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Study protocol for a Prospective Observational study of Safety Threats and Adverse events in Trauma (PrO-STAT): a pilot study at a level-1 trauma centre in Canada

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ABSTRACT

Introduction Traumatic injuries are a significant public health concern globally, resulting in substantial mortality, hospitalisation and healthcare burden. Despite the establishment of specialised trauma centres, there remains considerable variability in trauma-care practices and outcomes, particularly in the initial phase of trauma resuscitation in the trauma bay. This stage is prone to preventable errors leading to adverse events (AEs) that can impact patient outcomes. Prior studies have identified common causes of these errors, including delayed diagnostics, disorganisation of staff, equipment issues and communication breakdowns, which collectively contribute to AEs. This study addresses gaps in understanding the root causes of these errors by evaluating the most frequent AEs in trauma care through real-time video reviews of resuscitations in the trauma bay. Insights from this evaluation will inform targeted interventions to improve procedural adherence, communication and overall team performance, ultimately reducing preventable errors and improving patient safety.

Methods and analysis A prospective observational study will be conducted at St. Michael's Hospital, a level-1 trauma centre, to evaluate resuscitations in the trauma bay. All consecutive trauma team activations over 12 months will be included, with data collected using audio-visual recordings and physiological monitoring. A synchronised data capture and analysis platform will comprehensively assess AEs, errors and human and environmental factors during trauma resuscitations. The study aims to detect recurring error patterns, evaluate practice variations and correlate trauma team performance with in-hospital outcomes. Statistical analyses will include descriptive statistics, logistic regression models and multivariable analyses to identify associations and predictors of AEs and patient outcomes.

Ethics and dissemination Institutional research ethics approval was obtained (SMH REB # 21-009). A modified consent model will be employed for participants. Staff, physicians and learners will be provided with information regarding the study and will have the option to opt-out or withdraw consent. Similarly, trauma patients and their next of kin will be informed about the study, with provisions for opting out or withdrawing consent within 48 hours of recording. Measures will be implemented to ensure data confidentiality, anonymity and respect for participants' autonomy and privacy. The study results will be shared through peer-reviewed journal publications and conference presentations, and key institutional stakeholders will be informed about developing strategies to improve patient safety in trauma care.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study uses a prospective observational approach, allowing real-time assessment of events, errors and environmental factors in the trauma bay. It enhances the accuracy and reliability of data collection.
⇒ The study employs advanced technology, including audio-visual capture and synchronised data analysis, providing detailed insights into trauma resuscitations. It allows for thoroughly examining team dynamics, environmental factors and patient outcomes.
⇒ By identifying error patterns and adverse events in real time, this study offers opportunities for targeted interventions and continuous quality improvement in trauma care, ultimately enhancing patient safety.
⇒ This study will be conducted at a single level-1 trauma centre, which may limit the generalisability of the findings to other healthcare settings or trauma systems.
⇒ Retaining audio-visual data for up to 30 days may restrict the ability to conduct long-term follow-up or retrospective analyses beyond this timeframe.

STATEMENT OF PURPOSE

The purpose of this study is to prospectively assess events, errors and environmental factors in the trauma bay during the resuscitation of injured patients and correlate these with in-hospital outcomes. This analysis will identify error patterns leading to adverse

outcomes and define areas for improvement to enhance patient safety in the trauma bay.

INTRODUCTION

Impact of traumatic injury

Each year, over 5 million individuals succumb to fatal injuries, constituting 9% of the world's total deaths.[1 2] This staggering figure surpasses the combined fatalities caused by HIV/AIDS, tuberculosis and malaria by nearly 1.7 times.[1] The fatalities resulting from injuries leave a permanent mark on the families and communities affected, often leading to profound and irreversible changes in their lives. Among individuals aged 5–29 years, three of the primary causes of death are attributed to injuries, namely, road traffic injuries, homicide and suicide.[1] Moreover, over 50% of the global mortality resulting from road traffic injuries is concentrated among young adults aged between 15 and 44 years.[3] While the primary objective remains the prevention of injuries and violence, considerable efforts can also be directed towards mitigating the resulting disability and adverse health effects arising from such incidents.

Errors in the trauma bay

The initial phase of resuscitation in the trauma bay has been identified as the area where the most preventable adverse events (AEs) and errors in trauma care occur.[4] An inquest in Australia showed that there were 6.1 errors per fatal trauma case, with 3.5 errors directly contributing to patient death.[5] Errors identified include failure to perform therapeutic or diagnostic measures at the right time, with the correct frequency, or in the proper order.[6] Additionally, lack of familiarity with a trauma scenario, disorganisation of staff or equipment, failure to prioritise or realise the complexity, fixation error and misdiagnosis have also been identified as frequent errors in the trauma bay.[5] One study estimated that communication errors occur in over 50% of trauma cases.[7]

Additionally, latent safety threats (LSTs) in trauma are defined as 'system-based threats to patient safety that can materialise at any time and are previously unrecognised by healthcare providers, unit directors or hospital administration'.[8] Currently, it is unknown if LSTs directly result in AEs or the severity of such events. For example, if a resident is unaware of the location of a specific procedural equipment, it could result in a delay in insertion, which may or may not impact the patient's outcome. Linking LSTs and AEs in the trauma bay to in-hospital patient outcomes will enable the exploration of these relationships.

Leveraging technology for enhanced data acquisition

To better understand the complex interactions between team and task-based challenges in the trauma bay, a synchronised data capture and analysis platform (Trauma Black Box, Surgical Safety Technologies (SST), Toronto, Ontario, Canada) will be employed. This system continuously collects anonymised, encrypted audio-visual, patient physiological and environmental data via wall-mounted cameras, microphones and sensors that capture team positioning, movements and vital sign data. Expert analysts will then populate a data timeline of case events from start to finish. Trauma resuscitation is mapped into four phases: pre arrival, paramedic handover, acute resuscitation and pre departure. Key data points include procedures performed, medications and blood products given, disruptive environmental and organisational factors, non-technical team skills, safety threats and resilience support and AEs and errors. All data will be securely stored and used exclusively for predefined purposes, ensuring participant privacy.[9 10] Building on prior work with simulations and reviews of morbidity and mortality (M&M) cases, this study leverages video review to identify targeted areas of improvement.[11 12]

How novel technology can improve patient safety

A video capture system in the trauma bay overcomes the limitations of after-action reviews by prospectively capturing and analysing direct observational data on trauma resuscitations.[13] For example, in the case of a perceived delay in blood product arrival, our current M&M process involved a retrospective review of physician and nursing notes to identify when blood was requested and then arrived. This documentation may be incorrect or absent and often lacks meaningful details. Trauma video review (TVR) can record accurate times for these events and identify potentially actionable safety threats (eg, request for blood not acknowledged, no porter in the trauma bay, blood arrived but not announced, level 1 infuser not set up).

Video review also provides a consistent and reliable method for tracking specific quality metrics such as the time to trauma team assembly or time-to-blood product administration. These data can be linked to patients' electronic medical records, allowing us to explore the relationship between initial trauma resuscitation and downstream patient-oriented outcomes. It is anticipated to be pivotal in ongoing efforts for continuous quality improvement.

Legal considerations for TVR

Medicolegal concerns are often cited as the driving barrier to implementing a video review programme.[10 14 15] Despite this, a recent survey of trauma centres in the USA showed that of hospitals with a TVR programme, only 3% knew a medicolegal case involving a TVR.[14] This was similar to a study published in 1999 that found that in trauma centres with video review, none of them identified medicolegal issues as an actual problem,[16] suggesting that medicolegal concerns are often exaggerated. Video recordings may capture criminal activity, such as the assault of healthcare providers by a patient. If the police request a video through appropriate channels (eg, search warrants or court orders), the hospital must provide a video if available.

Limitations of prior work

Prior work examining team performance and AEs in the acute resuscitation of injured patients has revealed several significant limitations. First, retrospective studies have highlighted errors that contribute to preventable patient deaths, such as delays in diagnosis and treatment, clinical decision-making mistakes, technical mishaps and procedural errors.[17] However, prospective studies that meticulously document trauma resuscitation activities are scarce. Second, although many studies have assessed trauma team performance using simulated scenarios, these simulations often fail to replicate the complexities of real-life resuscitations.[14] Finally, there is a paucity of studies exploring the link between trauma team performance and in-hospital outcomes, leaving a gap in understanding the broader impact of team dynamics on patient care and recovery.[18] Addressing these limitations is crucial for developing effective strategies to enhance trauma resuscitation and improve patient outcomes for severely injured patients.

HYPOTHESIS AND NOVELTY

Our hypothesis posits the existence of identifiable and modifiable AEs associated with adverse patient outcomes in trauma care. Furthermore, we theorise that these incidents and AEs stem from a sequence of errors influenced by environmental and human factors. The understanding can inform identifying areas for improvement in organisational, technological and team or individual capacity. We aim to improve patient safety in the trauma bay by designing interventions to enhance individual and team performance. The novelty of our approach lies in the prospective assessment of human and environmental factors within the trauma bay, circumventing the limitations associated with the conventional practice of identifying post-occurrence events. By acquiring more dependable data via prospective collection, we anticipate a more accurate delineation of areas warranting further improvement. Ultimately, these insights can guide the development of training interventions, such as in situ simulations or ergonomic modifications in the trauma bay, to mitigate the escalation of error patterns into AEs and safeguard patient care and outcomes.

RESEARCH OBJECTIVES

The purpose of this study is:

1. To prospectively evaluate the prevalence of AEs, errors and human and environmental factors within the trauma bay and to identify common error patterns, LSTs and AEs.
2. To explore associations between identified AEs and patients' in-hospital outcomes.
3. To assess the variability in trauma care practices across different trauma teams and patient injuries during resuscitation procedures.

METHODS AND ANALYSIS

The overall study design is presented in figure 1. The TVR programme began on 28 August 2023. We anticipate that this study will be completed by January 2025.

Setting

The prospective observational study will be conducted at St. Michael's Hospital, a University of Toronto-affiliated tertiary care teaching hospital and level-1 trauma centre. St. Michael's Hospital has 1200 trauma activations per year, of which about a third have an injury severity score (ISS) above 16.

This study is designed as a pilot project to assess the feasibility of using TVR for real-time evaluation of trauma resuscitation and its impact on identifying AEs and LSTs. The pilot study aims to trial this novel procedure, establish power calculations for a full-scale research study, assess the recruitment feasibility of healthcare professionals and patients and evaluate logistical considerations for data collection, including video recordings and physiological monitoring. Insights from this pilot will inform the design and protocols for a subsequent, larger-scale investigation into trauma care safety.

Trauma team structure

At St. Michael's Hospital, trauma team activations are supervised by a trauma team leader (TTL), available 24/7. The TTLs are staff physicians in emergency medicine, anaesthesia, general surgery or orthopaedic surgery with specialised training in acute trauma resuscitation. In urgent cases, a staff emergency physician assumes the team leader role until the TTL arrives, typically within 15 min.

The core team includes the TTL, emergency nurses, respiratory therapists and residents from general surgery, orthopaedics and anaesthesia. These team members are directly involved in patient care and are included in the study's analysis. Supporting roles, such as pharmacy staff, social workers, X-ray technicians, porters and medical students, assist with tasks in the trauma bay but are not analysed for their impact on patient outcomes.

On arrival in the trauma bay, patients undergo primary and secondary surveys, intravenous insertion, imaging, blood product administration and necessary interventions such as intubation, chest tube placement, fracture reduction or resuscitative thoracotomy.

Study participants

Eligible participants include trauma patients aged 18 years or older who activate the trauma team at St. Michael's Hospital, a level-1 trauma centre. Patients will be excluded if they are paediatric patients or prisoners or if their resuscitation ends within 5 min. Detailed inclusion and exclusion criteria are outlined in table 1.

Video capture technology

This study will collect audio-video data using the Trauma Black Box, equipped with nine 1080p HD cameras (seven mounted on the ceiling and two mounted on the

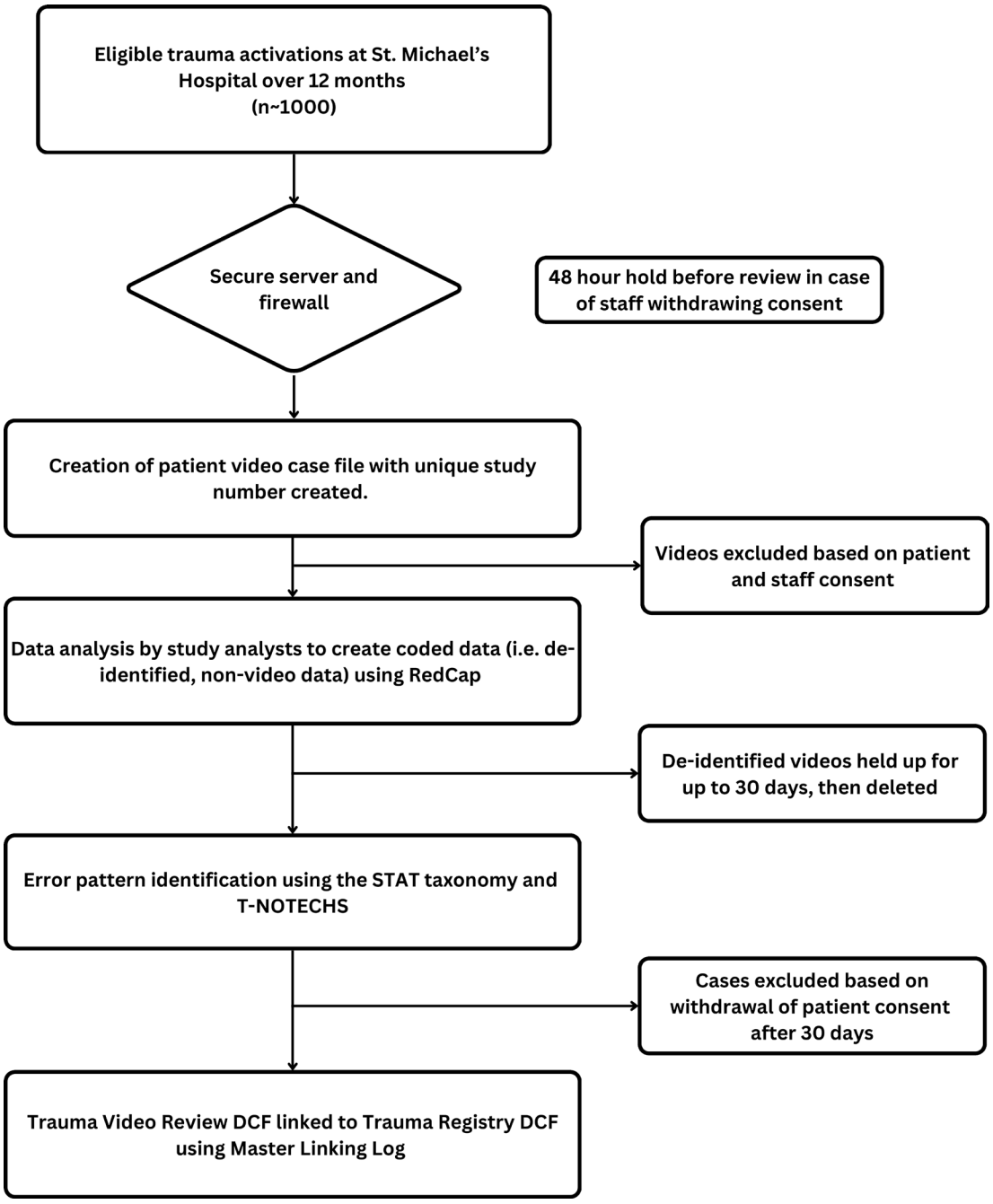

Figure 1 Data collection workflow for Prospective Observational study of Safety Threats and Adverse events in Trauma (STAT) methodology. DCF, data collection form; T-NOTECHS, Trauma NOn-TECHnical skills.

walls) and six ceiling array microphones throughout the trauma bay. Recording will begin 10 min before a trauma case activation or patient arrival and continue until the patient leaves the trauma bay, with a maximum duration of 60 min. This process will also document the trauma team's pre-brief and preparation activities,

Table 1 Inclusion and exclusion criteria for participants

Inclusion criteria	Exclusion criteria
► Patients over the age of 18 years ► Patients receiving care through trauma team activation at St. Michael's Hospital (regardless of transport mode) ► Trauma team	► Paediatric patients ► Patients and staff members who withdraw consent ► Prisoners and correctional patients ► Termination of resuscitation in less than 5 min of arrival ► Video recording captures <50% of resuscitation

ensuring comprehensive coverage of the resuscitation process.

The audio-video data collected as part of the TVR programme at St. Michael's, a Unity Health Toronto (UHT) institution, will be securely transferred to a UHT server (protected by institutional firewalls) before being transferred to SST, where they will be secured behind an additional firewall. Data files will then be organised by trauma case and labelled with a unique case number distinct from the study ID to ensure privacy and security.

Staff, physicians and learners will only be evaluated non-technical and team-based skills rather than individual performance to alleviate concerns about being recorded. Evaluations will focus on roles in the trauma bay, for example, TTL, nurse and respiratory therapist, without linking names or identifiers to performance scoring. Each trauma resuscitation will be anonymised and correlated only to its study ID to safeguard participant confidentiality and data integrity.

Data sources

Audio-visual data collected during trauma activations, as detailed in the Video capture technology section, will be analysed alongside physiological and patient outcomes data.

The data collection forms will use validated tools, such as the Safety Threats and Adverse events in Trauma (STAT) taxonomy and Trauma NOn-TECHnical Skills (T-NOTECHS) scale, to guide the data analysis (online supplemental file 1).[19–21] To link TVR data to the St. Michael's Hospital trauma registry for in-patient outcome data, a Master Linking Log will be used, allowing stratification of patient risk factors and identification of organisational factors, including delays and environmental influences, such as time of day. It will help assess the impact on in-hospital outcomes such as mortality, length of stay and hospital resources (eg, need for intubation, intensive care unit (ICU), blood products, surgeries). Additionally, the time and date of all data recordings, including audio and video, will be captured as these factors may influence vigilance and injury patterns.[22] All data records, documentation or information containing patient data will be de-identified with an assigned study ID to ensure that persons outside the study cannot identify the participating patients or staff, physicians or learners. The recorded audio-video files are retained on SST servers for up to 30 days (until analysis is complete) and then deleted. All other data will be stored in a restricted folder on the internal hospital network.

Disclosure of errors and AEs

LSTs in trauma are defined as 'system-based threats to patient safety that can materialise at any time and are previously unrecognised by healthcare providers, unit directors or hospital administration'.[8] Currently, it is unknown if LSTs directly result in AEs or the severity of such events. For example, a resident needs to be made aware of where to find the specific procedural equipment, resulting in a delay in insertion, which may or may not impact the patient's outcome. Linking LSTs and AEs in the trauma bay to in-hospital patient outcomes will enable the exploration of these relationships.

In the case of an AE that requires medical rectification, these will naturally, as per standard practice, be described and documented in the dictated TTL notes. It is the standard operating procedure for these types of events. In cases with more severe consequences, the complication will be discussed with the patient or family per the standard of care. It is already the standard operating procedure and will not be changed during the study. Incidental findings during the management or work-up during trauma care (such as lung nodules found on X-rays that require follow-up imaging) will be discussed with the patient since this is standard medical care.

Evaluation of trauma resuscitations

Trauma videos will be assessed using the following two assessments:

1. Identification of LSTs and AEs: The STAT taxonomy screens trauma resuscitations for identifiable errors and AEs.[19 23] To enhance the reliability and robustness of this assessment, approximately 25% of all trauma recordings will be evaluated by a second rater. This second rater, a physician or nurse with expertise in rating scales, will not be associated with the research team, ensuring independence and mitigating potential biases. Including the second reviewer for a subset of cases strengthens the validity by providing an opportunity for independent assessment and addressing potential biases or discrepancies in ratings. However, video review is resource-intensive, and using a single rater ensures efficiency and consistency while minimising resource impact.[23]
2. T-NOTECHS scale for non-technical skills (NTS): Video and audio recordings will also be evaluated by a trained research team member using the modified NTS scale for trauma (T-NOTECHS), which will be applied after the STAT taxonomy by the same rater.[21 24] The T-NOTECHS rating scales were derived from frameworks for observing team behaviours and have been modified to assess trauma teams.[24–26] It has previously been used in trauma team assessment and has been shown to have construct validity and good inter-rater reliability.[25] Analogous to identifying AEs above, a sample of randomly selected recordings of ~25% of all traumas will be assessed by a second rater blinded to the previous rater's assessment. Additionally, given that both the STAT taxonomy and T-NOTECHS scale have high inter-rater reliability, the consistency of these assessments across multiple raters has been well-established.[21 23]

Evaluation of clinical outcomes

The collection of in-hospital outcomes data for this study requires the abstraction of data from the existing St. Michael's Hospital trauma registry, which must be

accredited as a level-1 trauma centre. In essence, every patient who is a trauma activation at a trauma centre in Ontario has a comprehensive chart review to enter the required information into the local trauma hospitals' trauma registry.

The St. Michael's Hospital trauma registry is the locally housed dataset contributing to the Ontario Trauma Registry. All accredited level-1 trauma centres across Canada have a local trauma registry and produce reports that populate a provincial trauma registry. This dataset has an established data dictionary and data collection methodology.[27] Examples of specific patient variables of interest that will be collected include ISS, mechanism of injury, age, sex, hospital length of stay and mortality. Example of hospital resources that will be collected include blood product usage, need for ICU and number of surgical procedures.

Outcome measures

The primary outcome of this study is the association between AEs and in-hospital mortality. Secondary outcomes include the impact of NTS, as assessed by the T-NOTECHS scale, on AEs and the influence of AEs on patient outcomes such as hospital length of stay and resource use. Additional analyses will evaluate the measurement properties of the STAT taxonomy and T-NOTECHS scale, including inter-rater reliability and construct validity

Key variables of interest include patient demographics (age, sex), injury characteristics (mechanism of injury, ISS) and in-hospital outcomes (length of stay, ICU admission, surgeries and mortality). These variables will be abstracted from the St. Michael's trauma registry and analysed to explore associations with safety threats and AEs during trauma resuscitations.

Sample size

This study represents a pilot study to establish knowledge about AE rates during trauma resuscitation. The Trauma Resuscitation Using in situ Simulation Training Study identified 843 LSTs during 12 in situ simulation sessions using a video-based framework analysis. It is unknown how many AEs will occur during real patient care, as opposed to simulated environments, or how these events will affect various outcomes. The accumulation of LSTs or AEs can likely influence several outcome parameters, such as time in the trauma bay, time-to-blood product administration and even patient outcomes, such as in-hospital length of stay or mortality.

Given an annual volume of approximately 1200 patients at St. Michael's Hospital, an altered consent model is proposed to encompass over 1000 trauma patients. Assuming an AE rate of 2.5% (events with measurable impacts on mortality, hospital resource utilisation, etc), an estimated 50 patients may experience such occurrences. One year of observation is anticipated to yield sufficient data for the initial analysis of these interactions, facilitating power analyses and evaluations for subsequent studies in the field.

The number of AEs will be treated as a continuous predictor variable, with mortality as the primary outcome. Based on 2021 data, St. Michael's Trauma Bay had 1184 trauma team activations, with 30 deaths in the trauma bay. To achieve 80% power at a 0.05 significance level, 290 samples are required, assuming an AE rate of 2.5% (based on a Poisson distribution). This sample size will allow for robust analysis of the relationship between AEs and in-hospital mortality, adjusting for relevant confounders.

Statistical analysis

To identify associations between AEs and patient outcomes, we will initially conduct a descriptive statistical analysis to categorise the occurrence of defined events and outcomes. This analysis will include calculating proportions, ORs and relative risk to assess the relationship between AEs and patient outcomes.

Additionally, we will use the logistic regression model to evaluate the association between the number of AEs treated as a continuous predictor variable and in-hospital mortality among the sample of trauma patients. This model will quantify the impact of AEs on mortality while controlling for potential confounders.

Other factors may also influence the occurrence of AEs and patient outcomes. To address this, multivariable analysis will be performed to adjust for the severity of the injury (ISS) and other potential confounding variables. Subgroup analyses will stratify patients by factors such as injury type (blunt vs penetrating), mechanism of injury (eg, motor vehicle collisions, pedestrian or cyclist, falls, assaults), age categories, physiological stability (eg, Systolic Blood Pressure (SBP)<90 mm Hg, Glasgow Coma Scale (GCS) scores, and injury severity (ISS). These analyses will help identify patterns of AEs and outcomes across diverse patient populations. We will also consider using direct acyclic graphs to identify and assess assumptions regarding potential causal relationships, including confounders.[28] Missing data will be carefully evaluated and addressed using appropriate statistical methods to ensure the validity and reliability of the results. The impact of missing data on the findings will be evaluated, and sensitivity analyses will be conducted to explore the robustness of the results under various assumptions.

Additionally, categorical independent variables based on the STAT taxonomy will be incorporated to estimate their association with the binary outcome of an AE. This approach will help identify specific NTS and environmental factors that may contribute to the occurrence of AEs.

While we do not plan to stratify the sample a priori based on ISS due to uncertainty in the distribution of trauma patients with varying levels of injury, we will account for injury severity in the multivariate analysis. Injury severity will be included in the regression models as a covariate to assess its relationship with AEs and patient outcomes. This approach will allow us to evaluate the differential

impact of AEs and LSTs across varying injury severities once sufficient data are available for analysis.

Projected outcomes

A comprehensive database will be created to systematically capture AEs and LSTs that may compromise patient and healthcare worker safety in the trauma bay. The database will serve as a repository for documenting and categorising various types of AEs, including procedural complications, communication breakdowns, time metrics, etc. Additionally, it will facilitate the identification of LSTs, such as system flaws or vulnerabilities that may compromise patient and healthcare worker safety. Additionally, using the STAT taxonomy and T-NOTECHS scale to evaluate audio-video data from the TVR will allow us to objectively measure AEs and safety threats that can affect the quality of care and understand the implications on patient outcomes.

ETHICS AND DISSEMINATION

This study has institutional research ethics board approval (SMH REB # 21-009) from UHT research ethics board.

Participants and consent

Participating in the study poses no greater risks than providing routine care to patients for the following reasons:

1. All study findings will undergo de-identification.
2. Study results will be presented in an aggregated manner, except for immediate safety concerns.
3. Patient care will be provided as usual during the study, with no changes to the standard treatment protocols.

An alternative consent model will be used for this study, in keeping with Tri-Council Policy Statement (TCPS2) Articles 3.7A and 3.7B (Table 2).

Table 2 Summary of consent models and processes for staff, patients and the public

Consent model	Process
Staff	Consent is implied with opt-out/withdrawal requests available; posters placed in the trauma bay for awareness.
Patient (survive to discharge)	Notification included in routine discharge paperwork; posters placed in the family area/waiting room in the emergency department.
Patient (die in hospital)	Next of kin notified via letter; study posters placed in family area/waiting room.
Patient (die in trauma bay)	If identified, next of kin notified via letter; no notification if unidentified.
Public	Information made available via study website.

Staff consent model

Consent for this study follows an opt-out model for staff and an alternative consent process for patients, in compliance with Tri-Council Policy Statement (TCPS2 Articles 3.7A and 3.7B) guidelines. Staff and participants will receive study information, and their participation will be implied unless they actively opt-out. Staff members who choose not to participate will be asked to inform the study co-ordinator of their decision within 48 hours of the trauma case. Patients or their next of kin may withdraw consent during or after recording. Detailed consent processes for staff, patients and the public are outlined in table 2.

Patient and public involvement

Patients and the public were not directly involved in the design or conduct of this pilot study. However, the study is aligned with improving trauma resuscitation and patient safety, which are of significant interest to healthcare professionals and the public. The study findings will be shared with key institutional stakeholders, including trauma care teams, and the results will be disseminated through peer-reviewed journals and presentations at relevant conferences. We also plan to inform study participants and their families about the results in a manner consistent with standard clinical practice, ensuring they are aware of any findings that may directly impact their care.

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Contributors AN, MM and BN designed and led the study. AN wrote the paper. All authors critically reviewed and edited the paper. BN acted as guarantor. Grammarly was used to ensure accurate spelling and grammar in the manuscript. This technology was chosen for its proficiency in enhancing textual clarity and coherence. It primarily undertook the task of spell check and grammar correction, contributing to the overall quality and readability of the submission.

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Competing interests BN received funding as an affiliate scientist with the International Centre for Surgical Safety from January 2020 to December 2021. TG holds an equity interest in Surgical Safety Technologies. Additionally, TG has intellectual property ownership and a leadership role in Surgical Safety Technologies. EMS declares potential conflicts of interest, including receipt of payment from Hologic, consulting fees from Bayer Pharmaceuticals and holding a leadership role in Canadian Society for the Advancement of Gynecologic Excellence,

in an unpaid capacity. These interests were relevant during the lifespan of the work reported in this manuscript. AN, MM and CDGK-S declare no conflicts of interests. All participating investigators and coinvestigators are academically interested in successfully completing the pilot study, which is part of AN's PhD project. This interest is disclosed to maintain transparency and integrity in the research process.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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