctly perceived, correct intention is developed but wrong or unintended action is performed.

5. Prevention and mitigation

- Measures enacted to prevent further occurrence of the event.
- Commonly classified as: universal, selective or indicated.

Specific areas for improvement have been identified *a priori* and are contained in Table 2.

Phase 4. Identification of potential novel technologies to improve the care

A list of potential technologies and interventions was defined *a priori* (Table 3). These interventions, either unavailable at the time of the trauma death or not considered as part of the standard of care by the treating paramedic team, are interventions believed to be potentially helpful in the care of severely injured patients. These interventions are expected to potentially improve the notification system, the access to the trauma patient, the initial diagnostic accuracy or potentially helpful as a therapeutic measure.

As part of the expert panel reviews, we will assess the potential role and impact of novel interventions in the prehospital setting to improve survival of severe traumatic injuries.

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3 Furthermore, during the expert panel reviews, panellists will have the opportunity to
4 suggest interventions in addition to those defined *a priori*.
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10 **ETHICS**

11 The VACAR has approval from the Victorian Department of Health and Human Services
12 Human Research Ethics Committee (HREC) (No. 08/02). The VSTR has approval from
13 the Victorian Department of Health and Human Services HREC for 138 trauma-receiving
14 hospitals in Victoria (DHHREC 11/14) and the Monash University HREC (CF13/3040 –
15 2001000165). The present study was approved by the Victorian Department of Justice
16 and Regulation HREC (CF/16/272) and the Monash University HREC (CF16/532 –
17 2016000259).
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28 **DISSEMINATION**

29 Results of the study will be published in peer-reviewed journals and reports provided to
30 Ambulance Victoria, the Victorian State Trauma Committee and the Victorian State
31 Government Department of Health and Human Services.
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42 **DISCUSSION**

43 This state-wide study will provide large, comprehensive and population-based data on
44 the epidemiological profile of death occurring in the prehospital and early in-hospital
45 phases. This is a unique opportunity to acquire a population-based capture of relevant
46 trauma case fatality information and use expert panellists to review the system of care
47 provided to these patients. This comprehensive review will identify opportunities to
48 improve each component of the acute continuum of care for severely injured patients,
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3 including detection, initial dispatch, initial response, clinical management, transport and
4 communication. Additionally, the evaluation of potentially novel interventions by a panel
5 of experts will identify potentially beneficial interventions to implement during the
6 prehospital care of severely injured patients that may reduce mortality. Finally, the data
7 acquired by this study will allow the development of targeted injury prevention programs
8 using a comprehensive review of recent fatal traumatic events.
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Consent for publications

Not applicable

Availability of data

Not applicable for this study protocol. Results of this study are expected to be published in peer-reviewed journals.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

This study protocol was developed by EM, PC, KS and BB. EM and BB prepared the first draft of this summary protocol paper and revised in light of comments from PC and KS. All authors approved the final version of the manuscript.

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Data sharing: no additional data available.

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LIST OF ABBREVIATIONS

AIS: Abbreviated Injury Scale

EMS: Emergency medical services

HREC: Human Research Ethics Committee

ICU: Intensive Care Unit

ISS: Injury Severity Score

NCIS: National Coronial Information System

OHCA: Out-of-hospital cardiac arrest

PCR: Patient Care Records

VACAR: Victorian Ambulance Cardiac Arrest Registry

VSTR: Victoria State Trauma Registry

WHO: World Health Organisation

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Table 1. List of injuries considered ‘unsurvivable’

Laceration to the heart (more than 2 centimetres or ≥ 2 transmural holes)*
Laceration to the aorta or thoracoabdominal great vessels **
Massive brain tissue damage*
Massive brain hematoma*
Brainstem herniation*
Diffuse brainstem haemorrhage
Spinal column dissociation
C1 to C3 fracture or dislocation associated with spinal cord involvement (compression, tear or hematoma)
Cranio-cervical (or atlanto-occipital) fracture or dislocation with spinal cord involvement
Complete tracheal rupture
Fatal chemical exposure
Burns with charrings*

* Injuries used by Davis et al.(2014)

** Included as unsurvivable were the following vascular injuries: a) aorta (thoracic or abdominal) b) innominate artery c) subclavian artery d) thoracic or diaphragmatic vena cava.

Table 2. Specific areas for improvement based on the Joint Commission's patient safety event taxonomy

System factors	
	Long response time
Diagnostic factors	
	Missed/incorrect diagnosis
	Delayed diagnosis
Treatment/management factors	
	Delayed treatment
	Incorrect procedure
	Correct procedure, but with complication
	Correct procedure, incorrectly performed
	Equipment failure
	Inaccurate prognosis
	Excessive on-scene time
	Triage error

Table 3. List of potential novel technologies and interventions

Technologies and interventions unavailable during the study period	
	Early notification systems (such as crash detection systems or smartphones to alert EMS)
	Ultrasound
	Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)
	On-scene thoracotomy
	Ultrasound-guided needle pericardiocentesis
	Prehospital Decompressive Burr Hole Drainage
	Hemorrhagic control via Pelvic packing, abdominal packing or abdominal junctional tourniquet
	Tranexamic acid
	Freeze-dried plasma
	Decision support
Technologies and interventions implemented during or after the study period	
	Red cell concentrate/packed red blood cells
	Arterial tourniquets
	Finger thoracostomy

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Prehospital trauma death review in the State of Victoria, Australia: a study protocol

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TITLE

Prehospital trauma death review in the State of Victoria, Australia: a study protocol

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ABSTRACT

Introduction: Regionalised trauma systems have been shown to improve outcomes for trauma patients. However, the evaluation of these trauma systems has been oriented towards in-hospital care. Therefore, the epidemiology and care delivered to the injured patients who died in the prehospital setting remain poorly studied. This study aims to provide an overview of a methodological approach to reviewing trauma deaths in order to assess the preventability, identify areas for improvements in the system of care provided to these patients and evaluate the potential for novel interventions to improve outcomes for seriously injured trauma patients.

Methods and analysis: The planned study is a retrospective review of prehospital and early in-hospital (<24 hours) deaths following traumatic out-of-hospital cardiac arrest (OHCA) that were attended by Ambulance Victoria between 2008 and 2014. Eligible patients will be identified from the Victorian Ambulance Cardiac Arrest Registry (VACAR) and linked with the National Coronial Information System (NCIS). For patients who were transported to hospital, data will be linked the Victoria State Trauma Registry (VSTR). The project will be undertaken in four phases: 1) survivability assessment; 2) preventability assessment; 3) identification of potential areas for improvement; and 4) identification of potentially useful novel technologies. Survivability assessment will be based on predetermined anatomical injuries considered unsurvivable. For patients with potentially survivable injuries, multidisciplinary expert panel reviews will be conducted to assess the preventability as well as the identification of potential areas for improvement and the utility of novel technologies.

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3 **Ethics and dissemination:** The present study was approved by the Victorian
4 Department of Justice and Regulation HREC (CF/16/272) and the Monash University
5 HREC (CF16/532 – 2016000259). Results of the study will be published in peer-
6 reviewed journals and reports provided to Ambulance Victoria, the Victorian State
7 Trauma Committee and the Victorian State Government Department of Health and
8 Human Services.
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21 **KEYWORDS:**

22 Trauma, Prehospital trauma death, Traumatic injuries, Injury prevention, Survivability,
23 Outcome assessment, Quality assessment, Quality improvement, Medical errors
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30 **Strengths and limitations of this study:**

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- This study will be a population-based detailed review of prehospital and early in-hospital deaths following trauma.
 - This review will identify opportunities to improve each component of the acute continuum of care for severely injured patients.
 - Amid declining autopsy rates, the availability of full autopsies may limit the proportion of cases that can undergo detailed review.

BACKGROUND

The global burden of traumatic injuries is well established. Trauma remains the leading cause of death and disability in people aged between 1 and 44 years old.[1] However, temporal improvements in outcomes for trauma patients have been observed, which has been linked to the establishment of regionalised trauma systems.[2-5] Nevertheless, the focus of the evaluation of these trauma systems has been oriented towards in-hospital care. As a result, little is known about the epidemiology and care delivered to those patients that die in the prehospital setting.[6]

A recent systematic review including 27 studies on prehospital trauma death assessment highlighted the heterogeneity of methodology and terminology used in prehospital trauma death studies.[7] Furthermore, the heterogeneity and the lack of standardisation between the prehospital trauma death studies often precluded comparison between systems limiting potential improvements and translation from research to prehospital care.[7] Reviewing trauma death cases has been a core component of trauma research.[8] In addition to assessing the quality of clinical care delivered relative to a standard of care, reviewers may also assess preventability of death, and potential areas for improvement. Furthermore, deaths may be used as a performance indicator, measure of health service quality, help identify new strategies to improve the clinical care, injury prevention and implementation of novel technologies.[7] There is an urgent need for a consensus-based methodological approach and terminology standardisation to enable the current limitations of the prehospital death studies to continue the improvement of trauma patient care.

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5 Drawing upon existing literature, this study aims to provide an overview of a
6 methodological approach to reviewing trauma deaths in order to assess the survivability
7 and preventability, identify areas for improvements in the system of care provided to
8 these patients and evaluate the potential for novel interventions to improve outcomes for
9 seriously injured trauma patients.
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20 **METHODS**

21 **Study design**

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25 We will perform a retrospective review of prehospital and early in-hospital (<24 hours)
26 deaths following traumatic out-of-hospital cardiac arrest (OHCA) that were attended by
27 Ambulance Victoria during the period of 2008 to 2014. Paediatric (< 16 years old) and
28 adults (\geq 16 years old) will be assessed concomitantly but will be analysed separately.
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36 This manuscript does not differentiate between these two populations.
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40 Unlike previous prehospital trauma death studies, we decided to include early in-hospital
41 deaths because we believe they are likely to have been influenced by the prehospital
42 system and the care received. We believe focussing solely on prehospital deaths and
43 ignoring early in-hospital deaths may underestimate the scope for improvement in the
44 prehospital setting.
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51 **Patient and Public Involvement**

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56 Patients and or the public were not involved in the design of this study.
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Data sources

Prehospital and in-hospital deaths following traumatic OHCA will be identified from the Victorian Ambulance Cardiac Arrest Registry (VACAR). To obtain causes of death and detailed injury information, data will be linked with the National Coronial Information System (NCIS). For patients who were transported to hospital, but subsequently died in-hospital, data will be linked the Victoria State Trauma Registry (VSTR).

Victorian Ambulance Cardiac Arrest Registry

The VACAR is a population-based registry of all OHCA events attended by emergency medical services (EMS) in the state of Victoria, Australia. The registry captures in-field treatment data electronically and a highly sensitive search filter is used to identify potential cardiac arrest cases before manual review by registry personnel. The registry methodology, including data capture and completeness, and quality assurance processes have been described previously.[9] All deaths attended by paramedics are collected in VACAR.

National Coronial Information System

All deaths directly or indirectly resulting from injury or non-natural causes are reported to coroners. The NCIS is an Internet-based data storage and retrieval system for Australian coronial cases (<http://www.ncis.org.au>) and includes every death reported to the coroner since 2000. The NCIS contains coded data fields, including the intent, mechanism of injury, and event location. In addition to these coded data fields, the NCIS contains full text documents, including the police report on the circumstances of the death, the

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3 autopsy report, and the forensic toxicology report.
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8 The coroner is responsible for making a determination about whether a full autopsy
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10 (complete internal and external examination) is required, or if an external examination
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12 only is sufficient to establish a cause of death. The senior next of kin has the right to
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14 object to an autopsy being performed.
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19 To enable a robust evaluation of the system of care provided to each patient, there is a
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21 need to have complete coronial records. As a result, this study will exclude cases that do
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23 not have a full-autopsy. It is known that this can be limited by the unavailability of 'open'
24
25 coronial cases.[10] Furthermore, autopsy rates are declining over time, [11] which may
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27 reduce the proportion of cases with full autopsies.
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33 Victorian State Trauma Registry

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35 The population-based VSTR collects data about all hospitalised major trauma patients in
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37 Victoria.[12] A case is included in VSTR if any of the following criteria are met: (1) death
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39 due to injury; (2) an Injury Severity Score (ISS) >12 [Abbreviated Injury Scale (AIS)
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41 2005-2008 update]; (3) admission to an intensive care unit (ICU) for more than 24 hours;
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43 and (4) urgent surgery.[2] The VSTR collects AIS-coded injury information and data on
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45 the in-hospital management of major trauma patients.
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51 Data linkage

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53 Data linkage between VACAR and NCIS will be achieved using a combination of
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55 deterministic and probabilistic linkage methods. Identifiable information (full name, date
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of birth, event date, event address, residential address) is available in both VACAR and NCIS to enable linkage. Where the full name or date of birth is not available in VACAR, the event date and event address will be used for linkage.

Approach to the problem

During our prehospital trauma death study, the following phases will be undertaken and are detailed in this manuscript: 1) survivability assessment; 2) preventability assessment; 3) identification of potential areas for improvement; and 4) identification of potential novel technologies to improve the care of acutely injured patients.

REVIEWING TRAUMA DEATHS

The focus of this study will be on those cases that received attempted resuscitation from paramedics. This represents approximately 28% of trauma deaths attended by Ambulance Victoria.[13] It is acknowledged that there may be areas for improvement in the system of care provided to a subset of patients who did not receive attempted resuscitation, however, this is outside the scope of the current study.

Phase 1: Survivability assessment

It is anticipated that there will be greater than 700 prehospital and early in-hospital deaths following traumatic OHCA that received attempted resuscitation from paramedics over the 7-year study period. As a result, it is not feasible to use an expert panel review methodology on all of these cases. Previous studies have used a preliminary 'survivability' assessment as a filtration method to identify a specific subset of cases that

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3 have the potential for improved outcomes.[14] However, the methods used to define
4 'survivability' have been varied.[7] While some studies relied solely on expert clinical
5 opinion, most previously published studies have used a consensus-based approach.
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7 However, the inter-rater reliability is known to be poor.[15] Recently, studies have
8 started to use strict predetermined criteria with the expectation that it would decrease
9 the subjectiveness regarding survivability assessment.[16]
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19 In this study, each case will undergo detailed review to determine whether the
20 anatomical injuries were 'survivable'; that is, cases in which the anatomical injuries were
21 potentially survivable in ideal situations, but the patient subsequently died. Two
22 clinicians with experience in trauma management generated a list of 13 injuries that
23 were deemed unsurvivable. This list was adapted from Davies et al. (2014).[16] (Table
24 1). Two clinicians will independently review each autopsy to determine whether the
25 anatomical injuries were survivable. All disagreement will be solved by consensus first,
26 then a third clinician will be involved if the disagreement remains unsolved. Despite
27 being frequently used in prehospital trauma death studies, we decided to avoid using
28 any survival prediction algorithms or validated scores such as the ISS because we
29 consider them potentially misleading. They have been associated with significant missed
30 opportunities for improvement when used for case selection in trauma quality
31 improvement programs.[17]
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51 **Phase 2: Preventability assessment**

52 Definition of preventability

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3 Drawing from classifications of preventability from the World Health Organisation's
4 (WHO) Guidelines for Trauma Quality Improvement Programs, Shackford et al.,[18]
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6 (WHO) Guidelines for Trauma Quality Improvement Programs, Shackford et al.,[18]
7 MacKenzie et al.,[15] Vioque et al.,[19] and Oliver and Walter[7], preventability will be
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9 classified using the following classification:
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15 *Not preventable:*

- 16 • System provided appropriate and timely care
- 17 • Evaluation and management appropriate according to relevant clinical
- 18 guidelines at the time the death occurred
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26 *Potentially preventable:*

- 27 • System generally provided appropriate and timely care, although potential
- 28 for improvement
- 29 • Evaluation and management generally appropriate
- 30 • Some deviations from standard of care that may, directly or indirectly, have
- 31 been implicated in patient's death
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42 *Preventable:*

- 43 • Delivery of care was suboptimal
- 44 • Avoidable error is judged to have directly caused the outcome
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51 Preventability assessment using an expert panel review methodology

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3 Assessment of the care delivered was frequently performed using a panel of experts in
4 previous studies on prehospital trauma death.[20] The underlying methods used have
5 evolved substantially over the years. The initial studies used small panels relying mainly
6 on subjective impressions and implicit criteria leading to low reproducibility of implicit
7 judgments when they are made by different experts.[14] Recent studies have more
8 consistently used a standardized approach based on explicit criteria[20] leading to an
9 increase in the inter-rater reliability.[21-24] However, whilst most prehospital trauma
10 death studies use a panel at some point during their study, the review process and the
11 panel's objectives were widely divergent. Moreover, the panel composition has varied in
12 terms of member training levels and number of participants. While most studies included
13 at least one doctor with clinical experience in the care of injured patients (emergency
14 physician, trauma physician, general surgeon or others), the inclusion of a
15 multidisciplinary team involving members of the prehospital team was less frequent.[7]

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Multidisciplinary panels will be used to identify components of the system of care where
current best evidence care was not delivered. To ensure that the number of cases
reviewed by each panellist is manageable, we will use smaller sub-panels to
independently review cases. We plan to use four sub-panels that will comprise at least
one intensive care paramedic, one emergency physician / trauma surgeon and one
other (e.g. advanced life support paramedic, nurse, forensic pathologist, injury
epidemiologist).

Two weeks prior to the review, panellists will be provided with all relevant data related to
each case, in de-identified form. This will include the full autopsy, police report,

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3 toxicology data and the patient care records (PCRs) for each of the attending ambulance
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5 crews. For patients who survived to hospital but subsequently died early (<24 hours) in
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7 their hospital stay, data on all hospital interventions and timing of these interventions will
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9 be provided. Prior to the expert panel review, each panellist will make an independent
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11 assessment of preventability which will be submitted to the research team. At the panel
12
13 review meeting, the case will be discussed in-depth and if 100% agreement is achieved
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15 on preventability, this will be used as the final decision. If there is any disagreement,
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17 these cases will go to a larger panel review subsequent to the small sub-panel reviews.
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19 This wider panel review will comprise at least two intensive care paramedics, two
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21 emergency physicians / trauma surgeons and one other.
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28 To measure the inter-panel reliability, a random selection of ~20 cases will undergo
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30 review by two independent panels. Following these reviews, a percentage of agreement
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32 and kappa coefficient will be measured.
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37 **Phase 3: Identification of potential areas for improvement**

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39 Only a few studies have evaluated the potential areas for improvement during the
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41 prehospital care of severely injured patients using a standardised approach.[25]
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46 To facilitate the identification of areas for improvement, we will use the Joint
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48 Commission's (formerly the Joint Commission on Accreditation of Healthcare
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50 Organisations) patient safety event taxonomy.[26] This has been recommended by the
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52 WHO's Guidelines for Trauma Quality Improvement Programs[27] and is similar to that
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54 used by McDermott *et al.*[28] This classification uses five interacting root nodes:
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1. Impact

- The impact or outcome/harm to the patient is death in all cases.

2. Type (see below for a list of potential factors)

- Describes the implied or observed events/processes that failed or were faulty.
- These are categorised into factors that relate to:
 - *The system*: failure or insufficiency of the trauma system to deliver care appropriately and in a timely fashion.
 - *Diagnosis*: Injury not diagnosed because of misinterpretation, inadequacy or lack of clinical examination, or delay in diagnosis.
 - *Treatment/management*: therapeutic or diagnostic decision made contrary to available data/management plan and not in accordance with recommended optimal standards of care.

3. Domain

- Implies the setting in which the factor occurred (e.g. prehospital setting), the discipline of staff providers involved, as well as the target of the intervention (therapeutic or diagnostic).

4. Cause

- Refers to the factors and agents that led to the incident. This is commonly grouped into:
 - *System*: includes organisational (e.g. management, organisational culture, protocols/processes, training) and physical (e.g. facilities, equipment, infrastructure); and

- *Human*: factors that involve direct contact with the patient. Grouped as:
 - *Diagnostic factors*: data are incorrectly perceived, incorrect intention formulated and wrong action is performed
 - *Intention factors*: data are correctly perceived, but incorrect intention is developed and wrong action is performed
 - *Execution factors*: data are correctly perceived, correct intention is developed but wrong or unintended action is performed.

5. Prevention and mitigation

- Measures enacted to prevent further occurrence of the event.
- Commonly classified as: universal, selective or indicated.

Specific areas for improvement have been identified *a priori* and are contained in Table 2.

Phase 4. Identification of potential novel technologies to improve the care

A list of potential technologies and interventions was defined *a priori* (Table 3). These interventions, either unavailable at the time of the trauma death or not considered as part of the standard of care by the treating paramedic team, are interventions believed to be potentially helpful in the care of severely injured patients. These interventions are expected to potentially improve the notification system, the access to the trauma patient, the initial diagnostic accuracy or potentially helpful as a therapeutic measure.

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3 As part of the expert panel reviews, we will assess the potential role and impact of novel
4 interventions in the prehospital setting to improve survival of severe traumatic injuries.
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6 Furthermore, during the expert panel reviews, panellists will have the opportunity to
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8 suggest interventions in addition to those defined *a priori*.
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14 **STATISTICAL ANALYSES**

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16 Descriptive statistics will be used to describe the sample using percentages for
17 categorical variables and median and interquartile range (IQR) for non-normally
18 distributed continuous variables. Comparisons between those with and without a full
19 autopsy, and comparisons between potentially preventable/preventable deaths and non-
20 preventable deaths will be made using χ^2 test or Kruskal-Wallis tests. Data analysis will
21 be performed using Stata (Version 14.2, StataCorp, College Station, TX). A p-value
22 <0.05 will be considered significant.
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35 **ETHICS**

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37 The VACAR has approval from the Victorian Department of Health and Human Services
38 Human Research Ethics Committee (HREC) (No. 08/02). The VSTR has approval from
39 the Victorian Department of Health and Human Services HREC for 138 trauma-receiving
40 hospitals in Victoria (DHHREC 11/14) and the Monash University HREC (CF13/3040 –
41 2001000165). The present study was approved by the Victorian Department of Justice
42 and Regulation HREC (CF/16/272), the Monash University HREC (CF16/532 –
43 2016000259), the Ambulance Victoria Research Committee and the Victorian State
44 Trauma Outcomes Registry Monitoring Group.
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DISSEMINATION

Results of the study will be published in peer-reviewed journals and reports provided to Ambulance Victoria, the Victorian State Trauma Committee and the Victorian State Government Department of Health and Human Services.

LIMITATIONS

Amid declining autopsy rates, the availability of full autopsies may limit the proportion of cases that can undergo detailed review. Furthermore, a proportion of trauma deaths that are not attended by EMS, or are attended by EMS but do not undergo attempt resuscitation, may be preventable from a systems perspective, but will not undergo expert panel review.

DISCUSSION

This state-wide study will provide novel and detailed data on the epidemiological profile of death occurring in the prehospital and early in-hospital phases. This is a unique opportunity to capture of relevant trauma case fatality information and use expert panellists to review the system of care provided to these patients. This comprehensive review will identify opportunities to improve each component of the acute continuum of care for severely injured patients, including detection, initial dispatch, initial response, clinical management, transport and communication. Additionally, the evaluation of potentially novel interventions by a panel of experts will identify potentially beneficial interventions to implement during the prehospital care of severely injured patients that may reduce mortality. Finally, the data acquired by this study will allow the development

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3 of targeted injury prevention programs using a comprehensive review of recent fatal
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5 traumatic events.
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For peer review only

Consent for publications

Not applicable

Availability of data

Not applicable for this study protocol. Results of this study are expected to be published in peer-reviewed journals.

Competing interests

The authors declare that they have no competing interests.

Funding

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Authors' contributions

This study protocol was developed by EM, PC, KS and BB. EM and BB prepared the first draft of this summary protocol paper and revised in light of comments from PC and KS. All authors approved the final version of the manuscript.

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Data sharing: no additional data available.

For peer review only

LIST OF ABBREVIATIONS

AIS: Abbreviated Injury Scale

EMS: Emergency medical services

HREC: Human Research Ethics Committee

ICU: Intensive Care Unit

ISS: Injury Severity Score

NCIS: National Coronial Information System

OHCA: Out-of-hospital cardiac arrest

PCR: Patient Care Records

VACAR: Victorian Ambulance Cardiac Arrest Registry

VSTR: Victoria State Trauma Registry

WHO: World Health Organisation

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Table 1. List of injuries considered ‘unsurvivable’

Laceration to the heart (more than 2 centimetres or ≥ 2 transmural holes)*
Laceration to the aorta or thoracoabdominal great vessels **
Massive brain tissue damage*
Massive brain hematoma*
Brainstem herniation*
Diffuse brainstem haemorrhage
Spinal column dissociation
C1 to C3 fracture or dislocation associated with spinal cord involvement (compression, tear or hematoma)
Cranio-cervical (or atlanto-occipital) fracture or dislocation with spinal cord involvement
Complete tracheal rupture
Fatal chemical exposure
Burns with charrings*

* Injuries used by Davis et al.(2014)

** Included as unsurvivable were the following vascular injuries: a) aorta (thoracic or abdominal) b) innominate artery c) subclavian artery d) thoracic or diaphragmatic vena cava.

Table 2. Specific areas for improvement based on the Joint Commission's patient safety event taxonomy

System factors	
	Long response time
Diagnostic factors	
	Missed/incorrect diagnosis
	Delayed diagnosis
Treatment/management factors	
	Delayed treatment
	Incorrect procedure
	Correct procedure, but with complication
	Correct procedure, incorrectly performed
	Equipment failure
	Inaccurate prognosis
	Excessive on-scene time
	Triage error

Table 3. List of potential novel technologies and interventions

Technologies and interventions unavailable during the study period	
	Early notification systems (such as crash detection systems or smartphones to alert EMS)
	Ultrasound
	Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)
	Resuscitative thoracotomy
	Ultrasound-guided needle pericardiocentesis
	Prehospital Decompressive Burr Hole Drainage
	Hemorrhagic control via Pelvic packing, abdominal packing or abdominal junctional tourniquet
	Tranexamic acid
	Freeze-dried plasma
	Decision support
Technologies and interventions implemented during or after the study period	
	Red cell concentrate/packed red blood cells
	Arterial tourniquets
	Finger thoracostomy