

A Trigger-Tool-based Description of Adverse Events in Helicopter Emergency Medical Services in Qatar.

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Abbreviations

AE	Adverse Event
AE1:	Potential Harm
AE2:	Confirmed Harm
AP:	Ambulance Paramedic
BLS	Basic Life Support
CCP:	Critical Care Paramedic
CQI:	Continuous Quality Improvement
CRM:	Crew Resource Management
CSH	Combat Support Hospital
ED	Emergency Department
EMS	Emergency Medical Services
EMSTT	Emergency Medical Services Trigger Tool
ePCR:	Electronic Patient Care Report
GTT	Global Trigger Tool
HEMS	Helicopter Emergency Medical Services
HEMSTT:	Helicopter Emergency Medical Services Trigger Tool
HFE	Human Factors Engineering
HMCAS:	Hamad Medical Corporation Ambulance Service
ICU	Intensive Care Unit
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
LifeFlight:	The HEMS division of HMCAS
M-Sofa	Modified Sequential Organ Failure Assessment Score
MACC	Medication Administration Cross-Check
NCC:	National Command Center
OHCA	Out-of Hospital Cardiac Arrest
PC:	Proximal Cause
PCI	Percutaneous Coronary Intervention
PCR:	Patient Care Record
PI:	Primary Investigator
PittAETool	Pittsburgh Adverse Event Detection Tool
RSI	Rapid Sequence Intubation
SPC:	Statistical Process Control
STEMI	ST-Elevation Myocardial Infarction
TRAP	Transport Risk Assessment in Paediatrics Score

TRS Transport Risk Score
TT Trigger Tool

PART A: Background and Literature Review

1. Introduction

1.1 Background

Medical errors constitute a significant public health concern and patient safety risk.¹ The Harvard Medical Practice Study was amongst the first large scale investigations into the incidence of adverse events (AEs) resulting from negligence in hospitalized patients, with a specific focus on malpractice costs stemming from harm in healthcare.² A decade later, the landmark paper from the Institute of Medicine (IOM) “*To Err Is Human: Building a Safer Healthcare System*” estimated between 44,000 and 98,000 American deaths per year were attributed to medical error.¹ This heightened awareness within the media rekindled public interest, shifting the spotlight, and soon turned patient safety initiatives into a priority.³

Five years after the release of the IOM report, and despite efforts to improve patient safety, progress in healthcare improvement remained slow and had not sufficiently translated into a safer healthcare system.^{1, 4-6} The IOM report did, however, fundamentally change the way role-players viewed the task of error identification and prevention, how they enlisted the support of stakeholders, and accelerated changing practices through a combination of voluntary and legislative recommendations, and secured funds for patient safety research.⁴ Furthermore, a combination of healthcare complexity, a longstanding culture of physician authority and autonomy, and fear posed significant ongoing barriers preventing the implementation of practices and policies with the potential to improve patient safety.⁴ The primary lesson learnt was that patient safety is a choice. Our beliefs, intentions, cultures and choices underscore our ability to make the necessary changes.⁴

However, significant barriers impeding patient safety and improvement initiatives are entrenched within the difficulties and inconsistencies in defining and measuring harm. To this end, Vincent et al called for more systematic and standardised measurement.⁶ Furthermore, many healthcare leaders fall prey to the trap of relying solely on quality metrics as the only measures of quality within their organization. Cameron and Cooke describe a framework for the measurement of quality in the Emergency Department (ED), and caution against inappropriate use of quality indicators in isolation (i.e.- Quality Indicators should not replace appropriate use of AE detection methods to identify harm / potential for harm / highlight areas for improvement).⁷ While there simply appears to be no set standard for AE detection in healthcare, the reality is: “What you see depends on how you look” (i.e.- AE detection methodology matters).⁷⁻⁹

1.1.1. Defining Adverse Events, Error and Harm

Whilst healthcare leaders, practitioners, and patient safety experts grapple with the growing body of evidence that healthcare could potentially lead to patient harm, they also realize the success of improvement efforts depends on the ability of researchers to accurately measure error and harm.¹⁰ Unfortunately, known variations and a lack of universally accepted definitions threaten to limit our understanding of AEs, hinder data analysis, collaboration, and undermine improvement efforts.¹⁰

Hofer and Kerr¹¹ argue that medical error should only be defined in terms of “failed processes that are clearly linked to adverse outcomes”. However, not all medical error results in harm. Conversely, Grober and Bohnen¹⁰ propose an outcome and process-dependent definition of medical error: “An act of omission or commission in planning or execution that contributes or could contribute to an unintended result”. The four key domains of error are present (omission, commission, planning, execution), including the faulty processes independent of outcome. This definition therefore includes the “silent-majority” of errors that do not necessarily result in harm, but highlight faulty processes nonetheless.¹⁰

Of equal importance is the fact that AEs are not always a product of medical error. It is well acknowledged that numerous patient and system factors can and do also contribute to AEs (only some of which may result in harm), absent of medical error.^{10, 11} Furthermore, not all AEs result in harm. Therefore, the act of identifying harm (from whatever cause) in isolation, is to ignore the larger picture by not considering the overwhelming potential for harm within our healthcare systems.

1.1.2. Adverse Event Detection Methodologies

The question: “What is the most suitable methodology for the detection of AEs?”- is of utmost interest to patient safety researchers.^{12, 13} Traditional methods for detecting AEs include manual chart review, direct observation, morbidity & mortality rounds, voluntary reporting systems, and patient complaints.¹² Whilst the manual chart review has previously been considered the “gold standard” for the detection of AEs in healthcare, the costs, limitations and imperfections of this methodology are well documented.¹²

The concept of a *‘trigger’* was first described in 1974, and Trigger Tool (TT) methodology has since evolved.¹⁴ Trigger tool methodology is generally based on a retrospective or near-real-time structured chart review process, utilizing a small (weekly or monthly) sample plotted over

time, with the application of preidentified and validated triggers that are known to be closely associated with AEs in the domain or processes of interest.¹⁴ Triggers are typically more structured, well-defined, less subjective, and allow raters to focus on important aspects of the review. The process is typically conducted between two raters and is timed (i.e.- ten to fifteen minutes per review). Disagreement between raters is compared and consensus is sought. Disagreement is finally resolved by a more clinically senior and independent reviewer.

The subsequent development of the Global Trigger Tool (GTT),¹⁵ as described by the Institute of Healthcare Improvement (IHI), has shown significant potential in identifying AEs in a timely and cost-effective manner with good inter-rater reliability.¹⁶⁻¹⁸ Trigger tools have since been adapted for utilization in different healthcare domains and processes (e.g.- Adverse Drug Events,¹⁹⁻²¹ Ambulatory Care,^{22, 23} General Medicine,²⁴ Intensive Care Units,²⁵⁻²⁷ Oncology,²⁸ Orthopedics,²⁹ Pediatrics,³⁰⁻³⁶ and Surgery^{37, 38}). Furthermore, the GTT identified ten times more hospital-based AEs when compared to other traditional methods of AE detection.³⁹ This finding, coupled with its ease of use and adaptability in different healthcare domains has resulted in the emergence of the TT as: “The premier measurement strategy for patient safety”.⁴⁰

1.2. Literature Review Objectives

The aim of this literature review is to:

1. Describe the epidemiology of adverse medical events in Helicopter Emergency Medical Services (HEMS) in Qatar.
2. Describe the incidence of adverse medical events in HEMS in Qatar.
3. Describe adverse medical event detection methods in HEMS in Qatar.
4. Outline gaps in the literature.
5. Where Qatari literature is not available, international literature will instead be described.

For the purpose of this research, the following literature review will focus on AEs, error, and harm related to the practice of emergency medicine and medical care in HEMS. Harm related to aviation accidents are not the focus of this research question, and will therefore be excluded from the review.

1.3. Search Strategy

An advanced search was conducted in the PubMed, Web of Science, and CINAHL databases using Medical Subject Headings (MeSH) terms on 12th August 2020. The search was filtered to English texts only, and limited to full text original research articles no older than ten years (August 2010). The search strings below yielded the following results:

⇒ String 1:

((“Medical Errors”[Mesh]) OR (“Patient Harm”[Mesh])) AND (“Air Ambulances”[Mesh]) AND (“Qatar”[Mesh]): Zero results for all respective databases.

⇒ String 2:

((“Medical Errors”[Mesh]) OR (“Patient Harm”[Mesh])) AND (“Air Ambulances”[Mesh]): 16, 9, and 2 results for all respective databases.

⇒ String 3:

((“Quality Indicators, Health Care” [Mesh]) OR (“Medical Errors” [Mesh]) OR (“Patient Harm” [Mesh])) AND ((“Air Ambulances” [Mesh]) OR (“Emergency Medical Services” [Mesh]) OR (“Emergency Service, Hospital” [Mesh]))): 1789, 502, and 19 results for all respective databases.

A 4th search string was added due to the low number of hits achieved by the 3rd string search in the CINAHL database to include the word “Ambulance”:

⇒ String 4:

((“Quality Indicators, Health Care” [Mesh]) OR (“Medical Errors” [Mesh]) OR (“Patient Harm” [Mesh])) AND ((MH “Emergency Medical Services”) OR (MH “Association of Air Medical Services”) OR (MH “Ambulance”)): 73 results.

⇒ Other Sources:

References cross-checked and recommended from expert sources: 8 results.

A total of 2418 results were achieved from all search strings across all three databases. A total of 2349 papers were excluded by title, with 69 research papers remaining. All research articles were checked to ensure they were original research, English, and published within the previous 10 years. One paper marginally older than 10 years was included as the title was pertinent and relevant to the research topic and recommended from expert sources. All research papers were downloaded into Endnote reference manager software and 18

duplicates removed. A total of 51 research papers were then subjected to abstract and full-text review. A total of 25 papers were identified. See Appendix 1 (Prisma Diagram).

2. Literature Review

A total of 25 research papers are included in the following review. See Appendix 2 (*Literature Summary*). The literature will be presented under the following themes: 1) Epidemiology of AEs in HEMS, 2) Incidence of AEs in Emergency Medical Services (EMS) including AEs within the high-risk paediatric population and medication errors, 3) Common AE detection methodology in HEMS and EMS, and finally 4) outline the gaps in the HEMS AE literature. Each theme will expand from HEMS into the EMS domain where necessary (i.e.- where insufficient literature exists in the HEMS domain of interest).

2.1. Epidemiology of Adverse Medical Events in HEMS

The epidemiology and classification of AEs in HEMS in Qatar is not reported in the literature. Furthermore, AE classification in HEMS is poorly reported, as there appears to be no standard definition and taxonomy for AE reporting in the HEMS literature. Only 4 papers were published over the last decade, with the exception of one paper extending back to 2008 (as recommended by experts in the HEMS arena).

MacDonald, Banks and Morrison⁴¹ conducted an observational study to establish the frequency of all-cause AE epidemiology in a large scale Canadian HEMS system, with the intent to bridge the AE reporting gap in emergency medical services literature. In this paper, the frequency of AEs was established at 11.53 per 1000 flights or 6.56 per 1000 hours flown, with an event rate of 2.93 for aviation, 8.19 for nonaviation, and 0.41 AEs per 1000 flights for unclassified categories. The single largest AE contributor by category was classified as communication (33.7%), followed by transport vehicle (21%), medical equipment (12.9%), patient management (11.4%), clinical performance (10%), weather (4.4%) unclassified (3.5%) and patient factors causing death (3.1%). Possible harm was established in 1.99 per 1000 flights, and this represented a harm rate due to aviation (0.31), nonaviation (1.58), and unclassified categories (0.10) per 1000 flights. One significant limitation in this study was that the author used a known in-hospital taxonomy to retrospectively categorise AEs, as a transport-specific taxonomy does not exist. Furthermore, retrospective data collection, and data drawn from a self-reporting registry is highly suggestive of under-reporting of AEs by

paramedics, and therefore the findings of this study would most likely constitute an underestimate of the true AE rate.

Moreover, in a combat military setting, using retrospective data derived from the helicopter transport system used by the Combat Support Hospital (CSH) in Baghdad during Operation Iraqi Freedom, Lehmann, et al⁴² report AEs in the following categories: equipment failures (17%), clinical deterioration in-flight (30%), and the requirement for urgent intervention on arrival at receiving facility (9%). Furthermore, in patients with reported AEs, the mean Transport Risk Score (TRS) was significantly higher (9.1) compared to those with no AEs (7.4). TRS is a civilian risk-scoring system used in interfacility transfer to determine patients at greater risk for AEs during transport. In this study, AEs were defined as any in-transit equipment failure, hypotension, desaturation, arrhythmia, tachycardia, and the requirement for immediate interventions on arrival of the patient at the receiving facility. However, no AE rate was presented in this paper. While this study was conducted in a combat military environment, a major limitation exists in attempting to validate a civilian-derived TRS score in a military domain, and therefore may have limited relevance in a combat population where high TRS scores could be expected.

In a large scale population-based retrospective cohort study, Singh, et al⁴³ described both the incidence and predictors of critical events during air-medical transport. Critical events (defined as death, major resuscitative procedure, hemodynamic deterioration, inadvertent extubation, and respiratory arrest) were identified in 5.1% of all flights (1 event every 12.6 hours transit time; 1 event every 20 flights), where new hypotension (3.2%) and a major resuscitative procedure (2.1%) including airway management procedures were most prevalent. Female sex, assisted ventilation and hemodynamic instability prior to flight, transport by fixed-wing aircraft, increased transport time, on scene calls, and the type of crew were all identified as independent predictors of critical events. While this study represents the largest population-based cohort of transported patients, it is limited by retrospective data and bias in the way resources were assigned to patients and long transport distances resulting in preferential modes of transport. Furthermore, the author was unable to determine an injury / illness severity score that would allow direct comparison to other studies.

More recently, Stassen, et al⁴⁴ identified endotracheal intubation as a high risk procedure frequently performed by HEMS providers in the South African context. Adverse events were reported in a third of intubations (27%), the most prevalent being hypoxemia, hypotension and bradycardia.⁴⁴ A significant limitation of this paper relates to the small sample size, the self-reported nature of the data and AE reporting which lends itself to potential bias.

A paucity of evidence exists in the literature to firmly establish incidence rates of AEs in HEMS, especially in Qatar. As shown above, MacDonald, Banks and Morrison⁴¹ reported 11.53 AEs per 1000 flights; Singh, et al⁴³ reported critical events in 5.1% of all flights (1 every 20 flights); and Stassen, et al⁴⁴ reported AEs in a third of all intubations (27%). However, bias from reliance on self-reporting AE mechanisms, retrospective data collection, limitations in study design (population of interest, differences in primary outcomes) heterogeneity of data, and the vast differences in defining AEs, limit our interpretation of these studies. Furthermore, no established methodology or standardized taxonomy exists to facilitate standard reporting of AEs in HEMS.

2.2. Incidence of Adverse Medical Events in EMS

Due to the paucity of HEMS AE literature, a wider look at AE reporting in the prehospital literature might be helpful required. Eight papers relating to AEs in the EMS domain were found, of which 3 were systematic reviews. The first systematic review by Fan, et al⁴⁵ looked at literature to determine AEs of intubated mechanically ventilated adult patients during interfacility transport. Only 5 papers were included in this review. One death was reported. Whilst one study reported a 19% incidence of respiratory alkalosis; another showed a 30% Intensive Care Unit (ICU) mortality; and three of the studies reported no AEs after arrival at the facility. However, this review was limited due to the low number of studies included. Furthermore, heterogeneity prevented meta-analysis, and the scope was limited to mechanically ventilated adult patients.

In a second systematic review, Bigham, et al⁴⁶ identified threats to patient safety pertinent to the EMS domain. Eighty-eight studies met inclusion criteria, and were grouped in the following 7 themes: AEs and medication errors, clinical judgment, communication, ground vehicle safety, aircraft safety, interfacility transport, and intubation. This review shows that prehospital patient safety research is in its infancy, and many gaps in the literature exist (i.e.- safety culture, prehospital staffing, quality improvement techniques, near-miss reporting, and human factors engineering). The majority of papers identified in this review represent topics that are typically easy to retrospectively review, whereas interventional study designs are lacking in the EMS patient safety literature. Furthermore, clinical decision-making of prehospital providers has been identified as another area requiring further research. This paper may have suffered from publication bias.

A third and more recent systematic review by Alabdali, et al⁴⁷ aimed to identify the prevalence and types of AEs that occurred during interfacility transfers when paramedics lead patient transfer teams. Seven observational studies met inclusion criteria (adult patients 16 years and older; interfacility transfer between two facilities; paramedic as the primary or sole provider). Five studies were retrospective and two prospective; while two studies involved cardiac patients transported with Intra-Aortic Balloon Pump (IABP). The incidence of AEs reported ranged between 5.1% - 18%. However, difficulties in interpreting this data persist due to the following problems observed: Outcomes between studies differ significantly; heterogeneity prevented meta-analysis; authors' AE definitions differ; lack of longitudinal follow-up; accuracy of reported AEs; risk of bias; and small sample sizes.

In a cross-sectional survey study, Patterson, et al⁴⁸ identified strong associations between poor sleep, fatigue, and safety outcomes in EMS providers. In this study, the odds were 1.9 greater for injury, 2.2 greater for AEs and medical error, and 3.6 greater for safety compromising behaviour. These findings suggest that poor quality of sleep and fatigue are common in EMS and may contribute to poor safety outcomes. However, a number of limitations cloud interpretation and extrapolation of results. This study was unfortunately limited by convenience sampling. Also, when measuring respondent fatigue, they failed to measure work-load at the individual level and the varying amounts of work-loads for any given response. The amount of work required for a given response may have varied significantly between respondents, and therefore the fatigue level may have been perceived differently between respondents. Further research is required to investigate the possible impact poor sleep and fatigue has on quality metrics.

Data generated from anonymous incident reporting systems also help provide insight into AEs. Gallagher and Kupas⁴⁹ analysed data from a Web-Based State EMS Safety Incident Reporting System over a 7-year period, and categorized events as: actions / behaviour (32%), vehicle / transportation (16%), staffing (13%), communications (8%), medical equipment (9%), level of care (7%), medical procedures (6%), medication (5%), scene safety (3%), and protocol problems (1%). Furthermore, the largest reporting group came from EMS providers directly involved in the incident (33%), and this may indicate that prehospital personnel are interested in patient safety issues. Hohenstein, et al⁵⁰ also established an anonymous critical incident reporting system in Germany, and over a 7-year period categorized incidents as: staff related (56%), equipment related (20%), organization (16%), other (6%), and no incident (2%). Unfortunately, significant limitations exist with this type of data (i.e.- willingness to report; verification of facts and inability to follow-up and determine if harm occurred due to the anonymous nature of reporting; and the subjective nature of event classification).⁵⁰ However,

the usefulness of this type of data remains in the ability to identify common themes of AEs and system weaknesses, with the opportunity for organizational leaders to reduce errors and improve safety through policy change.^{49, 50}

A prospective multicenter cohort study between 2 Belgian hospitals aimed to assess the incidence of AEs and harm in interhospital transport (whereby a combination of land and air transport was used). In this study Lyphout, et al⁵¹ reported patient safety incidence rates (16.7% of transports) and health-care associated harm rates (3.9% of cases). The risk of patient safety incidences was significantly higher in helicopter transfers (45%). Furthermore, healthcare associated harm was significantly associated with 3 factors: operational incidents, communication incidents, and a high Modified Sequential Organ Failure Assessment (M-SOFA) score. However, interpretation is limited as recruitment relied on self-reporting; some data was excluded due to incomplete data capture; and despite efforts to use the M-SOFA severity score, no illness severity scoring system has been validated for the transport population.

More recently, Bussieres, et al⁵² investigated the incidence of clinical AEs on a large rural Canadian cohort of ST-Elevation Myocardial Infarction (STEMI) patients transported by Basic Life Support (BLS) paramedics for Percutaneous Coronary Intervention (PCI). An AE frequency of 30.7% was observed, with hypotension (6.1%) and ventricular tachycardia and ventricular fibrillation (5.1%) being the most frequently observed clinically important events (18.5%), compared to minor events (12.2%). Furthermore, transport time was not associated with AE occurrence, and no deaths were reported. This study, however, had two major limitations. Firstly, it suffered from non-differential information bias stemming from record reviews with the inability to link patient outcomes with hospital records after handoff. Secondly, selection bias appears to have potentially skewed the outcomes reported (i.e.- 38 patients who experienced 40 clinically important events were diverted to the nearest non-PCI center due to clinical instability).

Due to the vast differences in categorizing and defining AEs in EMS, and due to the limitations described and lack of robust published data on the incidence rates of AEs in both HEMS and EMS, it is necessary to cast a wider net and include literature reporting AEs in high-risk groups typically encountered in the pre-hospital environment, as well as high-risk interventions known to be associated with AEs (i.e.- medication administration).

2.2.1. Adverse Events in the High-Risk Paediatric Population

When paediatric patients are encountered in the prehospital environment, they present unique challenges to EMS providers. These challenges are partly due to infrequent encounters, anatomical and physiological differences in compensatory mechanisms, difficulties in assessment, differences in equipment, the need to dilute emergency medications with the use of weight-based drug calculations, and skill retention. Three studies highlight the significant risk of AEs and harm reported during prehospital emergency treatment and transportation of neonatal and paediatric patients by EMS.

The first study by Hansen, et al⁵³ identified safety incidents in 87% of all paediatric Out-of-Hospital Cardiac Arrest (OHCA) cases attended by EMS. In this study, the most common AEs occurred due to failed intubation attempts (20%), and medication errors, where epinephrine overdose (31%) and failure to administer epinephrine (17%) were common. Similar findings were corroborated in another study of adverse safety events in out-of-hospital paediatric airway management, where Hansen, et al⁵⁴ reported high AE frequency rates and increased odds (OR: 15.6) of an AE occurring in paediatric OHCA, especially when an airway intervention was performed. In this study, failed endotracheal intubation was common, and 58% of intubations required more than 3 attempts. A third study by Duby, et al⁵⁵ reported a high incidence of AEs during prehospital neonatal ambulance transport, with AEs occurring across all defined domains. However, medication errors were the highest recorded AE (90%). Furthermore, the observation of 10-fold epinephrine overdosing reported in both papers by Hansen, et al^{53, 54} was also observed in prehospital neonatal transports reported by Duby, et al.⁵⁵ While all three papers are somewhat limited by methodology involving retrospective chart review, and the bias commonly associated with under-reporting of AEs, they do however provide insight regarding the increased incidence and nature of AEs associated with the high-risk neonatal and paediatric patient population in the prehospital environment.

Efforts to reduce harm in this high-risk population are demonstrated by Colyer, et al⁵⁶ who investigated the effect of team configuration on the incidence of AEs during paediatric transport. While the author reported an AE incidence of 8.3%, no significant difference in team configuration (Nurse/Paramedic or Nurse/Nurse) was observed. However, patient acuity was stratified by calculating a pre-transport risk assessment score: Transport Risk Assessment in Paediatrics (TRAP). These results may have been influenced due to the large number of patients transported with a low TRAP score. Furthermore, it is not known to what degree the AE rate may have been influenced by the teams arranging themselves prior to transport.

AEs associated with transport by EMS are not uncommon in this high-risk population.⁵⁵ Furthermore, in paediatric OHCA, airway interventions and medication administration are shown to frequently result in AEs.^{53, 54} HEMS crews are called on (albeit infrequently) to provide emergency resuscitation and transport to this high-risk population, and therefore AEs should be anticipated in this cohort.

2.2.2. Medication Errors in EMS

Medication errors have been shown to frequently occur during prehospital emergency care and transport of the high-risk paediatric and neonatal population.⁵³⁻⁵⁵ However, medication errors are also known to occur across a wide spectrum of medicine and patients, of which the prehospital environment is no exception. While research regarding medication errors in medical, nursing, surgical and hospital practice is evident, only 3 papers were found (in addition to those already discussed) in the last decade describing medication errors in EMS.

Lifshitz, et al⁵⁷ investigated the incidence and characteristics of medication errors in the prehospital and emergency department (ED) setting, and reported medication errors in 12.76% of patients receiving medications prehospitally, compared to 36.1% of patients in the ED. Furthermore, an increase in both transport time and number of medications administered was associated with a higher risk of medication errors. However, several limitations were apparent in this study. Documentation of medication errors were limited due to the under-reporting bias associated with retrospective chart review study designs, with no follow-up. Furthermore, a large number of charts (12.12% of the sample) could not be found, further impacting the reliability of results.

In a retrospective review of a patient record electronic database, Hoyle, et al⁵⁸ measured the incidence of paediatric medication errors in 6 drugs administered by EMS paramedics. Medication errors were defined as a drug dose deviation greater or equal than 20% of the weight-estimated appropriate dose. In this study, drug errors were reported in the administration of Albuterol (23.3%), Atropine (48.8%), Diphenhydramine (53.8%), and Epinephrine (60.9%). Furthermore, the administration of Epinephrine was frequently associated with significant overdosing. These findings are also supported in other prehospital paediatric AE literature, where 10-fold Epinephrine overdosing was frequently described.^{53, 54} However, the paper by Hoyle, et al⁵⁸ has several limitations. Firstly, it suffers from the use of an administrative dataset and lacks direct observations. It is also unknown if a dosing aid was used by paramedics. Furthermore, it was not possible to determine how weights were

obtained in this study (i.e.- 8.6% of patients that had missing weights). Lastly, there was no access to hospital records to harm if errors resulted in harm.

Drawing on Human Factors Engineering (HFE), Misasi and Keebler⁵⁹ described an alternative approach to the traditional “5-Rights” for medication administration verification. Using a team-based approach, the Medication Administration Cross-Check (MACC) was implemented over a 54-month period. Measurement of pre/post intervention error rates (27 months / 27 months) using 4 different taxonomies to capture self-reported medication errors resulted in a 49% reduction in monthly errors, and a 71.1% decrease in Fentanyl administration medication errors. However, several limitations were reported by the author. The study lacks a non-equivalent control group to compare changes in error rates over time, and therefore results cannot be generalised. Other threats to validity that could also have explained the results were apparent, such as implementation of a Just Culture in the post-intervention phase; and organizational maturation. Finally, medication errors in the prehospital setting lack a universally accepted definition and taxonomy, with reliance on classification extended from the hospital setting, with limitations in applicability.

While the literature regarding medication errors in the EMS setting is somewhat limited, common contributory factors thought to impact medication errors include: Inadequate verification of medication administration, increased cognitive load, high-stress environments, and complex weight-based drug calculations required for infrequent drug administration.^{53, 57-59} These challenges are present during prehospital HEMS and EMS transport of critically ill and injured patients.

2.3. Adverse Event Detection Methodology in HEMS and EMS

While traditional methods for detecting AEs include manual chart review, direct observation, morbidity & mortality rounds, voluntary reporting systems, and patient complaints¹², it is important to use an appropriate methodology to detect AEs in the domain of interest (i.e.- methodology matters). A review of the literature found 6 studies of interest related to AE detection methodology in EMS over the last decade, with one paper relevant to HEMS.

The first paper by Patterson, et al⁶⁰ in 2012 employed a modified Delphi technique to develop a consensus definition of AEs specific for EMS and a method to define and rate the severity of harm. In this study, an AE in EMS was defined as: “A harmful or potentially harmful event occurring during the continuum of EMS care that is potentially preventable and thus independent of the progression of the patient’s condition”.⁶⁰ Based on this definition, a 7-point

AE severity rating index was developed to differentiate between AEs caused by omission or commission; AEs with harm but no fault; AEs with potential to cause harm by omission or commission; AEs with potential to cause harm with no fault; and no AE identified. However, one limitation was noted: The consensus definition was developed using Medical Directors, and not EMS workers. Therefore, the consensus definition may have been different had they included EMS reviewers.

A second paper by Paterson, et al⁶¹ in 2014 saw the development of a focused prehospital HEMS TT that sought to establish a content validated framework for the identification of AEs specific to the high-risk HEMS domain. This 3-stage framework, known as the Pittsburgh Adverse Event Detection Tool (PittAETool), involves: Utilisation of a TT, a method for rating proximal cause, and identification of harm with an AE severity rating mechanism. A total of 11 triggers were identified and content validated for the HEMS domain by experts in the field. Four trigger categories were identified, and included documentation triggers, operational and patient movement triggers, patient condition triggers, and finally intervention and medication triggers. This framework however, if analysed by a different group, could have resulted in a different framework and content. Furthermore, the framework was not assessed using standard tests of reliability and validity (i.e.- sensitivity and specificity).

A third paper by Patterson, et al⁶² in 2014 sought to compare 2 different approaches to AE classification in HEMS. Using the PittAETool developed by Patterson, et al,⁶¹ the authors compared independent chart review to group consensus-based AE detection. Higher levels of agreement / reliability were realised when using a consensus-based approach. The findings in this paper suggest that use of a content-validated tool (PittAETool) for the domain of interest (HEMS), whilst employing a consensus-based approach to AE detection, are worthy of further attention. However, several limitations were noted in this study. They used a convenience sample of clinicians and observed agreement could have been different if they used other clinicians in different settings; record review was not formally timed; and while random sampling was employed in selection of the medical records, selection bias cannot be ruled out completely. Lastly, reviewers were well-trained (20+ hours) including involved in tool-development and practice sessions. This could explain the high level of rater agreement observed.

In 2017 Howard, et al⁶³ developed the Emergency Medical Services Trigger Tool (EMSTT) for ground-based EMS in Qatar, consisting of 4 trigger categories: Clinical, Medication, Procedural, and Return-Call. In 2018 Howard, et al⁶⁴ operationalised the EMSTT and reported a rate of 2.48 AEs per 10,000 patient encounters, and a harm rate of 0.34 per 10,000

encounters with good inter-rater agreement. Whilst this study represents the first of its kind to employ an EMS-specific TT in a longitudinal analysis, the EMSTT was developed for AE detection in low-risk / high-frequency ambulance transports (i.e.- they intentionally excluded records within evidence-based care pathways with high-risk / infrequent interventions that were already subjected to clinical governance review). Therefore, application of the EMSTT cannot be broadly adopted to other EMS systems, and is dependent on co-existing clinical governance pathways to identify all AEs. Furthermore, the EMSTT showed high sensitivity and low specificity with the potential to produce false negatives and skew AE and harm rates.

More recent efforts in 2019 to detect prehospital AEs have started to emerge in Sweden, where Hagiwara, et al⁶⁵ attempted to use the PittAETool⁶¹ to identify AEs in a ground-based prehospital system. Hagiwara, et al⁶⁵ report an incidence rate of 4.3 AEs per 100 ambulance missions. However, the findings of this study are somewhat limited, as not only does it suffer from a small sample size, but attempts to use a TT content-validated for HEMS in a ground-based EMS system. Therefore, the tool may have limited application in this domain.

While traditional AE detection methodologies are well known, a paucity of evidence exists describing AE detection methods in HEMS and EMS. A review of the literature shows that AE detection in HEMS and EMS is in its infancy. The PittAETool represents the only available content validated AE detection methodology for the HEMS domain of interest.⁶¹

2.4. Gaps in the HEMS Adverse Event Literature

The incidence rates and classification of AEs in HEMS is not reported in Qatar, and very sparsely reported internationally. Limitations within the existing HEMS literature have been described.⁴¹⁻⁴⁴ Furthermore, when looking more broadly, the incidence of AEs in EMS is equally under-reported, and fraught with similar limitations.⁴⁵⁻⁴⁷

Whilst local efforts by Howard et al in Qatar have seen the development and longitudinal employment of the EMSTT,^{66, 67} application of the EMSTT was primarily developed with the intention to screen all low-risk / high-frequency ground-based prehospital transports that were not routinely subjected to scrutiny within the existing clinical governance framework. Therefore, attempts to utilize the EMSTT to identify AEs within a HEMS environment would be inappropriate, as HEMS typically transport low-frequency / high-risk cohorts requiring a more suitable AE detection tool, such as the PittAETool.⁶¹

Adverse event detection methodology matters. Recent development of the TT methodology modified for the prehospital arena has been identified as a novel approach to AE detection. The PittAETool represents the only TT in published literature that is specifically content-validated for the high-risk HEMS domain of interest.⁶¹

3. Conclusion

The dual goal to identify and eliminate or minimise possible harm before it occurs in the design of healthcare (a function of high reliability organisations) is of utmost importance to healthcare leadership, policy-makers, healthcare providers and patients.⁶⁸⁻⁷⁰ The cumulative effects of shift work, sleep deprivation, and sleep debt on fatigue in HEMS health care providers; the increased cognitive load and effects of cognitive bias during complex clinical decision-making; the negative effects of constant interruptions; environmental factors; teamwork dynamics and communication problems in high-stress fast-paced emergency systems create the ideal opportunity for AEs to occur.⁷¹⁻⁷⁵ Furthermore, the high acuity nature of interventions required in the treatment of critically ill and injured patients typically triaged for HEMS transport, as compared to prehospital ground transport, increase the potential for AEs and harm to occur.^{76.}

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The true incidence of adverse medical events in HEMS and the most appropriate AE detection tool is not well reported.⁴¹⁻⁴⁴ Singh et al⁴³ determined that critical events occur every 1 in 20 air medical transports. Lehmann et al investigated AE risks in a combat HEMS environment, and reported higher mean TRS in patients with AEs compared to patients without, whereby equipment failures and in-flight clinical deterioration constituted the majority of AEs.⁴² MacDonald et al report communication problems to be the most common cause of AEs in air-medical transport.⁴¹ Stassen et al report on AEs associated with Rapid Sequence Intubation (RSI) in South African HEMS, and confirm at least 1 AE occurring in 27% of cases, the most prevalent being hypoxemia, hypotension and bradycardia, and a first pass success rate of 79%.⁴⁴ Advanced airway management is commonly performed by HEMS teams, due to the high acuity nature of HEMS triaged calls, and therefore the potential for harm to occur is ever present.

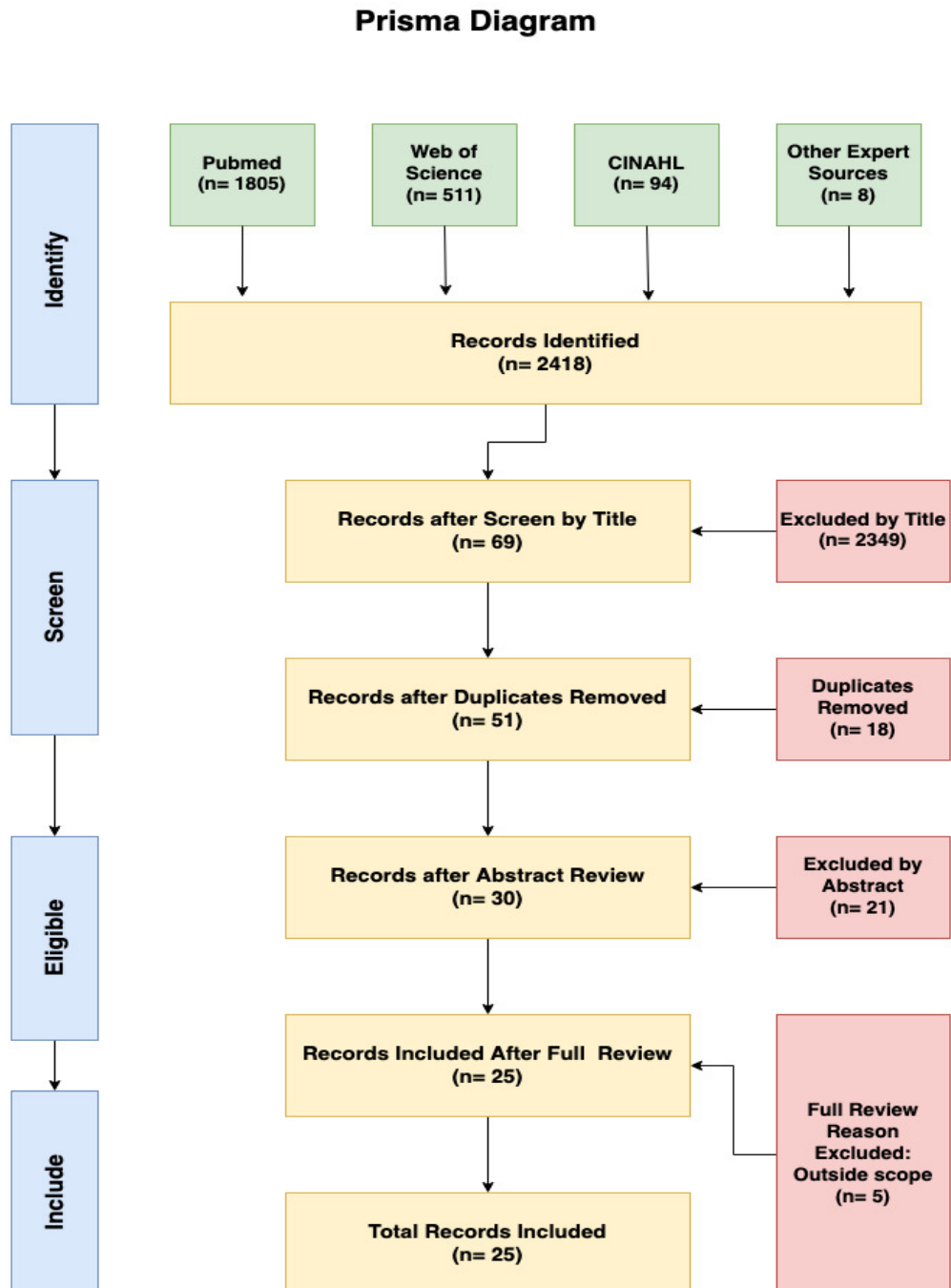
There is evidence to suggest that identification of AEs is highly dependent on the AE detection methodologies employed.^{8, 9, 12, 14, 39, 40} While utilization of the GTT has been shown to potentially identify ten times as many AEs compared with more traditional reporting methods,³⁹ a paucity of evidence exists for adaptation and utilization of focused TTs in the search of AEs

in the emergency setting.^{60, 62-65, 78-80} Furthermore, the design of TTs has historically focused on hospital care, with limited evidence for the utilization of TTs in the prehospital arena.¹⁸

It is incumbent on healthcare leadership, clinical governance teams, and policy-makers to actively search for and eliminate harm in healthcare using the most updated and appropriate AE detection methodology. Recent efforts by Howard, et al^{63, 64} and Hagiwara, et al⁶⁵ to employ the TT methodology for use within the prehospital environment are to be commended. However, in the context of HEMS, the PittAETool by Patterson, et al⁶¹ is more broadly suitable for the detection of prehospital AEs, is content-validated for the HEMS domain, includes by definition acts of omission and commission (identifying both harm and potential for harm irrespective of outcome),¹⁰ and therefore represents the most suitable available TT in published literature for the detection of AEs within a high-risk HEMS environment.⁶¹

4. Appendices

4.1. Appendices 1: Prisma Diagram



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4.2. Appendices 2: Literature Summary

Authors: Date Published: Paper:	Type of Paper:	Aim / Objectives:	Outcomes Measures:	Results:	Limitations / Comments:	GRADE BMJ Rating:
MacDonald, Banks and Morrison,¹ 2008 Epidemiology of adverse events in air medical transport.	Retrospective observational analysis	<u>Primary:</u> Frequency of all causes of AEs in large scale air medical program. <u>Secondary:</u> Describe the epidemiology of AEs.	Frequency of AEs per 1000 flights and per 1000 hours flown. Categorization of AEs using established methods. Inter-reviewer agreement for presence and categorization of AEs and harm using kappa statistic.	<u>Frequency:</u> 11.53 AEs per 1000 flights. 6.56 AEs per 1000 hours flown. <u>Frequency by category:</u> Communication (33.7%) Transport vehicle (21%) Med equipment (12.9%) Pt management (11.4%) Clin. performance (10%) <u>Harm:</u> Possible in 117 events (1.99 per 1000 flights).	Good sample size. Categorized events retrospectively using methods and taxonomy designed for hospital-based care. Self-reporting of and retrospective data collection may result in underestimate of AEs.	LOW
Lehmann, et al² 2009 Interhospital patient transport by rotary wing aircraft in a combat environment:	Observational analysis of prospectively collected data	Describe the epidemiology and patient outcomes associated with combat helicopter transfer.	Operative interventions prior to transfer. Mean time from hospital admission to transfer. Pre-flight variables and AEs in flight.	<u>Adverse Events:</u> Equipment failure (17%) In-flight clinical deterioration (30%) Urgent intervention on arrival (9%)	No AE rate calculated.	Very Low

Risks, adverse events, and process improvement.		Analyse the incidence of AEs. Analyze the ability of a civilian risk transport score to predict AEs in the combat setting.	Individual risk scores and AEs during transport. The Discriminative ability of the TRS to predict AEs by use of receiver operating characteristic curve.	Mean TRS significantly higher in patients with AEs (9.1) Vs those without (7.4)		
Singh, et al³ 2009 Incidence and predictors of critical events during urgent air-medical transport.	Population based Retrospective Cohort	Determine the incidence of in-transit critical events and identify factors independently associated with these.	<u>Primary:</u> Incidence rate of in-transit critical events defined as: Death, Major resuscitative procedure, Hemodynamic deterioration, Extubation, Respiratory arrest. <u>Secondary:</u> Multivariate logistic regression to identify factors independently associated with the AE.	<u>AE Rate:</u> In transit critical events occurred in 5.1% of transports (rate of 1 AE every 12.6 hours of transit time; approximately 1 in every 20 air medical transports). <u>Independent Predictive Factors:</u> Female sex, assisted ventilation and instability before transport, fixed-wing aircraft, increase call duration, on scene calls, type of crew.	<u>Strength:</u> Large scale population-based cohort of transported patients. <u>Weakness:</u> Limited by retrospective data. Ascertainment bias. Confounding. Unable to obtain a patient severity score to allow direct comparison. Definitions differ making comparison difficult.	Very low.
Stassen, et al⁴ 2018	Descriptive analysis:	Describe:	Intubation first pass success rate.	ETI first pass success rate of 79%	Small sample size.	Very low

A descriptive analysis of endotracheal intubation in a South African helicopter emergency medical service.	Retrospective chart review	<ul style="list-style-type: none"> - ETI success rate. - AE rates. - Rate of anticipated airway difficulty. 	AE rate. Rate of anticipated airway difficulty.	Overall success rate 98% AE rate 27% Hypoxemia, hypotension, and bradycardia most prevalent AEs.	Self-reported data lends to potential bias in AE reporting. Data on laryngoscopic view not available for entire dataset.	
Fan, et al⁵ 2005 Outcomes of interfacility critical care adult patient transport: a systematic review.	Systematic review	Determine AEs and prognostic factors associated with mechanically ventilated adult patients.	Searched the literature to identify the incidence of AEs in studies of mechanically ventilated adult patients during interfacility transport: MEDLINE, CENTRAL, EMBASE, CINAHL, HEALTHSTAR, Web of Science: From inception – Jan 2005.	5 studies found (all case series and 2 prospective design). Death was reported in 1 case. 1 study reported 19% incidence of respiratory alkalosis. 1 study showed a 30% ICU mortality. No AEs were reported after arrival in 3 studies.	Low number of studies. Heterogeneity prevent meta-analysis. Insufficient data to draw firm conclusions. The population of interest was limited to intubated and mechanically ventilated adult patients.	Very low
Bigam, et al⁶ 2012 Patient safety in emergency medical	Systematic review	To identify Emergency Medical Service (EMS) threats to patient safety.	Searched the literature to identify themes within the patient safety literature related to	88 studies identified. 7 common themes: 1) AEs and medication errors (22)	Methodologies were highly variable. Publication bias. Exclusion of non-English papers.	Very low

<p>services: A systematic review of the literature.</p>			<p>Emergency medical services: MEDLINE, EMBASE, CINAHL: 1999-2011.</p>	<p>2) Clinical judgement (13) 3) Communication (6) 4) Ground vehicle safety (9) 5) Aircraft safety (6) 6) Interfacility transport (16) 7) Intubation (16)</p> <p>A paucity of evidence exists exploring patient safety in EMS. Large gaps in research.</p>		
<p>Alabdali, et al⁷ 2017 A systematic review of the prevalence and types of adverse events in interfacility critical care transfers by paramedics.</p>	<p>Systematic review</p>	<p>Investigate if paramedics can safely transport critical-ill adult patients. Determine the prevalence and types of AEs when paramedics lead interfacility transfers.</p>	<p>Searched the literature to identify the prevalence of AEs in paramedic facilitated interfacility transport of critically ill adult patients: Medline, Web of Science, Embase, and CINAHL 1990-Feb 2016.</p>	<p>Total of 7 observational studies found: - 5 retrospective - 2 prospective</p> <p>2 studies were of cardiac patients transported with IABP. Frequency of AEs ranges from 5.1%-18%</p>	<p>Outcomes differ significantly. Heterogeneity prevent meta-analysis. Authors definitions of AEs differed. Lack of longitudinal follow-up in studies. ? Accuracy of reported AEs. Risk of bias. Small sample sizes.</p>	<p>Very Low</p>

					No standard method to detect and report AEs.	
<p>Patterson, et al⁸ 2012</p> <p>Association between poor sleep, fatigue, and safety outcomes in emergency medical services providers.</p>	<p>Cross-sectional survey design</p>	<p>To determine the association between poor sleep, fatigue, and safety outcomes in EMS providers.</p>	<p>Measured sleep quality, fatigue, and safety outcomes using the 19-item Pittsburgh Sleep Index (PSQI), 11-item Chalder Fatigue Questionnaire (CFQ), and 44-item EMS Safety Inventory (EMS-SI). Used consensus process to capture EMS worker injury, medical errors and AEs, safety compromising behaviors. Used hierarchical logic regression to test for association.</p>	<p>55% were classified as fatigued. 18% reported an injury. 41% reported a medical error or AE. 90% reported a safety compromising behavior.</p> <p>Fatigued respondents:</p> <ul style="list-style-type: none"> - 1.9 greater odds of injury - 2.2 greater odds of medical error & AE - 3.6 greater odds of a safety compromising behavior 	<p>Convenience sampling After controlling for confounders, the significance of observations was reduced. Failed to capture an important variable: workload measured at the individual worker level. Self-reported safety outcomes. ? under-reporting.</p>	<p>Very Low</p>
<p>Gallagher and Kupas⁹ 2012</p> <p>Experience with an anonymous web-based state EMS</p>	<p>Retrospective descriptive study</p>	<p>To identify common safety events and their incidence rates in an anonymous Web-Based State EMS</p>	<p>Analyzed 7 years data from an anonymous Web-Based EMS Safety Event Reporting System and categorized them.</p>	<p>AEs classified:</p> <ul style="list-style-type: none"> - Actions / behavior (32%) 	<p>45% of reports were excluded due to identifiable information and non-sensical descriptions.</p>	<p>Very low</p>

safety incident reporting system.		Incident Reporting System		<ul style="list-style-type: none"> - Vehicle / transportation (16%) - Staffing (13%) - Communications (8%) - Medical equipment (9%) - Level of care issues (7%) - Medical procedure (6%) - Medication (5%) - Scene safety (3%) - Protocol issues (1%) 	<p>Data is limited to willingness of reports to report.</p> <p>Anonymity does not permit formal investigation and therefore unable to verify facts and harm.</p> <p>Subjectivity of classification as there is no accepted method to classify reports.</p> <p>Good for system and policy change.</p>	
<p>Hohenstein, et al¹⁰ 2014</p> <p>Critical incident reporting in emergency medicine: results of the prehospital reports.</p>	Retrospective descriptive study	To identify incidents through an anonymous critical incident reporting system.	Analysed 7-years data from an anonymous pre-hospital physician-based EMS critical incident reporting system in Germany.	<p>Incidents Classified as:</p> <ul style="list-style-type: none"> - Staff-related (56%) - Equipment (20%) - Organization (16%) - Other (6%) - No incident (2%) 	<p>Limited by reporting bias (under-reporting).</p> <p>Anonymity prevents fact-finding.</p> <p>Subjectivity in analysis of data collected.</p> <p>Good for identifying system weakness.</p>	Very Low

<p>Lyphout, et al¹¹ 2017 Patient safety incidents during interhospital transport of patients: A prospective analysis.</p>	<p>Prospective multicenter observational cohort</p>	<p>To identify patient safety incidents and risk factors during interhospital transport.</p>	<p>Incidence of AE. Incidence of harm. Risk-factors associated with harm (using odds ratios)</p>	<p>Incidence rate of 16.7% of transports. Healthcare associated harm identified in 3.9% of cases. Factors associated with increased harm: <ul style="list-style-type: none"> - Operational incidents (OR 144.93) - Communication incidents (OR 11.05) - High M-SOFA score (OR 1.198) Helicopter transfers had higher risk of patient safety incidents (45%).</p>	<p>Recruitment relied on self-reporting of incidents (data may be skewed). Some data was excluded due to incomplete data fields. No standard severity scoring system validated for transport population.</p>	<p>Low</p>
<p>Bussieres, et al¹² 2018 Clinical adverse events in prehospital patients with ST-elevation myocardial infarction transported</p>	<p>Retrospective health record review</p>	<p><u>Primary:</u> Determine the frequency of clinical AEs in a rural population of STEMI patients <u>Secondary:</u></p>	<p>Measured frequency of all AEs. Classified clinically important and clinically minor AEs. Used multivariate ordinal logistic</p>	<p>AE frequency rate 30.7% <ul style="list-style-type: none"> - Clinically important AE rate 18.5% - Clinically minor AE rate 12.2% Clinically important events observed:</p>	<p>Subject to non-differential information bias. Inability to link hospital records to patient outcomes.</p>	<p>Very low</p>

<p>to a percutaneous coronary intervention center by basic life support paramedics in a rural region.</p>		<p>Evaluate the impact of transport time on AE occurrence.</p>	<p>regression to find associations between transport time and AEs.</p>	<ul style="list-style-type: none"> - Hypotension (6.1%) - VT / VF (5.1%) <p>Transport time was NOT associated with AEs No deaths recorded.</p>	<p>Unable to assess AEs occurring shortly after arrival at hospital. Selection bias may have excluded 38 patients who experienced clinically important events (n=40).</p>	
<p>Hansen, et al¹³ 2018 Safety events in pediatric out-of-hospital cardiac arrest.</p>	<p>Retrospective medical record review</p>	<p>To identify types of patient safety events in pediatric OHCA</p>	<p>Developed a chart review tool with domains to classify safety incidents. Assessed degree of harm. Univariate logistic regression analysis on each variable thought to be a predictor of OHCA.</p>	<p>35 OHCA (7%). Adverse safety events were common: AEs occurred in 87% of all OHCA. Common AEs:</p> <ul style="list-style-type: none"> - Epinephrine overdoses (31%) - Failure to administer epinephrine (17%) - Administration Atropine when not indicated (23%) - Failed Intubation attempts (20%) 	<p>Medical record review methodology therefore limited to what is available in chart. Biases due to underestimating safety events. No way to assess quality of CPR. No access to hospital records and follow-up to assess harm.</p>	<p>Very low</p>

<p>Hansen, et al¹⁴ 2016 Patient safety events in out-of-hospital pediatric airway management: a medical record review by the CSI-EMS.</p>	<p>Retrospective cross-sectional medical record review</p>	<p>To describe the frequency and characterize patient safety events in pediatric out-of-hospital airway management.</p>	<p>Frequency of AEs associated with airway management:</p> <ul style="list-style-type: none"> - Oxygen administration - Bag-valve-mask ventilation (BVM) - Airway adjuncts - Intubation (ETI) 	<p>Frequency of errors high in following interventions:</p> <ul style="list-style-type: none"> - Oxygen use (21%) - BVM use (9.8%) - Intubation (9.5%) - Airway adjunct (0.9%) <p>58% of intubations required more than 3 attempts or failed. Errors are common in pediatric OHCA and airway management.</p>	<p>Bias related to retrospective chart review. Underestimation of errors. Use of non-standard AE definitions. Assessment of harm subjective.</p>	<p>Very low</p>
<p>Duby, et al¹⁵ 2018 Safety events in high risk prehospital neonatal calls.</p>	<p>Retrospective chart review</p>	<p>To characterize the incidence of patient safety events during neonatal ambulance transport.</p>	<p>Developed a chart review tool. Identified safety events and classified into domains. Measured frequency of AEs within each domain.</p>	<p>Neonatal transport occurs infrequently However, AEs are common and serious. Medication errors (90%) 10-fold overdosing of epinephrine was also observed.</p>	<p>Retrospective chart review bias. Underestimation of errors. Subjective assessment of harm.</p>	<p>Very low</p>
<p>Colyer, et al¹⁶ 2018 The effect of team configuration on the</p>	<p>Descriptive study. Retrospective cohort</p>	<p>To assess the effect of team configuration on AE</p>	<p>Analysed retrospective records: 2 combinations of providers:</p>	<p>AE incidence of 8.3% No significant difference in AE incidence observed</p>	<p>Small sample size. Limited by retrospective chart review design. Only one reviewer.</p>	<p>Very low</p>

incidence of adverse events in pediatric critical care transport.		rate during pediatric transport.	Rn/Rn & Rn/CCP Identified AEs into pre-identified domains.	with different team configuration.	Excluded neonatal patients. Did not assess the degree of harm. AE definitions are subjective.	
Lifshitz, et al¹⁷ 2011 Medication prescribing errors in the prehospital and in the ED.	Retrospective chart review	To describe the incidence and characteristics of medication AEs in the prehospital and ED setting.	<u>Primary:</u> Number of drug errors per patient. <u>Secondary:</u> Type and severity of errors. Variables associated with incidence of drug errors.	12.76% of patients receiving medication experienced a drug error. Medication errors in prehospital environment were less than in the ED (36.1%). Increased drug errors were associated with the number of drugs given and duration of transport time.	Retrospective chart review design. Bias in assessing errors.	Very low
Hoyle, et al¹⁸ 2012 Medication dosing errors in pediatric patients treated by emergency medical services.	Retrospective database review.	Determine the frequency and magnitude of drug errors in children treated by paramedics in prehospital setting.	Measured incidence of drug errors for the following 6 drugs: - Albuterol - Atropine - Dextrose - Diphenhydramine	Medication errors occurred in 34.7% of drug administrations: Epinephrine drug dose errors were most frequently observed (60.9%)	Use of administrative dataset. Low frequency of pediatric encounters in EMS. Did not witness how weights were obtained.	Very low

			<ul style="list-style-type: none"> - Epinephrine - Naloxone 		8.6% of patients missing weights in dataset. Findings were consistent with similar studies.	
<p>Misasi and Keebler¹⁹ 2019</p> <p>Medication safety in emergency medical services: approaching an evidence-based method of verification to reduce errors.</p>	Observational	To evaluate the effectiveness of a Human Factors Engineering (HFE) team-based cross-check verification process to reduce medication errors in EMS.	Used a Human Factors Engineering (HFE) approach to design a Team-based method for verification: Medication Administration Cross-check (MACC) Compared pre/post intervention error rates over a 57-month period.	Achieved a 49% decrease in monthly medication error rate in post-intervention period. Measured a 71% error reduction in Fentanyl administration.	Study lacks a non-equivalent control group. Efforts to implement a “just culture” could have altered self-reporting levels of AEs. Hawthorne effect? No universally accepted prehospital definitions for medication errors.	Low
<p>Patterson, et al²⁰ 2011</p> <p>Identification of adverse events in ground transport emergency medical services.</p>	Modified Delphi	To develop a method to define and rate AE severity in EMS.	Used a modified Delphi technique to develop a consensus definition of AE. Reviewed 250 charts to determine agreement.	5 x iterations to reach consensus on defining an AE. Based on this definition, they developed a 7-point index for AE severity rating.	Used physicians only to develop the consensus definition of AE. Used a convenience sample of PCRs.	Low
<p>Patterson, et al²¹ 2014</p>	Trigger Tool Modified Delphi	To create a framework for detecting AEs in	Used a modified Delphi technique to develop a	Developed a Trigger Tool with 11 Triggers in Total.	Limited by selection of experts: different panel of experts could lead to	Low

Measuring adverse events in helicopter emergency medical services: Establishing content validity.		the high-risk HEMS setting.	framework for AE detection.	A method for rating Proximal Cause. Method for rating AE severity / harm.	different framework and content.	
Patterson, et al²² 2014 A comparative assessment of adverse event classification in the out of hospital setting.	Trigger Tool Validation study	To test the reliability of 2 approaches to classify AEs associated with HEMS transport.	Compared 2 groups: <ul style="list-style-type: none"> - AE identified by Independent chart review - AEs identified by group consensus Compared both groups to reference criterion.	A higher level of agreement / reliability in AE decisions was realized using a consensus-based approach to AE detection.	Limited by convenience sample of clinicians. Selection bias cannot be excluded. Limited to human error and reviewer fatigue.	Low
Howard, et al²³ 2017 Development of a trigger tool to identify adverse events and harm in emergency medical services.	Trigger Tool Study	Develop a Trigger Tool specific to ground-based EMS to identify AEs and harm.	57 triggers identified using affinity process: An interim TT comprising 9 triggers underwent 5 iterative rounds and derivation tests. Finally, an 8-item TT underwent a large sample test.	8 Triggers into 4 categories: <ul style="list-style-type: none"> - Clinical - Medication - Procedural - Return-Call Demonstrated an AE rate of 41.5% Harm rate of 19.3%	Excluded high-risk / low-frequency cases (deliberate). Low specificity of EMSTT could produce false negatives.	Low

<p>Howard, et al²⁴ 2018</p> <p>Application of the emergency medical services trigger tool to measure adverse events in prehospital emergency care: a time series analysis.</p>	<p>Trigger Tool Study</p>	<p>To operationalize the EMSTT.</p> <p>To report incidence and harm rates.</p>	<p>Analyzed 36 patient care record samples over 18-month period.</p> <p>Calculated inter-rater agreement across all triggers and harm classification.</p> <p>Measured AE and Harm rate.</p> <p>Generate control charts.</p>	<p>Rate of 8.20 Triggers per 10,000 cases.</p> <p>AE rate of 2.48 AEs per 10,000 cases.</p> <p>Harm rate of 0.34 per 10,000 cases.</p>	<p>Limited by small sample size per month.</p> <p>High-Risk / Low Frequency cases excluded from sample.</p>	<p>Low</p>
<p>Hagiwara, et al²⁵ 2019</p> <p>Adverse events in prehospital emergency care: a trigger tool study.</p>	<p>Trigger Tool Study</p>	<p>To investigate AE incidence and factors contributing to AEs in prehospital care in Sweden.</p>	<p>Analyzed 30 random monthly samples of prehospital medical records for 12 months.</p> <p>Measured AE rate and harm rate.</p> <p>Identified common contributing factors.</p>	<p>46 AEs identified (4.3%).</p> <p>4.3 / 100 ambulance missions.</p> <p>43 AEs were potentially harmful.</p> <p>3 AEs were harmful.</p> <p>Most common factors:</p> <ul style="list-style-type: none"> - Deviation from standard of care. - Documentation errors. 	<p>Under-estimation of AEs due to medical record reporting.</p> <p>Used a content-validated HEMS trigger tool for ground-based EMS.</p>	<p>Very low</p>

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PART B: Manuscript in Article Format

A TRIGGER-TOOL-BASED DESCRIPTION OF ADVERSE EVENTS IN HELICOPTER EMERGENCY MEDICAL SERVICES IN QATAR

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Declarations of Interest

CH and IH work for Hamad Medical Corporation Ambulance Service (HMCAS).

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Highlights

- The Trigger Tool methodology represents a novel approach to AE detection in healthcare.
- The Pittsburgh Adverse Event Tool (PittAETool) has 11 triggers, and is a consensus-based framework for AE detection in Helicopter Emergency Medical Services (HEMS).
- We identified a harm rate of 3.5 Harmful Events per 100 patient encounters

Keywords

Helicopter Emergency Medical Services, Trigger Tool, Patient safety, Adverse event, Harm.

Abstract

Introduction

Adverse Events (AEs) in Helicopter Emergency Medical Services (HEMS) remains poorly reported, despite the potential for harm to occur. The Trigger Tool (TT) represents a novel approach to AE detection in healthcare. The aim of this study was to retrospectively describe the frequency of AEs and their Proximal Causes (PCs) in Qatar HEMS.

Methods

Using the Pittsburgh Adverse Event Tool (PittAETool) to identify AEs in HEMS, we retrospectively analyzed 804 records within an existing AE TT database (21-month period). We calculated outcome measures for Triggers, AEs, and Harm per 100 patient encounters, plotted measures on Statistical Process Control (SPC) charts, and conducted a multivariate analysis to report harm associations.

Results

We identified 883 Triggers in 536 patients, with a rate of 1.1 Triggers per Patient Encounter, where 81.2% had *Documentation Errors* (n=436). An AE and Harm rate of 27.7% and 3.5% respectively was realized. The leading PC was *Actions by HEMS Crew* (81.6%; n=182). The majority of harm (57.1%) stemmed from the *Intervention and Medication* triggers (n=16), where *Deviation from Standard of Care* was common (37.9%; n=11). Age and diagnosis-adjusted odds was significant in the *Patient Condition* (6.50; 95% CI, 1.71-24.67; P= 0.01) and *Interventional* (11.85; 95% CI, 1.36-102.92; P= 0.03) trigger groupings, while age and diagnosis had no effect on Harm.

Conclusion

The TT methodology is a robust, reliable, and valid means of AE detection in the HEMS domain. Whilst an AE rate of 27.7% is high, more research is required to understand prehospital clinical decision-making and reasons for guideline deviance. Furthermore, focused quality improvement initiatives to reduce AEs and *Documentation errors* should also be addressed in future research.

Introduction

The call from the Institute of Medicine (IOM) to identify and eliminate harm in the delivery of healthcare is of paramount importance and worthy of our attention, as our healthcare systems have the potential to harm patients.¹ Healthcare delivery in the Emergency Department (ED) has been described as “*a laboratory for error*”.^{2,3} Furthermore, the potential for harm to occur in the delivery of emergency care by Emergency Medical Services (EMS) exists, with a multitude of contributing factors such as fatigue, differences in provider skill and training, errors in cognition and decision-making, communication, environmental factors and team dynamics.^{2,4-9} However, despite the risk for harm, the incidence of AEs within the prehospital arena and Helicopter Emergency Medical Services (HEMS) remains poorly reported, with no domain-specific AE taxonomy to draw from, no standardized way of defining harm, and no uniform AE reporting mechanisms.¹⁰⁻¹⁶

Traditional methods of AE detection in healthcare typically include direct observation, morbidity and mortality review, documentation review, complaints, and voluntary reporting systems.^{17,18} However, there is evidence to suggest that identification of AEs and harm is highly dependent on methodology employed.¹⁸⁻²¹ The last decade has seen the emergence of the Trigger Tool (TT) methodology as a robust means of identifying AEs and harm in healthcare.²²⁻²⁵

Patterson, et al²⁶ developed the Pittsburgh Adverse Event Tool (PittAETool), a consensus-based framework for identifying AEs in HEMS. The tool is content validated for the domain of interest, includes by definition acts of omission and commission (identifying harm and potential for harm irrespective of outcome),²⁷ and therefore represents the most appropriate published methodology available for AE detection in HEMS. As defined by the PittAETool,²⁶ the aim of this study was to describe the frequency of AEs and their PCs in Qatar HEMS.

Methodology

Design

A retrospective analysis using an existing AE HEMS TT database.

Setting

The study was conducted within the LifeFlight HEMS division of Hamad Medical Corporation Ambulance Service (HMCAS) in Qatar. HMCAS is a two-tiered service with both Ambulance Paramedics (APs) and Critical Care Paramedics (CCPs), which serves a population of

approximately 2.6 million people. The LifeFlight division (a 24hr operation of 2 x AW139 helicopters each with a dual medic and stretcher configuration) is staffed by HEMS-trained paramedics (AP and CCP), and facilitates an average of 40-60 transports per month.

Instrument

The PittAETool²⁶ consists of 11 triggers in 4 trigger groupings: 1) *Documentation*, 2) *Operational and Patient Movement*, 3) *Patient Condition*, and 4) *Intervention and Medication* Triggers. The most likely proximal cause (PC) is determined for each trigger and are divided into causes that relate to *Actions by Patient*, *Actions by Provider*, *Medical or Vehicle Equipment*, *Environmental / Scene Factors*, or *Undetermined by Chart Review*. Each PC category, excluding *Actions by Patient*, can be further classified as *HEMS Crew* or *Non-HEMS Crew*. Harm is classified on a severity scale rating as either *No AE*, *Potential Harm (AE1)* defined as “an action that may lead to injury or harm, but there is no evidence that an injury or harm occurred”, or *Confirmed Harm (AE2)* defined as “an action or omission that led to injury or harm regardless of severity” (*Appendix IV*).

Data Sources

Effective 1st August 2016- present, HMCAS established a HEMS TT database at LifeFlight as part of normal clinical governance and AE reporting practice. The following process was followed in the establishment of this database and continues as standard reporting practice at LifeFlight: Each month, the HMCAS Patient Care Record (PCR) database is used to identify records for review. A documentation clerk applies eligibility criteria, prepares records, codes data, and switches each teams' records for review. All HEMS records indicating a patient encounter (defined as: assessment, treatment, and / or transport by ground or air) are included. All non-HEMS records are excluded. Eight HEMS-trained CCPs (2 reviewers for each team) were identified, trained, and provided with computer access and opportunity to practice prior to data entry. All data is captured on a standardized data capture template (Microsoft Excel 2010, Redwood, WA), and all records are reviewed during normal working hours.

Baseline case and demographic details are captured (Code, Rater, Date, Incident Number, PCR Serial Number, Classification, Age, Case Classification, Provisional Diagnosis). No confidential information is captured from the PCR. Applying the PittAETool,²⁶ each record is independently reviewed by 2 primary reviewers for the presence of a trigger. If a trigger is found, the reviewer determines the most likely PC and appropriate harm classification. If no triggers are found, the record is not reviewed further. Fifteen minutes is allocated for each record review. Following each review round, the primary reviewers meet to compare findings,

reach consensus, and summarize results. In cases where consensus can't be reached, a third reviewer (HMCAS Consultant Paramedic involved in Clinical Governance) is asked to review the case and determine outcome. All consensus data is captured on a summated spreadsheet (Microsoft Excel 2010, Redwood, WA) for analysis and AE reporting. This data informs ongoing development of the LifeFlight AE HEMS TT database (*Appendix V*).

Data collection and Sampling

We retrospectively included all results (n= 839) for a 21-month period from 1st November 2016 – 31st July 2018. We excluded the first 3-months of data from 1st August – 31st October 2016 to account for potential inconsistencies that may have existed in applying the inclusion and exclusion criteria, and uniformity in application of the PittAETool.²⁶ This sample size is mirrored in similar recent published research.^{28, 29}

Data Analysis

Statistical analysis

We conducted univariate descriptive analysis on all continuous and categorical variables (i.e.- triggers, PCs, and harm classifications) using Statistica version 13.5.0.17 (2018, Tibco Software Inc.). Furthermore, in-line with the reporting standard created by Howard, et al,²⁹ we reported 3 outcome measures: Triggers, AEs, and Harm per 100 Patient Encounters. Finally, we conducted a multivariate analysis using Stata version 15 (StataCorp. 2017. *Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC.) to report any associations with harm across the dataset. We considered a p-value of <0.05 as significant. Inter-rater reliability was not measured due to consensus methodology applied upon database entry.

Quality Analysis

Outcome measures were calculated and plotted on Statistical Process Control (SPC) U-Charts using Statistica version 13.5.0.17 (2018, Tibco Software Inc.) and employed Western Electric Rules for detecting special cause variation.³⁰ SPC allows healthcare researchers to better understand and differentiate between special and common cause variation.^{31, 32}

Institutional Review Board

Ethical approval was granted by the Medical Research Centre of Hamad Medical Corporation, Qatar (MCR-01-19-291) and the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee, South Africa (HREC 438/2019).

Results

Statistical Analysis

Of the total population of HEMS patient encounters identified (n=839), 4.2% were excluded (n=35) due to missing, unknown, and incomplete TT database entries. The remaining 804 patient encounters were included for analysis. The majority of patients were adults (n=702; 87.3%), between the age of 15-35 (n=378; 47%). Trauma accounted for 56.5% (n=454) of records reviewed, and 65.5% of these were categorized as Trauma Other (n=298). Medical cases accounted for 42.9% of records (n=345) where 41% of these cases were Cardiovascular (n=143). Cardiac arrest was infrequently encountered (*Table 1*).

Classification	Category	Total	%
Cases		839	
Excluded	Missing data / Unknown fields	35	
Classification	Adult	702	87.3
	Paediatric	82	10.2
	Geriatric	20	2.5
Age	Age 15-35	378	47.0
	Age 36-60	290	36.1
	Age 1-14	77	9.6
	Age 61-80	48	6.0
	Age > 80	7	0.9
	Age < 12 mo.	4	0.5
Case Classification	Trauma	454	56.5
	Medical	345	42.9
	Combined	5	0.6
Diagnosis: Medical	Cardiovascular	143	41.0
	Neurological	78	22.3
	Medical Other	62	17.8
	Respiratory	34	9.7
	Cardiac Arrest Medical	32	9.2
Diagnosis: Trauma	Trauma Other	298	65.5
	Polytrauma	76	16.7
	Isolated Head Trauma	69	15.2
	Cardiac Arrest Trauma	12	2.6
Total		804	100

Table 1 Demographic Summary

The PittAETool²⁶ identified a total of 883 trigger events over a 21-month period in 66.7% of the HEMS population (n=536), where 62.7% of these patients had 1 trigger event (n=336) and 37.3% (n=200) had 2 or more triggers. *Documentation Errors* (n=436) occurred in 81.2% of patients whose records triggered, followed by *Deviation from Standard of Care* (26.1%; n=140), *High-Risk Interventions* (14.7%; n=79), *Use of High-Risk Medications* (13.2%; n=71) and *Worsening Trend in Vitals* (9.7%; n=52). Excluding *Documentation Errors*, 44.3% of all triggers (n=356) occurred in the *Intervention and Medication* trigger grouping, and 8.3% (n=67) in the *Patient Condition* grouping (*Table 2*).

Events as Proportion of 804									
Trigger	Trigger Type / Group	Triggers		Potential Harm		Confirmed Harm		Combined AEs	
		Total	%	Total	%	Total	%	Total	%
T1	Documentation Errors	436	54.2	25	3.1	0	0.0	25	3.1
T2-T4	Operational / Patient Movement Triggers	24	3.0	11	1.4	2	0.2	13	1.6
T2	Prolonged Scene Time *	21	2.6	10	1.2	2	0.2	12	1.5
T3	Injury to Patient or Self During Care	0	0.0	0	0.0	0	0.0	0	0.0
T4	Request for Additional Resources	3	0.4	1	0.1	0	0.0	1	0.1
T5-T6	Patient Condition Triggers	67	8.3	14	1.7	10	1.2	24	3.0
T5	Worsening Trend in Vitals	52	6.5	14	1.7	6	0.7	20	2.5
T6	Cardiac Arrest During Transport	15	1.9	0	0.0	4	0.5	4	0.5
T7-T11	Intervention and Medication Triggers	356	44.3	145	18.0	16	2.0	161	20.0
T7	High-Risk Interventions	79	9.8	7	0.9	1	0.1	8	1.0
T8	Failed Interventions *	35	4.4	20	2.5	1	0.1	21	2.6
T9	Use of High-Risk Medication	71	8.8	2	0.2	1	0.1	3	0.4
T10	Deviation from Standard of Care *	140	17.4	90	11.2	11	1.4	101	12.6
T11	Medication Errors	31	3.9	26	3.2	2	0.2	28	3.5
Total		883	109.8	195	24.3	28	3.5	223	27.7
Proportions as % of Patients									
T1	Documentation Errors	436	81.2	25	15.8	0	0.0	25	14.9
T2	Prolonged Scene Time *	21	3.9	10	6.3	2	14.0	12	7.1
T3	Injury to Patient or Self During Care	0	0.0	0	0.0	0	0.0	0	0.0
T4	Request for Additional Resources	3	0.6	1	0.6	0	0.0	1	0.6
T5	Worsening Trend in Vitals	52	9.7	14	8.9	6	43.0	20	11.9
T6	Cardiac Arrest During Transport	15	2.8	0	0.0	4	29.0	4	2.4
T7	High-Risk Interventions	79	14.7	7	4.4	1	7.0	8	4.8
T8	Failed Interventions *	35	6.5	20	12.7	1	7.0	21	12.5
T9	Use of High-Risk Medication	71	13.2	2	1.3	1	7.0	3	1.8
T10	Deviation from Standard of Care *	140	26.1	90	57.0	11	79.0	101	60.1
T11	Medication Errors	31	5.8	26	16.5	2	14.0	28	16.7
Total		536	100	158	100	14	100	168	100
Proportions as % of Adverse Events									
T1	Documentation Errors	25	11.2	25	12.9	0	0.0	25	11.2
T2-T4	Operational / Patient Movement Triggers	13	5.8	11	5.7	2	6.9	13	5.8
T2	Prolonged Scene Time *	12	5.4	10	5.2	2	6.9	12	5.4
T3	Injury to Patient or Self During Care	0	0.0	0	0.0	0	0.0	0	0.0
T4	Request for Additional Resources	1	0.4	1	0.5	0	0.0	1	0.4
T5-T6	Patient Condition Triggers	24	10.8	14	7.2	10	34.5	24	10.8
T5	Worsening Trend in Vitals	20	9.0	14	7.2	6	20.7	20	9.0
T6	Cardiac Arrest During Transport	4	1.8	0	0.0	4	13.8	4	1.8
T7-T11	Intervention and Medication Triggers	161	72.2	145	74.3	16	57.1	161	72.2
T7	High-Risk Interventions	8	3.6	7	3.6	1	3.4	8	3.6
T8	Failed Interventions *	21	9.4	20	10.3	1	3.4	21	9.4
T9	Use of High-Risk Medication	3	1.3	2	1.0	1	3.5	3	1.3
T10	Deviation from Standard of Care *	101	45.3	90	46.4	11	37.9	101	45.3
T11	Medication Errors	28	12.6	26	13.4	2	6.9	28	12.6
Total		223	100	195	100	28	100	223	100

Table 2 Triggers and Harm as Proportions of Events, Patients, and Adverse Events.

Denominator = 804 (Events); Denominator = 536 (Patients); Denominator = 195 (Potential Harm), 28 (Harm), 223 (Combined AEs). * As defined by the PittAETool and in accordance with HMCAS SOPs, Guidelines, and norms.

A total of 223 AEs were identified (*Table 2*) with a rate of 27.7 AEs per 100 patient encounters (27.7%). Of the 536 patients whose records triggered, AEs followed in 31.3% of these (n=168), where 78.6% (n=132) had 1 AE, and 21.4% (n=36) had 2 or more. The majority (72.2%) of

AEs occurred in the *Intervention and Medication* triggers (n=161), followed by *Documentation Errors* 11.2% (n=25), *Patient Condition* triggers 10.8% (n=24), and *Operational and Patient Movement* triggers 5.8% (n=13). While *Deviation from Standard of Care* was common, accounting for 45.3% of AEs reported (n=101), *Medication Errors* contributed 12.6% (n=28), followed by *Failed Interventions* 9.4% (n=21), and *Worsening Trend in Vitals* 9% (n=20).

Potential Harm (n=195) was identified in 29.4% of patients (n=158) whose records triggered (Table 2), with a rate of 24.3 Potentially Harmful Events per 100 patient encounters (24.3%). Similarly, 74.3% came from the *Intervention and Medication* triggers (n=145), where *Deviation from Standard of Care* was again frequently observed (46.4%; n=90), followed by *Medication Errors* 13.4% (n=26), *Failed Interventions* 10.3% (n=20), *Worsening Trend in Vitals* 7.2% (n=14), and *Prolonged Scene Time* 5.1% (n=10).

Confirmed Harm (n=28) was identified in 2.6% of patients (n=14) whose records triggered (Table 2), with a rate of 3.5 Confirmed Harmful Events per 100 patient encounters (3.5%). The majority of Harm (57.1%) occurred in the *Intervention and Medication* trigger grouping (n=16), followed by 34.5% in the *Patient Condition* triggers (n=10), whereas *Operational and Patient Movement* triggers (specifically *Prolonged Scene Time*) accounted for 6.9% of Harm (n=2). *Deviation from Standard of Care* (n=11) and *Worsening Trend in Vitals* (n=6) were frequent contributors to harm, 37.9% and 20.7% respectively, followed by *Cardiac Arrest During Transport* 13.8% (n=4) and *Medication Errors* 6.9% (n=2). *High-Risk Interventions*, *Failed Interventions*, and *Use of High-Risk Medication* accounted for the remaining 3 Harmful AEs identified, 3.4% respectively.

Actions By HEMS-Crew Provider (PC2.1) was the most frequent PC observed for all forms of harm identified (*Potential Harm*, *Confirmed Harm*, and all AEs), occurring 85.6% (n=167), 53.6% (n=15), and 81.6% (n=182) respectively. Similarly, the second leading PC was *Actions by Non-HEMS-Crew Provider* (PC2.2), occurring 8.7% (n=17), 21.4% (n=6), and 10.3% (n=23). The third leading PC was *Undetermined by Chart Review* (PC5) 3.1% (n=6), 17.9% (n=5), and 4.9% (n=11) (Figure 1).

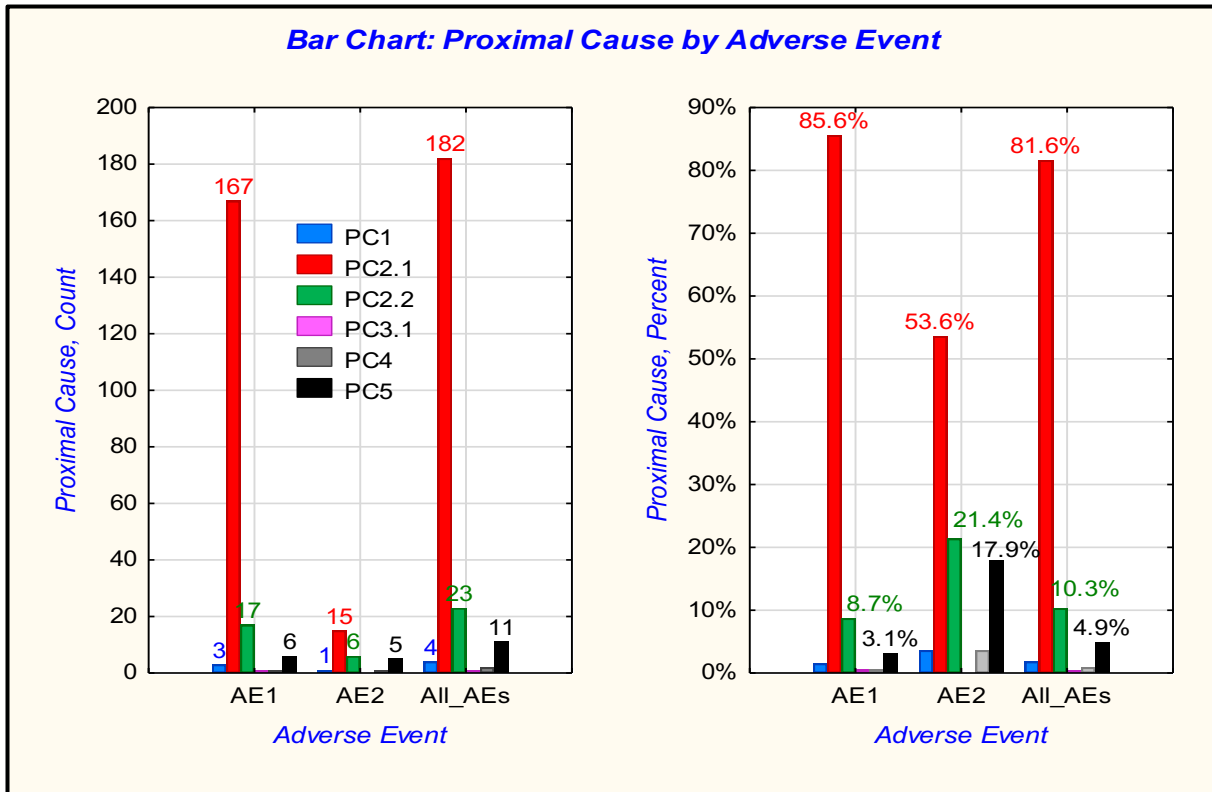


Figure 1 Proximal Causes by Adverse Event

For all AEs, age and diagnosis-adjusted odds was significant in the *Operational* (25.41; 95% CI, 7.31-88.26; $P < 0.01$) and *Interventional* (62.98; 95% CI, 33.80-117.36; $P < 0.01$) trigger groupings. While age had no effect, 2 diagnosis categories [*Respiratory* (10.12; 95% CI, 2.62-39.15; $P < 0.01$) and *Trauma Other* (3.55; 95% CI, 1.40-9.00; $P = 0.01$)] showed increased odds for AEs (*Table 3*).

Similarly, when adjusting for age and diagnosis, the odds for *Potential Harm* was significant in the *Operational* (26.96; 95% CI, 7.79-93.35; $P < 0.01$) and *Interventional* (55.13; 95% CI, 29.68-102.42; $P < 0.01$) trigger groupings. While age also had no effect, 2 diagnosis categories [*Respiratory* (11.03; 95% CI, 2.90-42.12; $P < 0.01$) and *Trauma Other* (3.87; 95% CI, 1.53-9.80; $P < 0.01$)] again showed increased odds for *Potential Harm* (*Table 3*).

Conversely, age and diagnosis-adjusted odds for *Harm* was significant in the *Patient Condition* (6.50; 95% CI, 1.71-24.67; $P = 0.01$) and *Interventional* (11.85; 95% CI, 1.36-102.92; $P = 0.03$) trigger groupings (*Table 3*). However, age and diagnosis had no effect on harm (*Table 3*).

Potential Harm	Odds Using Trigger Categories	Odds Ratio (95% CI)	P Value
	Operational Triggers	28.44 (8.70-92.94)	<0.01
	Patient Triggers	1.19 (0.61-2.30)	0.62
	Interventional Triggers	42.63 (23.86-76.16)	<0.01
	Age and diagnosis adjusted odds		
	Operational Triggers	26.96 (7.79-93.35)	<0.01
	Patient Triggers	1.65 (0.80-3.44)	0.18
	Interventional Triggers	55.13 (29.68-102.42)	<0.01
	Age Category		
	36-60	1.49 (0.85-2.60)	0.16
	>60	1.37 (0.55-3.42)	0.50
	Diagnosis		
	Cardiovascular	1.95 (0.76-5.00)	0.16
	Respiratory	11.03 (2.90-42.12)	<0.01
	Neurological	2.06 (0.66-6.39)	0.21
	Medical Other	1.53 (0.44-5.32)	0.45
	Head Trauma	1.62 (0.58-4.53)	0.36
	Poly Trauma	2.02 (0.70-5.82)	0.19
	Trauma Other	3.87 (1.53-9.80)	<0.01
Confirmed Harm	Odds Using Trigger Categories		
	Operational Triggers	2.82 (0.48-16.68)	0.25
	Patient Triggers	10.90 (3.32-35.71)	<0.01
	Interventional Triggers	14.70 (1.78-121.16)	0.01
	Age and diagnosis adjusted odds		
	Operational Triggers	3.02 (0.42-21.78)	0.27
	Patient Triggers	6.50 (1.71-24.67)	0.01
	Interventional Triggers	11.85 (1.36-102.92)	0.03
	Age Category		
	36-60	1.97 (0.49-7.91)	0.34
	>60	0.77 (-0.07-9.10)	0.84
	Diagnosis		
	Cardiovascular	0.25 (0.04-1.5)	0.13
	Respiratory	1	
	Neurological	1	
	Medical Other	1	
	Head Trauma	0.13 (0.01-1.37)	0.09
	Poly Trauma	0.42 (0.08-2.19)	0.30
	Trauma Other	0.23 (0.03-1.51)	0.13
Adverse Events	Odds Using Trigger Categories		
	Operational Triggers	27.48 (8.32-90.78)	<0.01
	Patient Triggers	1.60 (0.80-3.17)	0.18
	Interventional Triggers	47.78 (26.74-85.37)	<0.01
	Age and diagnosis adjusted odds		
	Operational Triggers	25.41 (7.31-88.26)	<0.01
	Patient Triggers	2.11 (0.99-4.50)	0.05
	Interventional Triggers	62.98 (33.80-117.36)	<0.01
	Age Category		
	36-60	1.72 (0.98-3.03)	0.06
	>60	1.22 (0.48-3.07)	0.68
	Diagnosis		
	Cardiovascular	1.82 (0.71-4.65)	0.21
	Respiratory	10.12 (2.62-39.15)	<0.01
	Neurological	1.67 (0.54-5.20)	0.38
	Medical Other	1.34 (0.39-4.65)	0.65
	Head Trauma	1.41 (0.50-3.96)	0.51
	Poly Trauma	2.50 (0.85-7.32)	0.09
	Trauma Other	3.55 (1.40-9.00)	0.01

Table 3 Multivariate Analysis

Quality Results

A trigger rate of 1,1 Triggers per patient encounter was observed. All trigger points fell within the 3-sigma bounds, indicating *Common-Cause* variation. A run test showed 4 out of 5 counts were within 1 standard deviation from the center line for the months August 2017- January 2018 (*Figure 2*). Furthermore, a rate of 24,3 Potentially Harmful Events per 100 patient encounters (24,3%) was observed. All *Potential Harm* points fell within the 3-Sigma bounds, indicating *Common-Cause* variation. No trends were observed (*Figure 3*). Moreover, a rate of 3,5 Confirmed Harmful Events per 100 patient encounters (3,5%) was observed. One Confirmed Harm point fell beyond the 3-sigma bounds. This indicates *Special-Cause* variation, and therefore indicates an unstable process that is “out of control”. A runs test showed 4 out of 5 counts were within 1 standard deviation from the center line for the months August 2017- January 2018 (*Figure 4*). Finally, a Combined AE rate of 27,7 AEs per 100 patient encounters (27,7%) was realized. All points fell within the 3-sigma bounds indicating *Common-Cause* variation, and no trends were observed (*Figure 5*).

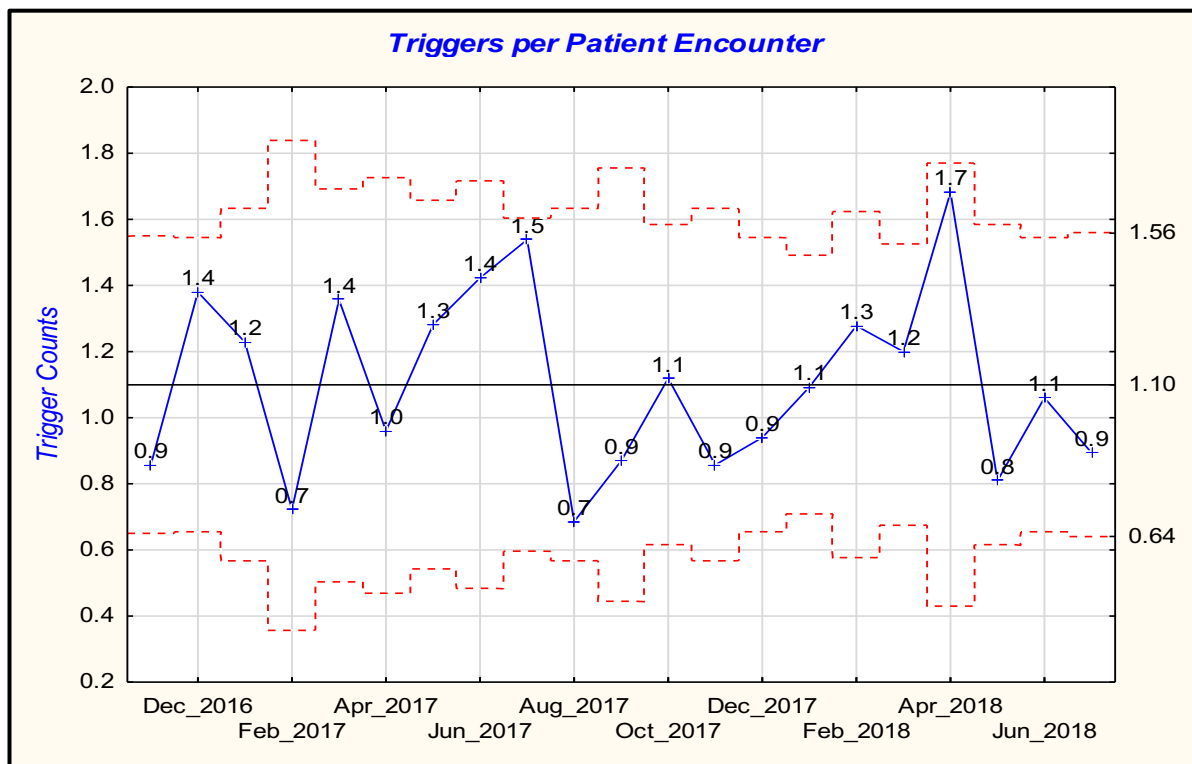


Figure 2 Triggers per Patient Encounter

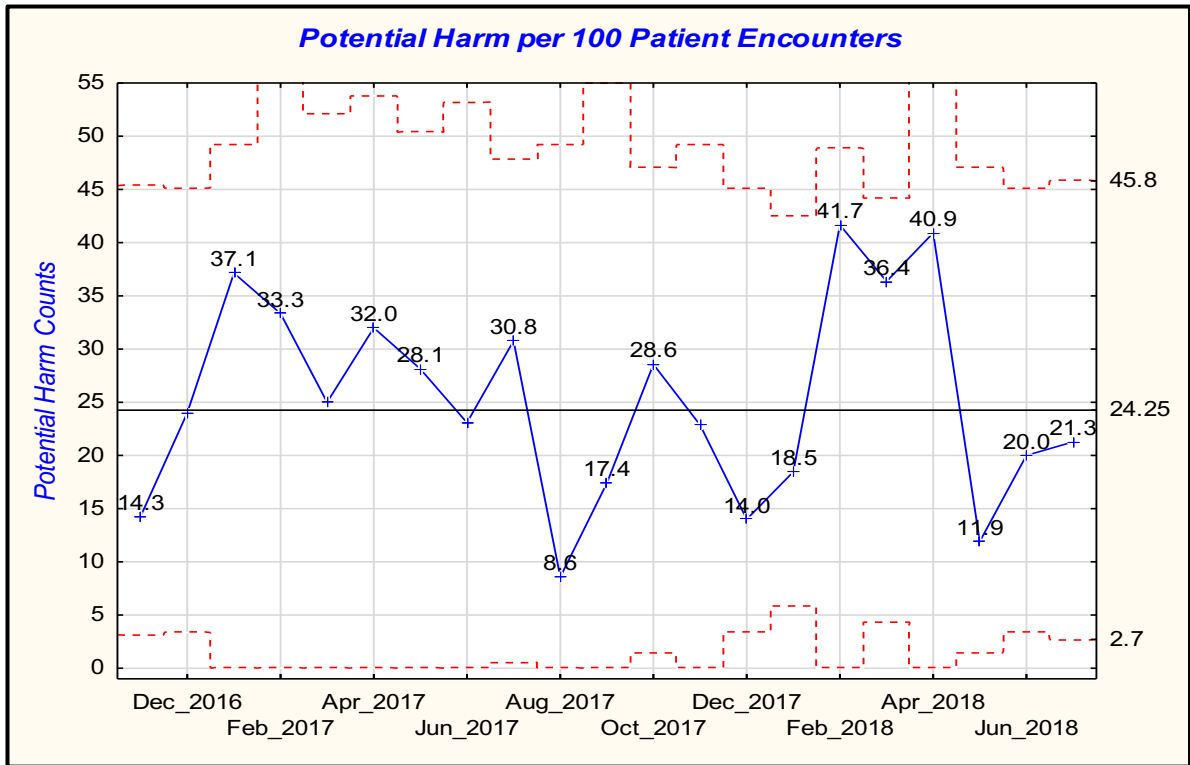


Figure 3 Potential Harm per 100 Patient Encounters

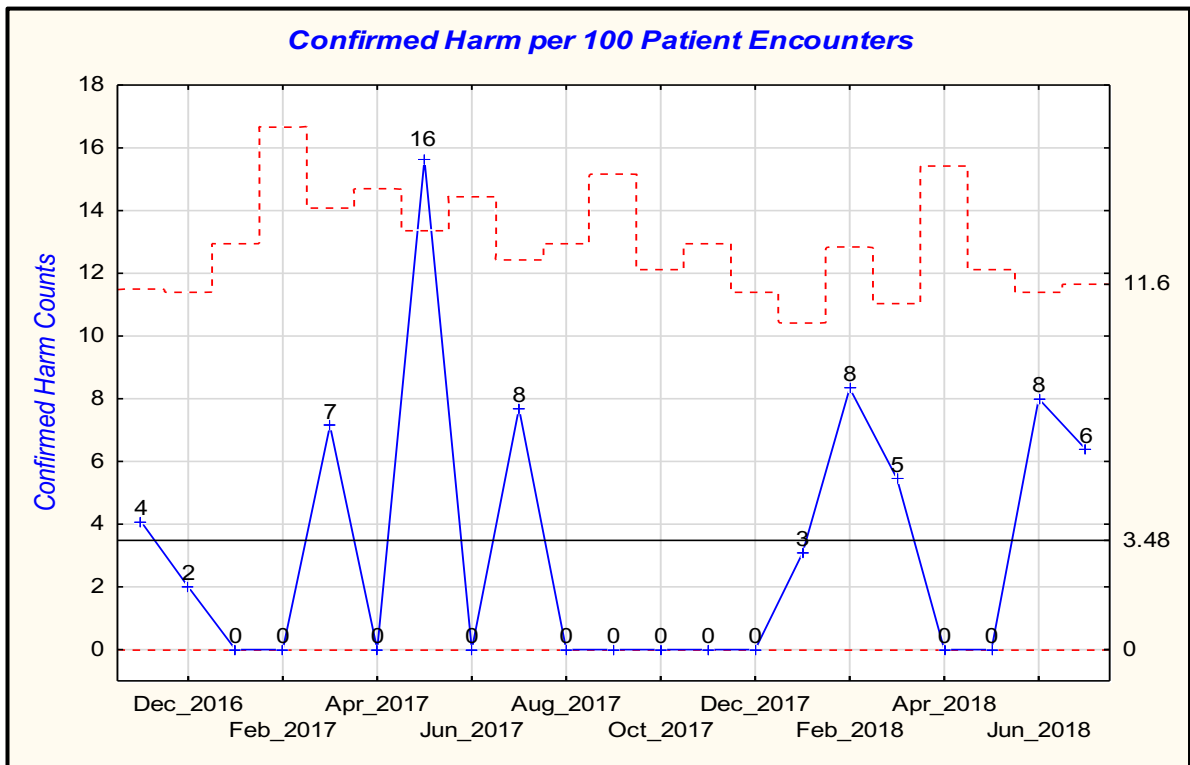


Figure 4 Confirmed Harm per 100 Patient Encounters

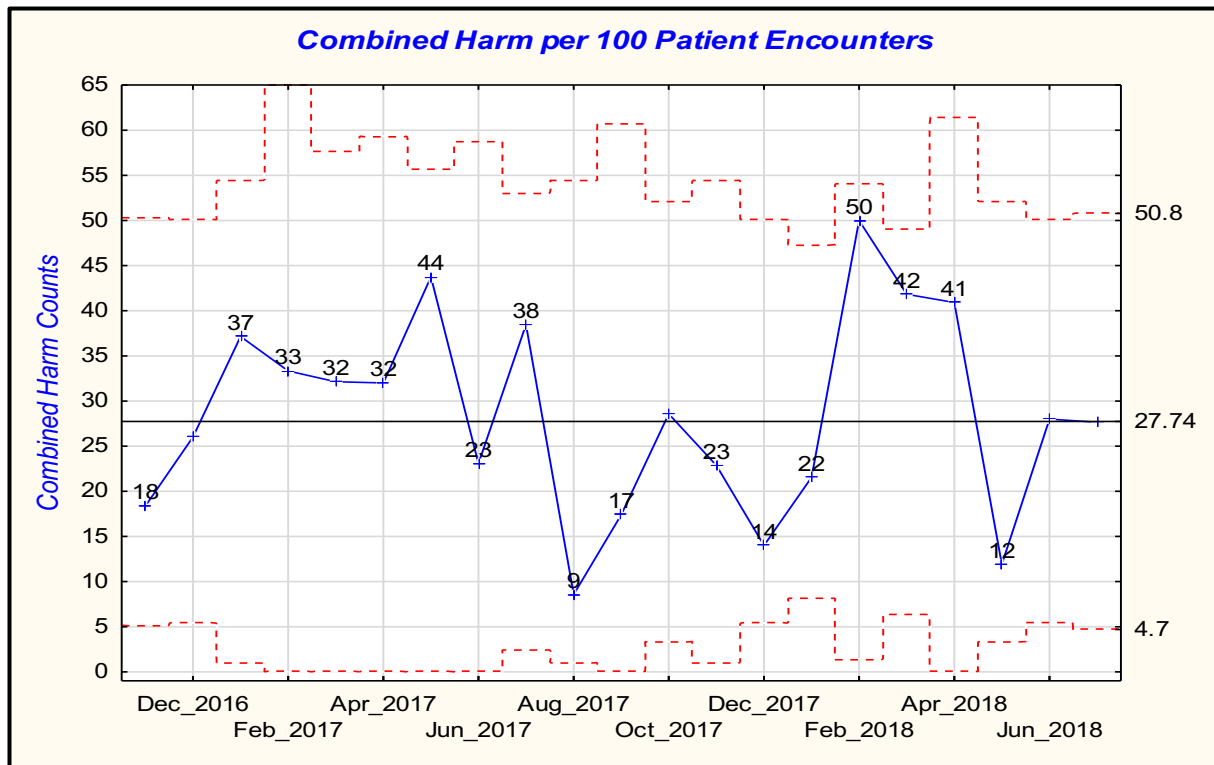


Figure 5 Combined Adverse Events per 100 Patient Encounters

Discussion

The aim of this study was to describe the type and frequency of AEs, and their PCs in Qatar HEMS. Although direct comparison of AE rates within the literature is not possible due to heterogeneity of data, differences in defining harm and reporting standards,^{10, 12, 16} our results do compare somewhat to a recent paper by Hagiwara et al who utilized the same tool in a ground-based EMS system, and reported an AE rate of 4,3% with a harm rate of 0.3%.²⁸ While our AE and harm rates were substantially higher (27.7% and 3.5% respectively), differences in patient acuity (e.g.- ground Vs HEMS), provider experience and training, and sample size may explain the difference in rates observed. Furthermore, recent efforts by Howard, et al^{29, 33} to adapt and operationalize the TT concept for the prehospital environment resulted in the development of the Emergency Medical Services Trigger Tool (EMSTT), where 0.34 Harm Events per 10,000 patient encounters was reported. When compared to the EMSTT, our harm rates were substantially higher. However, the EMSTT was designed to identify AEs in low-risk / high-frequency EMS ground transport, and cannot be routinely applied to a HEMS environment with a high-risk / low frequency cohort.

Our research observed the frequent occurrence of *Documentation* errors. Hagiwara, et al²⁸ reported similar findings. There is evidence to suggest that poor quality prehospital

documentation can be detrimental to patient safety and has been linked to increased mortality,³⁴ information loss,³⁵ and unavailability of information in times of critical ED decision-making.³⁶ Moreover, inadequate documentation can hinder detection of AEs, and has the potential to underestimate the true AE rate.³⁷ Of interest, HMCAS coincidentally transitioned from using paper to electronic records and this change was implemented in January 2017. However, it is uncertain how this transition affected the overall quality of records and documentation of AEs, and to what degree this change influenced the record review process. Furthermore, documentation triggers were common across the reporting period, and based on the control chart for triggers, no outliers were identified (*Figure 2*).

Interventional and Patient Condition triggers (*Worsening Trend in Vitals and Cardiac Arrest During Transport*) including 2 diagnosis categories (*Respiratory and Trauma Other*) were associated with increased odds of harm. Hagiwara, et al²⁸ report similar findings, where the risk of AEs was shown to be higher in patients with “high-risk life-threatening conditions”. From an HMCAS organizational point of view, we note that frequent AEs observed during routine clinical governance specifically following respiratory and trauma emergencies have led to the most changes in the associated pathways of the Clinical Practice Guidelines (CPG) in recent years.³⁸ Furthermore, transport stress (barometric pressure, hypoxia, thermal changes, dehydration, noise, vibration, gravitational forces, third spacing, and fatigue) affect both patient and HEMS crew, and these stresses are cumulative and can lead to significant compromise.³⁹⁴⁰ The effect of hypoxia and increased metabolic demand may be more apparent at altitude in patients with respiratory and trauma etiologies.⁴¹ Moreover, some clinical Interventions and patient assessments can’t be done in flight (i.e.- auscultation of a chest, insertion of an intercostal chest drain) and therefore patients with severe respiratory compromise (i.e.- pneumothorax, asthma, COPD, pulmonary oedema) are difficult to monitor and at risk of hypoxia.⁴² Therefore, high-acuity patients with respiratory and trauma etiologies are at increased risk for deterioration of vitals and cardiac arrest in flight.

Furthermore, we identified that 1 in 5 patients (17.4%) had a *Deviation from Standard of Care*, and the most common cause of AEs was assigned to the *HEMS crew*. Again, these findings were mirrored by Hagiwara, et al.²⁸ This brings into question factors that are known to influence clinical decision-making and guideline deviation (i.e.- fatigue, training, level of experience, interruptions to work-flow, work-load, team dynamics, communication, and cognitive bias).^{2, 4, 5, 43} Moreover, guideline compliance has been shown to vary.⁴⁴ While experience, background, and training may differ between healthcare providers, paramedics are dependent on guidelines and protocols.⁴⁵ Furthermore, use of inadequate tools has been identified as a possible factor for deviation from standards of care.⁴⁶ While transport stress is

cumulative (affecting both patient and HEMS crew), the link between stress and work performance is important.^{39, 47} HEMS crews often perform high-risk time-pressured interventions and taskings in a noisy environment where many distractions and competing priorities exist (e.g.- Hot-loading). Extreme environmental factors (heat and humidity) also have a cumulative effect on fatigue.^{39, 47} While all HMCAS HEMS crews receive formal Crew Resource Management (CRM) training, communications can be challenging for the medical crew, especially during short mission times, when “sterile cockpit” (periods when silence is mandated) procedures must be respected in the interest of mission safety, often presenting competing communication priorities between the flight and medical crew.^{48, 49} Furthermore, the multicultural diversity of the work force and hierarchical nature of structures within HMCAS has the potential to create an environment not conducive to effective communication.⁵⁰ Collectively, these factors may all contribute to poor clinical decision-making and guideline deviance with the potential to compromise patient care in flight.

One strength of the PittAETool²⁶ is its ability to differentiate between types of harm, as not all AEs have been shown to result in harm. Furthermore, our results clearly demonstrate that *Potential Harm* (24.3%) accounted for the majority of AEs, and that Intervention and Medication triggers contributed significantly (74.3%). This exposes the large window of opportunity for harm to occur in our healthcare system (i.e.- the greater the frequency or potential for harm, the more likely harm will occur). The ‘swiss-cheese’ model of system accidents and error outlines the relationship that *defenses*, *barriers*, and *safeguards* play in an accidents trajectory, and the role of human factors in error prevention.^{51, 52}

Lastly, from a quality standpoint, the SPC charts identified one harm point in May 2017 that fell outside the 3-sigma upper control limit, and is therefore criteria for consideration of special cause variation (Figure 4). However, on review of the data, we found no reason to explain or account for this variation.³¹

The TT methodology is an accepted method for AE detection in healthcare, especially in systems where time-constraints and resource limitations exist.^{17, 20, 22, 24, 25} Whilst more research is required to understand prehospital clinical decision-making and reasons for guideline deviance, focused quality improvement initiatives to reduce AEs and Potential harm should be addressed in future research. Furthermore, efforts to understand the role of human factors in error prevention and design-proofing of our healthcare systems to reduce potential for harm should also be addressed.⁶

Limitations

While the Global TT methodology²³ typically supports the use of a small frequent sample applied consistently over time, the PittAETool²⁶ was applied to the entire population of HEMS Patient Encounters over a 21-month period, effectively eliminating selection bias over the reporting period. Whilst efforts to eliminate selection bias were made, 3 other possible sources of bias can't be ruled out. Information bias stemming from under-reporting of AEs is commonly associated with retrospective chart review methodologies.³⁷ Furthermore, the follow-up of patients was not possible as we did not have access to hospital records, and were therefore unable to confirm the harm reported. Results are likely to be an under-estimate of the true harm rate. Lastly, the presence of any confounding factors and the degree to which they may or may not have influenced the results is not known. Sex should always be assumed to be a potential source of confounding.

The PittAETool²⁶ is content validated and has demonstrable internal validity. However, the external validity of the tool may be limited by factors such as case load, scope of practice, training, and experience. Whilst Hagiwara, et al²⁸ report similar AE findings, our results may not be entirely generalizable to other EMS or HEMS settings, and should be interpreted cautiously. Similarly, application of the PittAETool²⁶ may not be transferable to other settings.

Conclusion

An AE rate of 27.7% is high. Although *Documentation* errors were common, the majority of AEs came from the *Intervention and Medication* triggers, of which *Deviation from Standard of Care* was common, and *Actions by the HEMS crew* was the most frequent PC. *Operational* and *Interventional* triggers were associated with an increased risk of AEs and Potential Harm, where 2 diagnosis categories (*Respiratory* and *Trauma Other*) showed increased odds for AEs. Conversely, *Patient Condition* and *Interventional* triggers were associated with increased risk of *Harm*, where age and diagnosis had no effect on odds. While the PittAETool demonstrated a robust, reliable, and valid means of AE detection in the HEMS domain, where our findings echoed those reported in recent published literature, they may not be generalizable to other EMS systems.

More research is required to understand prehospital clinical decision-making and reasons for guideline deviance. Furthermore, focused quality improvement initiatives to reduce AEs and *Documentation errors* should also be addressed in future research, including efforts to understand the role of human factors in error prevention and design-proofing of our healthcare system to reduce potential for harm.⁶

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PART C: Appendices

I. **Emergency Medical Journal: Instructions for Authors**

Air Medical Journal

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II. Research Protocol

23 May 2019

1. Summary

The goal to identify and eliminate all forms of harm or 'potential for harm' in healthcare is of paramount importance and worthy of our attention.¹ Healthcare delivery in the emergency department has been described as: "A laboratory for error".² Moreover, the opportunity for harm to occur during the delivery of prehospital critical care in Helicopter Emergency Medical Services (HEMS) transportation of high acuity patients presents a significant risk to patient safety.³⁻⁷

Focused efforts to improve patient safety hinge on our ability to accurately measure harm.⁸ Furthermore, there are many different methodologies that can be utilized to identify and describe adverse events (AEs) in healthcare.⁹ The Global Trigger Tool (GTT) was designed to identify AEs in healthcare and has been shown to be ten times more effective as compared to traditional methods.¹⁰ Despite the growing trend and interest in this novel methodology, the development of more suitable adaptations of the GTT to detect AEs within the prehospital environment have been slow.¹¹ Patterson et al designed a content validated, HEMS focused, trigger tool: The Pittsburgh Adverse Event Detection Trigger Tool (PittAETT) that represents a more appropriate trigger-based tool for use within the prehospital HEMS arena.⁵

The goal of this research is to retrospectively describe and report on both the frequency of AEs and their proximal causes (PCs) identified in the LifeFlight HEMS division of Hamad Medical Corporation Ambulance Service in Qatar, as defined by the PittAETT methodology (*Appendix IV*). The study will involve a retrospective analysis of an existing continuous quality improvement (CQI) trigger tool database for the period November 2016-July 2018 (*Appendix V*). A combination of descriptive and Statistical Process Control (SPC) methodology will be employed (*Appendix VI*) to describe all identified AEs, their PCs, and harm classification. The study sample size is inclusive of the entire population of interest for the given reporting period (*see inclusion / exclusion criteria*). Percent agreement and agreement beyond chance will be calculated for raters using Cohens Kapa. Outcome measures will be calculated and results plotted on appropriate control charts.

It is envisaged this research will help inform future quality improvement initiatives.

2. Introduction

2.1. Background

Medical errors constitute a significant public health care concern, and patient safety risk.¹ Historically, the Harvard Medical Practice Study of 1991 was the first of its kind to investigate the incidence of adverse events resulting from negligence in hospitalized patients, with a specific focus on malpractice costs stemming from harm in healthcare.¹² A decade later, the landmark paper from the Institute of Medicine (IOM) “*To Err Is Human: Building a Safer Healthcare System*” estimated between 44,000 and 98,000 American deaths per year attributed to medical error.¹ This heightened awareness within the media rekindled public interest, shifting the spotlight, and soon turned patient safety initiatives into a priority.¹³

Five years after the release of the IOM report, and despite efforts to improve patient safety, progress in healthcare improvement initiatives remained slow and had not necessarily translated into a safer healthcare system.^{1, 14-16} The IOM report did, however, fundamentally change the way people viewed the task of error prevention, enlisted the support of stakeholders, and accelerated changing practices through a combination of voluntary and legislative recommendations and the securing of funds for patient safety research.¹⁴ Furthermore, a combination of healthcare complexity, a longstanding culture of physician authority and autonomy, and fear posed significant ongoing barriers preventing the implementation of practices and policies with the potential to improve patient safety.¹⁴ The primary lesson learnt is that patient safety is a choice. Our beliefs, intentions, cultures and choices underscore our ability to make the necessary changes.¹⁴ Another significant barrier impeding patient safety improvement lies in the difficulties in measuring safety. To this end, Vincent et al call for more systematic measurement.¹⁶

Whilst healthcare leaders, practitioners, and patient safety experts grappled with the growing body of evidence exposing the uncomfortable truth (i.e.- our healthcare systems are harming patients), they also realized the success of improvement efforts depends on the ability of researchers to accurately measure error and harm.¹⁷ Unfortunately, known variations and a lack of universally accepted definitions threaten to limit our understanding of AEs, hinder data analysis, collaboration, and undermine improvement efforts.¹⁷ Hofer and Kerr¹⁸ argue that medical error should only be defined in terms of “failed processes that are clearly linked to adverse outcomes”. However, not all medical error results in harm. Conversely, Grober and Bohnen¹⁷ propose an outcome and process-dependent definition of medical error: “An act of omission or commission in planning or execution that contributes or could contribute to an

unintended result". The four key domains of error are present (omission, commission, planning, execution), including the faulty processes independent of outcome. This definition therefore includes the "silent-majority" of errors that do not necessarily result in harm, but highlight faulty processes nonetheless.¹⁷ However, the ongoing problems encountered in defining medical error only represent one part of the puzzle.

Of equal importance is the fact that AEs are not always a product of medical error. It is well acknowledged that numerous patient and system factors can and do also contribute to AEs (only some of which may result in harm), absent medical error.^{17, 18} Furthermore, not all AEs result in harm. Therefore, the act of identifying harm (from whatever cause) in isolation, is to ignore the larger picture by not considering the overwhelming potential for harm within our healthcare systems.

The question: "What is the most suitable methodology for the detection of AEs?"- is of utmost interest to patient safety researchers.^{11, 19} Traditional methods for detecting AEs include manual chart review, direct observation, morbidity & mortality rounds, voluntary reporting systems, and patient complaints.¹¹ Whilst the manual chart review has previously been considered the "gold standard" for the detection of AEs in healthcare, the costs, limitations and imperfections of this methodology are well documented.¹¹

Many healthcare executives fall prey to the trap of relying solely on quality metrics as the only measures of quality within their organization. Cameron and Cooke describe a framework for the measurement of quality in the Emergency Department (ED), and caution against inappropriate use of quality indicators in isolation (i.e.- Quality Indicators should not replace appropriate use of AE detection methods to identify harm / potential for harm / highlight areas for improvement).⁸ While there simply appears to be no set standard for AE detection in healthcare, it has been suggested that: "What you see depends on how you look" (i.e.- AE detection methodology matters).^{8, 9, 20}

The concept of a *'trigger'* was first described in 1974, and trigger tool methodology has since evolved.²¹ Trigger tool methodology is generally based on a retrospective or near-real-time structured chart review process, utilizing a small (weekly or monthly) sample plotted over time, with the application of preidentified (typically by experts within the field of interest) and validated triggers that are known to be closely associated with AEs in the domain or processes of interest.²¹ Triggers are typically more structured, well-defined, less subjective, and allow raters to focus on important aspects of the review. The process is typically conducted between two raters and is timed (i.e.- ten to fifteen minutes per review). Disagreement between raters

is compared and consensus is sought. Disagreement is finally resolved by a more clinically senior and independent reviewer.

The subsequent development of the GTT,²² as described by the IHI, has shown significant potential in identifying AEs in a timely and cost effective manner with good inter-rater reliability.²³⁻²⁵ Trigger tools have since been adapted for utilization in different healthcare domains and processes (e.g.- Adverse Drug Events,²⁶⁻²⁸ Ambulatory Care,^{29, 30} General Medicine,³¹ Intensive Care Units,³²⁻³⁴ Oncology,³⁵ Orthopedics,³⁶ Pediatrics,³⁷⁻⁴³ and Surgery^{44, 45}). Furthermore, the GTT identified ten times more hospital-based AEs when compared to other traditional methods of AE detection.¹⁰ This finding, coupled with its ease of use and adaptability in different healthcare domains has resulted in the emergence of the *Trigger Tool* as: “The premier measurement strategy for patient safety”.⁴⁶

The dual goal to identify and eliminate or minimize possible harm before it occurs in the design of healthcare (a function of high reliability organizations) is of utmost importance to healthcare leadership, policy-makers, healthcare providers and patients.⁴⁷⁻⁴⁹ The cumulative effects of shift work, sleep deprivation, and sleep debt on fatigue in health care providers; the increased cognitive load and effects of cognitive bias during complex clinical decision-making; the effects of constant interruptions on teamwork and communication in a high-stress fast-paced prehospital emergency system create the ideal opportunity for AEs to occur.^{2, 50-53} Furthermore, the high acuity nature of interventions required in the treatment of critically ill and injured patients typically triaged for HEMS transport, as compared to prehospital ground transport, increase the potential for AEs and harm to occur.^{54, 55}

A literature review in search of trigger tool utilization for the detection of AEs in prehospital HEMS found two papers by Patterson et al.^{5, 56} The first paper in 2012 employed a modified Delphi technique to develop a consensus definition of AEs and develop a method to define and rate AEs in emergency medical services.⁵⁶ A second paper in 2014 saw the development of a focused prehospital HEMS trigger tool that sought to establish content validity of eleven HEMS triggers.⁵ However, there is no evidence to suggest this tool has been externally validated. Nonetheless, the PittAETT⁵ represents the only one of its kind (content validated for the domain of interest) in published research.

More recent efforts to detect prehospital AEs have started to emerge in Sweden.⁵⁷ Furthermore, local efforts by Howard et al in Qatar, have seen the development and application of the Emergency Medical Services Trigger Tool (EMSTT).^{58, 59} However, application of EMSTT in Qatar was primarily developed with the intention to screen all low-risk

/ high-frequency prehospital cases that were not subjected to a 100% Clinical Governance Audit, and therefore by design excluded all high-risk / low-frequency cases that were already subjected to a 100% Clinical Governance Audit, thus potentially limiting widespread application of the EMSTT within other prehospital EMS systems where both high and low acuity case-loads co-exist and no other mechanism for AE detection are employed.⁵⁹

The true incidence of adverse medical events in HEMS and the most appropriate AE detection tool is not well reported. Sing et al⁶ determined that critical events occur every 1 in 20 air medical transports. Lehmann et al investigated AE risks in a combat HEMS environment, and reported higher mean Transport Risk Scores (TRS) in patients with AEs compared to patients without, whereby equipment failures and in-flight clinical deterioration constituted the majority of AEs.³ MacDonald et al report communication problems to be the most common cause of AEs in air-medical transport.⁴ Stassen et al report on AEs associated with Rapid Sequence Intubation (RSI) in South African HEMS, and confirm at least 1 AE occurring in 27% of cases, the most prevalent being hypoxemia, hypotension and bradycardia, and a first pass success rate of 79%.⁷ Advanced airway management is commonly performed by HEMS teams, due to the high acuity nature of HEMS triaged calls, and therefore the potential for harm to occur is ever present.

2.2. Motivation

There is evidence to suggest that identification of AEs is highly dependent on the AE detection methodologies employed.^{9-11, 20, 21, 46} While utilization of the GTT has been shown to potentially identify ten times as many AEs compared with more traditional reporting methods,¹⁰ a paucity of evidence exists for adaptation and utilization of focused trigger tools in the search of AEs in the emergency setting.⁶⁰⁻⁶² Furthermore, the design of trigger tools has historically focused on hospital care, with little evidence for the utilization of trigger tools in the prehospital arena.

The PittAETT (*Appendix IV*) is broadly suitable for both low-risk / high-frequency and high-risk / low-frequency HEMS cases, is content validated, includes by definition acts of omission and commission (identifying harm or potential for harm irrespective of outcome),¹⁷ and therefore represents the most suitable available trigger tool for the detection of AEs within HEMS.⁵ It is incumbent on healthcare leadership, clinical governance teams, and policy-makers to actively search for and eliminate harm in healthcare using the most updated and appropriate AE detection methodology.

2.3. Research Question / Aim

The aim of this study is to retrospectively describe the frequency of AEs and their PCs (as defined by the PittAETT in *Appendix IV*) in the LifeFlight HEMS division of Hamad Medical Corporation Ambulance Service (HMCAS) in Qatar.

2.4. Objectives

- ⇒ To describe the frequency of AEs in the LifeFlight HEMS division of HMCAS in Qatar.
- ⇒ Describe the PCs for the objective above.

3. Methodology

3.1. Study Design

In August of 2016, a HEMSTT database was first established at LifeFlight with the implementation of the PittAETT to augment existing standard clinical governance reporting and provide improved understanding and identification of AEs and their PCs (*Appendix IV*). Critical Care Paramedics (CCPs) were identified on all four LifeFlight teams and trained as Raters prior to database entry. A documentation clerk facilitated the process by identifying all HEMS Patient Care Reports in paper (PCR) and electronic (ePCR) formats meeting pre-determined inclusion and exclusion criteria, coding data, and providing LifeFlight Raters with password protected computer access to the relevant data and data collection spreadsheets to commence database entry (*Appendix V*).

This research will involve a retrospective analysis of this existing HEMSTT database to describe the frequency of AEs and their PCs within LifeFlight. This study incorporates descriptive methodology using descriptive statistics and Statistical Process Control (SPC) methods commonly employed in improvement science reporting.

3.2. Study Population and Sampling

With the national Emergency Medical Service (EMS) system of Qatar as a backdrop, this study will be conducted within the LifeFlight HEMS division of HMCAS. This two-tiered ambulance service (consisting of Ambulance Paramedics and Critical Care Paramedics) serves an approximate population of 2.7 million people with an average of 600-700 calls per day. LifeFlight transports on average 40-60 patients per month. All “999” emergency requests for LifeFlight are channeled through the National Command Centre (NCC) in Doha, Qatar.

The study population of interest will include all “999” LifeFlight HEMS dispatches that resulted in a patient contact within the stipulated study period (i.e.- a flight to scene resulting in patient assessment, treatment, and / or transport by air or ground) facilitated by a LifeFlight CCP as documented by the HEMS crew on a PCR. Note inclusion criteria below.

All PCRs generated by non-HEMS crew are excluded (even if multiple resources were dispatched to the same case). Furthermore, in the event of bad weather and scheduled aircraft maintenance, there may have been times whereby HEMS crew were required to work on ground units. These cases are typically reflected on the PCR with a different Unit call sign and are excluded from the study population of interest. Note exclusion criteria below.

The sampling period will include a 21-month retrospective analysis of available data entries within the HEMSTT database from 1st November 2016 – 31st July 2018. The sampling period will therefore exclude the first 3 months of data collected between August – October 2016, to account for potential inconsistencies in implementation and interpretation between Raters in their initial understanding of the PittAETT Triggers, AEs, PCs and harm classification. With a sampling period of 21 months, and an average of 40-60 HEMS flights per month, a total sample size between 800 and 1200 HEMS data entries can be expected. This sample size is mirrored in similar recently published EMS Trigger Tool research.⁵⁸

3.2.1. Inclusion Criteria

- ⇒ All HEMSTT database entries between 1st November 2016 – 31st July 2018.
- ⇒ This will by default include all “999” LifeFlight dispatches resulting in a PCR generated by LifeFlight HEMS crew documenting a patient encounter (i.e.- patient assessment, treatment, and / or transport by air or ground), as indicated by inclusion within the HEMSTT database and evident by a database entry.

3.2.2. Exclusion Criteria

- ⇒ All database entries that fall outside the specified inclusion period.
- ⇒ All database entries indicating a non-HEMS Crew PCR (i.e.- assuming more than one EMS asset were dispatched to the same incident). There are likely to be none of these, as inclusion in the HEMSTT database is predicated on the inclusion criteria described above.
- ⇒ All database entries indicating a Ground Unit PCR generated by HEMS crew (i.e.- assuming LifeFlight was grounded due to bad weather or maintenance).
- ⇒ All duplicated database entries will be excluded from data analysis.

3.3. Recruitment and Enrolment

Development of the PittAETT database started in August 2016. The subsequent enrollment of Raters in data entry and the development of the HEMSTT database falls outside the scope of this research proposal. However, continuous data entry forms part of routine clinical governance activities within the LifeFlight division of HMCAS. Employee involvement and participation in quality improvement initiatives is therefore integrated into each employee's job description.

Therefore, for the purpose of this research study, recruitment and enrollment of participants is not required for retrospective analysis of the existing database. Furthermore, no data collection will be undertaken for the purpose of this study.

3.4. Research Procedures

Excluding data analysis (to be completed as formal research procedures), the HEMSTT methodology commenced on 1st August 2016 and forms the foundation for this study: (*Appendix VI*):

- ⇒ All LifeFlight HEMS records for Trigger Tool review were identified through the HMCAS centralized electronic database (Microsoft Access 2010, Redwood, WA).
- ⇒ A documentation clerk prepared and allocated all LifeFlight PCR data for the Raters (applied database inclusion / database exclusion criteria, coded the PCRs, and switched the PCR sample for each team to rate). This minimized the chances of Raters rating their own PCR.

- ⇒ PCRs were then reviewed by two independent Raters on each LifeFlight team.
- ⇒ The HEMSTT (*Appendix IV*) was applied to each PCR (*Appendix V*) and data captured on a Data Collection Spreadsheet.
- ⇒ Rater 1 and Rater 2 met and compared findings. If consensus was reached, it was captured on a Consensus Spreadsheet.
- ⇒ If consensus was not reached, the case was escalated to a third Rater who reviewed the PCR and finalized cases of disagreement.
- ⇒ A summary report was generated on a Data Summary Spreadsheet.

For the purpose of this study, the Primary Investigator (PI) will obtain authorized access to this established HEMSTT database in the form of a Data Summary Spreadsheet whereby 21-months retrospective data from all four LifeFlight teams for the stipulated study period will be extracted (by applying inclusion and exclusion criteria). Data will be analyzed according to the data analysis plan described in detail.

3.5. Database Development Methods

Clinical governance procedures at LifeFlight occur during normal working hours. For the purpose of understanding when these clinical governance procedures commenced and how the HEMSTT database is populated (*Appendix V*), the following methodology was employed at LifeFlight effective 1st August 2016 and continues to this present day:

- ⇒ A documentation clerk allocates each LifeFlight PCR, separates all PCR samples into one of four respective teams, applies a unique alpha-numerical Trigger code, and switches each team's PCR samples (i.e.- minimizing the chance of Raters rating their own PCR).
- ⇒ Raters receive the PCR samples from the documentation clerk.
- ⇒ Raters confirmed the PCR for database inclusion and exclusion criteria.
- ⇒ Each Rater documents baseline case and demographic details on the Data Collection Spreadsheet (Unique Trigger Number, Rater, Date, Incident Number, PCR Serial Number, Classification, Age, Case Classification, Provisional Diagnosis). No confidential information is captured from the PCR (i.e.- the treating practitioner nor the patients name).
- ⇒ Raters screen each sample PCR for triggers. If a trigger is present, the raters are required to document the trigger type, rate the most likely PC, and classify the level of harm. Records absent triggers are not reviewed further.

⇒ A maximum time limit of 15 minutes per PCR review is advocated, in accordance with similar record review timelines advocated by the GTT.

3.6. Data Safety and Monitoring

The HEMSTT database is secured on a password-protected computer server owned and maintained by HMCAS. A copy of the retrospective data will be made available to the PI after ethical approval is sought and obtained from both Medical Research Ethics Committee (HMCAS- Qatar) and EMDRC Ethics (UCT- South Africa). The PI will have access to the required database received from the Business Intelligence department of HMCAS. The PI's will undertake all retrospective data analysis on a password protected computer provided by HMCAS. All statistical analysis software and Statistical Process Control software will be provided by HMCAS. All HMCAS computers are backed up onto a computer server.

3.7. Data Analysis and Statistical Considerations

All data for reporting and analysis will be captured on standardized templates (Microsoft Excel 2010, Redwood, WA). Data analysis will employ Cohens Kappa as the measure of inter-rater reliability for each of the eleven Triggers and AE harm classifications. Univariate descriptive analysis will be utilized for each Trigger and level of harm classification, using descriptive statistics (Mean and IQR). Confidence intervals will not be required.

Statistical Process Control (SPC) is a methodology employed to differentiate between random and special cause variation, and involves plotting data over time. SPC charts will be generated on Minitab Version 17 (2010, State College PA) employing Nelson Rules for special cause variation detection. The data presented will be most suited to the use of U-charts.

The PI will retrospectively analyze data, calculate measures, percent agreement and agreement above chance (using Cohens Kappa for inter-rater reliability), plot run/U chart for each measure, and generate a Pareto chart of AE / harm severity classification.

Outcome measures, include:

- ⇒ Trigger rate per 100 patient encounters.
- ⇒ AE rate per 100 patient encounters.
- ⇒ Harm rate per 100 patient encounters.

No power calculations are required.⁶³

4. Ethical and Legal Considerations

4.1. Declaration and Conflict of Interests

The PI works for HMCAS and receives remuneration from in the form of a monthly salary for duties performed in his normal working capacity and job description. However, no financial incentive will be paid / received for participation in this research which forms part of standard clinical governance reporting structures within HMCAS.

4.2. Risks and Benefits for Participants

This research will contribute significantly to organizational learning and understanding of AEs within LifeFlight. The results will provide a clear foundation for future patient safety and quality improvement initiatives.

The PI (the only participant in this study) will derive certain benefit through the data analysis process in profiling, describing, and collating AEs within the LifeFlight division. There are no identified risks associated in analyzing the HEMSTT database, as the data contained within is anonymous with respects to both the patient and treating practitioner names. Furthermore, the HEMS Trigger Tool is a non-punitive methodology used to assess the frequency and PC of AEs, and not to assign blame. Rather, it's a tool to promote organizational learning.

4.3. Informed Consent Process

For the purpose of this study, no formal consenting is required, as all data extracted from the HEMSTT database forms part of standard clinical governance pathways within HMCAS, for which the patient, treating healthcare practitioner, and rater consent is not required.

4.4. Privacy and Confidentiality

No confidential information exists within the HEMSTT database. The only data available to the PI and extracted for the purpose of data analysis in this study is limited to 21-months of the following data entries:

- ⇒ Date
- ⇒ Case Number
- ⇒ Unique Alpha-Numeric Trigger Number

- ⇒ Patient Gender
- ⇒ Patient Age
- ⇒ Diagnosis
- ⇒ The presence of any eleven identified Triggers as defined by the PittAETT
- ⇒ The PC as defined by the PittAETT, and
- ⇒ Harm classification as defined by the PittAETT.

However, the PI retrospectively acknowledges that Raters (in the development phase of establishing the HEMSTT database) may have become aware of the names of the treating practitioners (i.e.- their work colleagues) documented on the PCRs, as each team would have been required to rate the opposite team's PCRs. However, this constitutes no greater risk to the treating practitioner than what they would ordinarily experience during normal clinical governance processes.

5. Limitations

5.1. Bias

The PI retrospectively acknowledges the opportunity for bias during rater PCR review (i.e.- throughout the HEMSTT database development) that may have presented in one of three possible ways:

- ⇒ Hand-writing recognition (paper PCRs).
- ⇒ The physical presence of the treating practitioners name on any given PCR.
- ⇒ The remote possibility of a Rater having to rate their own PCR (i.e.- if they worked an overtime shift on an adjacent LifeFlight team).

Application of the HEMSTT for case review effective August 2016 has transitioned from hand-written paper-based PCRs to an ePCR format. The PI acknowledges that any form of knowledge a Rater may have of the treating practitioner involved during case review may potentially lend itself to a somewhat biased assessment of the presence of an AE. However, the rating of any AE classification is typically preceded by the presence or absence of a Trigger. Each Trigger and AE have well defined criteria, to limit subjective and biased assessments during rating. Therefore, any potential bias or subjective Rater opinion is significantly limited. Furthermore, the HEMSTT agreement and consensus methodology of utilizing three independent Raters for each case review serves to further offset the potential bias any one particular Rater may have from inadvertent knowledge gleaned of the treating

practitioner concerned. Due to the time-consuming process typically required to anonymize PCR data, it was not considered cost-effective nor viable to prepare the data in such a way. Therefore, no attempts were made by HMCAS to anonymize the respective LifeFlight sample PCRs prior to rating.

Any methodology reporting agreement of observations between two independent Raters should be interpreted with caution, as the possibility of chance agreement and guessing exists. To test for this, data analysis will ensure the Kappa Statistic is used to assess the inter-rater reliability of the observed agreements, and correct for chance agreement.⁶⁴⁻⁶⁶

Due to resource limitations of LifeFlight personnel (i.e.- number of available Raters) within each LifeFlight team (i.e.- limited to a minimum of two CCP per team), there may have been times whereby a rater worked overtime on an adjacent team. This occasional circumstance may have inadvertently resulted in a situation whereby the rater would have rated his / her own PCR. In this unavoidable circumstance the PI retrospectively acknowledges that it would not be possible to prevent this. However, it would not bias the results significantly, as the HEMSTT methodology requires each PCR to be reviewed by 3 independent raters (where disagreement may exist).

5.2. Steps Taken to Decrease Impact of Limitations

Strategies to limit the potential bias described above are for the most part confined to the HEMSTT methodology and the way data will be analyzed in this study:

- ⇒ Utilization of the Trigger Tool methodology itself (limits bias described in *5.1 Bias*) by having three independent raters to resolve disagreement.^{21, 46} This is a documented strength of the trigger tool methodology, compared to more traditional case review methods.
- ⇒ Utilization of the Kappa statistic to measure agreement beyond chance (i.e.- to measure chance agreement and potential guessing described in *5.1 Bias*).^{64, 65}
- ⇒ A documentation Clerk prepared all PCR data for the respective teams. Each LifeFlight teams' sample PCRs were switched to minimize the frequency in which a Rater may have been required to rate his / her own PCR.

6. Dissemination of Findings Plan

6.1. Stakeholder Feedback

All relevant stakeholders within HMCAS have been appropriately engaged in this research proposal. Organizational approval has been sought and obtained from HMCAS. This includes:

- ⇒ Head of Professions, HMCAS (Dr. Nicholas Castle)
- ⇒ Senior Consultant Paramedic, HMCAS (Mr. Ian Howard)

All research results will be disclosed to all the relevant stakeholders concerned. Furthermore, the results of this research will be utilized to inform organizational learning and prioritize future patient safety and continuous quality improvement initiatives. We anticipate a number of quality improvement projects will stem from this research, with the intention to reduce and / or eliminate all potential sources of harm identified within the HEMS division on HMCAS.

6.2. Journal Publication

The intention is to publish this research in a reputable patient safety and quality improvement journal (e.g.- BMJ Quality and Safety Journal).

7. Project Timeline

Task:	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J
	2019												2020					
1. Proposal UCT (EMDRC)	■	■	■	■														
2. Ethics UCT (HREC)					■	■	■											
3. Proposal (HMCAS GROC)				■														
4. Proposal (MRC)					■	■	■	■	■									
5. Ethics (MRC)										■								
6. Postgrad Office (UCT)							■											
7. Data Collection										■	■	■	■	■	■			
8. Data Analysis													■	■	■	■		
9. Reporting Write Up																■	■	■
10. Intention to Submit																	■	■
11. Submit																		■
12. Graduate																		■

8. Budget

Jan - Sep 2019				
Item	Description	Unit	No	Total
Consumables				
1. Office Supplies	Provided by HMCAS (already in place)	00.00	20	00.00
2. Printing	Provided by HMCAS (already in place)	00.00	50	00.00
Research Travel				
Travel to HMCAS Headquarters Office	50km / per round trip (x 4 per month)	2	1600	3200.00
Research Equipment				
Computer	Provided by HMCAS (already in place)	00.00	1	00.00
Computer	Personal Laptop (already in place)	00.00	1	00.00
Printer	Provided by HMCAS (already in place)	00.00	1	00.00
Research Software				
Minitab Version 17 (2010, State College, PA)	Statistical Analysis Owned by HMCAS	00.00	1	00.00
MS Office 365		00.00	1	00.00
Personnel				
Primary Investigator	No payment received.	00.00	1	0
Research Supervisor (HMCAS)	Provided by HMCAS (already in place)	00.00	1	0
Research Supervisor (UCT)	Provided by UCT (already in place)	00.00	1	0
Statistician	Provided by HMCAS (already in place)	00.00	0	0
Total			QR	3200.00

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M: morbidity
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III. Ethics Approvals



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room E53-46 Old Main Building
Groota Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: shuretta.thomas@uct.ac.za

Website: www.health.uct.ac.za/fhs/research/humanethics/forms

16 July 2019

HREC REF: 438/2019

Dr W Stassen
Emergency Medicine
F51, OMB

Dear Dr Stassen

PROJECT TITLE: A TRIGGER-TOOL-BASED DESCRIPTION OF ADVERSE EVENTS IN HELICOPTER EMERGENCY MEDICAL SERVICES IN QATAR (MPHIL CANDIDATE - MR C G HEUER)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until 30 July 2020.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

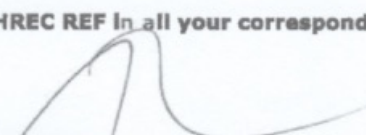
Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

The HREC acknowledge that the student, Calvin Grant Heuer will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Yours sincerely


PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.

HREC 438/2019

Institutional Review Board (IRB) number: IRB00001938

NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC 438/2019

APPROVAL LETTER
 MEDICAL RESEARCH CENTER
 HMC, DOHA-QATAR

Mr. Calvin Grant Heuer Ambulance Services HMC Ambulance Services (HMCAS) Hamad Medical Corporation		Date: 02nd June 2020
Protocol No.	MRC-01-19-291	
Study Title	A Trigger-Tool-Based Description of Adverse Events in Helicopter Emergency Medical Services in Qatar	
The above titled research study has been approved to be conducted in HMC summarized as below:		
Study type:	Data Review	
Data Collection Period:	01/11/2016 - 31/07/2018	
Team Member List:	Mr. Calvin Grant Heuer , Mr. Ian Lucas Howard	
Review Type :	'Exempt' under MOPH guidelines "Category 3: Research involving the collection or study of existing: Data, documents, records and the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects".	
Decision :	Approved	
Hospitals/ Facilities Approved:	HMC Ambulance Services (HMCAS)	

This study must be conducted in full compliance with all the relevant sections of the Rules and Regulations for Research at HMC and the Medical Research Center should be notified immediately of any proposed changes to the study protocol that may affect the 'exempt' status of this study. Wherever amendments to the initial protocol are deemed necessary, it is the responsibility of the Principal Investigator to ensure that appropriate reviews and renewed approvals are in place before the study will be allowed to proceed.

Please note that only official, stamped versions of the approved documentation are to be utilized at any stage in the conduct of this study. The research team must ensure that progress on the study is appropriately recorded in ABHATH, the online research system of the Medical Research Center.

We wish you success in this research and await the outcomes in due course.

Yours sincerely,

Prof. Michael Paul Frenneaux
 Chief of Scientific, Academic and Faculty Affairs
 Hamad Medical Corporation

18/06/2020

A handwritten signature in black ink, consisting of a circular mark followed by a long horizontal stroke and a small flourish at the end.

IV. PittAETool

Daniel Patterson P, Lave JR, Martin-Gill C, Weaver MD, Wadas RJ, Arnold RM, Roth RN, Mosesso VN, Guyette FX, Rittenberger JC, Yealy DM. Measuring Adverse Events in Helicopter Emergency Medical Services: Establishing Content Validity. *Prehosp Emerg Care.* 2014; 18(1)

Trigger Items

Documentation Triggers	
T1	Missing, incomplete, or unclear documentation for the following: chief complaint, physical assessment, vital signs, haemodynamic monitoring (e.g.: EtCO2), allergies, pertinent history or medications, patient condition at handover.
Operation & Patient Movement Triggers	
T2	Time from initial patient contact to transfer of care exceeds accepted standards.
T3	Injury to patient or team member during patient encounter/transport (e.g.: stretcher drop, needle stick, or other).
T4	Request for additional resources, personnel, or supervisor due to change in patient condition.
Patient Condition Triggers	
T5	A worsening trend (deterioration) in patient hemodynamic or mental status indicators (e.g., vital signs, LOC, GCS score).
T6	Cardiac arrest during transport.
Intervention & Medication Triggers	
T7	Use of any of the following interventions during patient care: (cardioversion, defibrillation, transcutaneous pacing, advanced airway attempt, surgical airway, Intraosseous (IO), chest decompression, chest tube).
T8	Failure of any intervention or procedure during patient care (some examples include: inability to obtain vascular access after a reasonable amount of time or number of attempts, failed IO, failed Nasogastric Tube (NG) placement, failed Foley placement, failed cardioversion, failed defibrillation, failed transcutaneous pacing, failed advanced airway or rescue airway, failed surgical airway, failed chest decompression).
T9	Use of following medications or fluids: (blood products, vasopressors or inotrope [e.g., dobutamine, dopamine], naloxone, RSI medications [e.g., succinylcholine]).

T10	Suggestive evidence of deviation from standard of care by performing an intervention or administering a medication that appears to be outside of protocol, or failure to perform an intervention or provide a medication that is within the standard of care.
T11	Medication error (e.g., administering wrong or unapproved dose, administering wrong or unapproved medication, administering medication via wrong or unapproved route).

Proximal Causes

	Actions by the Patient
PC1	<p><i>Definition:</i> The AE was the result of action(s) by the patient.</p> <p><i>Example(s):</i></p> <p>(A) Patient with capacity refuses transport to a specialty care facility.</p> <p>(B) Patient with capacity refuses treatment specified in protocol.</p> <p>(C) Patient with capacity discontinues ongoing therapy.</p> <p>(D) Patient takes action that results or may result in harm to themselves or others.</p>
	Actions by the Provider
PC2	<p><i>Definition:</i> The AE was the result of action(s) or inaction(s) by the crew.</p> <p>Category 2.1 – HEMS Crew (PC 2.1)</p> <p><i>Example(s):</i></p> <p>(A) Medication errors.</p> <p>(B) Procedural errors (i.e., oesophageal intubation).</p> <p>(C) Failure to zero the A-line prior to vehicle / aircraft moving.</p> <p>(D) Failure to confirm orders from medical command.</p> <p>(E) Failure to activate Cath-lab for STEMI patient.</p> <p>(F) Failure to treat pain (e.g., extremity pain or treatment as indicated by protocol or medical oversight).</p> <p>(G) Documentation error.</p> <p>(H) Inability to establish vascular access after a reasonable amount of time or number of attempts.</p>

	<p>(I) Failure to administer O2 to a hypoxic patient. (J) Failure to physically or chemically restrain a patient that is perceived to be at risk of harm to themselves or the crew.</p> <p>Category 2.2 – Non-HEMS (PC 2.2)</p> <p><i>Example(s):</i> (A) Delay in patient care due to delays by the referring or receiving facility (e.g., patient in CT scanner, patient receiving dialysis).</p> <p>NOTE - This is not where we will assign any issues related to equipment (i.e. stretcher drops) or failure to stock equipment. Those will be / should be assigned to Category 3; Medical or Vehicle Equipment.</p>
<p>PC3</p>	<p>Medical or Vehicle Equipment</p>
	<p><i>Definition:</i> Failure of the equipment, failure to troubleshoot and correct common problems with the equipment, or failure to remove defective equipment from service.</p> <p>Category 3.1 – HEMS Crew (PC 3.1)</p> <p><i>Example(s):</i> (A) Suctioning device malfunctioned during use. (B) An unanticipated malfunction with transport vehicle. (C) Nasal capnography not available or O2 supply diminished during transport. (D) All or any stretcher drop, tip, or malfunction. (E) Malfunction of laryngoscope or ET tube (e.g., bulb failure or balloon failure). (F) Fluid or medication pump failure or malfunction. (G) Ventilator malfunction. (H) Failure of cardiac monitor. (I) Missing equipment that is needed for use.</p> <p>Category 3.2 – Non-HEMS (PC 3.2)</p> <p><i>Example(s):</i> (A) Delay in transport due to patient’s weight. (B) Delay in transport due to lack of appropriate equipment (non-hems).</p>

	Environmental/Scene Factors
PC4	<p><i>Definition:</i> Factors that may result from weather conditions or factors on the ground/scene (or other). This includes temperature, light, and scene safety.</p> <p><i>Example(s):</i></p> <p>(A) Cold causing fogging of optics on a Video laryngoscope system.</p> <p>(B) Freezing of fluids or drugs (e.g., mannitol).</p> <p>(C) Diversion to a non-trauma centre due to weather conditions for a trauma patient.</p> <p>(D) Scene not safe delaying landing or take-off, prolonging on-scene time or pre-arrival (e.g., a remote landing zone).</p> <p>(E) Delay in managing patient's airway due to prolonged extrication.</p> <p>(F) Delay due to prolonged arrival by ground or intercepting crew.</p> <p>(G) A delay in patient packaging and transport due to weather.</p>
	Undetermined by Case Review
PC5	<p><i>Definition:</i> The proximal cause of the AE (regardless of severity) cannot be determined by the information available in the chart.</p>

Severity Rating

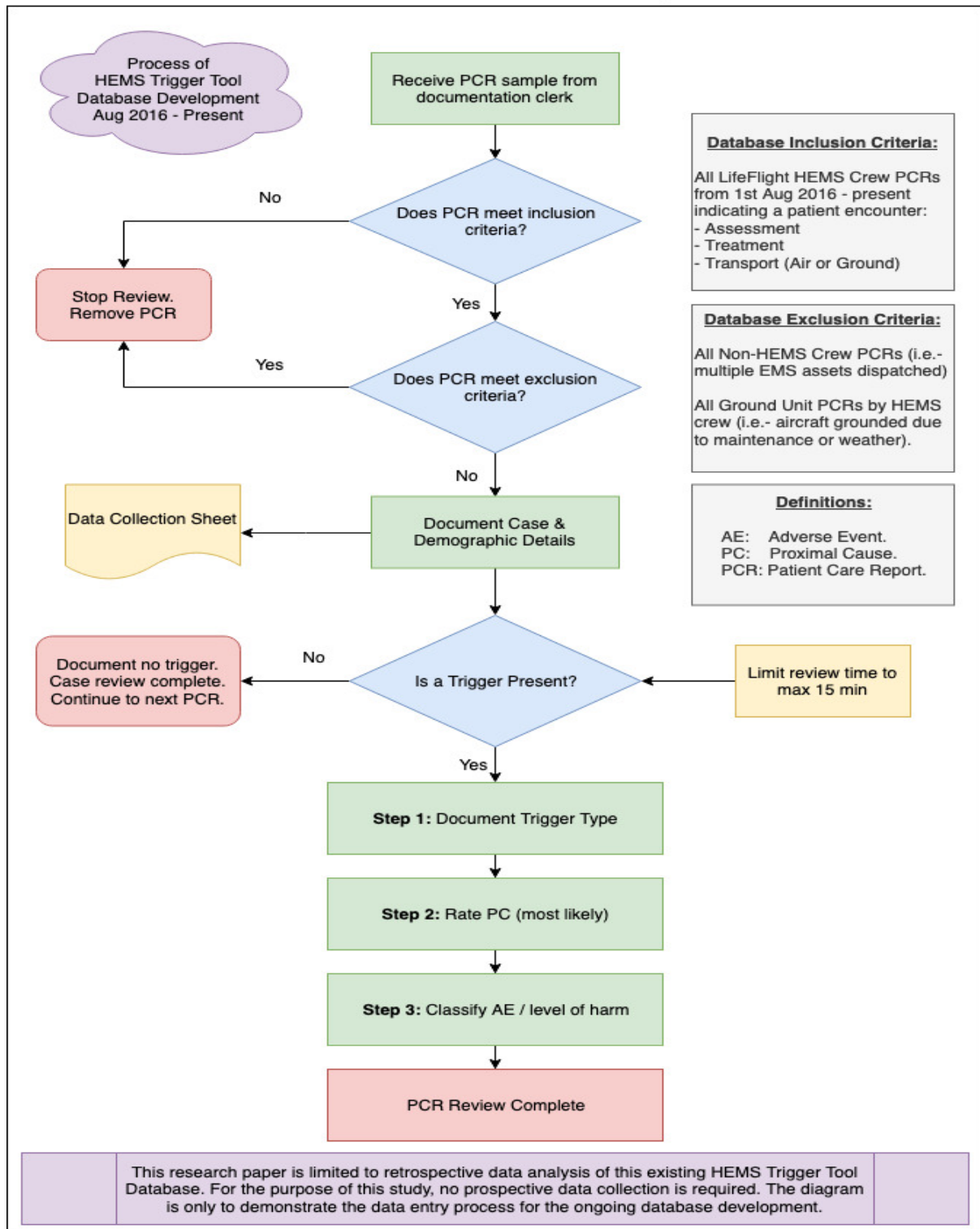
	No Adverse Event
AE99	<p><i>Definition:</i> A case where a Trigger was selected (e.g., cardiac arrest during transport), but no AE identified after full review.</p> <p><i>Example(s):</i></p> <p>(A) Cardiac arrest during transport, but all documentation supports the crews committed no error and followed protocol(s) as prescribed.</p> <p>(B) Trigger selected due to administration of a medication (e.g., naloxone). However, the use of naloxone was indicated for patient overdose of opiate and is not related to delivery of care (e.g., the crewmembers did not overdose the patient).</p> <p>(C) The time to transport the patient was delayed for necessary care, diagnostic procedures, or interventions outside control of medical crew (e.g. the patient was in the CT scanner at the referring facility or the patient requires</p>

	<p>a balloon pump, which will require longer time at bedside during the transition of care).</p> <p>(D) Missing, incomplete, or unclear documentation.</p>
<p>AE1</p>	<p>Adverse Event Present – Potential for Harm</p>
	<p><i>Definition:</i> An action that may lead to injury or harm but there is NO evidence that an injury or harm occurred.</p> <p><i>Example(s):</i></p> <p>(A) A medication error in which one type of medication (e.g., ketamine) was administered to an intubated patient for sedation in place of more appropriate medication or medication listed as the standard of care (off-line protocols e.g., Versed).</p> <p>(B) A 22kg paediatric burn patient received 0.2mg/kg of morphine (4.4mg total) for pain rather than 0.1mg/kg (2.2mg total). The paediatric patient may exhibit no adverse reactions (i.e. hypotension and reduced respirations).</p> <p>(C) Administration of 500cc of saline when 300cc bolus was ordered by medical oversight.</p> <p>(D) Patient received 4mg of Midazolam when the oversight physician ordered 2mg.</p> <p>(E) Failure to administer ASA for a patient with chest pain for suspected cardiac aetiology.</p> <p>(F) Failure to check vital signs before and after medication administration (i.e., Nitroglycerin).</p> <p>(G) Not adequately protecting patient's airway. For example, no airway adjunct utilized for an unconscious patient with normal vital signs and no evidence of desaturation.</p> <p>(H) Stretcher dropped or tipped, but no evidence the patient or crew member(s) were injured.</p> <p>(I) Failure to immobilize a fracture in a trauma patient.</p> <p>(J) Failure to control haemorrhage in a hemodynamically stable patient.</p> <p>(K) Administration of Nitroglycerin to patient with documented use of phosphodiesterase inhibitors (e.g., Viagra). No evidence of hypotension is found.</p> <p>(L) Immediately recognized and quickly corrected missed intubation with no evidence of patient deterioration.</p>

Adverse Event Present – Harm Identified	
AE2	<p><i>Definition:</i> An action or omission that led to injury or harm regardless of severity.</p> <p><i>Example(s):</i></p> <p>(A) Delay in recognition of missed intubation with evidence of patient deterioration; or failure to control airway within a reasonable amount of time or number of attempts with evidence of patient deterioration.</p> <p>(B) A seizure patient administered 4mg Midazolam when medical oversight gave orders for 2mg. The patient lost spontaneous respirations. Crewmembers responded by use of BVM ventilations and intubation.</p> <p>(C) Crew member intends to administer amiodarone for treatment of wide complex tachycardia at rate of 160. Crew member administers 10 mg Diltiazem and patient suffers a v-fib arrest.</p> <p>(D) Stretcher drop with injury to patient.</p> <p>(E) Failure to administer eclamptic patient Magnesium Sulphate and then seizes for a period of time.</p> <p>(F) Patient with a GCS <8 and evidence of respiratory compromise (i.e., SPO2 <90) but no airway intervention by crewmembers.</p> <p>(G) Crewmembers fail to activate specialty team where indicated (i.e. trauma team, Cath lab, stroke alert).</p> <p>(H) Failure to decompress a tension-pneumothorax</p> <p>(I) Failure to adequately sedate a patient that was intubated as evidenced by follow-up from receiving facility that documented patient recall of events.</p> <p>(J) Administration of Nitroglycerin to patient with documented use of phosphodiesterase inhibitors (e.g., Viagra). Hypotension results.</p> <p>(K) A patient suffering from anaphylactic reaction is administered 0.3mg of Epinephrine 1:1000 Intravenous (IV) instead of Intramuscular (IM) and develop acute chest pain and change on EKG monitor.</p> <p>(L) Use of unsynchronized cardioversion in a patient with unstable Atrial Fibrillation (AF) that results in Ventricular Fibrillation (VF) or asystole.</p>

V. HEMS Trigger Tool Database Development

HEMSTT Database Development



VI. HEMS Trigger Tool Methodology

HEMSTT Methodology

