

**ADVERSE EVENT REGISTRY ANALYSIS OF AN EMS SYSTEM IN A LOW
RESOURCE SETTING: A DESCRIPTIVE STUDY**

by

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Abbreviations

CINAHL: Cumulative Index to Nursing and Allied Health Literature

CIRS: Computer Incident Reporting System

EMS: Emergency Medical Services

HEMS: Helicopter Emergency Medical Services

HMPS: Harvard Medical Practice Study

HIV/AIDS: Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome

PICU: Paediatric Intensive Care Unit

PIE: Population/Issue/Effect

STROBE: Strengthening of Observational Studies in Epidemiology

Part A: Literature review

Introduction

Adverse events and near misses arising from medical error is a concern in international emergency medicine, for both the in-hospital and out-of-hospital setting. We noted a number of adverse events and near misses reported to an Emergency Medical Services Quality Assurance Committee in a resource-limited setting, and sought to establish the literature regarding preventable and non-preventable medical error in medicine, both in Sub Saharan Africa and internationally.

Before we are able to act to implement recommendations to decrease both individual and system error, we need to record and report current demographics and trends. The literature review that follows describes current ways of detecting, reporting, and trends in medical error reporting worldwide – especially in the emergency medical services located in resource-limited settings.

The possibility of doing harm to the patients we treat is a fear of every conscientious medical practitioner. Some harmful outcomes, or adverse events, are unpreventable – a classic example of this is the patient with an unknown penicillin allergy who is prescribed amoxicillin for the first time. However, preventable adverse outcomes (those that would have been prevented, had the error not occurred in the first place) happen daily in every area of patient care. Preventable adverse events are by their definition due to error. (1) Detecting error is not always straightforward. System errors and various types of personal errors occur, and adverse events do not necessarily result unless a few of these errors occur at the same time, and multiple systems fail to prevent the adverse outcome (holes in the Swiss cheese- model). In addition, even where errors are detected, they are often not reported, not spoken about, and not further investigated due to various factors, which we will be discussing in more detail. The fact remains that in order to prevent errors and the resultant preventable adverse outcomes, we need to know what is happening currently.

The reported numbers of adverse events are high; so high that in fact medical error was recently estimated to be the third leading cause of death in the United States. (2) Emergency medicine, and especially the emergency medical services, is far more prone to error.(3–6) The unpredictable, fast-paced, distraction-filled environment lends itself to error constantly.(5,6) The effect is compounded in low resourced systems with their unique challenges. We cannot entirely eliminate error, but as we recognise the factors surrounding error and adverse events, we can take steps to prevent and mitigate the harm being caused.

Aim

The aim of this literature review was to describe an overview of the types of errors that occur, recommendations reported, and systems in place to detect, measure, and improve patient safety in low-resourced, emergency care settings.

Methods and Search Strategy

We conducted a search of PubMed, AfricaWide, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) using the following search terms:

Emergency Medical Services OR prehospital care OR “out of hospital” care OR emergency health services OR ambulance* AND Adverse events OR safety management OR adverse occurrences OR iatrogenic OR error

We excluded non-English articles, commentaries, letters to the editor, and abstract-only publications. Articles that predominantly discussed provider safety (for example ambulance accidents) were reviewed, but excluded from the discussion. Citations that involved combat settings were also excluded.

Altogether 2951 references were retrieved. Most were excluded by title review. Articles deemed relevant were initially reviewed by abstract, and those considered for inclusion by reviewing the full article. We searched the references cited by all retrieved articles, in order to identify additional potentially relevant publications. Altogether 41 articles that related to patient safety in the emergency care setting were included in this critical review of the literature.

Quality Criteria

Articles were assessed by the authors using the Critical Appraisal Skills Programme (7) checklists. Each article was assessed for internal and external validity, including the presence of bias. Following this, each article was critically evaluated in order to assess whether or not the information could be applied to the local resource-limited emergency care setting.

Definitions

Error: The failure of a planned action to be completed as intended or the use of an incorrect plan to achieve an aim. (8)

Adverse event: An injury resulting from a medical intervention, rather than the patient’s underlying condition. (9)

Patient Safety: the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. (10)

Harmful incident (adverse event): an *incident* that resulted in *harm* to a patient. (10)

Near miss: an *incident* that did not result in the harm to a patient. (10)

Latent error: An error whose adverse consequences may lie dormant within the system for a long time, only becoming evidence when they combine with other factors to breach the system's defences. (11)

Cognitive error: An error in the process of thinking (11)

Affective error: An error when there is an inordinate intrusion of affect into the decision-making process that results in a poor decision and may lead to a poor outcome. (11)

System: set of interdependent components interacting to achieve a common aim. These components may be classified in various ways: sociographic factors include national, organisational/institutional, health-care provider, and patient/family. (11)

Patient safety and adverse events

The most well-known and widely cited study related to patient safety is the Harvard Medical Practice Study (HMPS, 1984). (12) This extensive and well-conducted trial was the first of its kind. During 1984, 31,429 records were screened for adverse events (and whether or not they were caused by negligence) by using a validated process. Adverse events were defined as complications that arose from medical management rather than from the patient's condition, and included both unpreventable events (an example is cited where a patient developed a deterioration in renal function after exposure to contrast during angiography) and preventable events (arising due to error, including negligence). The authors estimated that 3.7% of all patients hospitalized in 1984 in the State of New York sustained adverse events, and that the overall incidence of negligence was 1.0%. Extrapolated to the total number of patients discharged in New York in this year, they estimated a staggering 98 609 adverse events, of which 27 179 were due to negligence. Of these adverse events, 2.6% resulted in total disability and 13.6% resulted in death. Adverse events that occurred due to negligence were more likely to result in serious disability. (3,12) The authors noted possible sources of error in conducting the study, including missing records and the agreement and judgment of the physicians reviewing the records to identify the adverse events and/or negligence. (3,12)

Thomas et al used a similar methodology to detect adverse events in the states Utah and Colorado in 1992, and found 459 adverse events during that time. When extrapolated to discharges in the both states, they estimated 16 609 total adverse events, with a total cost of over 650 million US dollars. (4) The results of both studies made the medical community take notice that adverse events and negligence were occurring regularly and that patient safety needed to be addressed. In 1999, the Institute of Medicine in the United States released its

landmark report: *To Err is Human – Building a Safer Health Care system*. (8) In its opening statements, it not only quoted the two studies above, but further extrapolated the data from three states to the entire hospitalised population of the United States in one year by suggesting that between 44,000 and 98,000 Americans could die every year as a result of medical errors. This exceeds the fatalities due to motor vehicle accidents, breast cancer, or HIV/AIDS. In Australia, a large multi-centre, two-phase trial, consisting of medical record review, revealed an overall proportion of admissions associated with an adverse event of 16.6%. (13) In 1979, Steel et al examined the medical records of 815 patients admitted to the medical wards of a university teaching hospital, and discovered that 36% had iatrogenic illnesses which reflect a higher number than estimated by the studies above.(14) Similarly to the HMPS, *iatrogenic* implied an illness that resulted from either a diagnostic procedure or any form of therapy. According to the authors, their methodology did not include negligence or culpability on behalf of the carers, or that the event was preventable. However, although it was a smaller study with less stringent criteria, the incidence of adverse events was higher than in the HMPS. (14) The authors of the Institute of Medicine report noted that the report underestimated the prevalence of error. (8)

In 2013, in a review article of four more modern studies, James et al estimated that at least 210,000 deaths per year in the United States result from medical errors.(1) The most recent estimate, based on studies published since the report, estimates the deaths per year in the United States resulting from medical error at 251,454. This ranks medical error as the third leading cause of death in the United States with only cancer and heart disease causing more deaths. (2) These figures are staggering and therefore disallow further complacency. Unfortunately, the patient safety literature is limited in low resourced countries. The majority of data available on patient safety is based on chart review and single centre studies, particular topics such as transfusion, maternal morbidity, and paediatrics.(15)

An interesting alternative strategy to detecting adverse events was described by Andrews et al in the *Lancet* in 1997.(16) Ethnographers experienced in studies of medical error attended ward rounds and meetings in three different units within at large urban teaching hospital. These observers recorded all data mentioned about adverse events at morbidity and mortality meetings. Health care providers identified at least one adverse event (as defined by the researchers) in 45.8% of all patient admissions. These included events that did not lead to harm, and therefore according to our criteria would be defined as near misses. The authors noted that 17.7% of admissions suffered serious harm as a result of an adverse event. Some limitations of this study include that the observers were only present for discussions at ward rounds and formal meetings, and not for other discussions (or adverse events that have gone undetected). The authors believed that these results, although much higher than the HMPS, was still an underestimate of the true number of adverse events occurring. (16)

Adverse events in emergency medicine

Intuitively we anticipate a high prevalence of error in emergency medicine. Factors such as high levels of diagnostic uncertainty, high cognitive load, multiple interruptions, shift work, inexperience, and poor feedback lead to multiple opportunities for error to occur. (17) Emergency medicine was not studied as a specialty in the HMPS, but when the authors considered the location within the hospital at which that adverse events occurred, only 3% occurred in the emergency centre. (The highest number of adverse events, 41%, occurred in the operating theatre.) However, a disproportionately high number of adverse events due to negligence occurred in the emergency centre (70%) compared to other sites (41% in patient's hospital room, 14% in the operating theatre). The authors surmised that, because not many highly invasive procedures were performed in the emergency centre, the adverse events that occurred there were more likely caused by diagnosis or prevention errors and effects of non invasive treatment. Other possible factors listed by the HMPS included non permanent doctors in the emergency centre, a high patient load, and a higher acuity of the patient population. (3) Similar to the HMPS, in the Australian study, emergency centre errors accounted for only 1.5% of the total errors reported, however, the emergency centre errors had the highest preventable errors proportion (82%). (13) For all three major studies, the majority of adverse events occurred in the emergency centres were due to diagnostic error, which more commonly led to disability and death. (3,4,12,13) The first report on error in emergency medicine specifically was published in 1999, where Robert Wears compared the magnitude of adverse events in emergency medicine to two airliner disasters every three days and called for a change from the traditional way that errors are discussed. (18)

A study based on voluntary reporting in a busy emergency centre in the United States found an error rate of 18%, but an adverse event rate of only 0.36%. (9) The discrepancy in results when compared to the HMPS is most likely due to methodology used, but it is also worth noting that the authors mentioned that emergency centre patients were only in attendance for a short period of time, allowing less time for errors and subsequent adverse events to occur. The authors suspected that the study results were an underestimate of the true error and adverse event rates that occurred in the emergency centre. They had not questioned populations such as patients, cleaners, and radiographers in the study, and suspected that this, together with fear of liability and condemnation, may have led to under reporting of errors. (9) It is worth noting that patients in the study who were affected by errors were older, which may be an indication of the complexity of care involved in treating the elderly. (9)

The above studies highlighted a few important facts. Firstly, that a large amount of death and disability occurs worldwide in every speciality due to errors and preventable adverse events. Secondly, a large number of adverse events that occur in emergency medicine are preventable. A glaring limitation in the above studies is that only admitted patients were studied, and errors

that may have occurred in the emergency centre involving patients that were discharged, were not included in the analysis.

Adverse events in the emergency medical services

The emergency medical services (EMS), especially in low-resourced settings, are fraught with time pressure, lack of resources, poor communication, an often acutely ill patient population, and multiple other stressors that may lead to adverse events. (6,19) There is a paucity of research into out of hospital patient safety, which currently tends to examine areas of information that is easy to obtain and analyse retrospectively). (6) There are various themes in adverse event reporting literature, which include air transport safety, ground vehicle safety, personnel safety, qualitative studies on provider perceptions of adverse events, and review of various triggers such as patient fatalities and out of hospital intubation. While improved provider safety will obviously result in improved patient safety, we did not include specific studies regarding provider safety (including ground vehicle safety and prevention of collisions) in this literature review, as they do not bear much relevance to our study. Reasons to investigate adverse events in emergency medical services include identifying system and individual errors, mitigating risk, and improving future patient safety. (20) Various studies have attempted perform this in various ways.

In Canada, MacDonald et al looked at the adverse events in an air ambulance programme reported via a mandatory adverse event reporting system. This computerised system, known as the Decision Support Application, is a web-based portal which stakeholders can use to log inquiries, complaints, and adverse events. Adverse events in this case were not necessarily due to error, but included weather, aviation problems, and system difficulties. Adverse events that did not result in harm were also included. Over a four and half year period, the rate of adverse events was 11.53 for every 1,000 flights. This is much less than the rates reported by the in hospital studies. Reporting bias may have led to decreased reports of adverse events in this study. The authors also noted another source of under reporting of errors that occurred during air transport but that went undetected. They suggest that even if errors are detected at the receiving facility, they may not be attributed to the air transport, and will result in an even lower reporting rate. (20) Although the classification system used by the researchers did not specify the difference between individual and system failures, over one third of the adverse events leading to patient harm were clearly attributable to transport vehicle or equipment failures. Other errors such as communication and patient factors may also point to system errors rather than to individual errors. The study also did not interrogate any recommendations or implementations resulting from these investigations or reports. (20) The secondary outcomes of the studies involved the demographics of the patients who sustained adverse events. The number of males and females were nearly on par, and the two most common categories of cases

involved in adverse events were trauma and cardiac pathology. Interestingly, although no mention was made in the text, the mean age that sustained adverse events was 44, and paediatrics was not included as a separate patient category. (20) In Germany, Hohenstein et al implemented a computer based Incident Reporting System (CIRS) which comprised of a voluntary, anonymous, web-based reporting system for adverse events. They advertised via emergency medicine congresses and journals, and requested anonymous reporting of adverse incidents. An expert committee then evaluated the reports, determined whether or not the report met criteria for one or more incident(s). (21) The study analysed 845 reports over a seven year period. Of the reports analysed, 91% of patients were over the age of 14, and the most frequent complaint was medical problems (50%), followed by trauma problems (25%). Individual staff error attributed 57% of the incidents, and system errors such as *organisation and tactics* and *equipment* contributed 36%. The remainder were classified as *other cause* or *no incident*. (21) The study's advantage of anonymous reporting meant that a higher number of incidents were reported without fear of discipline or retribution; however, there were also additional concerns with voluntary reporting such as fictitious cases and competing commercial product companies trying to publish false reports about other company's products. However, these were suspected to form a very small number, of the reported cases. Other concerns with voluntary reporting include recall bias.

A high proportion of incidents were associated with life threatening situations. This may be due to either that more adverse events occurred during life threatening situations, or recall bias of life threatening situations – that potentially poor patient outcomes triggered the reporting of the incident. Another disadvantage of the voluntary reporting system is that latent errors may have been undetected. Due to the anonymous nature of the reporting, not only is a full investigation and root cause analysis impossible, but follow up to determine patient outcomes related to the adverse was also difficult. (21) Another interesting finding that the authors failed to comment on was that in only 23% of incidents did the person responsible for the incident actually enter the report themselves. (21)

In Victoria, Melbourne, a special committee used road traffic fatalities as a trigger to identify preventable deaths and various errors. From 1992 to 2003, the committee reviewed all data related to patient care of road traffic accident fatalities by only including patients who died after the arrival of an ambulance. They then categorised the errors identified into five categories: system error; treatment/management error, error in technique, delay in diagnosis, and error in diagnosis. Boyle et al reviewed all reports published by this committee, and noted an increase in the mean error rate over a 10-year period. The average age of those who demised was between 41 and 45 years, and the gender distribution 70% male to 30% female. (22) During the first half of the study period, the system errors decreased in number, while individual errors of diagnosis, technique, and management increased. However, during the second half of the study period, there was an increase in both system and individual error, while individual errors in

management declined. (22) The authors seem to attribute the rise in errors to the introduction of advanced life support paramedics in 2000, but there is no additional evidence to substantiate this or to demonstrate causality. Of note, throughout the study period, there were increased error rates in the rural areas when compared with metropolitan areas. (20) There were multiple limitations to this study. The study used a retrospective analysis model based solely on published data of fatality, and therefore could not have extrapolated errors in this prehospital system as a whole. The study examined only road traffic accident victims, and no other patient categories, and also only focused on patients that died. Errors that resulted in no to mild patient harm, or even in disability, would have been missed. (22)

Detection of adverse events in the emergency medical services

Detection of adverse events is a challenge, and always has been - both historically and globally. The landmark HMPS, Utah and Colorado, and Quality in Australian Health Care studies used record review which is a time and resource consuming process when done well. (3,4,12,13) In our Western Cape setting, 10% of patient report forms are scanned monthly for errors that may result in either adverse events or near misses. Alternative strategies include clinical surveillance, direct observation, (19) observers at ward rounds, (23) and morbidity and mortality meetings (23). However, there would need to be a trigger to initiate these conversations about adverse events, either during ward rounds or at the morbidity and mortality meetings. Voluntary reporting is effective, accurate, less time and resource consuming, and doesn't require a specific trigger other than detection of a potential event. (21) However, fear of stigma, liability, and perhaps even the effort involved to report an adverse event may result in severe under reporting.(24) Some studies used anonymous reporting tools in order to try to overcome this barrier. (24,25) A review of complaints and/or claims against a system is a simple, but limited, detection tool. Curka et al and Colwell et al identified many system and personal errors by examining complaints against EMS systems, although there were multiple limitations by the retrospective methodology used in the majority of cases. Even in affluent areas, patients and family members tend not to lodge formal complaints. (26,27) It is important to note that in under resourced areas, certain population groups may be less inclined to complain or to seek compensation for injury or damage. This may be due to cultural differences, illiteracy, or even a lack of knowledge about how to access reporting systems. Patterson et al, using a panel of experts, developed a complex adverse event detection framework for use in helicopter emergency medical services (HEMS), in which various documentation, operational, interventional and other triggers led to further investigation of the event. Further interrogation of each event aimed to describe proximal cause and ascribe severity to the event. (19) The committee's agreed definition of adverse event included

situations in which potential harm could have occurred to the patient, and therefore cases with our definition of near miss would be included. (19)

One very important reason for not identifying adverse events due to errors, as noted by Baylis in an article in the *Journal of Clinical Ethics* in 1997, is that adverse events are often due to multiple factors, and it is often difficult to distinguish whether in a series of events only one error led directly to harm. (28) This may also lead to under reporting, as the provider may not feel that the definition of adverse event may not explain the situation. A second reason for under reporting may be that the well-meaning clinician genuinely is concerned that disclosing or reporting the error may not have any benefit, and may actually lead to further harm (for example by undermining the patient's faith in the medical system as a whole).(28) Some of the less well-intentioned reasons are recognisable. Examples include fear of litigation, loss of professional reputation, and undermining relationships with colleagues, all conspiring to the under reporting of errors and/or adverse events. (28)

In emergency medicine particularly, despite the fact that (as already noted above) errors are likely to occur regularly, physicians, nurses, and EMS providers alike note a reluctance to report. In in a single centre survey, less than a quarter of providers who had committed an error in the past year had reported the error governing body or committee, or disclosed the error to the patient themselves. (29) There was no further questioning of the reasons for non-disclosure. (29) Fairbanks et al conducted a qualitative study to examine the perceptions of EMS providers regarding adverse events and near misses in prehospital care. (24) The methodology included an anonymous web-based adverse event reporting system linked to a popular online discussion board; semi structured interviews, and two focus group discussions. The respondents consisted of both career and volunteer EMS providers, ranging from basic to advanced life support providers. Altogether, 61 individual events were detected, of which 44% were near misses, and 56% were adverse events. (24,25) The definitions used correspond with those above. In both the overall analysis as well as a subgroup concerning paediatrics, the theme of under reporting was repeated. (24,25) Of the 61 incidents detected, the respondents were questioned about reporting in only 21 cases. Of these, 43% were reported to a physician, 48% were reported to a supervisor, and none were reported to a patient. These rates seem higher than the reporting rates of other studies. However, all of these incidents were "reported" in during the study, and so other unreported errors may not have been included in the final total. (24) It is interesting that the directly quoted statements (see box 1) seem to reflect a reluctance to report co-workers' mistakes. In the German anonymous critical incident reporting system, however, only 23% of reports were entered by the person responsible for the incident. (21) Is it possible that the anonymity of the reporting system removes the fear of reporting co-workers' errors? Some other reasons for under reporting that emerged include: a blame and shame culture, bravado and fear of failure, medico-legal concerns, antagonism and criticism – worsening with increasing seniority, and lack of understanding of the definitions of and differences between adverse

events, near misses, and errors.(21)

Box 1: Some direct quotes from EMS providers:

- “The job is an adverse event”, (24)
- “Some ambulance corps are so small that no one gets fired, so reporting errors doesn’t matter.”(25)
- “You don’t want to rat on friends and you want to save your own ass as well”.(25)

Themes associated with errors included a lack of standardisation, antagonism between providers, and a blame culture. (24) In another qualitative study in 2009, the interviewees identified that patient safety and adverse events should examine more than just medication errors and vehicle collisions. (30) Interestingly, 75% of participants identified clinical judgement (including recall and the processing of complex clinical information) as being the key issue in patient safety. Training inadequacy was noted as a significant factor, and non-transport of patients was another key issue in patient safety. The participants did relate patient non-transport to both clinical judgement and training. (30) The article was poorly written, not well referenced, and included only a small sample of 18 participants. The researchers specifically asked the participants (predominantly EMS providers from Canada) about medication errors. Once again, the concern emerged that medication errors are seldom reported. (30) Reasons given for under reporting of medication errors included fear of liability, but also that, errors go unnoticed, errors are not recorded, and EMS providers from multiple agencies do not feel that they are part of an overall system. (30)

Curka et al and Colwell et al examined complaints against EMS systems in the United States by retrospective review. (26,27) Both studies had some limitations, such as the data was limited to complaints filed previously, and in the Colwell study the medical director of the service in question had summarised the complaints for two of the years, which may have led to bias. (27) Another limitation of both studies is, once again, was under reporting. Despite errors, dissatisfied patients and family members, the authors suspected that the majority did not lodge formal complaints. (19,20) While the authors did not use the terms adverse event or error specifically, complaints are an important trigger tool for identifying potential errors that were made while the patient was under EMS care. Complaints highlighted personal errors in judgement, driving skills, non-transport decisions, and medical care, as well as system errors in response times, loss of personal belongings, and billing queries. No comment was made as if errors were found to be present by further investigation, or if adverse events had arisen from the noted errors made. (26,27) The authors of the Colwell study noted that the majority of complaints were initiated by the patients themselves, with less complaints originating from other medical personnel, and still less from patient family members. In the Curka study, most

complaints were initiated by family members of patients, or the patients themselves, with very few complaints originating from other medical personnel. The majority of complaints related to the provider/patient relationship, with 25% of total complaints (Cowell) and 34% of complaints (Curka) resulting from rude or unprofessional behaviour. (26,27)

Another high-yield area where adverse events and errors may occur is when patients are not transported to hospital. In a small US study examining a single city-wide EMS system for one month only, in almost half (47.8%) of all cases in which EMS contact was made, the patient was not transported to hospital. (31) This included both patients who refused transport themselves, as well as cases in which the EMS refused to transport a patient. With no statistically significant differences between the two groups, more than half (55.5%) of the patients in both groups later sought additional medical attention. (31) Zachariah et al retrospectively reviewed patients who had either refused or been denied transport to hospital, and found that in 64.5% of cases that were followed up, the patients sought further medical attention. (32) Burnstein et al prospectively enrolled consequent patients who refused transport to hospital and reviewed them telephonically. Follow up was possible in only 62% of cases, and of these, 48% of patients subsequently sought medical attention and 6% were admitted to hospital. (33) Both follow up bias and observer bias were suspected in this study, and due to the low follow up rate it is possible that the actual number of subsequent admissions was greater than reported. The authors concluded that where possible, every attempt should be made to transport patients who have contacted an EMS service for assistance, to formal medical care. (33)

Bigham et al performed a systematic review of all literature relating to prehospital adverse events and patient safety between 1999 and 2011. They included 88 papers in the final review, of which 16 related predominantly to field intubation. From the beginning, due to the large amount of literature available on prehospital intubation, it was decided to include intubation as a stand-alone theme. (6) Prehospital intubation is an area fraught with error and adverse events and is therefore a good trigger for the identification of adverse events within the emergency medical services. An unrecognised non-tracheal intubation (into either the pharynx or oesophagus) may be fatal and counted as an entirely preventable death.(34) Intubation is associated with an increased morbidity and possibly mortality in both adult (35) and paediatric (36–38) patients. Non-tracheal intubation; including tube placement above the vocal cords or misplacement in the oesophagus but excluding mainstem bronchus placement ranges from 2% to 25%. (34,39–42)

Even in cases where an endotracheal intubation attempt resulted in a successful intubation, the incidence of error, resulting in both near misses and adverse events, may be marked. Dunford et al, as a subset of the San Diego Paramedic RSI trial that was conducted between 1998 and 2002, analysed the incidence of desaturation (defined as a decreased in SPO₂ as measured by pulse

oximetry to less than 90% from a baseline greater than or equal to 90%, or any decrease from a baseline SPO2 of less than 90%) and pulse rate reactivity (an increase or decrease in the pulse rate of more than 20 beats per minute) during 54 pre-hospital rapid sequence intubations. (41) Of these, 31 (57%) of these cases showed evidence of desaturation during the rapid sequence intubation procedure, including 11 (36%) that developed a bradycardia of less than 60 heart beats per minute. What is of even more concern is that in 86% of the cases where desaturation occurred, the intubation was rated as easy by the intubating paramedic. (41) Wang et al evaluated the Pre-hospital Airway Collaborative Evaluation, Phase II (PACE II) data. (39,43) This was a large, prospective, observational study, involving feedback forms from 42 advanced life support EMS paramedics in Pennsylvania. Unfortunately, as noted by the authors, the study was based on self-reported data, and they expected the error rate to be higher than actually reported by the study. There was a returned data rate of only 68% (reflected by the returned data forms compared with the recorded number of intubations by computers at each service). (43) The results of the returned data forms showed an error rate of 22%. These errors included tube misplacement or dislodgement of 3%, failed intubation in 15%, and multiple intubation attempts in 3%. They later compared the data against registries such as the Pennsylvania death registry, in order to determine outcomes in these cases. Overall, the mortality rate of all reported patients who had attempts at endotracheal intubation was as high as 73%, of which in 60% of cases the patient was already in cardiac arrest (which most likely contributed to the poor outcomes.) Once the cases of cardiac arrest were corrected for, there was no statistically significant difference in the mortality outcomes of cases with intubation errors versus those cases in which no error was detected. However, the study shows that both error rates and adverse events were high in cases with prehospital endotracheal tube intubation. (39,43) In our Cape Town setting, Sobuwa et al evaluated prehospital intubations in 124 patients with traumatic injuries, and found a statistically significant improvement in outcome in patients managed with basic facemask ventilation over higher risk endotracheal intubation attempts. (44) The literature and argument is not clear as to whether pre-hospital intubation should be avoided, or whether better training should be implemented – however, it is clear that it is a high-risk area where adverse events should be identified and studied.

It is worth noting that paediatrics seems to be an area where proportionally more adverse events are reported, compared to other patient populations. In the qualitative Cushman et al study mentioned above on adverse events in EMS, 20% of cases mentioned by providers related to children which is substantially more than the 12% of paediatric cases transported by that EMS system during that period. (25) Authors suspected that this may be attributed to either recall bias or due to the relative importance of paediatric adverse events to providers. (25) Two major themes emerged related to adverse events in paediatrics:(25)

1. That children are different; not only did providers report increased stress and discomfort when treating paediatric patients, but errors of omission were more common due to an increased hesitancy to act.
2. The providers noted limited training and experience in treating paediatric patients.

In a recently published qualitative study on prehospital paediatric airway management, providers noted paediatric airway management as the most likely event that led to patient safety problems. Lack of experience was rated by 75% of participants as highly likely to lead to patient safety issues. (38) The study was based on a three phase Delphi survey, including emergency physicians, advanced and basic life support paramedical practitioners. (38) Hatherill et al studied interfacility paediatric transfers to a Paediatric Intensive Care Unit (PICU) in a low resourced setting over one year, and found an unacceptably high rate of technical (lack of monitoring, intravenous access or a dislodged/misplaced endotracheal tube), clinical (shock, hypoxia, or hypoglycaemia), and critical (need for emergency intubation upon arrival to the PICU, cardiac, cardio-respiratory, or respiratory arrest during the transfer) adverse events. One or more technical adverse events occurred in 36% of children, one or more clinical adverse event occurred in 27% of children, and one or more critical adverse event occurred in 9% of children studied. (45) notwithstanding the challenges in directly comparing rates across studies, when compared to the HMPS (3,12) these adverse events detected seem significant by suggesting that adverse events are more likely to occur in low resourced and out of hospital settings, and especially in paediatric cases. (45)

Overall, detection of adverse events is a challenge and multiple qualitative studies identified that a large proportion of adverse events and errors went unreported. Prehospital intubation, paediatrics, fatalities, and non-transport cases may be used as proxies to identify adverse events and near misses in the prehospital setting to combat their under reporting.

Recommendations

There is very little information in the literature regarding what recommendations are made from the information gathered when adverse events and error is identified. Fairbanks et al recommend a systems approach and noted that EMS providers expressed a desire for a non-punitive approach. (24) In the Canadian qualitative study, EMS providers requested more training, and suggested that changes be made at system level in order to decrease the amounts of errors, near misses, and adverse events that occurred. (30) Recommendations were also made for an aggressive educational and quality assurance programmes as well as for a follow up study. (42)

In Hatherill's study, less adverse events occurred when transfers were undertaken by Paediatric Intensive Care Unit (PICU) staff. A comparison between transfers undertaken by PICU staff and non-PICU staff was not possible, but the results seem to suggest that a specialised paediatric retrieval service would be indicated in a low resourced setting. (45)

Limitations

Very few of the studies included in the literature review were from low and middle income resourced cities. There is a paucity in the literature regarding adverse events in low and middle income settings.

Conclusion

Preventable adverse events due to error occur regularly in health care. The incidence of error may be even more marked in emergency medicine and out of hospital care, but errors are difficult to detect, and investigate further. In low resourced settings, the detection of adverse events is even more challenging. Interrogation of complaints, patient report form and medical records review, various triggers such as non-transport, airway management, and paediatrics may be high yield areas to detect adverse events. Near misses should also be included for analysis, because as we detect more errors, we can implement more recommendations to prevent or mitigate the risk from these errors in the future.

To the best of our knowledge, this will be the first study in a low resourced setting to investigate an adverse events registry that was configured by various methods for error detection (self-reporting, complaints, patient report forms review). This will also be the first study to analyse the recommendations made by a committee and investigate the nature of the recommendations made.

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Part B Manuscript in Article Format

A DESCRIPTION OF REPORTED ADVERSE EVENTS FROM THE PUBLIC EMERGENCY MEDICAL SERVICE IN THE WESTERN CAPE, SOUTH AFRICA

Abstract

Introduction

Out of hospital emergency medical service patients present unique challenges and ample opportunities for medical error to occur. Identifying medical error is important for mitigating future risk and improving patient safety.

Hypothesis/problem

Our study describes the adverse event registry of an emergency medical service system in a low resource setting over a six-year period.

Methods

The Western Cape Emergency Medical Services Adverse Event Registry were reviewed for the period 1 January 2010 to 31 December 2015. From these, all cases classified as an adverse event or near miss were extracted for in depth review. Demographics, type of error, and types of recommendations implemented are reported.

Results

Altogether 106 (69%) adverse events and 47 (31%) near misses were reported over the six-year period. The mean age of patients was 31 years (standard deviation ± 24.8). Of these 65 (42%) cases were adult medical patients, 31 (20%) adult trauma patients, 15 (10%) obstetric patients and 42 (27%) paediatric patients. The caseload was observed to increase over the six-year period, whilst system medical errors decreased and individual medical errors increased over the same period.

Conclusion

In this low resource emergency medical service system, individual medical errors increased and system medical errors decreased as more recommendations derived from adverse events caused by the system errors were implemented. This created a greater need for individual and group training of EMS clinical providers. We recommend further research in order to adequately describe the reason for the increase in individual medical error, as well as to find more effective means of detecting adverse events and near misses in this population.

Key Words

Emergency Medical Services; Patient Safety; Medical Error.

Conflicts of interest

The authors have none to declare.

Word Count Abstract

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Introduction

Primum non nocere (first do no harm) is one of the maxims on which our medical care system is built. Preventable adverse events are by their definition due to medical error. (1) Medical errors result in increased cost, complaints, patient morbidity, and mortality to the extent that it has been estimated to be the third leading cause of death in the United States.(2–6) Emergency medicine, and out of hospital emergency care in particular, present unique challenges that increase the risk for medical error to occur. (7–12) Higher rates of preventable medical error result in more adverse events and near misses and this is fairly well documented in Western literature. In contrast, in low resourced settings, literature on adverse events is limited to medical records review and single centre studies. (11, 13)

Reducing medical error is complex. Not only are worsened patient outcomes often the result of multiple types of medical errors, including latent errors, but the outcomes are also often incorrectly ascribed to the severity of the underlying disease. (14,15) Unfortunately most medical errors remain under reported and not highlighted, spoken about, or investigated further (sometimes even when detected). Possible reasons for the under reporting include recall bias, fear of litigation action, potential loss of health care workers' professional reputation, fear of undermining relationships with colleagues (or getting others into trouble), and a blame and shame culture that is still prevalent in many organisations. (15–18)

It is reasonable to argue that error in low resourced settings is at least on par with (and possibly higher than) what is reported in the more robust data collections reported in western literature. In depth analysis of errors may assist in preventing similar errors from re-occurring through structured risk management. This study aimed to describe the adverse event registry records of the public emergency medical service in the Western Cape, South Africa by focusing on medical error, adverse events, near misses and recommendations made over a six-year period.

Methods

Records review of the Emergency Medical Services Adverse Event Registry (Department of Health, Western Cape Government, South Africa) was conducted for the period 1 January 2010 to 31 December 2015. The study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist to report its findings. (19) Terminology used throughout this study is defined in Box 1

Box 1. Definitions of terminology used
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<i>Error</i> : The failure of a planned action to be completed as intended or the use of an incorrect

plan to achieve an aim. (18)

Adverse event: An injury resulting from a medical intervention, rather than the patient's underlying condition. (20)

Patient Safety: the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.

Harmful incident (adverse event): an incident that resulted in harm to a patient. (31)

Near miss: an incident that did not result in the harm to a patient. (31)

Latent error: An error whose adverse consequences may lie dormant within the system for a long time, only becoming evidence when they combine with other factors to breach the system's defences. (18)

Cognitive error: An error in the process of thinking (18)

Affective error: An error when there is an inordinate intrusion of affect into the decision-making process that results in a poor decision and may lead to a poor outcome. (18)

System: set of interdependent components interacting to achieve a common aim. These components may be classified in various ways: sociographic factors include national, organisational/institutional, health-care provider, and patient/family. (18)

Study setting and population

The Western Cape Emergency Medical Services (EMS) serve a population of 5.8 million people, covering an area of 129,462 square kilometres (roughly the size of Alabama). Approximately 170 ambulances are deployed daily across the province. The Emergency Medical Services also provide planned patient transport, disaster medicine, rescue, and aeromedical retrieval services. There are on average 640,000 requests for an ambulance transfer per year, and, of these, approximately 520,000 patient transports per year. The main reasons for non-transport include patients declining transport and delays in response times. The Emergency Medical Services consists of three levels of out-of-hospital care: Basic life support practitioners provide basic care including oxygen; intermediate level practitioners provide a higher level of care including intravenous access and administration of various drugs; and advanced life support paramedics perform advanced cardiac life support, advanced airway management (rapid sequence induction and endotracheal intubation), and advanced trauma and paediatric life support. An additional advanced life support staffed specialised paediatric retrieval service was introduced in 2011.

The Western Cape Emergency Medical Services Adverse Event Registry was established in January 2009, in order to record all cases investigated by the service's quality assurance

committee. Cases included in the register are identified by means of complaints from patients, family members, members of the public, hospital medical staff, self-reporting by Emergency Medical Services staff, and random screening of the patient report form (the document completed by emergency care providers for each transfer). The quality assurance committee is made up by the chair (an emergency physician) and four, regional quality assurance managers (all advanced life support paramedics with training and experience in quality assurance). The quality assurance committee investigates every reported incident, through review of the documentation associated with the incident. This may include reviewing patient report forms, logbooks, daily checklists, radio communication log, formal written statements from persons involved, and all computerised records (e.g. vehicle tracking and mission times). An investigation report is then compiled and once completed is sent for peer review. The classification of the medical error (), and whether or not patient harm occurred is made through a consensus decision by the committee. Depending on the nature of the classification, remedial recommendations are made to involved parties. These may include system improvements and/or individual or group retraining of practitioners. When intentional individual error was suspected, the incident is referred to a senior operational committee for an independent disciplinary investigation. All investigation variables are logged electronically into the registry, including: date of incident, demographics and incident detail, classification of the medical error (individual, system, neither, or both), if the incident qualified as an adverse event or near miss as well as the recommendations made. The quality assurance committee provides formal feedback to the complainant and all relevant individuals affected by the outcome.

Sampling, data collection and management

The Western Cape Emergency Medical Services Adverse Event Registry were reviewed for the period 1 January 2010 to 31 December 2015. From these, all cases classified as an adverse event or near miss were extracted for in depth review. For cases not clearly classified as an adverse event or near miss, a quality assurance committee member was approached for a decision. Cases not classified as an adverse event or near miss were excluded along with any cases with missing data (Figure 1). We reviewed all the case records of incidents, as well as the respective supporting documents. The objective of the additional records review was to obtain additional information that may not have been that apparent in the registry summary. Study data were captured on an Excel spreadsheet (Microsoft Office, Redmond, USA). Complainant, patient and staff identifiers were removed from the data sample. The study was approved by the University of Cape Town Health and Research Ethics Committee (ref no: 361/2015).

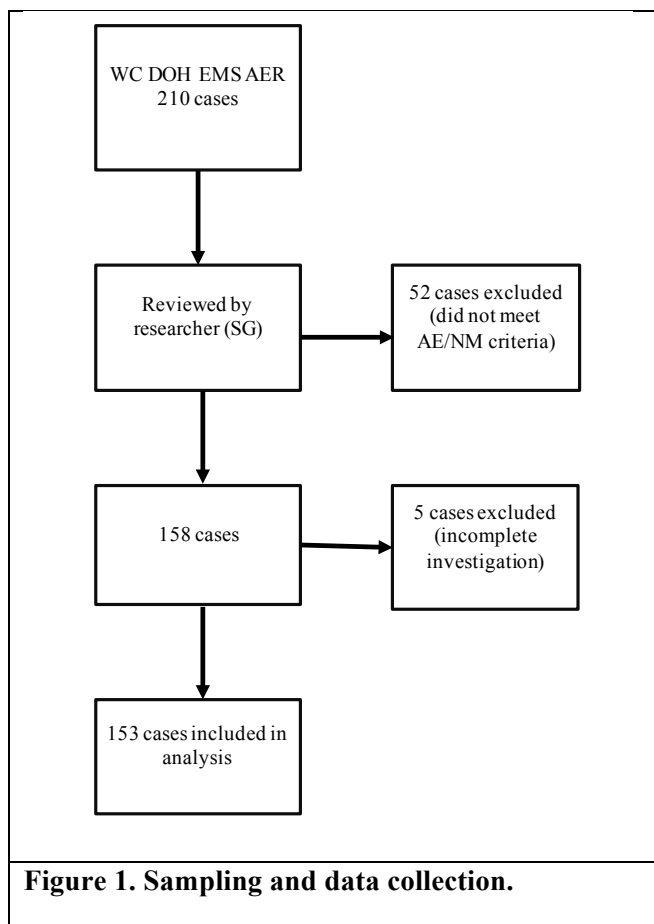
Data Analysis

An overall count of all cases entered into the study database was conducted initially, followed by the use of descriptive statistics to describe the categorical data, whether binary (male/female) or nominal (level of practitioner). Categorical variables were summarised using frequencies and

percentages. For percentage calculations, the denominator used was the overall count of cases analysed, or the total counted per category. Dates and times of day were analysed as ordinal categorical data, and the information was reported with the use of frequency tables and histograms. Continuous data was expressed as mean and standard deviation (SD). The data were analysed using Dell Statistica version 13 (Dell Software, Aliso Viejo, California, USA).

Results

The recruitment process for the sample of 153 cases is described in Figure 1. Table 1 reflects the demographics of the adverse event and near miss cases. The high proportion of unknown paediatric gender cases (10, 84%) can be attributed to neonatal cases where the gender was not recorded. The highest proportion of cases was facilitated by intermediate life support level practitioners (66, 43%) (Table 1).



		Total	Medical	Trauma	Obstetric	Paediatric
Total (n)		153	65	31	15	42
Mean age (SD)			53 (25)	36 (15)	25 (8)	1 (2)
Gender:	M	69	31(45%)	23 (33%)	0	15 (22%)
	F	72	33(46%)	7 (10%)	15 (21%)	17 (23%)
	Unknown ¹	12	1 (8%)	1 (8%)	0	10 (84%)
EMS provider level:	Advanced	53	17 (32%)	11 (21%)	5 (9%)	20 (38%)
	Intermediate	66	31 (47%)	18 (27%)	4 (6%)	13 (20%)
	Basic	24	14 (59%)	1 (4%)	2 (8%)	7 (29%)
	Unknown	10	3 (30%)	1 (10%)	4 (40%)	2 (20%)
Day of transfer:	Weekday	109	42 (39%)	19 (17%)	13 (12%)	35 (32%)
	Weekend	42	22 (52%)	12 (29%)	2 (5%)	6 (14%)
	Unknown ²	2	1 (50%)	0	0	1 (50%)
Time of transfer:	Working hours	76	37 (49%)	13 (17%)	6 (8%)	20 (26%)
	After hours	75	28 (37%)	18 (24%)	9 (12%)	20 (27%)
	Unknown ²	2	0	0	0	2 (100%)

¹ In 1 case, multiple casualties were involved, with no investigation into demographics.

² In 2 cases, the time of day/day of the week was not noted.

Altogether 106 (69%) adverse events and 47 (31%) near misses were reported over the six-year period (Figure 2). Thirty-five (23%) cases were investigated in 2015, the highest number of any year. The lowest number of cases was investigated in 2010 (17, 11%). The adverse events increased in a linear trend from 2010 to 2015. The near misses remained static over the same period. The system error linear trend decreased from 2010 to 2015 (Figure 3). Both individual cognitive errors with, and without intent, increased over the same period. Only three (2%) of 153 cases were affective errors detected.

Recommendations pertaining to EMS operational and clinical system changes, including the use of new or amended standard operating procedures, decreased slightly (Figure 4). Outcomes that recommended individual retraining of clinical practitioners formed the majority of recommendations and remained mostly static, while there was an increase in recommendations for group training, especially in 2015 (11 cases).

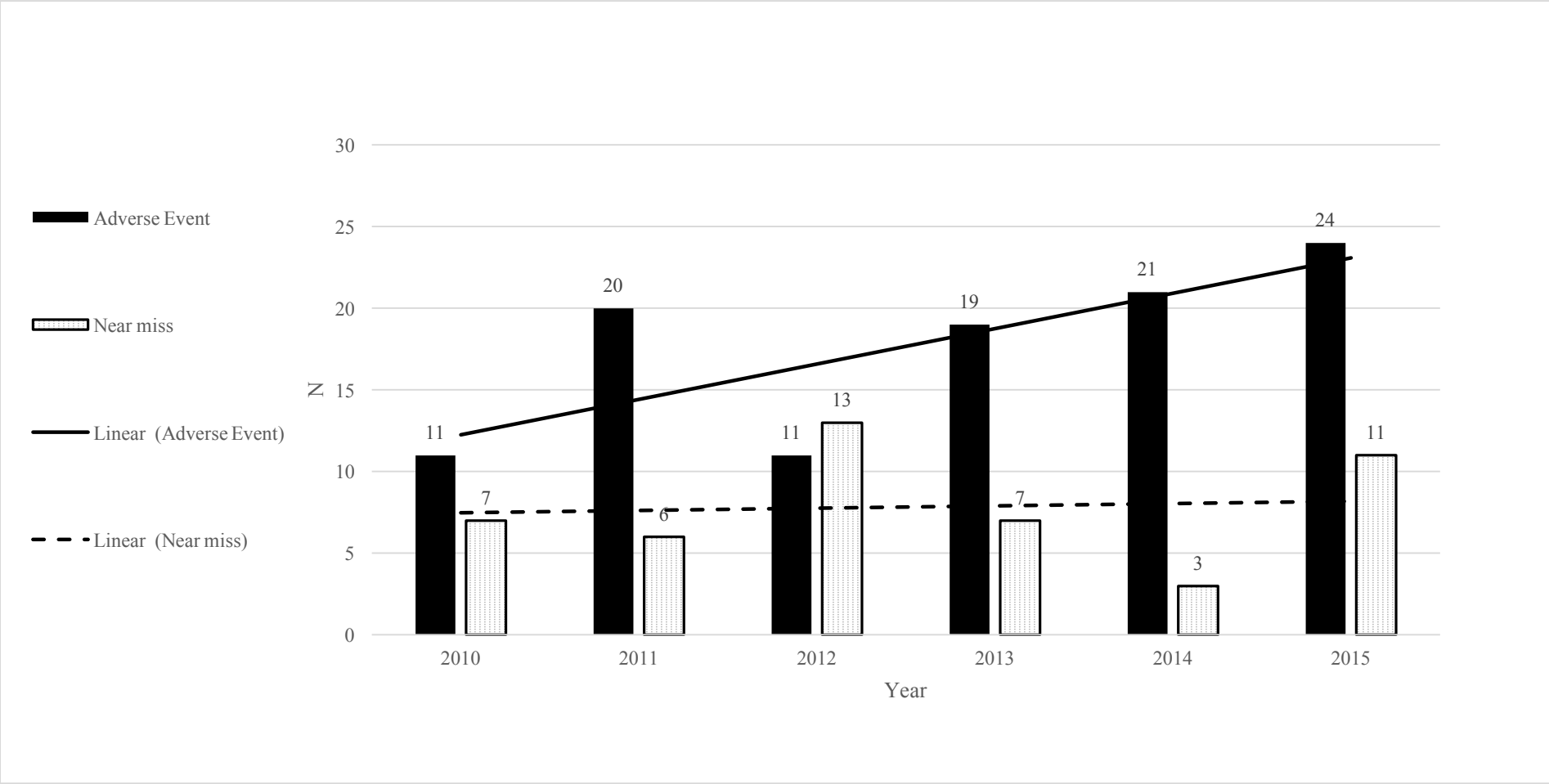


Figure 2. Adverse events and near misses cases and trends

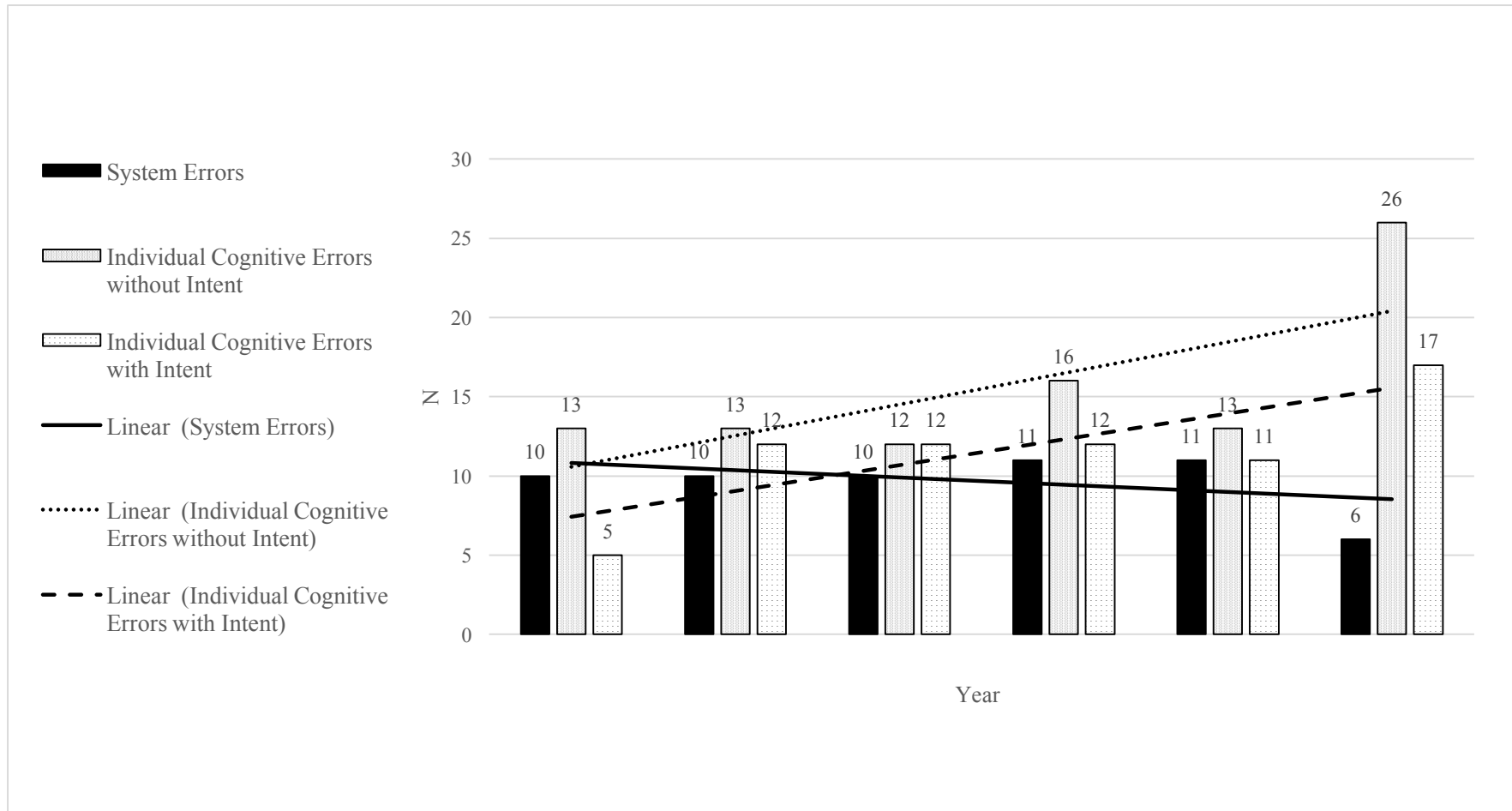


Figure 3. Types of errors that occurred and linear trends

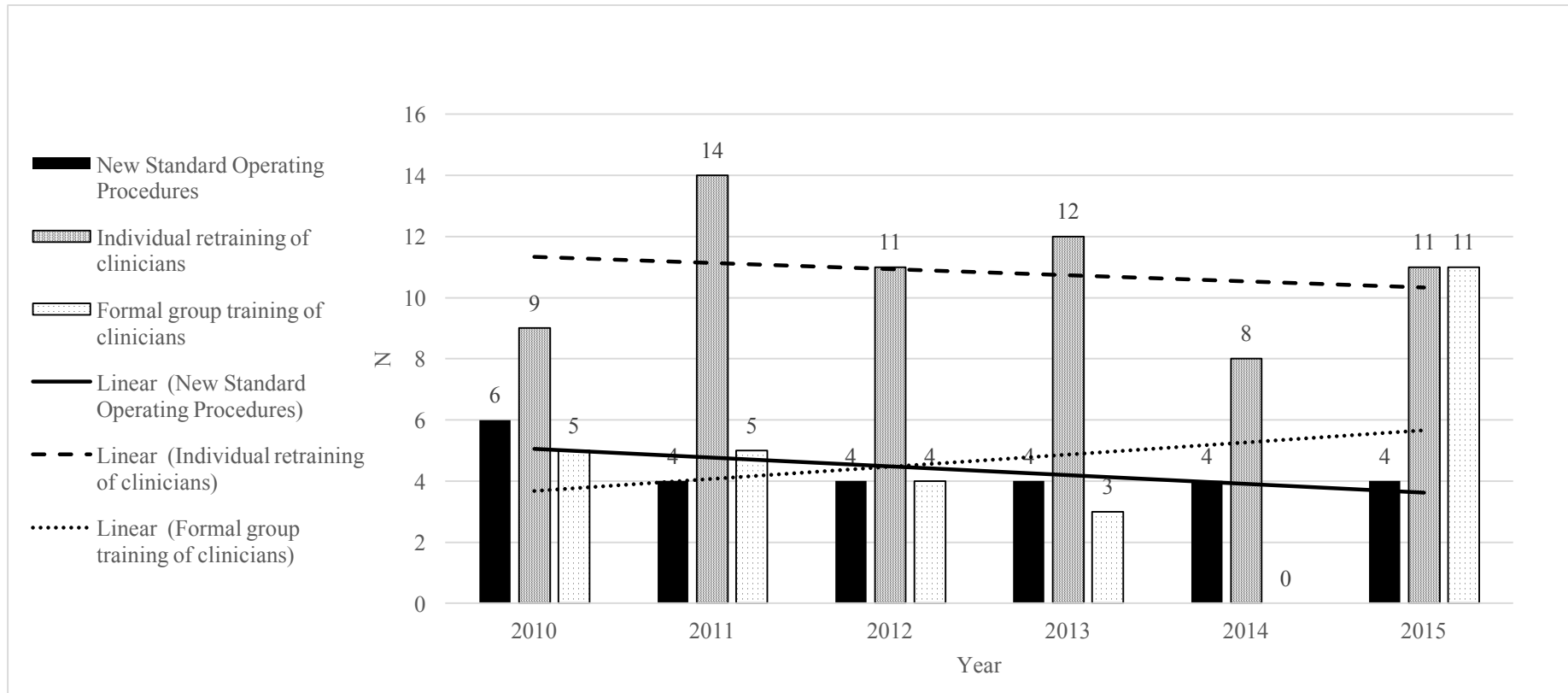


Figure 4. Categories of recommendation and linear trends

Discussion

A key finding of this study is that adverse event reporting increased over the study period. The fact that the least number of cases was reported in 2010, and the most in 2015, can likely be attributed to the quality assurance system becoming more rigorous in detecting new cases as it matured; the EMS adverse event registry was initiated in 2009, and underwent considerable development over its first seven years. Improved case screening by quality assurance regional managers, more self-reporting of potential medical errors by clinical staff, improved access for patients and families to report suspected medical error cases, and increased emphasis on medical error reporting, all may have contributed to the evolving culture of improved patient safety. The perception that bad patient injury outcomes prompted complaints from patients and their families may explain the higher detection rates of adverse events over near misses. However, this finding contrasts with the results of a German adverse incident reporting system, in which only 27% of reported cases had proven harm to the patient as a result of the incident. (16)

The fact that system medical errors decreased and individual medical errors increased may relate to multiple factors. A Canadian study that predominantly examined air transport adverse events found that over a third of errors were attributed to system failures (including equipment and transport vehicle failures), which aligns well with our study's findings. (14) However, an Australian study reported that 54% of incidents (including both adverse events and near misses) were caused by system factors, which is higher than in our setting. (19) The decrease in system errors over the study period is most likely attributed to the implementation of improved standard operating procedures, based on recommendations, as a result of the errors detected in the earlier years. In our study, 62% of the cases caused by individual medical errors compares well to the 56% in the German study, but is greater than the 42% of adverse events caused by human factors in the Australian air transport adverse events study, or the 21.3% of adverse events attributed to individual medical errors in a Canadian air transport adverse events study. (12,14,19) Individual medical errors, both intentional and non-intentional, increased over the six-year study period, while system medical errors decreased. The German study did not analyse the trends over their seven-year study period. (16) However, the Australian study investigated medical errors in an EMS system by examining road traffic accident fatalities and found that over a 10-year period, the individual errors increased, while system errors first decreased and then increased. Their researchers attributed the increase in individual errors to the implementation of an advanced life support paramedic structure, although there was no evidence to prove this. (20) It is also possible that more individual errors were identified by the paramedics, or that this was simply a coincidence. In our study, the reported adverse events and near misses occurred in cases with advanced, intermediate, and basic life support crews. In fact, the majority of cases reported occurred during transfers facilitated by intermediate level clinical providers. However, Western Cape EMS logistical data shows that intermediate life support

crews transported most of the patient cases triaged as priority 1 indicating a higher acuity of patient illness. This may have created a mismatch between the acuity of the patient and the required resources, and increased the potential for medical error to occur. The mismatch may be explained by the low resourced system not producing and/or employing sufficient numbers of advanced life support paramedic crew to facilitate the transfer of patients. In the authors' opinion, increased and improved reporting caused the increased medical error rate noted.

In this study, the majority of recommendations made by the quality assurance committee involved re-training of clinical and operational staff. The recommendations for increased training within the entire EMS system, increased over the six-year period, corresponding with the increase in individual medical errors over that period.

Limitations

No adverse event reporting system will ever fully detect all medical errors. (24,28,29) We too suspect a degree of under reporting, mainly because of the small ratio of reported cases compared to the large number of patients transported by EMS over the study period Baylis et al noted that that well-meaning practitioners are often not able to identify that a medical error resulted in a particular adverse patient outcome and therefore underestimate the benefits of incident reporting. (15) Self reporting would be a far more accurate means of detecting adverse events, however, very few practitioners self-report. (15,21,22) Improved patient safety awareness and education campaigns on the benefits of self-reporting whenever medical error is suspected may change the current silence culture. Low resourced setting EMS quality assurance systems should focus their efforts on the detection of medical errors that may occur during high risk patient transfers to extract maximum yield. Examples include cases where patients are discharged on scene by EMS clinicians and therefore not transported, advanced airway management cases, and all paediatric and obstetric transfers. (21,23–30) Intensive record review of these high-risk cases may improve medical error detection.

Conclusion

In the low resource EMS system, individual medial errors increased and system medical errors decreased as more recommendations derived from adverse events caused by the system errors were implemented. This created a greater need for individual and group training of EMS clinical providers. Further research is recommended in order to investigate the reasons for the increase in individual medical errors, as well as how to improve methods of adequately detecting errors in this setting.

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Part C: Addenda

1. Instructions to Authors: Prehospital and Disaster Medicine

(Available from: <https://www.cambridge.org/core/journals/prehospital-and-disaster-medicine/information/instructions-contributors>)

3. Research Protocol (FHS 15)

FHS 015: Research Protocol: Section C

**Adverse incidents in a new Emergency Medical Services
quality improvement (QI) programme within a resource
limited setting: a descriptive study**

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Declaration (use the correct option)

(For UCT degrees)

I, *Sian Geraty* hereby declare that the work on which this proposal/ dissertation/ thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature:

Signed by candidate

Date: 11 May 2015

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Appendix A: Data collection spread sheet

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1. Purpose of the study

1.1 Aim

To describe the adverse events reported to a novel pre-hospital emergency medical services (EMS) quality improvement committee in a resource-limited setting.

1.2 Objectives:

To *describe*:

1. the demographics of all recorded adverse events/near misses
2. the errors that contribute to the adverse events/near misses
3. the resulting recommendations from the adverse events/near misses registry

1.3 Research Question

“What were the demographics, causative errors and recommendations recorded in a novel Emergency Medical Service Adverse Incident Registry in a low-to-middle income area?”

2. Background

Pre-hospital emergency care in resource-limited settings poses unique challenges and much room for patient injury to occur. An adverse event can be described as patient injury due to a preventable error. One or more such errors, from individual to system, lead to increased cost, morbidity, and/or mortality. (1) Adverse events are commonly unrecognized, and worsened patient outcomes are often incorrectly ascribed to the severity of the underlying disease. Patient safety is an area where retrospective review and prospective risk management can lead to changes for improved outcomes and quality improvement. If we can describe and adequately analyse errors made in the past, we can take steps to prevent these similar errors in the future. This should result in improved patient safety and overall quality of care.

The Harvard Medical Practice Study (HMPS, 1984) noted a large burden of iatrogenic injury. Of 98609 hospitalised patients studied in New York State during that year, 3.7% suffered adverse events (defined by the study as an injury caused by medical management rather than the patient’s underlying condition.) Of those, 2.6% suffered permanent total disability and 13.6% died. (2) The United States Institute of Medicine (1999), prompted by the HMPS, noted that up to 98000 deaths per year in the United States may occur due to error, and that error takes its toll not only in the loss of human life, but on disability, cost, loss of income, loss of education, and loss of morale. (3) In 2002, the World Health Organisation noted that “the

incidence of adverse events is a challenge to quality of care, a significant avoidable cause of human suffering, and a high toll in financial loss and opportunity cost to health services;”(4) and recommended that “member states pay the closest possible attention to the problem of patient safety.”(4)

Although the HMPS did not specifically note emergency medicine as a specialty, negligence in emergency cases caused a large number of adverse events. (2) Three important studies noted that although a relatively small amount (1.5-3%) of adverse events occurred in the emergency department (ED), a high percentage of the preventable events (70-82%) did occur in the ED. (1) Emergency and especially pre-hospital care is unique in terms of time pressures, constantly changing environments, and unplanned patient contact with challenges in terms of not only presenting complaints but communication and co-morbidities. Prompted by the IOM publication, the Society for Academic Emergency Medicine held a conference on error in 2000, and commented on the complexity of emergency medicine and the need for focus on various errors, from systems to human. (5)

Despite the emphasis on preventing patient injury, there is still a lack of studies on adverse events in ground based pre-hospital emergency care. In developed countries, pre-hospital emergency care-based studies have focused on either complaints or insurance claims, and many found the health care provider – patient relationship to be a greater reason for complaints than technical or clinical errors. (6 - 8)

Resource limited settings could also be more prone to error, due to decreased resources, decreased amount of personnel, an overall more ill and poor patient population, and worse communication due to language difficulties. Study data on adverse events in resource-limited settings are limited. (9) However, a study on critically ill paediatric transfers in a resource limited setting, prior to the initiation of a specialised paediatric retrieval team, found unacceptably high rates of clinical (27%), technical (36%) and critical (emergency intubation and/or cardiac, cardio-respiratory, or respiratory arrest, 9%) adverse events. (10)

In summary, the related literature emphasises the importance of further research into adverse events, especially in resource limited and pre-hospital settings. The incidence of error in emergency medicine is high, and may be even more pronounced in resource limited settings. (10)

An examination of adverse events in a resource limited setting should aid in identifying areas for potential change. As preventable factors are identified, there will be more evidence supporting change in these areas. As we focus on these preventable factors, we can influence training, support, communication, resource allocation, duty times, systems, and others. Ultimately patient risk is decreased – and decreased morbidity and mortality in turn results in

decreased cost, decreased complaints, and an overall healthier patient population. Pre-hospital (and in-hospital) systems can be addressed, and improved staff support and resource allocation will be beneficial to staff, resulting in increased morale and better outcomes overall for patients. Identifying errors and the factors leading to them is an education to all involved, and may also pave the way for further research in this area, especially in similarly under-resourced pre-hospital settings.

3. Methodology

3.1 Study design

Observational, descriptive study, involving retrospective interrogation and analysis of the Department of Health Western Cape EMS adverse incident registry (DoH WC AIR) since its inception in 2009, up to and including 2014.

3.2 Study population

The study population includes all patient cases entered into the Western Cape EMS QI registry over a six year period (from January 2009 to December 2014).

The Western Cape EMS serve an area of approximately 129 462 square kilometres and a population of 5.8 million people. Between January 2009 and December 2014, approximately 210 patient cases were entered into the database. These cases were reported by the following means:

- 1) Complaint from patient, family member, or member of public regarding patient care provided by EMS
- 2) Complaint from medical personnel, hospitals, EMS, or other agencies
- 3) Self-reporting by EMS staff
- 4) Random patient report form (PRF) screening by trained QI managers (10% of all cases transported by EMS)

In the cases of complaints or self-reporting, the incident was logged and entered into the database via the QI manager for the district. PRF oversight was performed by senior QI managers in every district, who reviewed 10% of all PRFs for possible adverse events or near misses. Each logged case entered into the database was formally investigated by the regional EMS QI manager.

The QI committee consists of 5 members: the chair (a senior emergency medicine medical specialist) and 4 experienced paramedical practitioners (most with masters degrees). All have undergone extensive national and international formal training in patient safety.

The QI committee reviewed each case thoroughly and used international criteria to decide if individual cases fulfilled the description of “adverse event” or “near miss.” For each case, demographic and other data was recorded in the registry. Recommendations made were also recorded in the registry.

The process by which potential adverse events/near misses were collected and reported has severe limitations. However, the study’s advantages outweigh the limitations if the results are described via the resource limited context specific nature of the study. *See section 4.2, below.*

3.3 Inclusion and exclusion criteria

All incidents classified by the WC EMS AIR as “near miss” or “adverse event” will be included in the study. The WC EMS AIR base their definitions of these terms on a glossary identical to the one contained in Appendix C.

All cases that did not fit the committee’s definition of “near miss” or “adverse event” will be excluded from the final analysis.

3.4 Research procedures and data collection methods

The researcher will then review information from the registry systemically. All entered records from January 2009 until December 2014 will be reviewed. The researcher will enter information onto the data collection form (excel spread sheet – see appendix 1). This database will be kept on a locked, password protected computer that only the researcher will have access to. Dates and times will be entered according to a specific format, and categorised data will have up to 3 options.

The researcher will enter all data related to AE or NM cases into an excel spreadsheet (see Appendix A), and sub-categorise the information pertaining to adverse events/near miss cases as follows:

- a. Demographics of adverse event cases
 - i. Age of patient
 - ii. Male/Female
 - iii. Highest qualification of EMS crew involved in the transfer of the patient
 - iv. Incident occurrence: Day of week, time of day
 - v. Event category: Medical, trauma, or obstetric.
- b. Errors that contribute to adverse events
 - i. Categorisation of errors: Individual vs system,
 - ii. If individual, cognitive vs. affective and if cognitive: negligence vs. intentional.
 - iii. If system, description into themes and subthemes
 - iv. Trends of all the above from year to year
- c. Recommendations arising from adverse event reports
 - i. Individual, description into themes and subthemes
 - ii. System, description into themes and subthemes
 - iii. Trends from year to year

The time of day will be based on the time the initial call was received, rounded to the nearest hour.

In the event of cases with missing data, the EMS QI committee will be approached to see if the missing data is located within different data storage package. In case of data not being able to be retrieved, incomplete cases will be excluded from the final analysis, but documented.

3.5 Data safety and monitoring

The DoHWC EMS AIR registry is stored in Sinjani, an electronic archive on the DoHWC computer network. Access is user name and password protected. Rigorous screening of eligible DoH

employees exists to control personnel access. Only after HREC approval is obtained will approval be sought from EMS to access the registry content. All patient identifiers will be removed before providing access to the researcher. The generic data will be stored on a locked, password protected computer and the back-up on another locked, password protected computer that only the two supervisors and the researcher will have access to. The generic registry data will be transferred in person from 1 representative of the EMS QI committee to the primary researcher, directly from computer to computer using a thumb drive, from which the registry data will immediately be deleted and the drive formatted. No information obtained from the registry committee will be altered, except all patient identifiers as described earlier.

The raw registry data will be stored on the researcher's locked, password protected computer that only the researcher will have access to. All study data will be deleted upon completion of the study.

All patient identifiers will be removed, and the anonymised data will be coded by means of a linking document. The linking document will be kept separately to the coded data, and held only by the primary researcher. The only identifying features possible to link to the initial patient case will be the age range and gender, which will be removed as soon as the analysis of age group and gender have been performed.

Figure 1. Methodology

3.6 Data analysis

Data analysis will be performed with the help of a statistician. The spreadsheet will be shared with the statistician alone and analysis will be performed along the following guidelines:

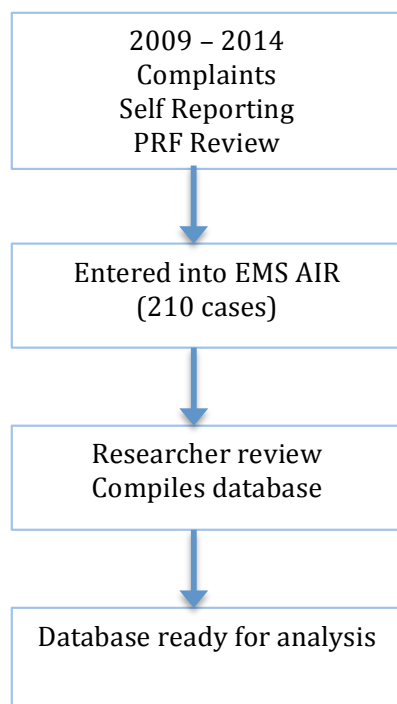
Descriptive statistics will be employed in the analysis of categorical data, whether binary (male/female) or nominal (type of case i.e. medical/surgical/obstetric). Dates and times of days can be described as ordinal categorical data. These will be analysed and the information reported by means of frequency tables, histograms, means, and standard deviations.

The data can be divided into two groups: AE and NM. Comparisons between the two groups will be made using cross tabulation (with the Chi-square test) for categorical variables, and ANOVA for continuous/ordinal measurements. Assumptions will be checked and the necessary non-parametric methods employed depending on the nature of the data.

Once the data analysis has been performed, the dates will be obscured or removed in order to prevent identification of individual cases.

The qualitative aspects of the research (descriptions of errors, descriptions of recommendations) will be analysed within the specific context of the study.

The described data will be included into the final document and the researcher will do the final write-up.



4. Ethical Considerations

4.1 Description of risks and benefits

The potential ethical risks pertaining to the study are low.

1. Risk to patient population included in the QI database

This will be a low risk study with no patient contact and no potential for direct patient harm. The researcher will remove all patient identifiers. There is no possibility of negative repercussions to complainants, patients, or family members. Patient confidentiality will be protected at all cost.

2. Risk to EMS personnel

Potential risks include stigmatisation, economic risks, damage to career pathways, or psychological harm if the details surrounding some adverse events and near misses are published. These will be minimised by removing all health care worker and patient identifiers.

3. Risk to Department of Health

Removing patient and health care workers identifiers will negate potential risks to the Department of Health.

Benefits:

The purpose of any adverse event reporting should be to improve learning and prevent error recurrence by implementing change. The motivation for conducting this study is to share the registry content to peer start up quality assurance systems, specifically in resource limited settings, so that they can learn from the challenges and will not repeat the same mistakes. For example, multiple adverse events due to advanced airway management failures have lead to multiple patient deaths. Only after implementation of an airway and ventilation checklist for practitioners, did the AI/NM begin to taper off. New QA committees can avoid unnecessary patient harm by extrapolating from the local recommendations to avoid reoccurrences in their own health system.

The results of the study should:

- 1. Assist the current EMS QI committee in their future operational planning to adapt to the changing trends in AE/NM reporting**

The EMS QA committee is both reactive (acting on complaints) and proactive (screening high patient safety risk scenarios.) As the QA programme became more mature, it uses

adverse events identified in the past to assist with prevention and mitigation efforts regarding future adverse events. It does this by proactively screening all high risk events (in the practitioner's medical records) flagged by previous AE/NM and directly intervenes if any trend changes are detected.

The proposed study will provide a detailed, thoughtful summary of the events reported in the past 6 years that can be circulated to the committee itself, as well as to all stakeholders. This descriptive study will demonstrate trends in adverse events as well as their detection. One example of an advantage is that the EMS QI committee will be able to use this information to improve the rate of detection of adverse events, by noting areas in which detection is poor. The EMS committee will also be able to use the information to assist with future risk planning in all areas.

The descriptive study analysis may also highlight errors that recur and system problems that can have not been rectified previously. Training and operational managers can use the information to assist in training and operational planning – for example if recurrent obstetric adverse events are reported due to lack of staff training in obstetrics, a targeted training programme focussing on the gaps and relating to the specific context of the practitioners could be recommended.

2. Assist similar QI committees in resource – limited countries

There are multiple QI committees being developed all over South Africa and in peer resource-limited settings who will be able to use the information disseminated through this study to assist with their planning. The description of types of patients, types of errors that occurred, and types of recommendation, and especially how these changed as the QI committee matured, will assist the strategic planning of these new upstarts. A reflection on the numbers reported would assist them to plan for about the number of event reports expected and how to plan staff and resources appropriately.

3. Provide a baseline for further research

During the data collection and analysis it is possible that further events and aspects may be uncovered which may open questions that cannot be answered within the aims of the this

study; the answers to these questions may be beneficial to the healthcare community. In this way the study may open up further opportunities for research.

4.2 Limitations

The process by which potential adverse events/near misses were collected and reported has severe limitations. I expect under reporting and therefore exclusion of potential cases due to the restricted pathways by which complaints could have been lodged. Processing bias may also occur due to potential cases that have already been excluded or included by the QI managers and committee. Self-reporting of adverse events amongst EMS staff tends to be low within EMS, possibly due to fear of self-implication. (7,12) In resource limited settings, lack of education or medical knowledge of patients and their families may also lead to an under reporting of complaints resulting in a reduced adverse event/near miss incidence. Reviewing only 10% of the total PRFs may mean that errors in the other 90% have been overlooked. All these reasons may lead to the study population reflected in the data base being under-representative of the true study population of all adverse events/near misses that occurred over the six year period.

Adverse event reporting is by its nature dependant on detection and as such will always be subject to the influences on detection Patient report forms (PRFs) are the pre-hospital equivalent of hospital patient files, and the data (or excluded information) available from these forms is the standard of pre-hospital care review.

However, the study's advantages outweigh the limitations if the results are described via the resource limited context specific nature of the study, *and in themselves provide motivation enough for the study to be conducted. The study is important despite the noted limitations. See section 4.1, above.*

4.3 Informed consent process

Due to the low ethical risk of the study, I will apply for waiver of consent (Refer to 4.1.)

4.4 Privacy and confidentiality

1. Patient and health care worker identifiers will be removed and not included in the researcher's database. *The entries will be anonymised before the information is made accessible to the researcher.*

2. *All dates will be removed after the initial date analysis is done.*
3. *It will not be possible to trace the information back to the patients involved in the cases in the registry. Patient confidentiality will thus be strictly maintained.*
4. *It will also not be possible to trace the information in the registry back to the medical staff involved in each case. They will therefore be protected from any negative effects, including stigmatisation or career damage, that could possibly arise from the study's publication or from the researcher having knowledge of the staff involved.*
5. Refer to "data safety and monitoring" above.

4.5 Reimbursement for participation

No participants will be paid or reimbursed.

4.6 Emergency care and insurance for research-related injuries

No insurance will be required, due to no patient contact.

5. At the end of the study:

There is no further treatment for the population involved (retrospective descriptive study).

The findings will be disseminated to the study population and greater medical community via 1 publication.

6. Conflicts of Interest

The researcher and supervisors hereby both state that she has no conflict of interest with conducting this study.

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ADVERSE EVENT REGISTRY ANALYSIS OF AN EMS SYSTEM IN A LOW RESOURCE SETTING: A DESCRIPTIVE STUDY

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