BUILDING A MODEL FOR DEVELOPMENT OF A NATIONAL TRAUMA REGISTRY: DESIGNING AND IMPLEMENTING STANDARDISED TRAUMA FORM AT REGIONAL HOSPITALS IN TANZANIA

By

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Declaration

I, Hendry Robert Sawe, hereby declare that the work on which this 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 authorise the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever. I further declare the following:

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Approval for inclusion of publications in thesis

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1. Trauma care and capture rate of variables of World Health Organization data set for injury at regional hospitals in Tanzania: first steps to a national trauma registry. **Sawe HR**, Reynolds TA, Weber EJ, Mfinanga JA, Coats TJ, Wallis LA. BMC Emerg Med. 2020 Apr 23;20(1):29.
2. Barriers and facilitators to implementing trauma registries in low- and middle-income countries: Qualitative experiences from Tanzania. **Sawe HR**, Sirili N, Weber E, Coats TJ, Wallis LA, Reynolds TA. African Journal of Emergency Medicine [Internet]. 2020 Jul [cited 2020 Oct 9]; Available from: https://linkinghub.elsevier.com/retrieve/pii/S2211419X20300562
3. Perceptions of health providers towards the use of standardised trauma form in managing trauma patients: a qualitative study from Tanzania. **Sawe HR**, Sirili N, Weber E, Coats TJ, Reynolds TA, Wallis LA. Inj Epidemiol. 2020 May 1;7(1):15
4. Development and pilot implementation of a standardised trauma documentation form to inform a national trauma registry in a low-resource setting: lessons from Tanzania. **Sawe HR**, Reynolds TA, Weber EJ, Mfinanga JA, Coats TJ, Wallis LA. BMJ Open 2020;10:e038022. doi:10.1136/bmjopen-2020-038022
5. The burden of trauma in Tanzania: Analysis of prospective trauma registry data at regional hospitals in Tanzania. Injury [Internet]. **Sawe HR**, Wallis LA, Weber EJ, Mfinanga JA, Coats TJ, Reynolds TA. 2020 Sep [cited 2020 Oct 9]; Available from: https://linkinghub.elsevier.com/retrieve/pii/S0020138320307713

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Abstract

Background: Trauma registries are vital to a well-organized trauma system. However, registries are non-existent in most low and middle-income countries, largely due to the difficulty of reliably capturing patient-level data. The aim of this thesis was to develop and implement a context appropriate standardised trauma form incorporating the World Health Organization Data Set for Injury, for both clinical documentation and use in a trauma registry.

Methods: This mixed methods participatory action research utilised Susman and Evered's approach to develop and implement a standardised trauma form, using its five steps: diagnosis, action planning, intervention, evaluation and specifying learning. In the diagnosis phase, an assessment of baseline documentation was performed. In the action-planning phase, focus group discussion revealed the barriers and facilitators to completing documentation. Then, in the action-taking phase, semi structured interviews, training of health care providers, and feedback enabled the development, review, pilot, and implementation of a standardised trauma form. In the evaluation phase, we compared the number and types of variables captured after the form was implemented to the baseline collection. Finally, we specified learning to inform the next steps in the amplification of the observed impact.

Results: The diagnosis phase established that many injury variables were not captured routinely at the participating regional hospitals. Analysis of barriers and facilitators and feedback on perceptions of providers toward using standardised documentation informed the development, piloting, modification, training of providers and implementation of a context appropriate standardised trauma documentation form for clinical charting and data capture. Implementation of the standardised trauma form was associated with improved capture of injury variables from baseline pre-implementation (33.6%), during 30-days initial pilot (86.4%) and after seven months post implementation (96.3%). The providers reported the form was user-friendly, resulted in less time documenting, and served as a guide to managing trauma patients.

Conclusions: Through participatory action research a contextually appropriate, standardised trauma documentation form was successfully developed and implemented, yielding marked improvement in the capture of essential injury variables. This model can serve as a working guide to other low- and middle-income countries seeking to establish sustainable national injury registries.

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List of abbreviations

AMO	Assistant Medical Officer
CO	Clinical Officer
CRF	Case Report Form
DSI	Data set for injury
EU	Emergency Unit
GACI	Global Alliance for the Care of Injured
HIC	High Income Country
HIV	Human Immune Virus
HMIS	Health Management Information System
ICU	Intensive Care Unit
IRTEC	International Registry for Trauma and Emergency Care
ISS	Injury Severity Score
KTS	Kampala Trauma Score
LMIC	Low- and/or Middle-Income Country
MD	Medical Doctor
MNH	Muhimbili National Hospital
MOHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
MTOS	Major Trauma Outcome Study
NTDB	National Trauma Data Bank
OPD	Out Patient Department
REDCAP	Research Electronic Data Capture
SPSS	Statistical Package for Social Science
TARN	Trauma Audit and Research Network
TR	Trauma Registry
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

Chapter 1: Introduction

Trauma contributes significantly to the burden of disease and mortality throughout the world, but particularly in low- and middle-income countries (LMICs) (1–4). Injuries cause over five million deaths annually, 70% more than the deaths from HIV, tuberculosis and malaria combined (3). Ninety percent of injury-related deaths occur in LMICs, where limited resources are available to provide the appropriate care necessary to optimize outcomes (5). In Africa, it is projected that by the year 2030, road traffic injuries and falls will be among the top ten and twenty leading cause of death respectively (6). Beyond the human cost in lives and productivity, the estimated annual cost of road traffic injuries alone is more than 500 billion United States dollars, an amount that far surpasses Africa's global developmental assistance (3).

Sauma care systems that are well-organized and incorporated into the existing infrastructure are known to decrease mortality and improve functional outcomes of injured patients (7–9). The organization and operationalization of such systems requires three key components: a public entity with authority to establish and enforce trauma system policy, centres for clinical trauma care, and a prehospital trauma care system (10). In most High Income Countries (HIC), these systems are well developed and resourced to care for patients throughout the injury continuum, from the scene of injury to the acute care hospital (including emergency, critical and operatative care) through rehabilitation and recovery (10). Most LMICs do not have functioning trauma care systems (11).

Trauma registries (TRs) are an essential component of a trauma system as they support both quality improvement, resource allocation, injury prevention and policy development (12). In most HICs, TRs have evolved parallel to the development of formal trauma care systems (13). This parallel deployment has enabled different trauma systems to reduce morbidity and mortality from injuries, and improving the structure of the system itself (14). In LMIC, TRs are mostly non-existent, and in the few places where they exist, they are poorly developed and managed, and in most cases unsustainable (13). Trauma data for epidemiology, trauma quality improvement, and intervention planning is mostly reliant on single site, hospital-based chart reviews or mortuary-based data logs. Several efforts have been made to develop and implement hospital-based TRs in hospitals in LMICs with varying levels of success (15–18). While TRs have been successfully implemented in LMICs through research initiatives, sustaining and expanding them beyond the research period has proven difficult. Challenges include funding to recruit, train and retain the skilled personnel to collect and manage the TR, lack of electronic medical records to consistently populate trauma data, and a lack of infrastructure (software and computers) to support the TRs (13).

The World Health Organization (WHO) has published a data set for injury (DSI) that contains the basic injury variables that can be collected to inform the injury burden, quality improvement and policy development within a specific country or region (19). In total, the WHO DSI contains 62 variables, addressing patients' demographics, injury event, location and mechanism, facilitators of injury, injury severity measures, prehospital- emergency unit (EU)- and hospital (including operating theatre and intensive care) clinical care processes, disposition, and final outcome. This data set was developed from country-specific TRs through a consensus process involving injury experts from different countries. The final version of the data set was reviewed and approved by the experts of the Global Alliance for the Care of Injured (GACI), an international collaborative network of governmental, intergovernmental and nongovernmental organizations, including professional societies, that works to improve pre-hospital, hospital and rehabilitation care for the injured (19). In principle, the data set is available to use by member countries for facility-based registries to facilitate consistent and reliable collection of injury data, which will be comparable within and outside the country, henceforth supporting the initiatives aimed at improving trauma care.

In Tanzania, there is no formal national TR, and most of the trauma data that are published are based on isolated hospital-based initiatives(20). The Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) maintains a national Health Management Information System (HMIS) that gathers information from all health facilities within Tanzania (21). However, the HMIS does not collect dedicated trauma data, but rather focuses on gathering aggregated diagnoses from outpatient departments (21).

Tanzania has several challenges related to injury care which may limit the capacity to implement appropriate TR, these challenges includes the lack of a formal pre-hospital care system; most patients are brought to health facilities by lay-bystanders who happen to be on the scene, or in some cases by the police (22). This creates a challenge in getting the pre-hospital data of patients, such as injury characteristics or care provided to patients at the scene of injury or at the first level care centre. The second major challenge is the lack of standardised and uniform hospital records, as each facility has its own mode of documentation and storage of patient charts; this creates a challenge when trying to retrieve consistent and reliable patient data from different institutions. This challenge is further compounded by the lack of electronic charting in nearly all the hospitals. Lastly, inadequate health care system funding and staffing makes it hard for the health facilities to designate personnel to compile TR data.

The first Tanzanian effort to develop a TR to understand nature and severity of injuries was at the Muhimbili National Hospital (MNH) in Dar es Salaam (23); however, its demonstrable success has been limited to MNH. The MNH's TR success is largely attributed to the fact

that the tool was also the clinical chart, of note this was introduced at a hospital with a new training program in emergency medicine. The clinical chart also served as a way to guide learners in their assessment and management of trauma, by clearly indicating what needed to be recorded and what actions might be important to take. This methodology would need to be modified for use at other hospitals, adapted to their clinical operations, expertise and availability of equipment. Given the need for standardised data to inform initiatives focused on improving outcomes for injured patients in Tanzania, the overarching aim of this project is to develop and implement standardised clinical documentation, with the WHO data set for injury embedded, for injury at regional hospitals. Once developed, this documentation tool will serve two purposes: Firstly, the tool will provide prompts for healthcare practitioners to standardise assessment and treatment of trauma patients, and secondly the tool will ensure that key standardised data points would be captured. . By integrating the data collection into the clinical chart, we can ensure consistent data collection as health care providers will be able to assist in recording this data without additional effort. By studying this approach at regional hospitals in Tanzania, our work is intended to be a foundational model working towards establishment of a national TR

Aim

The aim of this thesis is to build a model for the development and implementation of a national trauma registry in Tanzania

Objectives

To achieve this aim, the objectives of this thesis are;

1. To determine the frequency with which each of the variables of the WHO Data Set for Injury among trauma patients are captured in clinical charts at five selected regional hospitals in Tanzania.
2. To explore the barriers and facilitators of current trauma documentation practices that may affect implementation of a standardised trauma form at regional hospitals in Tanzania.
3. To explore healthcare providers' perceptions of using a standardised trauma form to manage trauma patients and collect key registry data at regional hospitals in Tanzania.
4. To describe the process of development, structure, and implementation of a context-appropriate standardised trauma form for clinical documentation and data collection for a national trauma registry.
5. To determine the change in proportion of variables of Data Set for Injury captured after implementation of a standardised trauma documentation form.
6. To characterise the burden of injury using prospectively collected injury data in the standardised documentation form among patients presenting to regional hospitals in Tanzania

Ethical clearance

This study was approved by the Human Research Ethics Committee of the University of Cape Town (Reference: HREC REF: 632/2017 and 427/2018). In addition, the study was approved by the Senate Research and Publication Committee of Muhimbili University of Health and Allied Sciences (Reference: No. DA.282/298/01.C/31 and No. 2017-12-06/AEC/Vol.XII/88).

Reporting structure

This study has five objectives, which were investigated as individual studies and are presented in the subsequent chapters. In each chapter we present a peer-reviewed publication, reporting the methodology and results from each study. Furthermore, and whenever appropriate, supplementary methods, results and limitations, which were not published, have been discussed relating to each study. In the final part of this thesis (Chapter 8) we link the findings from all of the related work, and derive conclusions and recommendations for future work.

Chapter 2: Literature Review

Objectives of literature review

In this chapter we present the literature that is appropriate to the theoretical basis of this study as well as the methodological approach taken in this dissertation. The main objective of this literature search is to provide critical appraisal of the existing body of knowledge pertaining to development and implementation of trauma registries, type, role, utility, cost, sustainability as well as its impact in trauma care systems within LMICs. Furthermore, this review will focus on how the current literature relates to this thesis as well as gaps within the existing literature.

Literature search strategy

The literature review was conducted by searching through MEDLINE Ovid, EMBASE Ovid and Web of science for a period of 1978 to 2020 using a predefined series of search strategy as follows:

(Trauma registry or TRs) or ((Registries (mesh/txt) and (Traumatology (mesh/txt) or "Wounds and Injuries" (Mesh/txt) or Trauma))

[AND]

Developing countries (Mesh/txt)

[OR]

or Africa (Mesh/txt) or Algeria or Egypt or Libya or Morocco or Tunisia or Cameroon or Central African Republic or Chad or Congo or "Democratic Republic of the Congo" or Equatorial Guinea or Gabon or "Sao Tome and Principe" or Burundi or Djibouti or Eritrea or Ethiopia or Kenya or Rwanda or Somalia or South Sudan or Sudan or Tanzania or Uganda or Angola or Botswana or Eswatini or Lesotho or Malawi or Mozambique or Namibia or South Africa or Zambia or Zimbabwe or Benin or Burkina Faso or Cabo Verde or Cote d'Ivoire or Gambia or Ghana or Guinea or Guinea-Bissau or Liberia or Mali or Mauritania or Niger or Nigeria or Senegal or Sierra Leone or Togo

[OR]

Developing countries or developing country or developing nation or developing nations or under-developed countries or underdeveloped country or under-developed nations or under-developed nation or underdeveloped countries or underdeveloped country or underdeveloped nations or underdeveloped nation or least developed countries or least developed country or least developed nations or least developed nation or less-developed countries or less developed country or less-developed nations or less-developed nation or less developed countries or less developed country or less developed nations or less developed nation or third-world country or third world country or low income country or low resource country or

middle income country or low-middle income country or third-world countries or third world countries or low income countries or low resource countries or middle income countries or low-middle income countries or third-world nation or third world nation or low income nation or low resource nation or middle income nation or low-middle income nation or third-world nations or third world nations or low income nations or low resource nations or middle income nations or low-middle income nations

[AND]

Development or implementation or implement or implemented

All duplicate studies were removed from the search result, after which studies were interrogated by their title to identify studies that are relevant for inclusion. Studies focusing on description of trauma or general trauma care only without utilization of registry were removed. Below is a summary of the search result:

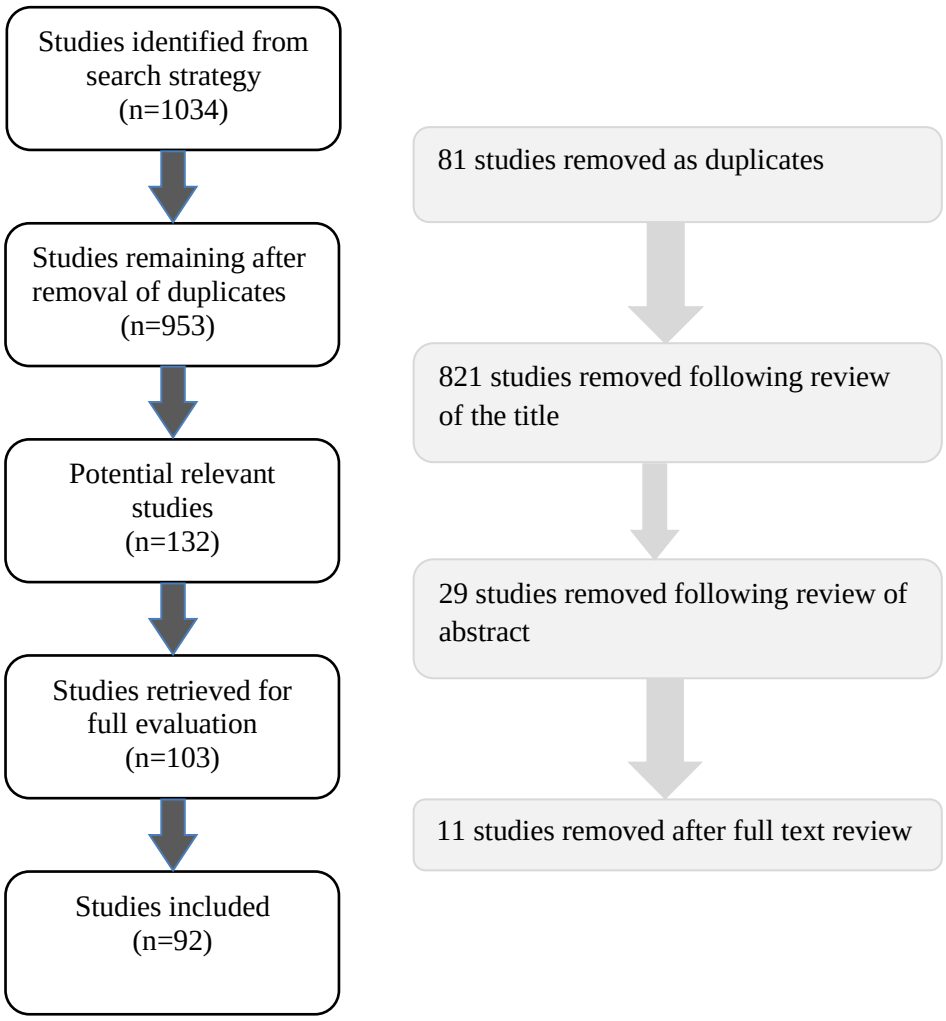


Figure 1: Results of search strategy

Interpretation of literature

Origin of Trauma Registry

A Trauma Registry (TR) is a uniform set of data on injured patients, containing demographics, injury details, and information on pre-hospital care, in-hospital care, diagnosis and outcome (12). In HICs, TRs are an integral component of the trauma care system, providing necessary data for continuous quality improvement in the care processes and clinical outcomes of patients. The establishment of a TRs in most HIC was necessitated by the need to provide accurate evidence of clinical processes, gaps, outcomes of injuries, and means of improving both care and outcomes (24,25).

The first TR was set up in 1969 at the Cook County Hospital in Chicago, United States of America (USA), and was expanded to include other hospitals in the state of Illinois, becoming the Illinois TR (26). This first registry was computer-based. Subsequent advances in computer technology have enabled individual health facilities and regions to set up large databases using microcomputer technologies (27). In 1982, the American College of Surgeons' Committee on Trauma coordinated the Major Trauma Outcome Study (MTOS), one of the first large studies of trauma which provided a retrospective description of injury severity and outcomes (25). The data that was collected for this study, which included over 80,000 patients from institutions located in USA and Canada, created one of the first trauma databases enabling description of major injuries, setting up quality assurance measures, and guided development and implementation of trauma systems.

The implementation of MTOS was a precursor for the establishment of TRs in other HICs-, including the United Kingdom (UK) and Australia, both of which had initially submitted data for inclusion in the MTOS. In the UK, initial efforts to develop TR began in 1988 when a commission of the Royal College of Surgeons of England set out to identify the causes of high morbidity and mortality from trauma (24). The recommendations of the commission led to the establishment of the Trauma Audit and Research Network (TARN) in late 1990 (28). Since its establishment, TARN has provided data on processes of care and outcomes of trauma around UK, Wales and Republic of Ireland, allowing critical analysis of clinical processes and evidence-based guidance for improvements (29).

In 1993, The Royal Australasian College of Surgeons and the Australasian Trauma Society strongly advocated for a TR, leading to the establishment of the Australian and New Zealand National TR Consortium in 2003 (30). The consortium was responsible for the standardising data collection to enable benchmarking, as well as development of a trauma dictionary comprising 67 trauma data points to inform care processes, as well as clinical outcomes of trauma (31).

In LMICs, TRs have not been widely implemented owing to challenges related to the infrastructure, policy, and human and financial resources to both care for the patients and

provide a structure for data collection and management (13). The process of implementation, and status of TRs is discussed in detail in a subsequent section of this literature review chapter.

Functions of TRs

TRs serve key functions related to the care and prevention of injuries across regions and countries. Specifically, a TRs provides the data necessary for:

- Quality improvement in trauma care
- Identification of key measures of injury prevention
- Delineating the medical, economic, and social impact of trauma
- Developing and testing research hypothesis
- Supporting provider accreditation, verification, and designation

Quality improvement in trauma care

TRs provide crucial mechanisms for setting up and monitoring quality measures in the management and outcomes of trauma patients, both at the individual institution level and on a national scale. In HICs, the utility of TRs in informing quality measures in trauma is well elucidated (29,32,33). In the USA, the use of the National Trauma Data Bank has enabled the generation of risk-adjusted analyses that have been critical in evaluating trauma outcomes at the state and national level (32,34,35). *Demetriades et al* utilised the USA National Trauma Data Bank to evaluate the effect of American College of Surgeons' trauma centre designation as well as the volume and outcomes of patients with injuries. This study, compared the clinical outcomes of patients who were managed at level I and II trauma centres, finding that level I trauma centres have better outcomes that lower-level centres in those patients with injuries associated with high mortality and poor functional outcomes. These findings had direct implications in the planning and financing of trauma care (36). Similarly, in the UK, studies using the TARN database have provided insight into the quality of care delivered at specialised trauma centres for patients with certain injuries. Using prospectively collected data from the TARN database for patients seen between 1989 and 2003, *Patel et al* were able to show that patients with severe head injuries who were treated in non-neurosurgical centres had a significantly higher mortality and odds of death than those who were treated at a neurosurgical centre (37). Such findings play a crucial role in designating patient referral patterns, as well as prioritizing care among patients who are at an increased risk for mortality. The Australian Trauma Quality Improvement Program collaboration conducted an audit of patients admitted to 26 major trauma centres across the country who sustained major injury or death after injury (38). In this study, *Cameron et al* were able to show both the time to care and time spent in hospital among these patients; such

findings have enabled the benchmarking of quality of care following injury across Australia, as well as enhancements to data collection and reporting to enable the improved management of trauma victims.

Despite the lack of major and long-term injury registries, TRs in LMICs have enabled improvements in trauma care. In South Africa, *Nicol et al* implemented an injury surveillance system at Groote Schuur hospital and used the registry to conduct a prospective analysis of 9000 trauma admissions to the hospital. The authors demonstrated the high burden of intentional interpersonal injuries as well as road traffic collisions. The utility of this registry enabled the future development of the South Africa's trauma system.

In Uganda, *Kobusingye et al* set up a hospital based registry that was crucial in the development of the Kampala Trauma Score (KTS), a simple context appropriate tool for low resource settings in predicting the clinical outcomes of injured patients presenting to emergency unit of tertiary and district hospitals in Uganda (16). In their study, *Kobusingye et al* were able to demonstrate that KTS is a robust tool for predicting the need for admission as well as death among injured patients presenting to the emergency unit. The KTS uses five parameters (age, number of serious injuries, systolic blood pressure, respiratory rate, and neurological status) all of which can easily be collected in resource limited settings without requiring a highly technical infrastructure or training (39). The incorporation of KTS in different registries, as well as validation of the tool by different studies in LMICs, has provided an opportunity for development of various strategies to improve both care as well as clinical outcome of injured patients in low resource settings (40,41). Beyond the use of TRs in the development of KTS, the use of registries has enabled countries to define the burden of injuries as well as providing insight predictors of outcomes that has been useful informing planning for the quality of injury care (42,43).

In Tanzania, there is general paucity of registry; however, the few available studies on injuries based on hospital wide records have provided an opportunity to understand the quality of care and outcomes of injured patients. *Kuzma et al* conducted a prospective study of a convenience sample of patients with injuries presenting to the emergency unit at a tertiary hospital in Tanzania, through which they were able to show the gaps and inadequacy of pre-hospital care for injured patients, and long delays to definitive care (22). The gaps identified by the authors will support the establishment of a formal pre-hospital system to improve the care and outcomes of injured patients in Tanzania. In another prospective study, factors associated with outcomes of patients who have sustained a road traffic crash were found to include the use of police vehicles to transport patients, delays in receiving care, motorcyclists not using helmets and severe injuries, factors that can be addressed by implementation of a prehospital care system, quality improvement at facility level and public health interventions (44).

Identification of key measures of injury prevention

TRs can be used to support different components of injury prevention by describing the circumstances of injury as well as the geographical patterns of these injuries. In efforts to reduce the burden of injury, understanding the scope and nature of injury is a crucial first step. Information on the cause of injury, and factors associated with injuries are crucial to designing preventive interventions, as well as developing legislation that can support the oversight of programs to curtail injury occurrence. In the USA, the National Trauma Data Bank has provided vital information on the utility of helmet in protecting injuries resulting from road traffic crashes. One such example is a study by *Croce et al* who analysed the National Trauma Data Bank to understand the contribution of motorcycle helmet use to outcome, and the efficacy of state helmet laws (45). This study found that unhelmeted motorcycle crash patients suffered more severe brain injuries and consumed more resources, and there was a survival advantage for patients who wore a helmet during the motorcycle crash. This study led to advocacy for universal helmet use and instituting laws to enforce this in many states of the USA. Similarly, *Stacey et al* conducted a study using data from the National Trauma Data Bank to understand the effect and patterns of facial fractures and lacerations during motor traffic crash in patients using protective equipment (airbags-installed car and seat belts) and found that the use of these protective equipment was associated with a significant decrease in incidence of facial and laceration injuries (46). The use of the TARN database in the UK has enabled scientists to put forward several recommendations on injury prevention (47–49). Such recommendations include road designs that reduce the occurrence of crashes, more effective road speed regulations, and education focused on the young generation for road safety as well as limits in levels of alcohol while driving.

One important component of a TR, as opposed to regular hospital or billing data, is the inclusion of physiological parameters of patients, such as the triage status, vital signs and information to determine injury severity. The availability of such physiological data provides a picture of factors that may impact outcomes of patients when injuries occur, crucial to support the development of secondary preventive strategies. The evaluations performed by the Centres for Disease Control and Prevention in USA have led to recommendations regarding the high value and importance of on-scene triage by trained providers to assist in prioritisation of care and transfer, leading to improved clinical outcomes (50). The ability to accurately use such information and predict the outcomes of patients with undifferentiated injuries has paved the way for protocols that are currently in use as the main means of secondary prevention once the injury has occurred. TRs have also helped identify the impact of primary and secondary prevention on reduction of mortality from injuries within different health care systems. *Mock et al* used the information gathered from registry studies to

estimate the number of lives that could be served if the health care systems in LMICs were similar to those of HICs (51). Such findings are critical in informing future investments in health care systems within LMICs. The global burn registry, which is active in 30 countries, was set up through a collaborative effort of WHO, CDC, and has yielded valuable information on global burn epidemiology that has informed the development and testing of interventions for burns in resource-limited settings (52).

Despite issues of data quality and sustainability in sub-Saharan Africa (SSA), the information contained in hospital-based TRs in this region has led to a number of injury prevention strategies. In South Africa, use of a prospective TR at a tertiary level hospital in Cape Town provided an understanding of the factors associated with intentional injuries among patients presenting to this facility. In this study, the authors were able to define both the burden of these types of injuries and, based on information contained in the TR, set forth recommendations that could be used to prevent such injuries (53).

Lack of a formal pre-hospital care system in most LMICs poses a unique challenge to improving the care and outcomes of time-sensitive injuries among patients presenting to various health facilities (22). Despite these challenges, hospital-based TRs provide valuable information that can be used to prevent injuries, as well as identify key areas of focus for road related interventions. In Malawi, *Chokotho et al* used a hospital-wide TR to locate the hot spots along the main highway where patients who presented to their hospital with undifferentiated injuries were most likely to have accidents. Similarly, in Rwanda the use of geographic information systems (GIS) enabled similar identification of red zones that have a high level of road traffic crashes as well as determine the associated outcomes from these zones (54). The knowledge of hot spots for injuries is an important step towards the development of specific interventions along the roads, and this methodology has been shown to decrease the rate of accidents and the morbidity associated with the incidents (55). In addition to identification of key spots for injuries, the use of a prospective injury registry can enable identification and characterisation of accidents occurring due to individuals driving under the influence of alcohol or illicit drugs, and hence serve to target interventions within the community to address these behaviours (56). Beyond the major commercial cities in Africa, TRs have been used to better understand the nature, patterns and incidence of injuries and aspects of prevention that can be instituted in rural settings (57).

Delineating economic and social impact of trauma

TRs may be used to document economic and social impact of trauma within societies, as well as informing on impact of investments in trauma care systems. Whether the registry describes the impact of a specific injury or the general impact of injury care at a single facility or region, registries can identify the short and long-term economic and social effects

of injuries treated throughout the health care system. As one example, the TR of the Netherlands has been used to measure the overall cost of injuries, demonstrating a total annual cost of injuries of € 3.5 billion, with an additional € 1.5 billion in productivity costs in 2016 (58). This study used detailed cost analysis to identify groups with the highest risk of injury and cost, from which the authors suggested preventive measures. Understanding the economic burden of injuries goes hand in hand with developing models of cost-effective approaches to care of the injured. In the USA, *Zarzaur et al* used a TR available at a level I trauma centre to evaluate the cost of survival for patients with moderate to severe injuries. In this study, there was no difference in the cost of survival among different age groups, leading to the authors' recommendation for aggressive funding for injury prevention efforts specifically aimed for the vulnerable populations (59).

Information on the cost of care incurred by patient and families due to injuries can help the community and government to offer legislation on heath financing measures that will ensure sustainable health care provision. In India, *Prinja et al* evaluated the out-of-pocket expenditure as well as magnitude and determinants of catastrophic health expenditure among patients presenting to a public health hospital. In this study, the authors demonstrated a high economic impact in terms of out-of-pocket expenditure (prevalence of catastrophic expenditure being 22.2% with 12.2% slipping below poverty line) as well as the loss in productivity resulting in high rates of impoverishment as a result of injuries (60). A study done in Benin, Africa to a determine the social demographic factors and direct cost of management of traumatic brain injuries during initial phase was able to demonstrate the higher average cost of care (with average cost €285.67 ± 310.15) compared to the normal income of the general population. The study further notes that there was an inability of many patients to cater for such services, and hence proposed recommendations to develop and set up an insurance system that could support the care of patients who have sustained road traffic injuries (61). Beyond the cost associated with care, TRs can be used to track and document the impact of trauma due to disability and loss of ability to work, leading to impoverishment and dependency. This is particularly important in LMICs, where the most population work in the casual sector and depend on daily wages for survival. In Uganda, the use of trauma data has enabled the quantification of profound socioeconomic impact, with one study showing that patients with long bone lower extremity fracture lost 88.4% ($1822 USD) of their annual income in the 12-months following their injury, as compared to pre-injury earnings (62). Furthermore, *O'Hara et al* used a TR in another study to follow up patients who had sustained isolated tibia or femoral fractures following road traffic injury, in Uganda. In this study, the authors followed the patients for 2 years and found out that less than one-quarter of patients with such injuries had recovered economically and physically (63).

Developing and testing research hypotheses

The implementation and maintenance of TRs is crucial to development and testing of various research hypotheses, which are crucial to discovery of new life saving interventions as well as prevention of injuries. Most high impact published studies on injuries have been derived from long term injury registries that have been in place for decades (64). The ability to test various hypotheses using a large database of prospectively collected data allows for valid conclusions about the hypothesis. This provides for a safe approach to finding associations about risk factors for injuries, and therapies that appear before one implement care process or prevention strategies (65). For example, the use of the National Trauma Data Bank in the USA has enabled testing of various research questions on the impact of use of protective equipment on reducing the morbidity and mortality resulting from road traffic crash (45). Furthermore, in a prospective study conducted in Pennsylvania USA using a registry of all patients treated at the trauma centres, *Wang et al* demonstrate the adverse outcomes of out-of-hospital endotracheal intubation in patients who have sustained severe traumatic brain injury (66). This study set a platform for the discussion and further evaluation of the best methods of securing a compromised airway in patients who sustain severe traumatic brain injury.

The evolution and validation of the KTS is an important output of an established TR in Uganda (57). In addition to the validation of KTS, other registries in the region have been used to test various research questions and hypothesis related to both clinical and resource utilization related to trauma care processes. In Kenya, a TR set up at the main national hospital provided insight into morbidity, mortality and resource utilization related to the care of injured patients (43). In Tanzania, a single hospital based TR has enabled both the faculty and trainees to develop and test research questions on various components of injury care, such as the quality of pre-referral stabilization (67), feasibility of provider initiated HIV testing in trauma patients (68), and the adequacy of pain assessment and treatment in trauma patients (69).

Supporting provider accreditation, verification and designation

TRs can provide essential data on the type and level of care provided by a particular health facility over a period of time, taking into account the nature of injuries that are common in a particular geographical location. In USA, the trauma centres are normally identified by a designation and verification process, for which different levels (i.e. Level I, II, III, IV or V) are normally assigned based on the resources available, educational commitment as well as the volume of trauma patients. The process is overseen by the American College of Surgeons Committee on Trauma verification and State designation of trauma centres (70). TRs have provided data on nature, type and outcomes of patients managed different levels of care, and

these data have reinforced the value of designating health facilities with specific trauma care designation (36). This accreditation process has proven to impact the outcomes of patients with major injuries, justifying and highlighting the need for more resources, education and prioritization of transfer of patients to these centres (71). Similarly, in Australia, the Australasian Trauma Verification Program designates which hospitals can serve as trauma centres, so as to streamline the referral pathway of trauma patients, linking them to the best possible resources and expertise for care (72). The Royal Australasian College of Surgeons supported by other relevant colleges oversee this process, which in part utilises the Australian TR to identify nature of injuries as well as the associated outcomes, and resource utilization (31). In the UK, the trauma care process was reorganized in 2012, paving the way for prioritising the transfer of patients to centres with higher levels of resources, and expertise for care, commonly referred to as Major Trauma Centres (MTC) (73). The designation of MTCs came as a result of recommendations of the reports of the National Enquiry into Perioperative Deaths, which found that almost 60% of major trauma patients received less than good practice, with continued occurrence of avoidable deaths (74). In Africa, while the trauma centre designation is not common for most of countries, the use of Hospital TRs has provided useful information on volume, nature, resources and outcomes of patients at most of the facilities (53,75,76). Thus, establishing sustainable injury registries at national or regional levels will provide a wider opportunity to better understand the performance and needs of different health facilities, and hopefully lead to a better resource allocation as well as creating a referral pathway that can reduce morbidity and mortality resulting from injuries.

Types of Trauma Registries

TRs are highly variable in design, nature of implementation, hosting, variables and inclusion criteria. Studies describing registries in different countries have grouped the registries into different categories depending on the design, nature, storage and implementation method:

- Core and extended data elements collection
- Concurrent versus retrospective variables collection
- Electronic versus paper-based data source
- Single versus multi-site data collection

Core and extended data element collection

TRs across the world use different inclusion criteria, and collect different variables depending on the reason for inclusion. Specific inclusion and exclusion criteria are based on a number of factors, both related to clinical progression of specific illness that has been learnt over time, as well as the complexity of collecting data on all trauma patients regardless

of the complexity of their injuries (13).

In HICs where registries are well developed, inclusion criteria have evolved over time as the face of trauma changes. One such example is the TARN in the UK, which uses three criteria to decide on type of patient to be included in the registry (77). The decision to include the patient in the registry is based on the following three criteria being met:

1. Trauma patients irrespective of age
2. AND Who fulfil one of a set of criteria on length of hospital stay:
    - In hospital for ≥ 3-night stay
    - Admitted to critical care area (regardless of LOS)
    - Transfer out for specialist care or repatriation
    - Transfer in for specialist care or repatriation
    - Deaths (including EU death)
3. AND those whose isolated injuries include the following: Head, Face, Neck Thoracic, Abdominal, Spinal, Femoral, Pelvic, Upper and lower limb, Hand and feet, Burn or inhalational injuries, and other specific injuries. In each of these categories, there is an additional set of inclusion and exclusion criteria based on the anatomical location that is involved in the injury.

Similarly, in the USA, the NTDB utilises a set of inclusion criteria that combines the international Classification of Disease (ICD-10) diagnosis as well as the clinical course of patient during care process (78).

In LMICs, the nature and design of TRs is very variable, especially given that most settings utilise different modes of data collection, over a period of short period of time, usually as part of research. Most TRs in LMICs are single centred (involving only one health facility) and temporary, covering the duration of the research project. As an example, in *Nicol et al* set up a TR in South Africa that included all injured patients presenting to an urban tertiary hospital in Cape Town, with no exclusion criteria, over a period of one year (75). The implementation of TRs at specific hospitals in Uganda and Kenya involved all patients, but only for a specified period of time (16,43). While these TRs have provided initial important information about the face of trauma in these settings, lack of sustainability and their single site nature limits their generalisability as well as long term utility of data, including regular quality assurance measures for the data that emerge from these registries.

Concurrent versus retrospective variables collection

Collecting injury variables for TRs can happen in two distinct ways depending on the set up and design of the facility that is running the TR. Concurrent data collection occur as the patient is receiving care; in most situations the clinical care is linked with data collection, for which the documented care of patient is part of the registry data, and the information for the

registry is normally retrieved from the system (79). In retrospective variable collection, data collection happens after the patient has completed their care in at least one part of the hospital, and data personnel or a researcher will review the existing patients' files (either electronic or paper based) for patients meeting specified inclusion criteria for the registry, and then abstract the data for utilisation in the registry (57,80). In LMICs, most sites utilise a combination of both concurrent and retrospective data collection, for which there is a use of specific data form to gather information as the patient is receiving care at the health facility, and similarly the form is also used to supplement data points that were missed when patient care process is ongoing (75).

Electronic versus paper-based data sources

The source of data elements to inform the registry is either electronic or paper-based records, depending on the capability of the health facility. Most HICs have electronic medical record systems for the care of patients, and these have significantly improved both ease and accuracy of access to information pertaining to injured patients. In these settings, the main source of initial injury and treatment data, and follow up of patients, is largely through remotely tracking the patient's course through the electronic medical record system and either manually or automatically entering the agreed standardised trauma variables into the registry. Contrary to HICs, most LMICs have do not have electronic medical record systems, and in places that they exist, are often non-functional and unsustainable (81). In such places, the data source becomes either a paper clinical form, or the direct notes that are taken by the research assistants in the course of collecting data. The lack of electronic medical record system creates a challenge in tracking, validation and follow-up of patients who are enrolled into the registry.

Single versus Multi-site data collection

The scope and generalisability of TRs is largely dependent on the catchment area of the health facilities involved. In HICs, TRs have evolved to include multiple health facilities, each contributing a set of standardised data elements for patients meeting the pre-defined set of inclusion criteria (28,30,78). The inclusion of a large amount of data from multiple sites enables researchers to draw meaningful and generalizable conclusions. In LMICs, most TRs use data from a single site and are limited to the research period, mostly owing to lack of consolidated national strategy and resources to develop and manage large databases.

Registry variables

Defining the set of variables to be collected in TRs is an important initial step in ensuring the database provides the necessary output to inform the purpose of setting up the registry. First,

the organisers should have a clear and mutually agreed understanding of the definition of a trauma patient, which may be based on local or regional guidelines and care pathways. For most regional or national registries, patients to be included meets specific inclusion and exclusion criteria that are standardised across collection sites (77,78). Most registries include basic patient demographics, injury mechanism, vital signs, investigations, treatment procedures, and patient outcomes. Beyond these common variables, TRs usually include measures of injury severity, although there are recognised limitations associated with labelling and identification of severity (33,38,82).

TRs in most LMICs include a minimum number of injury variables in order to maximize the enrolment of patients in the registry; however, this presents a challenge to capturing variables that are comparable with other registries across the world (80,83). In implementing the registry in LMICs, various innovations have been used to support the calculation of the severity of injury, such as the development of KTS and its subsequent validation in various settings in Africa (84). The disparities in variables included in the TRs across many LMICs has limited the ability of countries and regions to have a standardised set of data that can generate comparisons to inform both the quality and outcomes of injuries in these settings.

WHO Data Set for Injury

The World Health Organization through the Global Alliance for the Care of Injured (GACI) has developed a standardised Data Set for Injury (DSI), which has both core and extended versions which countries can adapt for use in implementing their registries (85). The WHO DSI has seven main sub-sections:

- Patient registration
- Initial Clinical Condition
- Details of Injury
- Prehospital and Prior Facility Care
- Injury Examination
- Emergency Unit Details, and
- Inpatient Details.

Within these sections, there are 74 DSI variables (46 core and 28 extended), from which 62 variables are collected in the emergency unit and the remaining 12 from the inpatient setting (**Appendix 2.6)**. The goal of the DSI is to standardise the variables being collected across multiple sites, and offers the ability to utilise the data in the newly developed WHO International Registry for Trauma and Emergency Care (WHO IRTEC) (86). The IRTEC is freely available to all countries for input data points which can then be analysed automatically analysis, generating a dashboard of key results, without need for an expert

Trauma registry software

In developing a TR it is important to consider how the database will be handled and managed, as the number of patients will keep growing over a period of time. The NTDB now includes over eight million patients, enrolling over eight hundred thousand annually (87). Having a repository that can handle such large numbers of patient variables requires dedicated software, hosted in an operating system that has sufficient memory and security specifications (13). *Asad et al* used an applied research technique to engage a group of experts through a Delphi process to identify general and specific criteria for TR software. Four main requirements were identified: usability, security, maintainability and interoperability (88). These identified criteria are crucial for the successful and sustainable implementation of a TR in any particular setting. In HICs, there are number of commercially available software applications on the market that are currently used by different trauma centres to collect and manage trauma data, and which allow interoperability among institutions. The procurement and maintenance of such software is both expensive and requires expert management throughout the process; as such most institutions have a dedicated team to deal with handling of trauma data and linkage with regional or national databases (12).

In most LMICs, the prohibitive cost to procure appropriate software, coupled with a lack of appropriate infrastructure and expertise to support the system, has prevented utilisation of formal trauma software (89). This challenge has resulted in utilization of different platforms for collecting and handling of data in most LMICs. One frequently used modality is open access online data capture software, such as Research Electronic Data Capture (© REDCap version 7.2.2, Vanderbilt, Nashville, TN, USA) which can be used to collect, export and analyse the injury data (56,67,89). One advantage of such a system for resource limited settings is the open-source nature of the software, as well as the simple requirements for daily operations, which includes the ability to use simple mobile devices in collecting data, regardless of connectivity to internet services. Despite these crucial advantages, set up of such software requires a server for hosting the software as well as maintenance of the server. Other researchers have resorted to the use of basic Microsoft Excel spread sheets (Microsoft Corporation, Redmond, WA, USA) which are then imported into statistical analysis packages when the authors wish to conduct formal analyses (76). The use of simple means of data collection such as Excel provides the means of gathering data but poses a number of challenges with regard to security, quality and analysis of data.

Trauma registry validation

The reliability and effectiveness of any TR in performing its designed functions is largely dependent on the quality of data that is collected and stored for analysis. Different studies have evaluated the level of data quality within TRs, and set forth recommendations on how other registries can conduct internal audit control (90–92). These studies have proposed modalities to validate the data in the TR in different parts of the registry input process:

- *Proportion of case capture*. This represents the proportion of cases that are recorded in the registry out of all those that should have been recorded based on the inclusion criteria set by the registry team (93). Validation of the proportion of case capture can be done through comparison of actual clinical notes or health facility register logs of all trauma patients seen as a health facility, with the total numbers of patients entered into the TR (90,93). The completeness of patients capture in the registry is the first step in assessing the quality of the data, as it determines the generalisability of the results that are coming from the registry.
- *Data completeness*. This is the proportion of the data values documented in the registry out of the total number of data values that should have been documented in the registry. *Heinanen et al* described the process of validating data completeness (93), which can be done by selecting a sub-set of data (e.g., within a specified time frame) then using trained registry clerks to enter selected parameters for cases seen during that time. The variables entered by this trained group is used as the reference standard and compared with the variables found in the registry to determine level of data completeness in the TR
- *Data accuracy*. An important component of any TR, data accuracy is calculated as the percentage of data that matches exactly to the verifiable source. Establishing the level of data accuracy can be done during the validation of the level of completeness (93).
- *Data correctness.* In each registry can be reported as a proportion of values for any variable that are likely to be correct or within a tolerable range. An example of deviation might be reporting of a respiratory rate that is beyond the normal expected values even for a pathological presentation (90).In his validation study, *Heinanen et al* reported the level of correctness within different variables noting that some proportion of the variables were deviating from normal expected range (93). The quality of a TR is largely dependent on the rigorous and regular validation process for each of the data points that are supposed to be captured. In most HIC settings, the use of computer software and availability of sufficient resources to provide dedicated staff and infrastructure for managing institutional and regional level registries, have enabled these registries to generate high quality data with success in most of these

components (30,77). In LMIC the lack of dedicated infrastructure and funding to develop and maintain the registry, as well as their relatively short duration, has made it challenging to have a rigorous and regular process of validating TRs (13).

Limitations of trauma registries

The use of TRs has enabled the development of different strategies in the care and prevention of injuries across different settings. Despite notable success in the use of information coming from the registries, there are several limitations associated with most registries (94). Lack of the following important components limits the utility of TRs in assessing the full effectiveness of trauma care as well as assessing any new preventive and therapeutic approach:

- *Pre-hospital deaths* are not recorded in many TRs as they only include those who reach health facilities. This presents a substantial omission of an important outcome for the trauma system. In particular, in countries without a formal prehospital care system, many injured patients succumb to death the scene of the injury, or site en route to the health facility due to lack of immediate interventions in the prehospital environment or the severity of their injuries (44). Incorporating the pre-hospital deaths will provide a crucial opportunity to inform secondary prevention, and also support the justification for implementing or strengthening a formal pre-hospital care system. Furthermore, the identifications of settings that are associated with fatal injuries will help to implement measures to decrease the incidents of injuries, and eventually reduce deaths associated with such incidents (76).
- *Long term survival outcome* is not registered in most TRs (94), which limits the ability to understand the full scale of the impact on trauma patients especially those who suffer severe injuries that necessitate long-term recovery. *Davidson et al* conducted a retrospective review of long-term survival of adult trauma patients following injury using the Washington State TR by linking the State TR to death certificate data and found a cumulative mortality rate of 16% at 3 years compared to expected population cumulative mortality of 5.9%. Furthermore, the authors demonstrated that the discharge of patients to a nursing facility was associated with higher risk of mortality. The utility of such evidence is crucial in supporting the strategies associated with improving long-term outcomes of patients who have sustained injuries.
- *Rehabilitation and long-term quality of life outcome* after injuries is crucial in determining the effectiveness of rehabilitative care to patients who have sustained injuries. *Malec et al* used data from a national database examined outcomes of post-inpatient rehabilitation programs to support understanding of which modality of

rehabilitation provides benefit for injured patients. The authors found that intensive residential and community-based rehabilitation had more positive functional outcomes (95), a finding that can have a huge impact in the delivery of rehabilitative services in the community.

- *Limitations on minor injuries*. Most injury registries have a set of inclusion and exclusion criteria for nature, severity, and type of injuries that are to be captured (28,87). While this practice allows for easier data management and standardization of outcome of patients in different settings, the practice limits generalisation of results, as they will not be representative of all injuries in the population.
- *Cost of set up and operationalization*, Implementation of TRs is associated with cost implications that can far exceed what most facilities or regions can support, especially in LMICs. Sustainable funding for the registry is often at the centre of these challenges; *Purcell et al* describe the costs associated with setting up a TR in Malawi, which enrolled 12,616 patients over a period of one year. In this study, the total annual cost of developing and running the registry was $33,361.64 annuals (an estimated $2.64 per patient enrolled in the registry in 2018) (96). Sustaining and expanding such a registry beyond the research period in a low resource setting has proven to be a major challenge especially given the competing needs for resources simply for patient care.

Identification of gaps for further research

***TRs** implementation in low resource settings*

In low resource settings, owing to a number of challenges facing their establishment and sustainability, there are very few TRs. Implementation of TRs in these settings has largely been unsuccessful, with most published data coming from either one-time research projects, retrospective clinical data, or general population surveys (16,43,76,83). A systematic review by *Bommakanti et al* including 28 articles focusing on challenges and opportunities of TR implementation, revealed data quality issues, lack of resources, insufficient pre-hospital care and difficulty with administrative duties and hospital organisation as some key challenges of implementation (96). Similarly, in a review of the history and development of TRs, *Nwomeh et al*, outlines some of the key barriers that hamper the establishment of reliable and efficient TRs in LMICs which include lack of formal pre-hospital care, lack of proper evacuation and transport mechanisms, lack of standardised hospital data formats, lack of electronic data systems for storage and retrieval, lack of funding, government health policies, inadequacy of population level data, and lack of general awareness in the communities. Similarly, in Malawi, *Chokotho et al* described their experience of establishing a TR at an emergency unit of a tertiary level hospital to support identification of high risk geographic areas (76). In this

single centre study, the authors identified several key challenges in establishing this TR, which included the incompleteness of data due to utilisation of a paper-based registry, a backlog of paper data not captured electronically due to manpower shortage, lack of sustainable funding, the large volume of variables being collected, a shortage of trained personnel to collect data, lack of motivation and administrative buy-in to the project, and challenges with patient care pathways. Developing a sustainable TR in these settings requires finding solutions to these challenges and limitations. The use of standardised definitions and variables, as well as minimizing the number and complexity of the variables to be collected, is a key element for increasing the success of injury registries in these settings. Furthermore, reducing the burden of dual documentation as well as the amount of paper that has to be handled will help ensure compliance and reduce loss of data from contributing sites. This is particularly important because of the lack of sufficiently trained personnel and limited infrastructural resources, most of which need to be prioritised for patient care. Despite these challenges, there are several individual efforts to establish and maintain registries, however much of the resultant data come from single facility registries that are implemented under a research environment that may not be representative or scalable (44,97–99). In Kenya, a multi-national collaborative partnership led to an establishment of pilot TR in three sites, which provided an opportunity to document the burden of injuries, as well as delineating the challenges of establishing a country-wide registry. This initiative relied on external funding to support both implementation and continued data collection, which limits its long-term sustainability beyond the funding period (80). In Rwanda, *Kearney et al*, describe the development of a local TR that is based on a retrospective chart review of data from pre-hospital, emergency unit and inpatient records. In this 3-year retrospective review, the use of an electronic medical record system was used to support the retrieval process of trauma patient data (100). In addition to being only a single facility retrospective review, this study was also funded as a research project through multiple partners, limiting its potential scalability as well as sustainability beyond the research and funding period.

A simplified trauma registry was trialled at district and regional hospitals in Kampala, Uganda by *Kobusingye et al*. It was a paper-based system utilising a minimal data set on one page of paper (84). Another approach towards developing a TR was described by *Chichom-Mefire et al* at a regional hospital in Cameroon. Using a paper-based system, research assistants documented the demographic information for the patient, while the clinicians completed the clinical information in the trauma data form, in addition to their regular clinical responsibilities (101). Authors of this study demonstrated that the implementation of TR in resource-constrained setting was both feasible and provided high quality data that informed trauma care quality improvement and policy.

In South Africa, there have been multiple efforts to develop and implement TRs at facility

and regional levels (102–104). Unlike most of SSA, the South African efforts have largely involved the use of electronic medical record system, which provides the advantage both to retrieve records as well as data. *Laing et al* describe the process of design, construction and implementation of a computerised TR for the Pietermaritzburg Metropolitan Trauma Service, leading to a reliable audit of trauma data, with limitation on compliance due to lack of integration of registry in the process of clinical care (102). *Nicol et al* describe a prospective study using a TR of all trauma admissions at an academic hospital in Cape Town over a period of one year (75). In this study, the implementation of injury surveillance provided insight to the risk of injury as well as access to service. These experiences have since informed and influenced the development of an electronic application that will be used by clinicians for both patient care as well as data capture for a registry (105).

TR experience in Tanzania

In Tanzania, like most of SSA, there is no formal TR. The Government of Tanzania utilises Health Management Information System (HMIS) registers to gather and aggregate data from individual facilities on diseases, and clinical and diagnostic processes (21). The Government maintains twelve different HMIS registers for gathering different data points on disease conditions, clinical processes and staff information. Trauma care documentation normally starts at the emergency units (which are largely "casualty" or outpatient departments), using HMIS register number five (known as HMIS for outpatients). The outpatient HMIS has a total of 14 data points namely: date, attendance number, patient name, address, age, sex, weight, height, investigations ordered, investigation results, diagnosis, treatment, outcome and remarks. In the event the patient is admitted, the HIMS register number 14 (referred as HMIS for inpatient), is normally used for documentation of the continuity of care. The inpatient register has a total of 14 data points; patient name, file number, sex, age, address, date of birth, diagnosis on admission, treatment, investigations ordered, investigation results, final diagnosis after investigation, treatment, outcome of treatment, and date of final outcome.

The HMIS registers are supposed to be completed by the clinicians attending patients, in addition to the usual documentation in clinical charts. The HMIS registers from each clinician are normally collected and aggregation of data is expected to be done at each facility, and subsequently submitted to the Ministry of Health for country-level compilation and dissemination (106). While HMIS registers have been widely disseminated, several challenges in compliance, data type, relevance, quality, and consistency have been major challenges of utilising the HMIS as a source of data to inform quality improvement initiative as well as burden of diseases including trauma (107). In addition to the use of HMIS as a source of trauma data, the Department of Roads Traffic Division of the Tanzania Police

Force maintains a Road Accident Information System (RAIS), which is a database of Road Traffic Crash (RTC) (108). The use of data from RAIS has supported the understanding of the burden and trend of RTCs, however its utility is limited to RTCs and events on the road only, with no continuity with hospital care or associated outcomes.

In the past decade, there have been several initiatives to document the burden of trauma; however, these efforts have mostly been limited to one-time research studies done at a single or limited number of sites (44,109–111). Similar to other studies in SSA, most of these studies have also been confined to the duration of research, dictated by the availability of funding. In a data collection initiative involving six sites, *Lalande et al* implemented a tablet-based data archiving system for trauma data that was collected by local data collectors using a paper form. This project, which involved a partnership between local leads, and international leads, and funded by an international collaborator, was able to demonstrate a substantial completeness of trauma data, more so than the data collected in hospital records (112). However, the sustainability of such a system beyond the period of funding and infrastructure supported by international collaborators remains largely unknown. At the main National Hospital in Dar es Salaam Tanzania (113), the first attempt to establish the first sustainable TR model was implemented using a novel African Federation for Emergency Medicine form (23). While this implementation has been successful at documenting the burden of disease, its impact has been limited to this single site, reducing the generalisability of the data across the country, given the nature and capacity of this tertiary care emergency department and trauma centre.

Summary

In summary, the current literature narrates the history of development of TRs across different HICs, showing wide variability in the nature, inclusion criteria, management and implications these registries. The data available has demonstrated the utility of having a TR, specifically in the improvement of quality of trauma care, setting up preventive strategies, as well as developing a strategy for high impact therapeutic interventions (28,29,38,87). In LMICs, current evidence shows a lack of organized and sustainable TRs, with most based on short-term research projects, or review of retrospective data from various health facilities, with limited long-term sustainability (13,57,112). Several key reasons for lack and failure of implementation of TRs in LMIC have been identified, including data quality issues, lack of resources, insufficient pre-hospital care, conflict with administrative duties and hospital organisation as some key challenges of implementation (96). There is a proposed data set for injury that is available for use from the WHO, and this can be adopted by the member countries and used to inform injury data collection (114). The literature lacks clear guidance on how to develop a TR for LMICs, given the challenges identified in several research

projects that had initially focused on the documentation of the burden of injury. This thesis aims to bridge this gap by developing and implementing context-appropriate, sustainable standardised trauma documentation that is part of clinical documentation, utilizing and adopting the proposed WHO DSI. This data can be used in documenting the care of patients, and at the same time generating data to inform national registries across LMICs. This thesis aims to provide much-need evidence and guidance for implementing TRs in LMICs.

Chapter 3: What is the capture of WHO DSI variables among trauma patients?

Reference:

Sawe HR, Reynolds TA, Weber EJ, Mining JA, Coats TJ, Wallis LA. Trauma care and capture rate of variables of World Health Organisation data set for injury at regional hospitals in Tanzania: first steps to a national trauma registry. BMC Emerge Med. 2020 Apr 23;20 (1):29.

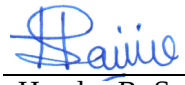
Declaration from author and co-authors

The following co-authors contributed to the paper: Hendry R. Sawe, Teri A. Reynolds, Ellen J Weber, Juma A. Mfinanga, Timoth J Coats and Lee A Wallis. In the case of Chapter 3, contribution by authors to the work was as follows:

HRS contributed to the conception and design of the study, acquired, analysed and interpreted the data, and drafted and revised the manuscript. TAR, EJW, JAM, TJC and LAW contributed to the design of the study, data interpretation and critically revised the manuscript. All authors read and approved the final manuscript. All authors approved the final published version and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Extent of contribution:

1. Dr. Hendry R. Sawe: 75%,
2. Prof. Lee A. Wallis & Prof. Ellen J Weber together: 15%,
3. Prof. Teri A. Reynolds, Dr. Juma A. Mfinanga & Prof. Timoth J Coats together 10%



12th April 2021

Hendry R. Sawe Date

Declaration by co-authors

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other author of the publication according these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from date indicated below

Location of stored data:

Data set analysed during the current are stored on the authors (HRS) encrypted Research Electronic Data Capture (RedCap) account allocated through the Emergency Medicine Association of Tanzania, research portal.

16th April 2021

Prof. Lee A. Wallis — Date

14th April 2021

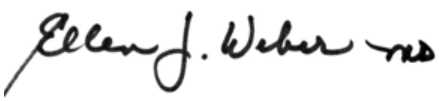
Dr. Juma A. Mfinanga — Date

20th April 2021

Prof. Timothy Coats — Date

29th April 2021

Prof. Teri A. Reynolds — Date



23rd April 2021

Prof. Ellen J Weber — Date

Main findings

- In the regional hospitals of Tanzania, there is low capture of the minimum trauma variables specified in the WHO injury data set.
- Only half of trauma-related visits seen in the regional hospitals of Tanzania are documented in the Health Management Information System by the treating clinicians.

Motivation for conducting the study

The successful implementation of TR is dependent on reliable and sustainable availability of data set for injuries from the health facilities (90,91). In most HIC the availability of data set for injuries is guaranteed by a robust system of documentation supported by both electronic medical record systems and dedicated team of full time personnel managing the TR (232). In most LMICs there are several challenges related to documentation and management of TRs, as such there is very limited ability to implement and sustain such registries beyond the research environment (76,115,116). In recent years, several attempts have been made to develop and implement sustainable injury registries in LMICs, however most of these efforts have been faced by number of challenges including incomplete data recording, increased workload on personnel who are already stretched with clinical care, inconsistent and large number of variables to be documented, lack of motivation and poor administrative support (76,115,116).

In efforts to address challenges associated with inconsistent and lack of standardised injury variables, the WHO has published a DSI available for different memberstates to use, having variables that can inform both the injury burden and patient care process. (19). This WHO DSI has provided opportunity for specific member countries to adopt and utilise these as well as being able to compare with countries with similar settings.

In Tanzania there is no TR, and this has created a gap in understanding the true burden of injury, as well as informing efforts to improve care and preventive strategies for injuries. The lack of enough human and infrastructural resources has limited the ability to focus on building sustainable injury registry. In effort to address this gap, we proposed to utilise WHO DSI as standard set of data that can be used to inform national registry. In order to understand the feasibility of adopting the WHO DSI as standard variables, we ought to determine the current status of documentation of these variables, as well as the nature of reporting of injury through the Ministry of Health, Heanlth Information Management System registers. With this research information, we will be able to set a roadmap and propose changes in documentation, training of health care providers as well as the minimum resources required for a sustainable TR in Tanzania.

Aim

The aim of this study was to determine the capture for each of the variables of the WHO Data Set for Injury among trauma patients at five regional hospitals in Tanzania.

Objectives

1. Determine the proportion WHO DSI variables documented for each trauma patient presenting to Emergency Unit of regional Hospital.

2. Determine the proportion of WHO DSI variables documented for each trauma patient in the Ministry of Health, Health Information Management System register.

A copy of the published paper follows over the next nineteen pages.

Copy of published paper

Trauma care and capture rate of variables of World Health Organization data set for injury at regional hospitals in Tanzania: first steps to a national trauma registry

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Abstract

Background: In Tanzania, there is no national trauma registry. The World Health Organization (WHO) has developed a data set for injury that specifies the variables necessary for documenting the burden of injury and patient-related clinical processes. As a first step in developing and implementing a national Trauma Registry, we determined how well hospitals currently capture the variables that are specified in the WHO injury set.

Methods: This was a prospective, observational cross-sectional study of all trauma patients conducted in the Emergency Units of five regional referral hospitals in Tanzania from February 2018 to July 2018. Research assistants observed the provision of clinical care in the EU for all patients, and documented performed assessment, clinical interventions and final disposition. Research assistants used a purposefully designed case report form to audit the injury variable capture rate, and to review Ministry of Health (MoH) issued facility Register book recording the documentation of variables. We present descriptive statistics for hospital characteristics, patient volume, facility infrastructure, and capture rate of trauma variables.

Results: During the study period, 2,891 (9.3%) patients presented with trauma-related complaints, 70.7% were male. Overall, the capture rate of all variables was 33.6%. Documentation was most complete for demographics 71.6%, while initial clinical condition, and details of injury were documented in 20.5% and 20.8% respectively. There was no documentation for the care prior to Emergency Unit arrival in all hospitals. 1430 (49.5%) of all trauma-related visits seen were documented in the facility Health Management Information System register submitted to the MoH. Among the cases reported in the register book, the date of EU care was correctly documented in 77% cases, age 43.6%, diagnosis 66.7%, and outcome in 38.9% cases. Among the observed procedures, initial clinical condition (28.7%), interventions at Emergency Unit (52.1%), investigations (49.0%), and disposition (62.9%) were documented in the clinical charts.

Conclusions: In the regional hospitals of Tanzania, there is inadequate documentation of the minimum trauma variables specified in the WHO injury data set. Reasons for this are unclear, but will need to be addressed in order to improve documentation to inform a national injury registry.

Key words: injury registry, emergency care, trauma burden, trauma care, Africa, Tanzania

BACKGROUND

A trauma registry (TR) is a key infrastructural component of a well-functioning trauma care system, facilitating appropriate deployment of resources, quality improvement, injury prevention initiatives, injury-research execution, and policy development (12). In most high income countries (HICs), parallel deployment of TR with development of formal trauma care systems has played a key role in decreasing injury-related disability and mortality (14). Few low- and middle-income countries (LMICs) have TRs; in the places where they exist, they are poorly developed and managed, and in many cases unsustainable (13). Trauma data are mostly reliant on single site, hospital-based chart reviews or mortuary-based data logs (15–18) which are often incomplete, or subject to interpretation.

In Tanzania, like most LMICs, there is a substantial shortage of both human and infrastructural resource for optimal provision of health services (117,118). The public health system, which attends to majority of patients, is organised in a pyramidal structure with most emergency care for trauma occurring at the lower tier of the system - most of which have no dedicated emergency care providers (117,119). Emergency Medicine is still a new concept in most of the regional hospitals, which are not well equipped and staffed to provide trauma care.

There is no national TR in Tanzania, and most of the trauma data that are published in the literature are based on isolated hospital-based initiatives (120–122). Implementation of an appropriate model of TR in Tanzania faces several challenges, including the lack of standardised and uniform hospital records, lack of electronic charting for nearly all the hospitals, and inadequate health care system funding and staffing which makes it hard for the health facilities to designate personnel to compile TR data. The lack of TR has substantially affected the country's ability to create initiatives to improve injury related outcomes, and plan for appropriate preventive measures against injuries

The World Health Organization (WHO) has developed a data set for injury (DSI) that specifies the variables necessary for documenting the burden of injury and clinical processes, with the main goal of informing both quality improvement and system planning activities at the facility and at national level (123). The WHO DSI has a set of core and extended variables that are categorized into: patients' demographics, initial clinical condition, details of injury, pre-hospital and prior facility care, injury examination details, and Emergency Unit (EU) details, and in-patient details. An email (*WHO, Emergency Care Systems, Clinical Services and Systems Unit, personal communication, 16 March 2020*) confirmed that, WHO expects to publish the metadata for the WHO DSI as an open source, and at the moment member countries can request to participate in implementing WHO DSI, as well as utilizing the WHO International Registry for Trauma and Emergency Care for aggregation and analysis of injury case based data from emergency units (86).The DSI has a component that

will also allow patients details to be recorded. This data set was developed from country-specific TRs, with the advice of injury experts from across the world through a consensus process.

We propose to develop a TR for Tanzania based on the WHO DSI. As a first step in developing the TR, this study aimed to determine the current capture rate of trauma variables that form part of the WHO DSI. The results of this study will help to understand which of the variables are currently being documented, and therefore to what extent current trauma data are inadequate. This will provide the guide towards next steps in training of health care providers and availability of resources to develop a robust and sustainable TR model for Tanzania and, by extension, and other LMICs.

METHODS

Study Design

This was a prospective, observational cross-sectional study of all trauma patients (adult and paediatric) presenting to EU) at a sample of regional hospitals in Tanzania conducted for a period of six months, from 1st February 2018 and 31st July 2018.

Study Setting

The United Republic of Tanzania is a country with a population of 55 million people, located in the Eastern Africa, and designated as a Low Income Country with estimated per capita income of approximately US$ 920 (124). At the time of the study, Tanzania had 25 geopolitical regions, and a public health system provided in a pyramidal structure from dispensary, health centre, district hospital and regional hospital to consultant hospitals. There is no formal trauma care system, hence trauma patients are taken to the nearest available health facility that might provide definitive care or refer the patient to a higher level of care, depending on the capacity and resource availability (125). Most of the lower level facilities are not adequately prepared for stabilization of trauma patients needing emergency care (126,127). This study was conducted in the EU of five regional referral hospitals in Tanzania: Morogoro, Arusha, Mwananyamala, Coastal and Tanga hospitals (**Figure 1**). Together, these represent 20% of the regional hospitals in Tanzania: regional hospitals are expected to provide specialist level management (including trauma care), and receive referrals from all districts within the catchment area. The median bed capacity of these hospitals during the study time was 440 (range: 295-500), and Arusha (500 beds) had both the highest bed capacity and number of EU beds compared to other hospitals (**Table 1**). These hospitals were purposively selected, as they are representing the variety of emergency care settings for regional hospitals in Tanzanian, and see a high volume of emergency cases.

Coastal Regional Hospital is located in the Coastal region, in eastern Tanzania, positioned along the busiest road connecting the north and south of Tanzania. Hospital caters a catchment area of 1.2 million people.

Morogoro Regional Referral Hospital is the regional referral hospital for the Morogoro region, which is about 200 km from Dar es salaam city. Hospital serves a catchment area of 2.3 million people.

Arusha Regional Hospital, also known as Mt. Meru Regional Hospital is the regional hospital of Arusha region, located in the north of Tanzania. The hospital has a catchment area of approximately 1.7 million people.

Tanga Regional Hospital is the regional referral hospital for the Tanga Region, located in North-Eastern Tanzania along the Indian Ocean. The hospital has a catchment area of 2.0 million people.

Mwananyamala Regional Hospital is the designated regional hospital for the Kinondoni administrative region, within Dar es salaam city. The hospital serves a catchment area of 1.1 million people.

These five hospitals are in various stages of the development of emergency and trauma care in Tanzania. During the time of the study, Arusha and Tanga Regional hospital's EU were undergoing structural renovation and equipment improvement to support enhanced care processes over the next three years. Morogoro and Coastal Regional hospitals are along a section of the Dar es Salaam to Morogoro corridor along which a pre-hospital emergency care pilot study/program will be implemented. Mwananyamala hospital does not have any planned emergency care system improvement.

Study population

All trauma patients (adult and paediatric) presenting to the study EUs for whom care was documented by a treating provider (medical doctor, Assistant Medical Officer or Clinical Officer).

Study Protocol

This study was conducted from February to July 2018. Trained research assistants - clinical officers (middle level providers with clinical medicine) and diploma nurses - observed in real time the provision of clinical care in the EU for every consecutive patient, and documented all the performed assessment, clinical interventions, and final disposition. In each EU we recruited and trained a total of 3-research assistant to allow 24/7 coverage. After clinicians

completed their documentation, research assistants used a purposefully designed case report form (CRF) incorporating the WHO DSI to perform data abstraction from the clinician clinical chart. The research assistants audited the clinical documentation to determine which fields in the WHO DSI were documented by the clinicians, as documented, not documented or incorrectly documented. Furthermore, the research assistants reviewed Ministry of Health issued Facility Register book that is specific for outpatients department (OPD) record (*Health Management Information System (HMIS) book number 5-OPD Register*) and recorded the documentation of variables for each patient in the book. The HMIS book number 5 is a designated book that the Ministry of Heath captures all the disease burden and demographics of patients who presents to the OPD (which includes the EU and designated acute intake areas). Lastly, the research assistant used a structured survey tool to interview the administrative providers in each hospital on the human, equipment and structural infrastructure that are relevant for provision of emergency care.

Data Analysis

Data from hand-written CRFs were transferred to an online data capture software (REDCap version 7.2.2, Vanderbilt, Nashville, TN, USA) and then exported to Statistical Package for Social Science (SPSS version 22.0, IBM, Ltd, Carolina, USA) for analysis. Procedure frequency and univariate functions was performed to check for any outliers and clean the dataset. The capture rate of each variable within the WHO DSI was calculated as the number of recommended WHO variables calculated for each patient divided by the total recommended number. A summary proportion of rate of capture for each of the variables with 95% CI's was calculated for each hospital and measured collectively across all sites. The descriptive statistics of total patients and trauma cases seen in each EU was summarised by frequency distribution tables of proportions for each variable, and median and range were calculated for overall availability of infrastructure and EU coverage. In effort to gain an understanding of whether the registry should be limited to patients with potentially severe/major trauma, we performed a subgroup analysis of rate completeness of WHO recommended documentation for patients who were admitted for inpatient care, died at EU or were transfer to higher level of care.

RESULTS

Hospital Characteristics and Patient volume

A total of 31,013 patients were seen in all five Regional hospitals during the study period, of which 2,891 (9.3%) presented with trauma-related complaints. The proportion of trauma patients ranged from 4.9% to 10%. Tanga and Mwananyamala had no ICU capacity, and none of the hospitals had a CT scan. Ultrasound was available in each of hospitals at the

imaging centre. None of the hospitals had an emergency physician, while in each hospital there were 1 to 3 trauma surgeons, and 3 to 7 medical doctors. Overall, Coastal (3 Registered nurses) had fewer registered nurses compared to the rest of Regional hospitals. On average the night coverage of EUs was 1 clinician, and 2 (Range 1-4) nurses. **Table 1**

Documentation of variables of WHO data set for injury

Overall, the capture rate of all variables was 33.6%. (**Table 2)** Mwananyamala Regional Hospital had the lowest (29.9%) while Morogoro Regional hospital had the highest (36.4%) capture rate. Documentation was most complete for demographics (71.6%), while the initial clinical condition and details of injury were documented in 20.5% and 20.8%, of the total variables respectively and GCS (Glasgow Coma Scale) / AVPU (Alert, Verbal, Pain and Unconscious) was captured in just 3.1% of cases. There was no documentation for the care prior to EU arrival at any hospital; the number of defined serious injuries by the clinical provider's gestalt was recorded in only 1.3% of cases. The capture rate (33.2%) of variables for sub-group of patient (admitted, died at EU or transferred) was slightly lower than the overall capture rate for all patients (**Table 7**).

Completeness of Ministry of Health required documentation on facility HMIS

Overall, 1430 (49.5%) of all trauma-related visits seen were documented in the HMIS book by the treating clinicians. (**Table 3**) Mwananyamala had the highest (57.6%) and Tanga the lowest rate (39.3%) of documentation in the HMIS book. Among the cases reported in the HMIS book, the date of EU care was correctly documented in 77% cases, age 43.6%, diagnosis 66.7%, and outcome in 38.9% cases.

Performance of interventions and rate of respective documentation

Among the observed procedures, 28.7% of charts documented the assessment of initial clinical condition. Assessment of SBP was the least documented in (20.5%) of charts, while Ultrasound (13.2%) was the least recorded investigation done in EU. Most of patients discharged home (96.0%) were not documented, while most of deceased (96.6%) were recorded in the clinical charts. **Table 4**

DISCUSSION

Our manuscript describes a comprehensive assessment of the baseline capture rate of WHO-defined injury variables in a Sub Saharan country. In this study, we found a substantial lack of documentation of trauma variables in both general trauma patients as well as a sub-group of patients with potentially severe or major injuries. There is paucity of studies in this field, but some available studies have demonstrated the usability of implemented TRs without

evaluating the baseline capture rate of variables (115,128). The development of successful national TRs is dependent on availability of standard set of injury variables that are consistently collected from all trauma patients (115,129,130). In all facilities, we also found significant under-documentation of patients in the facility HMIS register that is used to submit the facility trauma data to the Ministry of Health.

Many attempts to develop TRs in sub Saharan Africa have largely been unsuccessful or unsustainable beyond the initial research phase for a number of reasons, including lack of uniform clinical documentation of injury variables (131). The HMIS register is currently the only tool that provides injury data to inform the Ministry of Health about the national burden of injury, and so the quality and consistency of the data gathered is of paramount importance (21). However, while we recorded a very low rate of variables documented in the facility HMIS register, we also note that even at full capture the variables will not serve the needs of a TR, given that it records less than one fifth of WHO DSI variables.

Despite an overall low capture rate of injury variables, we found a high rate of documentation for patients demographics, which is attributed to the fact that most of the patients have to be registered for billing purposes (132). The initial clinical presentation of the patient was not documented for over three quarter of variables needed to inform the TR. Conscious level is an important marker that informs both care pathways and clinical prognosis: despite this importance, GCS or AVPU was almost never recorded (133–135).

The documentation of pre hospital care and mechanism of injury variables can inform TRs and help to demonstrate the priority areas for strengthening care to optimize outcome (13). Care prior to EU, signs of life, and mechanism of injury were documented in less than half of patients, and in some data providers mixed the chief complaint and mechanisms of injuries, limiting potential usability of data gathered to inform on the status of recommended injury prevention interventions. Training of providers on importance of injury variables can improve understanding and improve documentation (136).

Lack of resources and increased patient workload are known to impact documentation of vital signs in different settings (137). Vital signs were documented in less than one fifth of patients, with saturation of oxygen being recorded in the lowest proportion of patients. Only two hospitals had either a cardiac monitor or a pulse oximeter, obviously contributing towards the low oxygen saturation capture rate. In the current reality of the emergency care system, it will be very difficult to document severity of injuries seen in Tanzania (82).

We observed that a substantial proportion of performed assessment and interventions were not documented in the clinical chart. Surgical interventions, for example chest tube placement, was documented more thoroughly, and we believe this is related to both billing and administrative needs of documentation of surgical procedures (21). In all EUs, most discharged patients do not receive any documentation; we observed most patients receiving

verbal discharge with follow up dates. We believe this is related to the lack of standardised EU documentation, and lack of EU filing system for patients who are not admitted. In facilities with the filing system the patients are provided with a copy of the discharge instructions that are filed with the hospital registry.

We noted a substantial shortage of EU beds with an average of one bed for every 43 patients in all EUs, giving ratio of one bed to four trauma patients. Compounding the challenge of EU bed capacity is the shortage of ICU bed in all the regional hospitals; two regional hospitals had no ICU capacity at all. In all EUs we found a low staffing level, similar to that observed in previous studies of EU staffing in Tanzania (118). A combination of limited infrastructure, low staffing and shortage of supplies might further explain the observed low capture rate of injury variables.

Limitations

The study was conducted in five regional hospitals with variable resources, patient flow system and volume. This may not reflect the reality in the rest of the health facilities in Tanzania. Our utilization of trauma form with complete WHO data set to assess the capture rate of variables in all patients regardless of the severity of injury might have contributed to poor documentation of and a low capture rate given that providers might not document variables they feel irrelevant for minor trauma, however we noted the same poor documentation for a sub-group of trauma patients with likelihood of serious or major injuries (admitted, died in EU and referred), as well as for variables that are part of core WHO data set, meant to be documented for any patient.

CONCLUSION

In regional hospitals of Tanzania, there is inadequate documentation of the minimum trauma variables specified in the WHO DSI. Reasons for this were not explored in this study, but will need to be addressed in order to improve documentation to inform a national injury registry.

Declarations

Ethics approval and consent to participate

The study protocol was reviewed and approved by the Institutional Review Board of the Muhimbili University of Health and Allied Sciences (MUHAS) and The Ministry of Health and social Welfare of Tanzania issued a permission to survey all of the hospitals (Ref.No.HB.209/450/01A/135). As no patient or provider identifying details were kept, and no patient contact was made, no patient consent was required.

Consent to publish

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare no conflicts of interest.

Funding

This was a non-funded project; the principal investigators used their own funds to support the data collection and logistics.

Authors' contributions

HRS contributed to the conception and design of the study, acquired, analysed and interpreted the data, and drafted and revised the manuscript. TAR contributed to the design of the study, data interpretation and critically revised the manuscript. EJW contributed to the design of the study, data interpretation and critically revised the manuscript. JAM contributed to the design of the study, acquired, analysed data and critically revised the manuscript. TJC contributed to the conception and assisted in the initial design of the study, data interpretation and critically revised the manuscript. LAW contributed to the conception, design of the study, data interpretation and critically revised the manuscript. All authors read and approved the final manuscript.

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TABLES OF RESULTS

Table 1. Hospital Characteristics and Patient volume

Regional Hospitals	**Overall**	**Mwananyamala**	**Coastal**	**Tanga**	**Arusha**	**Morogoro**
Hospital characteristics	**N=2891**	**N=764**	**N=555**	**N=211**	**N=950**	**N=411**
Patient volume						
Total patients in EU	31013	7678	5656	4345	8767	4567
Trauma cases: n (%)	2891 (9.3)	764 (10.0)	555 (9.8)	211 (4.9)	950 (10.8)	411 (9.0)
Gender: Male (%)	2891 (70.7)	764 (74.3)	555 (78.6)	211 (86.7)	950 (63.7)	441 (57.4)
Infrastructure	Median (Range)	n	n	n	n	n
Total hospital beds	440 (295-500)	295	210	440	500	450
Emergency Unit beds	4 (2-10)	2	4	4	10	3
Operating theatre	2 (2-3)	2	2	2	3	2
Intensive care beds	1 (0-4)	0	4	0	1	3
X-Ray	1	1	1	1	1	1
CT Scan	0	0	0	0	0	0
Ultrasound	1 (1-3)	1	1	1	3	1
Staffing resources						
Clinicians (N=47)	n (%)	n	n	n	n	n
Trauma Surgeon	9 (19.1)	1	2	3	2	1
General Surgeon	9 (19.1)	2	2	2	1	2
Medical Doctors	22 (46.8)	5	3	7	3	4
Assistant Medical Officer	7 (14.9)	1	0	2	1	3
Nurses* (N=69)	n (%)					
Registered Nurses	25 (36.2)	6	3	4	6	6
Enrolled Nurses	17 (24.6)	3	4	2	4	4
Health Attendants	27 (39.1)	5	5	4	8	5
Emergency Unit coverage	Median (Range)					
Clinician per day shift	2 (2-4)	2	2	4	2	3
Clinician per night shift	1	1	1	1	1	1
Nurses per day	4 (2-7)	3	4	2	7	4
Nurses per shift	2 (1-4)	3	2	2	4	1

**Providers allocated to provide care at Emergency Units*

Table 2. Completeness of WHO recommended documentation on clinical chart

Regional Hospitals	Overall	Mwananyamala	Coastal	Tanga	Arusha	Morogoro
Variable	**N=2891**	**N=764**	**N=555**	**N=211**	**N=950**	**N=411**
Patient Demographics	%	%	%	%	%	%
Name of the patient	99.3	99.7	98.6	99.1	99.1	100.0
Age or date of birth	82.0	98.0	75.5	91.0	66.9	91.2
Gender	69.7	73.4	76.8	86.7	62.6	60.6
Address of the patient	83.8	98.7	82.3	83.9	67.8	91.5
Injury Geographical location	14.1	25.4	11.7	11.4	11.2	4.6
Date of EU care	80.9	74.6	82.2	76.8	80.7	93.7
Initial clinical condition						
Referral status	8.3	1.8	11.4	23.2	5.6	15.1
UE arrival mode	23.6	0.7	18.6	11.4	50.8	16.5
Signs of life	31.2	0.7	9.9	4.7	73.8	31.9
Time of first vital signs	32.2	40.8	32.1	39.3	15.7	50.6
Initial Heart rate	24.5	1.8	31.4	32.2	31.6	37.2
Initial SBP	18.7	1.4	18.4	18.3	27.9	29.9
Respiratory rate	18.0	1.3	17.3	16.8	27.5	28.5
Saturation of oxygen	13.1	0.1	8.6	9.1	23.1	21.9
Initial GCS/AVPU	3.1	0.1	10.6	8.7	0.6	1.5
First provider assessment time	32.2	40.8	32.1	39.3	15.7	50.6
Details of injury						
Mechanism of injury	45.0	44.8	42.3	50.7	46.9	41.8
Mass casualty event	0.5	0.0	1.3	0.5	0.0	1.7
Injury event date	52.2	46.0	58.0	53.6	54.9	49.0
Injury settings	5.3	5.9	4.3	2.4	6.0	5.4
Activity at time of injury	3.3	2.5	2.3	2.4	4.0	3.3
Injury intent	6.8	3.9	7.4	4.3	8.3	9.5
Protective Devices	32.0	31.8	38.2	23.2	30.6	31.9
Injury Examination						
Type of injury	72.1	61.0	80.7	95.2	67.8	78.8
Injury anatomical location	9.2	3.1	17.7	17.1	9.4	4.4
Defined Serious Injuries	1.3	1.3	1.6	1.4	0.6	2.2
Emergency Unit details						
Interventions done at EU	33.0	30.2	22.4	64.9	34.8	31.8
Time of EU departure	15.3	14.8	21.1	15.2	13.7	11.9
EU disposition	62.9	61.9	77.1	59.2	58.0	58.4

Table 3. Completeness of Ministry of Health required documentation on facility HMIS

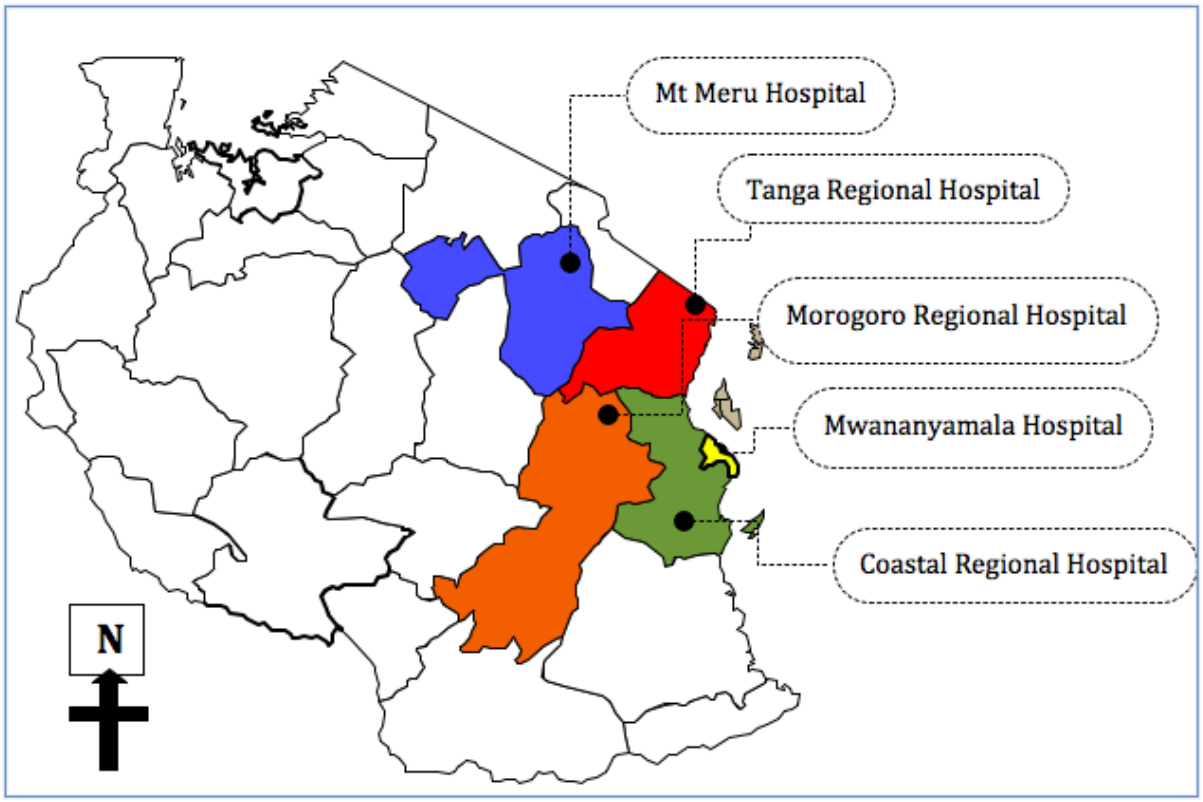
Regional Hospitals	**Overall**	**Mwananyamala**	**Coastal**	**Tanga**	**Arusha**	**Morogoro**
Total patients in EU	2891	764	555	211	950	411
Patients recorded in HMIS	1430 (49.5)	440 (57.6)	232 (41.8)	83 (39.3)	486 (51.2)	189 (46.0)
Patients in HMIS	**N=1430**	**N=440**	**N=232**	**N=83**	**N=486**	**N=189**
Trauma variables in HMIS	**%**	**%**	**%**	**%**	**%**	**%**
Date of EC Care	77.0	77.3	74.1	75.9	77.0	80.4
Registration number	39.4	34.1	38.4	50.6	43.2	28.1
Name of the patient	84.0	86.6	80.2	83.2	84.1	82.5
Address of the patient	48.7	48.0	46.6	51.8	52.1	43.4
Age	43.6	45.2	43.5	42.2	41.8	45.5
Sex	79.5	79.5	75.0	75.9	81.1	82.5
Weight	19.3	19.3	20.3	20.5	18.1	20.6
Height	11.7	10.9	7.8	12.0	16.9	4.8
Investigations	46.7	48.2	47.0	55.4	43.0	48.7
Diagnosis	66.7	68.9	62.1	51.8	74.1	55.0
Treatment	56.2	55.7	56.9	41.0	63.8	43.4
Outcome	38.9	36.1	34.5	43.4	42.4	39.7
Remarks	10.8	10.0	10.8	6.0	14.6	5.3

Table 4. Performance of interventions and rate of respective documentation

Variable	Performed	Documented
Initial clinical condition	**N**	**n (%)**
Assesment of signs of life	2891	902 (31.2)
Heart rate measurement	2553	708 (27.7)
Measurement of SBP*	2626	539 (20.5)
Respiratory rate	1875	519 (27.7)
Saturation of oxygen	657	377 (57.4)
Interventions done at EU		
Fracture Reduction	11	4 (36.4)
Fracture splinting	320	308 (96.3)
Open wounds repair	29	21 (72.4)
IVF administration**	1708	570 (33.4)
Antibiotic administration	397	28 (7.1)
Analgesic administration	1983	1525 (76.9)
Blood transfusion	39	20 (51.3)
T.T Administration	781	218 (27.9)
Chest tube placement	125	125 (100)
Foreign body removal	12	1 (8.3)
Investigations done		
Chest X-ray	447	261 (58.4)
Long bone X-ray	754	420 (55.7)
Ultrasound	257	34 (13.2)
Disposition		
Referred to higher facilities	537	514 (95.7)
Admitted to inpatient service	1248	1122 (89.9)
Died in EU	148	143 (96.6)
Discharged home	958	38 (4.0)

**SBP-Systolic Blood Pressure, **IVF-Intravenous Fluid*

Figure 1. Map of Tanzania indicating study sites



Discussion of the paper

Supplementary methods

To inform the audit process, prior to data collection and audit, the principal investigator (HRS) visited each facility to learn about trauma documentation practices. In each facility there was significant variability on trauma documentation process, depending on several key issues including whether the patient would be admitted to an inpatient service, whether they are able to be registered in the system i.e. provide payment for the clinical service, and whether the patient would be transferred (referred) to a higher health facility. No facilities used standardised clinical documentation tools and all documentation was in free text on paper (commonly referred to as a continuation paper) that was provided by the facility. Alternatively, patients were asked to present with a plain exercise book that was be used for documentation and follows the patient to admission or discharge.

In each facility, there was one site coordinator for the study who served s a point person, overseeing the data collection process. The site coordinator worked with the principal investigator (HRS) to recruit research assistants who included clinical officers (middle level providers with clinical medicine) and diploma nurses, at any particular site. The research assistants and site coordinators received onsite training on how to conduct the clinical documentation audit and were given an opportunity to pilot the tool prior to the onset of the study.

This prospective clinical chart and HMIS register audit was conducted from February 2018 to July 2018 at the EUs of five regional hospitals in Tanzania to determine if providers documented in the clinical chart each of the variables in the WHO DSI after completing patient care. The process of audit was conducted using purposefully designed tools. The audit tools used in this process had three main sections: The first part of the tool was a case report form (CRF) that allowed the research assistant to indicate whether or not each of the WHO DSI variables was captured in the chart for each individual patient who presented at the facility (**Appendix 2.1**). The second part of the audit tool was focused at assessing the entries in the HMIS register books that clinicians are expected to complete for each of the patients that they see, regardless of the diagnosis of presentation (**Appendix 2.2**). This section of the tool incorporated all the HMIS variables, with options for research assistants to indicate which variables have or have not been documented for a particular patient in the registry. In addition, the tool was used to record whether or not the patient has been captured in HMIS register. The third part of the tool was aimed at assessing elements of the human, equipment and structural infrastructure that are relevant for provision of emergency care (**Appendix 2.3)**. This tool used variables adopted from the WHO emergency unit assessment

tool; accompanied by a clinician at the facility research assistants conducted an inventory of the physical presence of these necessary resources at the time of data collection at the site.

Supplementary results

Documentation of performed interventions by Regional Hospital

Among the observed procedures, Mwananyamala had the lowest percentage of charts (3.4%) that documented the assessment of initial clinical condition, while Arusha had the highest (45.7%). In documentation of clinical condition, Mwananyamala documented only 0.7% of the assessment of signs of life that were performed in the EU; Arusha had the highest documentation rate (73.8%). Tanga EU documented the performance of all fracture reductions, open wound repair and chest tube placement. There were two observed reductions of fractures in Arusha EU that were not documented, while Tanga and Morogoro did not perform any reduction. The documentation of EU ultrasound ranged from least (9.8%) in Mwananyamala, to the most recorded (20%) in Tanga. Mwananyamala and Morogoro did not perform documentation for any patients they discharged from the EU. **Table 5.**

Completeness of documentation for additional variables on clinical chart

The overall capture of additional variables available on standardized clinical chart was 10.1% **(Table 6).** Mwananyamala had the lowest (8.9%) while Tanga had the highest (11.1%) capture of the additional variables on standardised clinical chart. Overall, the documentation was least for inquiry of alcohol use prior to injury (1.3%) and physical examination of the patient; neurological (1.1%), Genital Urinary (1.4%) and back (0.2%). There was no documentation of the status of physical examination of the patients' back in Coastal, Tanga and Morogoro EUs. There was an overall low capture of reassessment of vital signs in all EUs, with all vitals documented in less than ten percent of cases.

Table 5. Documentation of performed interventions by regional hospital

Regional Hospital Variable	Overall %	Mwananyamala %	Coastal %	Tanga %	Arusha %	Morogoro %
Initial clinical condition						
Assesment of signs of life	31.2	0.7	9.9	4.7	73.8	31.9
Heart rate measurement	27.7	2.7	33.7	38.1	31.9	38.6
Measurement of SBP*	20.5	1.9	19.2	20.1	28.1	31.0
Respiratory rate	27.7	4.2	27.1	20.5	31.3	42.1
Saturation of oxygen	57.4	7.7	41.7	47.5	63.5	62.5
Interventions done at EU						
Fracture Reduction	36.4	37.5	100	0	0	0
Fracture splinting	96.3	98.3	85.0	100	96.7	98.4
Open wounds repair	72.4	68.2	100	0	75.0	0
IVF administration**	33.4	36.5	44.2	34.1	29.3	24.4
Antibiotic administration	7.1	8.5	4.8	5.0	7.1	7.8
Analgesic administration	76.9	82.9	82.2	71.6	68.1	79.4
Blood transfusion	51.3	60.0	54.5	50.0	25.0	66.7
T.T Administration	27.9	42.9	18.7	16.0	19.6	38.0
Chest tube placement	100	100	100	100	100	100
Foreign body removal	8.3	11.1	0	0	0	0
Investigations done						
Chest X-ray	58.4	41.3	45.5	42.1	63.8	44.6
Long bone X-ray	55.7	54.3	37.2	71.6	57.7	65.9
Ultrasound	13.2	9.8	13.2	20.0	16.0	15.8
Disposition						
Referred to higher facilities	95.7	100.0	100	62.1	100	85.4
Admitted to inpatient service	89.9	78.5	100	83.3	99.7	76.3
Died in EU	96.6	86.4	100	90.0	100	100
Discharged home	4.0	0.0	9.9	18.9	2.5	0

Capture of WHO DSI variables for patients admitted, died or transferred

The capture rate (33.2%) of variables for the sub-group of patients who were admitted, died at EU or transferred was slightly lower than the overall capture rate for all patients (**Table 1.3**). Mwananyamala Regional Hospital had the lowest (30.3%) while Morogoro Regional Hospital had the highest (36.2%) capture rate. Documentation was most complete for demographics (71.8%), and least complete for initial clinical condition (19.3%). In the initial clinical condition, the GCS (Glasgow Coma Scale) / AVPU (Alert, Verbal, Pain and Unconscious) was captured in just 4.1% of cases, while for whether or not the injuries were from a mass casualty incident was recorded in only 0.5% of the charts, with Arusha and Mwananyamala having no capture of this variable. Similarly, in the injury examination there was very low documentation for the number of serious injuries (1.2%), the lowest being in Arusha EU.

Table 6. Completeness of documentation for additional variables on clinical chart

Regional Hospitals	**Overall**	**Mwananyamala**	**Coastal**	**Tanga**	**Arusha**	**Morogoro**
Patient Demographics	%	%	%	%	%	%
Occupation (N=2885)	4.8	4.6	4.9	2.4	5.2	5.6
Initial clinical condition (N=2891)						
Triage	5.4	6.9	5.8	4.3	0.7	13.7
Chief complaint	43.0	15.7	48.2	64.4	61.5	33.4
Pain score	15.0	15.4	19.3	26.1	11.6	10.5
Medical History (N=2891)						
Past medical history	5.2	6.0	4.7	7.1	4.3	5.6
Past surgical History	1.8	2.0	1.8	2.4	2.1	0.5
History of allergies	4.0	3.1	5.2	2.8	4.1	4.4
Vaccination status	1.8	2.6	1.4	1.4	1.8	1.0
History of present illness						
Hours since last meal (N=2877)	2.9	1.4	4.9	3.4	3.3	2.0
Alcohol use (N=2878)	1.3	0.8	0.9	0.5	1.5	2.7
Physical examination (N=2891)						
General examination	32.9	31.3	37.5	32.7	29.7	37.2
HEENT	13.6	14.3	13.9	13.7	12.8	13.4
Neck	6.5	5.9	8.6	7.1	6.6	4.4
Neurological	1.1	0.9	0.5	1.9	1.3	1.2
Chest	31.6	29.8	36.6	30.3	28.7	35.3
Cardiovascular	19.3	19.5	21.6	17.5	18.0	20.0
Abdominal	17.6	16.6	21.1	15.6	16.4	18.7
Pelvic	17.7	17.5	20.2	14.7	16.8	18.5
Genital Urinary	1.4	0.9	0.5	0.9	2.2	1.7
Back	0.2	0.1	0.0	0.0	0.4	0.0
Patient reassessment (N=2814)						
Time of reassessment	3.9	2.8	3.3	4.8	5.1	3.8
Heart rate	6.9	8.4	5.9	6.6	7.1	5.1
SBP	7.1	8.2	5.8	6.6	7.6	5.8
Respiratory rate	6.8	8.1	5.4	7.1	7.2	5.1
Saturation of oxygen	6.4	7.5	5.0	6.6	6.8	4.9
Patient condition	4.2	3.6	4.2	7.6	4.2	3.5

Table 7. Completeness of WHO recommended documentation for patients who were admitted, died or transferred to higher-level facility

Regional Hospitals	Overall	Mwananyamala	Coastal	Tanga	Arusha	Morogoro
Variable	**N=1933**	**N=547**	**N=374**	**N=177**	**N=534**	**N=301**
Patient Demographics	%	%	%	%	%	%
Name of the patient	99.4	99.8	98.9	98.9	99.3	100
Age or date of birth	83.3	97.4	75.1	90.4	67.6	91.7
Gender	70.2	73.9	75.9	88.1	62.0	60.5
Address of the patient	83.9	98.5	82.1	82.5	66.3	91.4
Injury Geographical location	8.5	18.6	5.1	12.4	2.4	2.7
Date of EU care	86.0	81.4	88.2	75.1	87.8	95.0
Initial clinical condition						
Referral status	10.0	1.8	14.4	21.5	5.8	20.3
UE arrival mode	22.7	0.7	20.1	12.4	54.7	15.3
Signs of life	31.2	0.5	8.6	5.1	85.6	34.2
Time of first vital signs	26.0	32.7	26.7	39.0	3.4	45.2
Initial Heart rate	24.2	1.6	30.7	31.6	32.8	37.9
Initial SBP	18.4	1.1	19.3	18.4	28.7	30.6
Respiratory rate	17.6	1.1	17.9	16.7	28.1	28.9
Saturation of oxygen	13.0	0.2	8.0	9.2	24.9	23.3
Initial GCS/AVPU	4.1	0.2	13.4	9.2	1.1	2.0
First provider assessment time	26.0	32.7	26.7	39.0	3.4	45.2
Details of injury						
Mechanism of injury	51.4	53.9	57.2	48.0	43.6	55.5
Mass casualty event	0.5	0.0	1.9	0.6	0.0	0.7
Injury event date	50.5	48.0	55.9	49.7	52.1	46.0
Injury settings	6.3	6.2	5.6	2.3	8.4	5.6
Activity at time of injury	3.7	2.6	1.9	2.8	5.6	5.0
Injury intent	7.9	4.4	8.6	5.1	11.0	9.6
Protective Devices	29.5	30.7	37.4	26.6	23.6	29.9
Injury Examination						
Type of injury	69.7	71.8	77.5	62.7	68.1	63.1
Injury anatomical location	9.7	3.3	16.6	18.1	11.2	5.0
Defined Serious Injuries	1.2	1.1	1.6	1.1	0.4	2.4
Emergency Unit details						
Interventions done at EU	35.1	37.8	25.0	59.9	31.3	34.8
Time of EU departure	13.0	13.7	18.4	12.4	10.5	10.0
EU disposition	60.4	63.8	79.7	52.0	47.4	58.5

Supplementary limitations

Our study only assessed the emergency units' capture rate of trauma variables; we did not assess the capture of WHO DSI variables in prehospital care (if any) (including clinical care given at scene of injury, and scene to first care transport mode), nor at a prior facility, or in documentation of inpatient care (inpatient interventions, operation theatre details, complications, and final inpatient disposition). Given the lack of formal prehospital care in Tanzania, and patients being brought to health facilities in private or police vehicles (138) with no formal documentation or hand-over notes, we thought that this information was unlikely to be available in substantial quantity to allow for auditing of the capture rate of specific variables. The availability of prehospital trauma data is crucial for TRs, as it enables health system to understand the impact of prehospital services, as well as those of specific interventions applied to patients in prehospital settings, which may have impact on clinical outcomes of patients within a stipulated shortest possible time frame of care (139). Similarly, our inability to audit capture of trauma variables for inpatient documentation limits the generalisability of our findings for WHO DSI variables in these settings. In most TRs, the availability of inpatient information is crucial to inform the full continuum of patient care, and outcomes beyond the EU care (28). Most TRs reports on clinical pathway (operating theatre, intensive care and rehabilitation units) mortality and functional outcomes of patients (87), all of which requires a follow-up of patients beyond the EU. Future studies will focus on understanding the capture and quality of variables that can be generated from inpatient documentation so as to have a complete picture of trauma variables from these settings to improve quality of care and patient outcomes.

As discussed in the paper, our utilisation of a trauma form with most of WHO DSI to assess capture rate of variables of all patients in EU regardless of the severity and disposition plan may not be generalised to other health facilities given the wide variability in how patient documentation is handled at each of the EU. As an example, at Morogoro Regional Hospital EU, patients arriving at EU were expected to have their documentation paper with them (or purchase plain exercise books) for clinicians to use for documentation of care. In actual practice, patients who were discharged, normally had left with their documentation books home, while for those who were admitted, the clinicians used on paper provided by the facility, whereas for those transferred out of the facility, a separate form was used. These differences in documentation might affect the capture of trauma variables for different facilities and different kinds of patients depending on their severity and disposition status. We did however try to account for documentation capture of potentially severely ill (admitted, died in EU and referred) by performing a sub-group analysis, which yielded a similarly poor capture rate for most variables.

Chapter conclusion

We found inadequate documentation of WHO DSI in selected regional hospitals in Tanzania. Therefore, the next stage of this project is to explore the barriers and facilitators of current trauma documentation practices towards the development of a national TR.

Chapter 4: Exploring the barriers and facilitators to trauma care documentation

Reference:

Sawe HR, Sirili N, Weber E, Coats TJ, Wallis LA, Reynolds TA. Barriers and facilitators to implementing TRs in low- and middle-income countries: Qualitative experiences from Tanzania. African Journal of Emergency Medicine [Internet]. 2020 Jul [cited 2020 Oct 9]; Available from: https://linkinghub.elsevier.com/retrieve/pii/S2211419X20300562

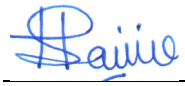
Declaration from author and co-authors

The following co-authors contributed to the paper: Hendry R. Sawe, Nathanael Sirili, Ellen J Weber, Timoth J Coats, Lee A Wallis and Teri A. Reynolds. In the case of Chapter 4, contribution by authors to the work was as follow:

HRS contributed to the conception and design of the study, acquired, analysed and interpreted the data, and drafted and revised the manuscript. NS, EJW, TJC, LAW, and TAR contributed to the design of the study, data interpretation and critically revised the manuscript. All authors read and approved the final manuscript. All authors approved the final published version and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Extent of contribution:

1. Dr. Hendry R. Sawe-75%
2. Dr. Nathanael Sirili-5%
3. Prof. Ellen J. Weber-5%
4. Prof. Timoth J. Coats-5%
5. Prof. Lee A. Wallis-5%
6. Prof. Teri A. Reynolds-5%



16 April 2021

Hendry R. Sawe Date

Declaration by co-authors

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other author of the publication according these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from date indicated below

Location of stored data:

Data set analysed during the current are stored on the author's (HRS) encrypted Dropbox account allocated through the Emergency Medicine Association of Tanzania.

16th April 2021

Prof. Lee A. Wallis Date

14th April 2021

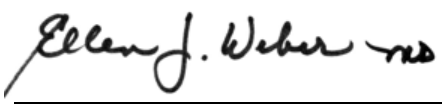
Dr. Juma A. Mfinanga Date

20th April 2021

Prof. Timothy Coats Date

29th April 2021

Prof. Teri A. Reynolds Date



23rd April 2021

Prof. Ellen J Weber Date

Main findings

Main findings were categorised into two broad groups, with themes as follows:

1) **Facilitators towards the implementation of TR**
    - Facility commitment to standardising care
    - Data reporting requirement by the Ministry of Health
    - Insurance claims tied to documentation
    - Medico-legal reporting requirements
2) **Barriers to the implementation of TR**
    - Inconsistent documentation and archiving systems
    - Inadequacy of human and infrastructural resources in health facilities
    - Disparity in knowledge of and experiences with trauma care documentation
    - Attitudes surrounding documentation

Motivation for conducting the study

The documentation of a standardised set of injury variables is crucial to implementation of a TR, and it is facilitated by having a standardised collection method that can be used at multiple health facilities and across regions (115). According to the WHO, trauma will become the fifth leading cause of death in all groups by 2030 (140), and hence key interventions to prevent injury as well as post injury care need to be instituted to support the halt of this progression. In LMICs, the documentation of a standardised set of variables of trauma is limited by a number of factors related to both human and infrastructure resources, and lack of policy and political will, both at the health facility and regional level (13). This lack of trauma data limits the ability of health systems to better understand their status of patient care quality, and key areas of improvement that the health facilities need to address, as well as enabling them to plan key preventive strategies that can help mitigate or prevent the occurrence of injuries (12).

In Tanzania, like most of LMIC there is no formal TR, and data availability is mostly dependent on the facility based Ministry of Health, Health Management Information System (HMIS) register, which has several key challenges related to data quality and quantity as well as timeliness of information for such system (107). The process of documenting for patient is not standardised and is dependent on a paper based clinical form that is blank template, on which a provider is expected to scribe the clinical information of the patient that has been attended. Details of the patients attended, is usually then transferred to the HMIS books, which each individual clinical provider has a copy to document the patient attended during the clinical shift. This practice brings a dual responsibility to treating provider, for which they have to a patient and documenting on regular clinical form, as well as recording the information of this patient on a separate HMIS register. In addition to the dual burden of

documentation, the HMIS register records only 13 parameters (*Date of care, Registration number, Name of patient, Address of the patient, Age, Sex, Weight, Height, Investigation, Diagnosis, Treatment outcome and Remarks*). While these variables are important, but they are only part of what will be required to have a robust TR that can inform quality of clinical care, and preventive strategies that can reduce incidence of injuries. In our recently conducted study we found both low rate of recording for the number of cases in HMIS registers as well as the overall completion rate of individual HMIS variables. In our audit of the clinical documentation in the existing clinical charts patients attended, we found an overall low capture rate of injury variables across all the EUs. This low documentation rate of injury variables, coupled by the low documentation in the HMIS registers hinders the ability of a health facility to provide information necessary for an injury registry.

To address these challenges, one potential solution is to develop a standardised set of variables that should be documented in the clinical chart for each injured patient presenting to the Health facility, and also recorded for the TR. However, this requires a stepwise and multidisciplinary approach to enable each EU to implement this documentation practice. Henceforth, we conducted this study to understand the current barriers and facilitators toward complete charting in current documentation practices, and associated factors that would affect the implementation of standardised trauma form to capture essential data for the TR. With this information, we would be able to plan the best way of implementing a standardised clinical documentation, and address the factors that affect its utilisation, which will be key to setting forward the pathway to successful implementation of a sustainable TR in Tanzania.

Aim

The aim of this study was to determine the factors affecting current trauma documentation practices that may influence the implementation of a standardised trauma form to inform a national TR.

Objectives

1. To explore the barriers and facilitators of current trauma documentation practices at Emergency Units of Regional Hospitals in Tanzania
2. To explore how these factors that may influence implementation of a standardised trauma form at regional hospitals in Tanzania.

A copy of the published paper follows over the next eighteen pages.

Copy of published paper

Barriers and Facilitators to Implementing Trauma Registries in Low- and Middle-Income Countries: Qualitative experiences from Tanzania

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ABSTRACT

Background: The burden of trauma in low and middle-income countries (LMICs) is disproportionately high: LMICs account for nearly 90% of the global trauma deaths. Lack of trauma data has been identified as one of the major challenges in addressing the quality of trauma care and informing injury-preventing strategies in LMICs. This study aimed to explore the barriers and facilitators of current trauma documentation practices towards the development of a national trauma registry (TR).

Methods: An exploratory qualitative study was conducted at five regional hospitals between August 2018 and December 2018. Five focus group discussions (FGDs) were conducted with 49 participants from five regional hospitals. Participants included specialists, medical doctors, assistant medical officers, clinical officers, nurses, health clerks and information communication and technology officers. Participants came from the emergency units, surgical and orthopaedic inpatient units, and they had permanent placement to work in these units as non-rotating staff. We analysed the gathered information using a hybrid thematic analysis.

Results: Inconsistent documentation and archiving system, the disparity in knowledge and experience of trauma documentation, attitudes towards documentation and limitations of human and infrastructural resources in facilities we found as major barriers to the implementation of trauma registry. Health facilities commitment to standardising care, Ministry of Health and medico legal data reporting requirements, and insurance reimbursements criteria of documentation were found as major facilitators to implementing trauma registry.

Conclusions: Implementation of a trauma registry in regional hospitals is impacted by multiple barriers related to providers, the volume of documentation, resource availability for care, and facility care flow processes. However, financial, legal and administrative data reporting requirements exist as important facilitators in implementing the trauma registry at these hospitals. Capitalizing in the identified facilitators and investing to address the revealed barriers through contextualized interventions in Tanzania and other LMICs is recommended by this study.

Key words: Trauma registry, Tanzania**,** barriers and facilitators, trauma, Low-and Middle-Income countries

African Relevance

- Trauma constitutes significant morbidity and mortality in Africa.
- Trauma registries are non-existent in most African countries.
- Lack of trauma registries is a major challenge in understanding care and preventive strategies to reduce the burden in Africa.
- There is a need to understand different factors whose interplay affects the implementation of trauma registries in Africa.

BACKGROUND

The burden of trauma in low- and middle-income countries (LMICs) is disproportionately high, accounting for nearly 90% of all trauma-related deaths worldwide (141). The World Health Organization (WHO) predicts that trauma will become the fifth leading cause of death in all groups by 2030 (140). Lack of trauma data has been identified as one of the major challenges in addressing the quality of trauma care and informing injury-preventing strategies in LMICs (142–145): without data, strategies to improve the situation cannot be informed. It is estimated that nearly two million deaths - one-third of all trauma fatalities - could be prevented in LMICs if case fatality rates among seriously injured persons were reduced to levels seen in high-income countries (145). In Africa, injury is among the top ten causes of mortality, claiming more lives than cancer, malaria, and HIV/AIDS combined (146,147). While the burden of injury in Africa is very high, it remains understudied. (11)

Tanzania, like most LMICs, has no formal trauma care system, and no formal trauma registry. The Ministry of Health has a purpose-designed handwritten Health Management Information System (HMIS) register that is used to record patient-level information at various levels of the healthcare system and share aggregate data for national-level compilations (21). The HMIS register is designed to captures patient demographics, along with diagnoses, investigations, and dispositions.

Knowledge of the location and mechanism of injuries, along with subsequent patient outcomes, is key to developing a robust trauma care system, as these insights can focus efforts on parts of the system in greatest need of improvement. Trauma registries (TRs) - uniform sets of data on injured patients, containing demographics, injury details, information on prehospital and in-hospital care, diagnoses and outcomes - can help achieve this aim (12). Prior efforts to establish and sustain TRs in Tanzania have been limited by many factors, including lack of resources and researcher time, and minimal buy-in from local institutions and stakeholders (148). The current Road Accident Information System (RAIS) initiated by

the Ministry of Works, Transport and Communications provides some data related to road traffic injuries (149). RAIS is limited in many ways: it only conducts surveillance for road traffic injuries, and only injuries captured by the police system are reported, and it lacks outcomes data for patients taken to healthcare facilities. Due to these challenges, trauma data used for epidemiological studies, quality improvement (QI), and intervention planning are mostly reliant on single-site, hospital-based chart reviews or mortuary-based data logs (16,25,109,150).

Data on injury diagnoses, relevant interventions, and patient outcomes inform QI strategies and thus have become an essential component of all developed trauma systems (151–154). However, in LMICs, lack of information gathering and sharing mechanisms, and limited documentation to define disease burdens and support monitoring activities, have been identified as major barriers to global emergency care development (154–156); Tanzania is no exception.

In effort to address this gap, we are working to build a model for development of a national TR that is sustainable and scalable in Tanzania, and generalizable to other LMICs. This study aims to explore the barriers and facilitators of current trauma documentation practices, and factors that may affect implementation of a standardised trauma form at regional hospitals in Tanzania that will capture data essential to a TR.

METHODS

This was an explorative qualitative research study that used focus group discussions (FGDs) to gather information.

Study setting

This study was carried out in five of the 31 regional hospitals in the United Republic of Tanzania - Morogoro, Arusha, Mwananyamala, Coastal and Tanga Regional Hospitals - between August and December 2018. Tanzania is a country with a population of 55 million people, located in Eastern Africa, and designated as a low-income country (124). The average life expectancy is 65 years (124).

Tanzania's operates a decentralized health-care sector that is organized in a pyramid, with three levels of health-care services provision: primary, secondary and tertiary facilities (118). Each higher-level facility acts as a referral site for its immediate lower level. The five regional hospitals represent 16% of regional hospitals and were purposefully selected based on their representativeness of regional hospital emergency care provision in the country, with varying stages of progress to implementation of formal emergency and trauma care centres. In all five regional hospitals, there was no standardised trauma documentation form, and each hospital had its modality of documenting for injured patients.

Selection of participants

We employed a purposeful sampling strategy to select participants among staff with permanent placement in the emergency units, surgical and orthopaedic inpatient units within each selected hospital. The selection of these staff was based on their involvement in the care of trauma patients and documentation of relevant data. We, therefore, targeted the specialists, medical doctors, assistant medical officers, clinical officers, nurses, health clerks and Information and Communication Technology Officers. We targeted to have a focused group discussion of 6-10 participants from each hospital. We conducted one FGD in each hospital and the total number of participants after data collection was 49 nine participants **(Table 8).**

Data collection and processing

FGDs were conducted in Kiswahili, moderated by the principal investigator using a semi-structured FDG guide. The FGD guide included questions, which sought to explore the barriers and facilitators to capturing trauma-related variables at respective hospitals. Multiple aspects of trauma care and documentation processes were inquired about, including capacity and capabilities for care, the capture rate of variables, and reasons for disparities in the documentation.

FGDs were held privately in a hospital conference room away from the site of patient care. Each FGD lasted approximately 60 minutes. The FGDs were audio-recorded using a digital recorder by the research assistant who accompanied the principal investigator. Each FGD continued until saturation was reached (when no new information was coming up despite different styles of probing).

Data analysis

The audio recorded FGDs were transcribed verbatim, translated into English, and then imported into ATLAS.ti (Version 1.0.4, © ATLAS.ti, Berlin, Germany) qualitative data management and analysis software.

We used a hybrid thematic data analysis approach; this approach used both inductive and deductive reasoning (157). We developed an initial codebook for data analysis, based on our study objectives. We then refined the codebook from the themes, which emerged during the analysis. The first author developed the initial codebook and shared it with all authors. The codebook was discussed, further developed, and a final codebook was imported into ATLAS.ti qualitative data analysis computer software. The agreed codebook was tested by coding the first two interview transcripts by three authors independently. Their coding was almost similar and, hence, the codebook was not modified at the time.

At this stage, although the data analysis was guided, it was not confined to the primary codes. Inductive coding was assigned to text segments, which represented a new theme that was not pre-determined. The new codes were assigned as separate codes or an expansion of the codes available in the initial codebook. Themes and emerging sub-themes were identified using Braun and Clarke's approach of thematic analysis (158). The whole process of analysis was iterative, further scrutiny was carried out by going back to the interview transcripts to identify, summarize, and retain the patterns and similarities, differences, and newly emerged themes. Finally, we further clustered the sub-themes and the themes into two major categories of barriers and facilitators of implementing the trauma registry.

Ethics approval and consent to participate

Ethical approval was received by the University of Cape Town Human Research Ethics Committee and Muhimbili University of Health and Allied Sciences Institutional Review Board. All participants provided both written and verbal informed consent prior to participation.

RESULTS

From the five FGDs with 49 participants we have categorized the themes into broad group of themes; facilitators towards the implementation of trauma registry and barriers to the implementation of trauma registry **(table 9).**

Facilitators towards the implementation of trauma registry

From the analysis of the FGD transcripts we unveiled four themes, which we have grouped them as facilitators towards the implementation of TR. These are facility commitment to standardising care, data reporting requirement by the Ministry of Health, insurance claims tied to documentation and medico-legal reporting requirements **(table 9).**

Theme one: **Facility commitment to standardising care**

In all facilities, providers expressed strong urge to improve quality of care to conform to standards. They stated that it is through a proper documentation process standard care will be realised. They further added that, to ensure provision of standardised care, there is a need of having a standard patient care documentation chart that will align all the providers towards one uniform format of recording data across all the departments and facilities.

"….I believe this will really guide our care because, if you have many patients and working a very long shift and you have many patients, it's easy to forget important components of the care…"

- Coastal participant no. 2

Respondents felt that having a standard form will help to reduce proportion of missing variables and improve the care process for junior doctors by providing them with guidance and prompt on necessary interventions that are crucial to care of trauma patients.

"…. this will be the best, even when interns come and go, then they will all follow the same format, you know at times you train an intern how to document well, and after they have gained very well, then their rotation ends and they move on. This brings a new intern and then it becomes like a cycle so the documentation doesn't really improve because of this…"

- Morogoro participant no.1

Theme two: **Data reporting requirement by the Ministry of Health**

Most respondents expressed strong aspirations to meet the expectation of reporting correct data to the Ministry of Health (MoH). Participants felt that sharing the correct data will reflect local workloads and burdens of disease; so as to support facilities' needs for appropriate allocation of human and infrastructure resources.

" .....there is a challenge as this data is sometimes not consistent you know what I mean…this really worries me sometimes that we are underreporting the volume of patients…the Ministry may see that we have very few patients…"

- Mwananyamala participant no.1

Theme three: **Insurance claims tied to documentation**

The discussants cited poor documentation as the main cause of insurance claims rejection from the National Health Insurance Fund (NHIF) and other insurers. This is problematic because these income sources are crucial to financially sustain facilities. Insurance reimbursement requires proper documentation of every component of care for the claim to be considered valid. The potential for additional revenue will likely incentivise providers to better document their care.

"… without the proper billing, we are losing money because the insurance [NHIF] company rejects as high as 25% of our billings, and this is just because of poor billing. So you find that you have done so much to the patient and, since you are lazy to document, then we all lose so much money…."

- Tanga participant no.5

Theme four: **Medico legal reporting requirements**

During the discussion, it was narrated that patients who are involvedly in motor vehicle accidents or have sustained intentional injuries or injuries with legal implication are supposed to have a special police form filled by the treating provider. This form details the incident resulting to injury and gravity of injury so as to inform legal proceedings when necessary. Better documentation and archiving will allow for these forms to be more easily completed, and for data to be retrieved should legal action be taken.

.....the police cases have to be properly documented you know some become court cases, so we are sometimes challenged to have the documentation and when we fail it becomes a major issue…."

- Mwananyamala participant no.6

The discussants further indicated the challenge on filling of the requisite police form:

"*...you see we have people and police sometimes visit us to fill the forms, the PF3 this makes its very tricky when we have no records…."*

- Arusha participant no.5

Barriers to the implementation of trauma registry

This analysis unveiled four themes, which we grouped under barriers to the implementation of TR. These are inconsistent documentation and archiving systems, inadequacy of human and infrastructural resources in health facilities, disparity in knowledge of and experiences with trauma care documentation and attitudes surrounding documentation **(table 2).**

Theme one: **Inconsistent documentation and archiving systems**

The discussants cited limitations in the hospital archiving system as a significant hindrance to developing of TR. This limitation was noted to particularly problematic for patients discharged directly from EUs.

"...you know, if a patient is discharged from the casualty, we normally do not file any card. We usually discharge the patients, as you know random papers in EU is regarded as poor quality in our 5S arrangements…."

- Mwananyamala participant no.3

In one hospital, discharged patients typically kept their own files in the form of personal booklets; these booklets are brought by patients, used for the duration of illness to document care, and then taken with the patient upon discharge.

"...the filing system for documentation is not consistent. Most patients have personal booklets [used as files]; hence, if someone is sent for investigation and comes back with results, clinicians might write the medication on the results paper due to lack of continuation form."

- Morogoro participant no.8

Theme two: Inadequacy of human and infrastructural resources in health facilities

- The participants stated that inadequate human and infrastructural resources in health facilities may further limit the development and implementation of a TR. They cited challenges associated with inadequate EU staffing as one of the major reasons for poor documentation: the few available staff must prioritise care provision at the expense of proper documentation.

- *"…you know our casualty (EU) is very understaffed and you will find you have one doctor at night and ten patients shows up at once, which makes it very hard for the doctor to document everything on a system that is also not user friendly…"*

- Arusha participant no.1

- The majority of respondents further reflected that the documentation burden shouldered by EU providers have created a fatigue that limits the breadth and accuracy of documentation for details of clinical care provided to trauma patients.

- **"….** *In emergency unit we HMIS books and we have to fill it, and then we clerk on patient's booklets and have to fill some investigation forms then separately have to write prescription… so my concern is too much paperwork causes us to skip important parts."*

- Coastal participant no.3

Theme three: Disparity in knowledge of and experiences with trauma care documentation

The majority of respondents noted the variability in level of training and experience amongst clinicians as a significant reason for poor and inconsistent documentation. As illustrated in Table 1, the majority of clinicians were interns rotating in the EU for a variable period, typically about one month, and they become primary providers of care in this duration.

"….most of the time, we have a medical doctor but also we do have interns who document for the patients, so there is, of course, a difference in the content of the documentation…"

- Tanga participant no.9

Some respondents cited that level of training and experience has strong influences on how documentation is done for all trauma patients.

"**…***you see, it also depends on who is seeing the patient. Sometimes, a senior doctor will see patient and do all important care, but will document only important elements."*

- Coastal participant no.4

Theme four: Attitudes surrounding documentation

Participants reported that individual attitudes of some clinicians towards documentation affected the amount and quality of documentation reported. Some respondents recognised negative attitude towards documentation amongst clinician as a challenge that will require concerted effort to change.

"…there are individual behaviours…and this has also been discussed in the department level meetings… you find someone is only focused on the continuation form and ignores HMIS and other important books."

- Morogoro participant no.4

"…also, people here have to change to know that documentation is important even in medical cases, as you know patients who complain will have to go back to the system for which documentation has to be proper…"

- Arusha participant no.4

DISCUSSION

To the best of our knowledge, this is the first study that explored the barriers and facilitators to implementing a TR in low-income country. Our findings provide insight into factors whose interplay may lead to improved documentation processes and facilitate the development of a TR. Three of our findings on barriers to implementation of a TR among providers resonate with findings previously reported on poor quality of data generated from the HMIS in Tanzania: low awareness and knowledge of importance of trauma data and HMIS, high volume of patients, and significant shortage of human resources (117,118,127,159).

Shortages in providers and equipment were described by participants at all hospitals. The shortage of equipment might lead to decreased care and documentation. Previous studies focusing on execution and documentation of care under limited resources demonstrated that poor documentation is a result of both of lack of enough equipment, and frustration of staff towards inability to deliver care of conditions within their capacity (160,161).

Additional aspects not previously described in the literature were also identified, including factors affecting data documentation and storage, and provider attitudes towards documentation. Documentation of data was limited by numerous factors. Handling of individual files by patients was a reason for the lack of data in patients who have been discharged after receiving care. Most participants clearly highlighted the lack of archiving of data from patients as one of the main reasons for low or no documentation of injury variables. The lack of variables from these patients was further compounded by frequent reported loss of the clinical files handled by the patients, which necessitated the need for acquiring new files and hence the loss of prior patient records.

Multiple documentation and reporting pathways were reported to impact the quality of documentation as providers indicated that they traded care provision for documentation. We noted duplication of reporting systems for the same data, which creates redundancy and adds more work to few available providers in the EU. In order to ensure success of gathering high quality clinical data, any reporting needs to avoid duplicating work of providers as this has already been reported to be counterproductive (162,163).

The hindrance of medical-legal data collection requirements to inform justice processes is a well-documented phenomenon (164). In our findings, providers indicated a struggle to meet this requirement for some of the trauma patients due to lack of data records for patients, especially for those patients who have sustained injuries in a motor traffic crash. The need for such information on most trauma patients may facilitate the implementation of

standardised documentation system, which can be archived to generate information when needed by the legal system.

The influence of providers' behaviour and attitudes towards quality of care have been reported in other medical contexts (165,166); this impact is quite evident in the findings of this study. Provider fatigue has been previously identified as a major factor for medical errors and poor quality of care, that may have an impact on patient outcome and satisfaction (167,168). Providers in this study reported how fatigue impacts documentation, directly affecting development and implementation of a TR. Training levels and experience of providers are known to impact care of injured patients (169,170); existing literature aligns with that we found - that providers perceived junior doctors as being unreliable to perform proper documentation linked to the care provided. Some participants highlighted that the provision of care was not matching documentation; consequently, the patient would receive more care and less documentation, especially if the attending provider is senior. However, this phenomenon was unclear in junior clinicians, as absence of documentation might also have indicated lack of proper care.

Benefits of trauma data collection were also identified by participants, suggesting that these participants are ready and motivated to improve the situation. These facilitators are promising for the successful implementation and sustainment of a TR in Tanzania.

One facilitator of implementation found in this study was the incentive of having good documentation to increase the insurance reimbursement claims. Providers highlighted that facilities and individuals have been losing out to insurance claims despite provision of care, as a result of incomplete documentation to support claims. Providers indicated enthusiasm to ensure all clinical care provided to insurance beneficiaries is reimbursed, for the benefit of the facility and individual providers.

The requirement to submit data to inform decision-making process at the MoH was also facilitator to collecting adequate trauma data in EUs. Previous studies of HMIS have demonstrated inaccuracies and unreliability in data collected (171), aligning with reports from providers in this study. Interestingly, most providers felt frustrated by the potential inaccuracy of data in their facilities, as they felt this impacts them in two ways: firstly, their ability to secure additional staff and resources is compromised because of lack of supporting data, and, secondly, their status as a regional care facility is undermined by the low volume of data reported to the MoH. Most facilities demonstrated clear commitment towards implementing a system that could positively impact the reporting of injury data to the MoH. Towards this effort, there have been consistent suggestions to generate a standard template

documenting care process, utilised by all staff, to ensure consistency in the reporting structures.

TRUSTWORTHINESS

We adopted Guba's four criteria of credibility, dependability, transferability, and conformability to enhance the trustworthiness of our study findings (172). In qualitative studies, the findings are trustworthy if they are worth believing (173). The credibility of the findings of this study was enhanced through the triangulation of study participants from the different units, which bring rich experiences from each hospital setting. To enhance the credibility and dependability of this study, triangulation of study settings and researchers were used. Conformability of the findings was enhanced through members debriefing after each FGD to confirm if what was captured by the researcher was what they said and clarity was added in areas needed. Furthermore, to ensure that the findings reflected participants' perspectives rather than the researchers' understanding of the question under study, themes were inductively generated and presented with the support of succinct quotes. The transferability of the findings of this study is enhanced through the description of the study setting, context, data collection process, and analysis.

The fact that a health worker (Emergency Medicine Physician) was involved in conducting the interviews, might have introduced social desirability from the participants. However, the triangulation of participants, setting and having research assistants with a social sciences background offset this limitation. Finally, the findings of this study reflect the situation during the period in which data collection for this study was carried out.

CONCLUSION

Implementation of a TR in regional hospital is impacted by multiple barriers related to providers, volume of documentation, resource availability for care, and facility care flow processes. However, several facilitators to this implementation process are present, including monetary and resource incentives that are likely to result from taking advantage of financial, legal and administrative data reporting requirements. Capitalizing in the identified facilitators and investing to address the revealed barriers through contextualized interventions in Tanzania and other LMICs is recommended by this study.

Dissemination of results

The results of this study were shared with all the heath facilities involved through the respective heads of the emergency units, in the form of the first draft of this manuscript.

Authors' contribution

Authors contributed as follow to the conception or design of the work; the acquisition, analysis, or interpretation of data for the work; and drafting the work or revising it critically

for important intellectual content:

HRS contributed 50%; NS 20%, EB 5%, TJC 5%, and LAW and TAR contributed 10% each

All authors approved the version to be published and agreed to be accountable for all aspects of the work.

Declaration of Competing Interest

The authors declared no conflicts of interest

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TABLES OF RESULTS

Table 8: Hospital roles of focus group discussion participants

Cadres	Participants N=49 n (%)	Gender: Male: %	Experience > 5years: %
Nurse	13 (26.5)	23.1	69.2
Medical officer	11(22.4)	81.8	27.3
Assistant Medical Officer	8 (16.3)	87.5	87.5
Clinical officer	7 (14.3)	85.7	85.7
Specialist Doctor			
Emergency Physician	1 (2.0)	100	0
Orthopaedic/Trauma specialist	2 (4.1)	100	50.0
Surgery Specialist	2 (4.1)	100	50.0
Administrator	2 (4.1)	50	100
HMIS officer	2 (4.1)	50	100
ICT officer	1 (2.0)	100	100

Table 9: Summary of findings

No.	Broad Group	Themes
1	Facilitators towards the implementation of trauma registry	Facility commitment to standardising care Data reporting requirement by the Ministry of Health Insurance claims tied to documentation Medicolegal reporting requirements
2	Barriers to the implementation of trauma registry	Inconsistent documentation and archiving systems Inadequacy of human and infrastructural resources in health facilities Disparity in knowledge of and experiences with trauma care documentation Attitudes surrounding documentation

Discussion of the paper

Supplementary methods

Participants

This exploratory qualitative research employed a purposive sampling strategy to enrol selected clinical and administrative staff at each of the hospitals. The principal investigator (HRS) visited the study sites with preliminary results of the audit of the capture rate of trauma variables which had been conducted six months prior. At each site, the principal investigator asked the EU management about the role played by different disciplines in daily management of trauma patients, from which a list of key personnel was drawn as potential candidates to participate in the study. The target for each facility was 6-10 participants in a focus group discussion (FGD).

Data collection and analysis

After the list of potential participants from each of the sites was prepared, the participants were invited to a focus group discussion, which was held at a separate venue, away from the EU, to ensure maximum attention during the FGDs as well as confidentiality (**figure 2.1**). The principal investigator developed a consent process and a guide to introduce the sessions. The invited participants provided written informed consent for participating in the research prior. It was explained to them that the investigators were looking for their personal views which do not necessarily reflect the view of the EU or health facility. Furthermore, they were informed of the right to decline participation or withdraw their consent to participate at a later time. A semi structured FGD guide was used to guide the discussion, which was conducted in Kiswahili, the preferred language for the participants. Prior to embarking on the formal FGD guided questions, the principal investigator spent the initial part of the session reviewing the results of the audit of capture of trauma variables at each of the EU, as well as the specific variables that had the lowest and highest capture rate.

The FGD guide had three main parts that with guiding questions, as well as follow up: trauma data processing and management, current trauma documentation, and concept of standardised trauma form (**Appendix 2.4**). All interviews were audio recorded and additional handwritten notes were taken during the sessions to complement the information recorded as well as inquire for more questions. Data collected in Kiswahili was transcribed verbatim, and then translated into English, and used to develop the codebook that was imported and analysed by the qualitative data management software ATLAS.ti (Version 1.0.4, © ATLAS.ti, Berlin, Germany). We used Braun and Clarke's approach of thematic analysis (158) to identify themes and emerging sub-themes. These were further clustered into two major categories of barriers and facilitators of implementing the TR.

Figure 3: Focus Group discussion session at Morogoro Hospital

Supplementary results

In reporting our results, we used two broad themes: facilitators towards the implementation of TR, and barriers to the implementation of TR. In addition to the results that are presented in the study, the following sub-themes were recorded within each broad category of facilitators and barriers.

Facilitators towards the implementation of TR

Sub-themes: Disease burden quantification and Patient care follow-up needs.

Sub-Theme one: Disease burden quantification

The respondents expressed the desire for each of their facilities to have an accurate account of the disease burden, including trauma, so as to be able to better plan for resources as well as the training needs within the facilities.

"…..We see many patients but our reports show the opposite….For instance, one day I counted and realised that we saw 58 patients in my shift but the documentation showed only 33,…. this underreporting is frustrating as it does not show how difficult it is to work at casualty…."

- *Arusha* participant no. 5

The discussants further reported the current system of documentation and filing through the HMIS does not offer enough details to support the accurate documentation of the burden of disease.

"... The system of documentation is very inconsistent here, we rely on HMIS books and as you have seen we don't have good data and not very well reported all the times…."

- *Morogoro* participant no. 3

Another discussant added;

"...our main challenge is underreporting of the data to the management because these HMIS books do not have enough details and many clinicians feel that filling these books is an additional paperwork..."

- *Tanga* participant no. 2

Theme two: Patient care follow-up needs

Some participants described the challenges they currently face in retrieving initial visit information during patient follow-up. In most cases the patients will return to the facility for either re-dressing of wounds or for a follow-up surgical procedure that has been planned or already undertaken. Following this, participants stated they strongly believed having standardised documentation and TR will support recall of information on patients previously attended at the same facility.

"....in the minor theatres there has to be a standard documentation because we have interns who rotate there regularly and if you see what is written to the patients card, most of time is really a shame because you cant understand what really happened to the patient and what was done…."

- *Mwananyamala* participant no. 3

.... The standardised form will help us to trace patients, as you know now we discharge patients with their forms and when they come back, most of them have lost the books so we struggle to find the previous management….

- *Morogoro* participant no. 4

Barriers to the implementation of TR

The analysis of FGD transcripts revealed additional one theme that was grouped under the barriers to the implementation of TR, the theme was: rotating providers with limited continued medical education.

Theme one: Rotating providers with limited continued medical education

The participants narrated that one of the barrier in implementing the standardised documentation is the fact that providers in EU are often times rotated to different disciplines

without a clear guideline or timelines. Additionally, the rotating providers do not receive any continued medical education during times when they are rotating.

"….you see we have rotations that are brought by hospital management, so at one time you may be asked to rotate to surgical or gynaecology department without notice, and no training hence it limits our efficiency…."

- *Arusha* participant no. 6

Additionally, another participant added;

"…in EU we do not have regular training for staff and this makes it hard to set dedicated training for staff in the EU, this creates a challenge to enforce good practices in trauma care and documentation…."

- *Tanga* participant no. 3

Supplementary limitations

In addition to the limitations described in the study, we conducted this qualitative study on a purposefully selected sample of participants from five regional hospitals, and hence these findings may not be generalised to the entire health care system of Tanzania. The moderator's reflexivity is a potential limitation to the views provided by the participants. *Linda Finlay* discussed the importance of considering reflexivity in qualitative research, and the means to navigating their potential impact in ensuring we enhance the trustworthiness, transparency, and accountability of our qualitative research outcomes (174). Five key considerations for addressing reflexivity identified by *Finlay* are introspection, inter-subjective reflection, mutual collaboration, social critique, and discursive deconstruction. Our awareness of the potential for misconceptions through this reflexivity led us to develop the FGD guide questions that supported the participant's understanding of the discussion outcomes and guaranteed the utilisation of their views and opinions on different matters related to implementation of standardised trauma documentation. In addition to these measures, we used a research assistant with social science background to offset this limitation during interview sessions.

Chapter conclusion

In this chapter, several barriers to implementing a TR were identified, mostly related to EU providers and resources to provide appropriate trauma care. Successful implementation of a TR will rely heavily on the ability to address these challenges. Despite these barriers, several crucial facilitators to successful implementation of TR were revealed during the FGD, including specific incentives directly linked to EU providers, and facility in general, and statutory reinforcements such as health, medical-legal and reimbursement requirements related to proper documentation. In Chapter 5, we evaluate the perceptions of providers at

these EUs in utilising standardised trauma documentation that can support both modification and improvement to ensure sustainability of collecting the data necessary for a national TR.

Chapter 5: Perceptions of health providers' towards the use of a standardised trauma form in managing trauma patients

Reference:

Sawe HR, Sirili N, Weber E, Coats TJ, Reynolds TA, Wallis LA. Perceptions of health providers towards the use of standardised trauma form in managing trauma patients: a qualitative study from Tanzania. Inj Epidemiol. 2020 May 1;7 (1):15

Declaration from author and co-authors:

The following co-authors contributed to the paper: Hendry R. Sawe, Nathanael Sirili, Ellen J Weber, Timoth J Coats, Teri A. Reynolds and Lee A Wallis. In the case of Chapter 5, contribution by authors to the work was as follow:

HRS contributed to the conception and design of the study, acquired, analysed and interpreted the data, and drafted original manuscript and revised the manuscript. NS contributed design of the study, data review and validation, and analysis and also critically revised the manuscript. EW and TC contributed to the design of the study, data validation, and analysis and also revised the manuscript, TAR and LAW contributed to conception and design of the study, data validation, review, analysis and also critically revised the manuscript. All authors read and approved the final manuscript.

The following co-authors contributed to the work:

7. Dr. Hendry R. Sawe-70%
8. Prof. Lee A. Wallis-10%
9. Dr. Nathanael Sirili-10%
10. Prof. Ellen J. Weber-5%
11. Prof. Timoth J. Coats-5%
12. Prof. Teri A. Reynolds-5%

15th April 2021

Hendry R. Sawe Date

Declaration by co-authors

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other author of the publication according these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from date indicated below

Location of stored data:

Data set analysed during the current are stored on the author's (HRS) encrypted Dropbox account allocated through the Emergency Medicine Association of Tanzania.

16th April 2021

Prof. Lee A. Wallis — Date

14th April 2021

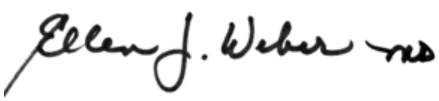
Dr. Juma A. Mfinanga — Date

20th April 2021

Prof. Timothy Coats — Date

29th April 2021

Prof. Teri A. Reynolds — Date



23rd April 2021

Prof. Ellen J Weber — Date

Main findings

The findings of semi-structured interviews revealed three main analytic themes (and six sub-themes) of regarding the perception of health care providers in the use of standardised trauma documentation.

1. The potential benefits of a trauma form (**Sub-themes**: *perceived positive impact on quality of care, and anticipated reduction of work and increase in efficiency of providers*),

2. Perspective on concept of standardised trauma form (**Sub-themes:** *acceptance of standardised form in clinical care, and form content and usability*), and

3. Concerns regarding successful and sustainable implementation *(***Sub-themes:** *process for improving the form, and training on understanding and use of the trauma form for accuracy and compliance*).

Motivation for conducting the study

The lack of a TR in most LMICs significantly limits the availability of trauma data to inform quality improvement and injury prevention strategies. In most HICs, the availability of electronic medical records to document patients' clinical information has enabled facilities in these settings capture injury variables using specified data fields, and allows the information to be easily entered into a trauma registry and to be retrieved when patients present again for care (13). The presence of well-resourced and dedicated TR personnel in most HICs has also ensured both quality and reliability of the data and the sustainability of the registry which can then be used to inform clinical and research processes (115). In most LMICs, the implementation of TRs has been constrained by multiple factors including (but not limited to) infrastructural and human resources (13). One key challenge to creating a TR in most LMICs is documentation of the specifics of any injury, including patient characteristics, mechanism of injury, and location and severity of injuries. One important barrier to documentation in LIMCs is lack of electronic medical record system; and the few places were they exist, they are used only for registration or billing purposes (129). For the most part, health care providers use paper-based documentation, which do not contain guidance for what documentation is needed and would require manual data abstraction for submission to a registry. In addition, the high volume of patients, limited number of health care providers who are already charged with multiple tasks beyond patient care, means that the documentation of history and clinical care may be sub-optimal in these settings.

In Tanzania, like most LMICs, there are several challenges related to clinical documentation at health facilities, as well as the archiving system for different disease burden (107). We

conducted a qualitative study to explore the barriers and facilitators of current trauma documentation practices, as well as the factors that may affect implementation of a standardised trauma form at regional hospitals in Tanzania (175). The analytical outcome of this qualitative study provided useful insight regarding several barriers to be addressed, as well as facilitators that were available to be capitalised upon, and bring about change in the clinical documentation, as well as implementation of an injury registry. One important consideration to improving the documentation was the role of standardising the clinical information that should recorded, through provision of a standardised clinical documentation tool. Such a tool would not only prompt the clinician to record important variables but such prompts would also provide guidance as to considerations for management. At the same time, the form would collect standardised trauma variables that can be used for research and quality improvement projects. The availability of WHO DSI, with the accompanying WHO Using the WHO DSI template, we drafted a standardised trauma form (176) for clinical care and data collection, and then presented this form to health care providers in EU of each regional hospitals for their review, input and pilot utilisation.

Following this, there was a need to explore healthcare providers' perceptions on using a standardised trauma form to manage trauma patients and collect key registry data at regional-level hospitals in Tanzania. We believed that understanding their perceptions regarding utilisation of a standardised form is crucial to their adapting the form, pointing out necessary modifications of the content, as well as proposing the appropriate flow patterns that should enable them to use the form, in manners which will ensure sustainability in documentation of trauma care, as well as availability of injury data to inform the TR.

Aim

The aim of this study was to gain providers' insight and input on the feasibility of implementing a standardised trauma documentation form for dual function of documenting the findings and management of trauma patients and data collection for a TR.

Objectives

1. To explore healthcare providers' perceptions on using a standardised trauma form to manage trauma patients and collect key registry data at regional hospitals in Tanzania.
2. To utilise the health providers' input in updating and modifying the draft standardised trauma form to be used for managing trauma patients and for collecting key registry data at regional hospitals in Tanzania.

A copy of the published paper follows over the sixteen pages.

Copy of published paper

Perceptions of health providers towards the use of standardised trauma form in managing trauma patients: A qualitative study from Tanzania

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ABSTRACT

Background: Trauma registries (TRs) are essential to informing the quality of trauma care within health systems. Lack of standardised trauma documentation is a major cause of inconsistent and poor availability of trauma data in most low- and middle-income countries (LMICs), hindering the development of TRs in these regions. We explored health providers' perceptions on the use of a standardised trauma form to record trauma patient information in Tanzania.

Methods: An exploratory qualitative research using a semi-structured interview guide was carried out to purposefully selected key informants comprising of healthcare providers working in Emergency Units and surgical disciplines in five regional hospitals in Tanzania. Data were analysed using a thematic analysis approach to identify key themes surrounding potential implementation of the standardised trauma form.

Results: Thirty-three healthcare providers participated, the majority of whom had no experience in the use of standardised charting. Only five respondents had prior experience with trauma forms. Responses fell into three themes: perspectives on the concept of a standardised trauma form, potential benefits of a trauma form, and concerns regarding successful and sustainable implementation.

Conclusion: Findings of this study revealed wide healthcare provider acceptance of moving towards standardised clinical documentation for trauma patients. Successful implementation likely depends on the perceived benefits of using a trauma form as a tool to guide clinical management, standardise care and standardise data reporting; however, it will be important moving forward to factor concerns brought up in this study. Potential barriers to successful and sustainable implementation of the form, including the need for training and tailoring of form to match existing resources and knowledge of providers, must be considered.

Key words: Trauma registry, standardised documentation, provider perception, Africa, Tanzania

BACKGROUND

Trauma registries (TRs) are systems that provide timely injury data collection to support evaluation and monitoring of quality of care, and development of resource-specific treatment and prevention interventions (13,115,177). Despite burdens of trauma being highest in low and middle-income countries (LMICs), TRs are effectively non-existent in these regions

. In most high-income countries (HIC), the existence of formal trauma care systems incorporating functional TRs have significantly contributed to the reduction of injury morbidity and mortality (33,178). In these countries, the development and implementation of TRs required significant financial investment, human resource engagement and commitment to ensure high quality data can be collected and aggregated sustainably (179).

The use of TRs to document and interpret data on trauma and injuries is key to prioritising prevention efforts, monitoring injury diagnosis, management and outcomes in any trauma care system (180). However, in Africa, absence of formal trauma care systems and lack of TRs to generate accurate injury data make it difficult to clearly delineate the incidence, mechanism, and management of injury; this hinders the development of context-appropriate interventions to support the prevention of injuries and improve the quality of trauma care (1,181,182).

In Africa, the implementation of TRs has been largely unsuccessful or unsustainable, with most registries being limited to single health facilities during a defined research period, with no sustainability past the research phase (15,84,183). Lack of a defined standardised injury set and absence of resources to centrally compile and analyse injury data are among most African countries' documented reasons for failure to establish TRs (13). In an efforts to standardise reporting and generation of trauma data, the World Health Organization (WHO) recently developed a standard data set for injury (DSI) through the WHO International Registry for Trauma and Emergency Care platform (184). The WHO platform is available locally to each member country as to use as a national trauma registry, and the standardisation of data collected will allow for international comparability.

In order to address the lack of standardised injury data and prepare for a national TR, a standardised trauma form for trauma patients was developed using the WHO DSI (176). This form was intended to facilitate both clinical care and data collection within healthcare facilities across Tanzania. This study aimed to describe healthcare providers' perceptions on using standardised trauma form to manage trauma patients and collect key registry data at regional-level hospitals in Tanzania.

METHODS

Study design

This exploratory qualitative study utilised key informant interviews with healthcare providers across the five hospitals. This study was conducted at five regional hospitals in Tanzania - Mwananyamala, Coastal, Arusha, Morogoro and Tanga - between August 2018 and December 2018. The United Republic of Tanzania is a low-income country with a population of 55 million. It has a pyramidal health system structure spanning dispensaries, health centres, and district, regional and consultant hospitals (185). At the time of this study, Tanzania had a total of 25 regional hospitals. Five regional hospitals (representing 20% of all regional hospitals) were purposefully selected based on their representativeness of emergency care provision in the country. None of the included hospitals had formal documentation system for trauma cases; however, each hospital was mandated to document basic patient data in a Health Management Information System (HMIS) register book provided by the Ministry of Health (MoH). The HMIS records a small amount of data -only basic demographic information (age and sex), diagnosis, investigation, and disposition - and is intended to be submitted monthly to MoH (21).

Sample population

Principal investigator chose the participants from each hospitals based on their involvement with care process of trauma patient. A purposive sampling strategy was employed in all five sites to ensure a maximum variation of cadres and work experience of the study participants. This included the Clinicians (Specialist Doctors, Medical Officers, Assistant Medical Officer, Clinical Officers), Nurses, Administrative staff (Hospital administrators, Information and Communication Technology officer, and Health Information Records Officers). The initial target sample size of 35 participants (7 from each site) was earmarked based on the proportion of staff that have role in the care process of trauma patients in each of these hospitals. However, as interviews were being conducted, we realized that at the 33rd respondents there was no new relevant information coming out as we had attained information saturation and thus stopped data collection (Table 1). At this point even with different probing styles no new information, concepts or themes were disclosed, after which no additional interviews were conducted (186) The sample size for the interview portion of the study was determined by the principle of theoretical saturation at each site.

Data collection

Interviews were conducted by the principal investigator (specialists emergency physician) with short course training in qualitative research methodology. A semi-structured interview guide, with questions aimed at exploring the perceptions surrounding the use of standardised clinical charts versus current trauma patient data documentation practices (187,188).

Interviews opened with questions about participant demographics and professional experiences. Current and previous experiences with trauma charting were explored, were beliefs about the most important aspects of trauma charting and how a specific trauma form might change documentation and patient management. In the course of the interview, participants were given a paper copy of a proposed trauma form and time to review it, after which they were asked to provide feedback (**Appendix 2.6**).

At all hospitals, interviews were held in a dedicated office or conference room away from the site of patient care. Written informed consent was gained from all participants prior to initiation of the interviews, and participants were not reimbursed for participating in the interview. Interviews lasted 30 - 45 minutes, conducted in the participant's preferred language (Swahili), and were audio-recorded. All interviewers were all trained in qualitative methods and worked from the same interview guide.

Data analysis

All interview transcripts were transcribed verbatim. The research team cross-checked the accuracy and completeness of translations against the original transcripts. Any gaps identified or clarifications needed were discussed and corrections made accordingly.

We used a hybrid thematic data analysis approach; this approach used both inductive and deductive reasoning (189). We developed an initial codebook for data analysis, based on our study objectives. We then refined the codebook from the themes, which emerged during the analysis. The first author developed the initial codebook and shared it with all authors. The codebook was discussed, further developed, and a final codebook was imported into qualitative data management and analysis software ATLAS.ti (Version 1.0.4, © ATLAS.ti, Berlin, Germany). The agreed codebook was tested by coding the first two interview transcripts by three authors. Their coding was almost similar and, hence, the codebook was not modified at this time. Transcripts were reviewed interactively for representative phrases, which were coded and grouped into themes. Categories and emerging themes were identified, using Braun and Clarke's (2006) approach for thematic analysis (158). Constant comparative methods and memos were used to develop codes, review interview questions, and make changes to develop the trauma form (24). Inter-ratter reliability was enhanced by using two reviewers who were each independently responsible for qualitative data analysis with equitable concordance of descriptive themes and sub-themes.

Ethical clearance

Ethical approval for this study was received from the University of Cape Town Human Research Ethics Committee and Muhimbili University of Health and Allied Sciences Institutional Review Board.

RESULTS

Participants' characteristics and experience with use of trauma form

A total of 33 healthcare providers were interviewed, with a median length of experience of 6 years (interquartile range (IQR): 2 - 7). Most (82%) were male. The job roles of the participants are shown in Table 10. Most (84.8%) of respondents had not used a standardised charting prior to this interview.

Analytical themes and sub-themes

The findings of semi-structured interviews (SSI) revealed three themes:

1. **Potential benefits of a trauma form,**
2. **Perspectives on the concept of a standardised trauma form, and**
3. **Concerns regarding successful and sustainable implementation.**

These themes are supported by six sub-themes, as described below (Figure 4).

Theme one: Potential benefits of trauma form

Several participants explained the potential benefits of having a standardised trauma form in their Emergency Unit (EU). These benefits ranged from individual facility benefit to collective national level matters.

Sub theme 1: Perceived positive impact on quality of care

Many participants believed that the form would lead to improved quality of care within their hospitals. This perception emanated from the nature of design of the form, using mostly check boxes and hence serving as a prompt to the next most appropriate clinical intervention as well as reducing the amount of documentation required from the clinicians.

> *"….I will advocate to adopt this form as it is very useful because there are things I now realise we were omitting in evaluating trauma patients…..for example, we do not document primary, secondary survey, we only write very important information….but this is systematic…" [Participant no.25]*

One respondent noted how important it was to have the laboratory results listed on the form, as this would ensure accessibility in one platform and reduce the frequency of missing results.

> *"…the fact that we are also documenting the findings on this form is very nice, because one of our major problem has been accessing the laboratory results, as there is frequent loss of documents…" [Participant no.30]*

Sub theme 2: Anticipated reduction of work and increased efficiency of providers

Respondents perceived that having a standardised trauma form at the EU would reduce the clinical and administrative documentation workload that each facility is mandated to provide, such as manual recording in the HMIS register book.

> "*..this form will make our work of filling MTUHA (HMIS) simpler as we will always have standard information when we need it…*" *[Participant no.8]*

Another respondent added that the use of the standard form will lead to more accuracy in recording due to reduced burden of recording in the MTUHA book.

"….yes indeed, I believe we shall be more accurate and efficiency as we shall have less burden of documentation, and MTUHA (HMIS) records can easily be pulled from this form even when the patient has already left." [Participant- no.1]

Furthermore, participants added that the availability of the form at the Ewell address the challenges of documenting legal cases, as mandated by the police force. They stated that the latter is essential as most of the trauma cases are treated as legal cases in Tanzania, and necessitate police permission to provide care, this permission being documented using a police form.

"*….if the papers are filled properly and they are taken to registry, then when we need to file a PF3 [police legal form number 3] it will be much easier as this has been a challenge in the past.." [Participant no.23]*

Theme two: Perspective on the concept of standardised trauma form

This theme illustrates providers' perceptions about the concept of using a standardised template trauma form for documentation.

Sub theme 3: Acceptance of standard form

Respondents commonly indicated a positive perception and acceptance of the use of standardised documentation across all sites. There was a general readiness to utilise the form and some participants advocated for immediate adoption of the form at their facility.

"…yes, this is very usable form, and I think [name of hospital] should definitely adopt I; however, there are few areas I would change because as you know our resources are low…" [Participant no.9]

They suggested that the standardised trauma documentation might serve as precursor to implementation of a Government HMIS (GOTHMIS) that is currently under development and implementation in some Regional Hospitals.

"…this form is like a steppingstone to our new GOTHMIS plan [planned implementation of Government owned electronic medical record], hence I think we should move with it even though I think we may encounter some challenges during our initial stages…" [Participant no.13]

Sub-theme 4: Form content and usability

Respondents expressed widespread agreement on the form content. Most participants expressed satisfaction with variables and some noted that the form captured substantially more variables than were currently being documented.

"…. this form is very comprehensive in all sections, as there are many variables that we are not normally documenting on regular basis, that I am seeing here for the first time but I think they are important…"[Participant no.6]

Furthermore, the majority of participants perceived the form to be user friendly, in particular because of the use of checkboxes to reduce free text documentation. They believed that this would reduce their burden of documentation, especially given the large volume of patients and shortage of human personnel.

"…this form looks user friendly because it has very little free text documentation, to the most it is check…check….check [referring to checklist format] and you are

done…I think will make my life very easy especially when we get overwhelmed by patients…"[Participant no.13]

Theme three: Concerns regarding successful and sustainable implementation

Despite overwhelming support for and acceptance of the use of standardised documentation, some participants expressed concerns.

Sub-theme 5: Needs to improve the form

While there was a strong agreement on the form's setup and components, respondents expressed concern that the variables within the form might be too detailed for the facilities that do not provide advanced care for trauma patients. To reduce potential frustration, they proposed some modifications of the form that incorporate limited variables or components that may be available in their respective facilities.

"…I see this as a good form, however there are several variables that are too detailed for patients we see at [name of hospital] since we refer most of severe injuries, such as those needing ORIF [open reduction and internal fixation], or TBIs [Traumatic Brain Injuries].....I think we should modify and reduce those [variables] to make it [the form] more user friendly ……" [Participant no.1]

Some interviewees highlighted concerns that prehospital details are not available if there is no prehospital care, and so the form needed to be adjusted to reflect this reality.

"….the section that ask details about patient before they get to our facility will be tricky because we don't have ambulances except if the patient are referred to us from our health centres, but otherwise this information will be missing in most of our patients…"[Participant no.24]

Furthermore, some of the participants expressed the need to create a mechanism within the form that would clearly show which variables were not completed as a result of lack of resources or capacity to provide required care; this was perceived as important for quality of care and, in event of medico legal cases to give clarity on why the patient had not received particular care.

"….I think there are certain variables that are necessary to be included; for example, having the components related to lack of resources to care will help to show that we left the blank because was not performed due to lack of resources…this will help alleviate the burden of complaints that we often shoulder when there is an issue with the care of patient.."[Participant no.4]

Sub theme 6: Training on trauma form for accuracy and compliance

Participants noted a need for training of all providers in the use of the trauma form prior to its implementation, to ensure compliance and accuracy:

"…one important issue will be training, as this form seems to have a lot of good information, but most of us [clinician] may document wrongly if we are not trained…" [Participant no.23]

Another participant added:

"….awareness and training is key for both the doctors and nurses so as we remind each other during care, especially when there is mass casualty…" [Participant no. 4]

In addition to the existing providers who need training to familiarise them with a new form, respondents highlighted the need to have regular and sustainable training beyond the implementation period because most of these facilities have doctors on brief rotations, who become primary care providers in the EU:

> *"…….you see we have interns here who rotate for 4 weeks, and they cover both night and day shifts, hence I think they will have to be trained regularly each time they come to our department for rotation…otherwise we will have only benefited those who are available during this period of implementation….."[Participant no.17]*

Some respondents expressed the need to have dedicated people who have additional training (similar to training of trainers) who will be the lead at each EU to ensure that the other providers receive continuous training, as the implementation is on-going. This was idealised as a way to achieve regular and sustainable training that could last beyond the initial implementation phase. The participants said:

> *".....I think the hospital should designate among us someone who will take one the role of trainer for all of us (champion), and he/she should receive additional training and become a leader for the registry……since we have new staff regularly this model will help ensure there is on-going training for each of new staff..." [Participant no.29]*

DISCUSSION

Results of these key informant interviews demonstrated support for adoption of a standardised trauma documentation form to be use as a clinical management guide to standardise care processes, reduce documentation burden, and improve data acquisition and reporting. It was clear that the majority of participants had not previously used standardised trauma documentation, or any standardised documentation; however, the majority had positive beliefs that a standardised template would bring benefits to patients, individual providers and the healthcare system at-large.

There was a wide acceptance and positive attitude towards use of standardised documentation across all the sites. Similar to observed impact of TR in most HICs (191) providers believe that successful implementation of standardised trauma documentation form at regional hospitals in Tanzania will have a wide reaching impact in care process as well as developing the first regional injury registry that is sustainable and can be replicated in other low income countries. Most of prior registries in Sub Saharan Africa have been largely limited, in part due to lack of engagement of providers in developing and implementing the form, as well as resource intensive nature of the design and modality of aggregating data (13).

In this study, we found that the content of the proposed form overwhelmed some of the providers, who reported being unaware of some of variables in the form and called for their

omission. In addition to the concern about provider knowledge, some participants highlighted resource challenges that may limit the capacity to completely fill in all of the variables according to the template. In contrast, other providers requested training to inform an understanding of unfamiliar variables, to improve compliance and accuracy of form completion. However, there was not agreement on whether to remove these variables, or leave them in, but with a means to record the lack of resources.

For example, most providers advised retaining the component on documentation of ultrasound finding, but adding a sub section of "not done" and "not indicated". This would highlight a gap in care as well as reminder to clinicians of the importance of this assessment. None of the hospitals had a point of care ultrasound available, and this meant that the documentation of bedside ultrasound findings was not practical. Tailoring of the form to match the existing resources of the facility was perceived as one of the main factors that will determine sustainability and compliance towards successful implementation and utilisation.

Most providers expressed the need for training to support their understanding of the form content and utilisation, which might imply a limited understanding of the trauma care process. Our study did not assess the level of knowledge of respondents in providing trauma care; however, care gaps among trauma patients referred from regional to national hospitals are well-documented in-country (192). Also, in the present study, mistrust of care provision by junior and rotating clinicians further strengthened participants' beliefs that robust training on the form will be necessary. Individual provider buy-in is central to implementation of new processes within health facilities (193); a form such as this will be no exception. There was positive perception towards the use of the proposed trauma form, mostly owing to the view that the form, with its checklist nature, will improve care and reduce workload.

Implementation and use of standardised guideline and templates in LMICs is closely linked to the availability of the right human resources to provide optimal care (194). Contrary to our expectation, human resource shortages were perceived a strong rationale for implementation of a standardised form, as the form was expected to reduce the overall amount of time spent in documentation. The regular filing of HMIS to MoH, as well as reporting on police forms for all injured patients, was noted to be a daily burden for all healthcare providers. The majority of respondents also expressed the belief that the trauma form would enable the retrieval of the documentation of previous patients when necessary.

Implementation of registries in Sub Saharan Africa have been largely unsustainable, or limited within the research environment, mostly due to the nature of registry set up requiring continuous resources to sustain, as well as lack of provider engagement in supporting the implementation process (96). Our study highlighted healthcare providers' views on the

utilisation of a standardised trauma form. These insights have provided crucial guidance towards the development and implementation process to ensure compliance and long-term sustainability. Finally, it is important that the development process of the trauma form takes into account the facility resources. This will ensure the form is fit for purpose across a healthcare system with variation in capacity to care for injured patients.

TRUSTWORTHINESS

Trustworthiness is attained in a qualitative study when the findings of such a study are worth believing (173). In this study we adopted the four Guba criteria; credibility, dependability, transferability, and conformability to enhance the trustworthiness (172). The credibility of the findings of this study was enhanced through the triangulation of informants with experiences and rich information on the study questions. In order to enhance the credibility and dependability of this study, we used the triangulation of informants, study settings, and researchers. Data were collected using a semi-structured interview guide that allowed for probing. In order to confirm that the findings reflected informants' perspectives rather than the researchers' understanding of the question under study, themes we inductively generated using thematic analysis approach and presented with the support of sub-themes and quotes. The transferability of the findings of this study is enhanced through the description of the study setting, context, data collection process, and analysis.

LIMITATIONS

As for other qualitative studies, the generalisability of this study is likely limited by the small sample size of healthcare providers and number of sites. However, the thick description of the study context provides room for the transferability and thus applicability of these findings in other similar contexts. Interviews were conducted in Kiswahili, transcribed verbatim, and translated into English language for analysis, which might have introduced some errors. To counteract this effect, two authors reviewed the translated scripts.

IMPLICATIONS OF THE STUDY

As a key first step in building a national TR, we explored perceptions of providers towards the use of a standardised trauma form at regional hospitals in Tanzania. Findings of this study revealed wide acceptance of moving towards standardised clinical documentation for trauma patients, with providers citing the potential benefits of improving quality of care, reducing workload and increasing efficiency in trauma care. Potential barriers to successful and sustainable implementation of the form were also noted, specifically the need for training and tailoring of form to match existing resources and knowledge of providers.

DECLARATIONS

Ethics approval and consent to participate

Ethical approval for this study was received from the University of Cape Town Human Research Ethics Committee and Muhimbili University of Health and Allied Sciences Institutional Review Board. All participants provided written informed consent prior to participation.

Consent to publish

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are presented as additional supporting files in this manuscript.

Competing interests

The authors declare no conflicts of interest.

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This was a non-funded project; the principal investigators used their own funds to support the data collection and logistics.

Authors' contributions

HRS contributed to the conception and design of the study, acquired, analysed and interpreted the data, and drafted original manuscript and revised the manuscript. NS contributed design of the study, data review and validation, and analysis and also critically revised the manuscript. EW and TC contributed to the design of the study, data validation, and analysis and also revised the manuscript, TAR and LAW contributed to conception and design of the study, data validation, review, analysis and also critically revised the manuscript. All authors read and approved the final manuscript

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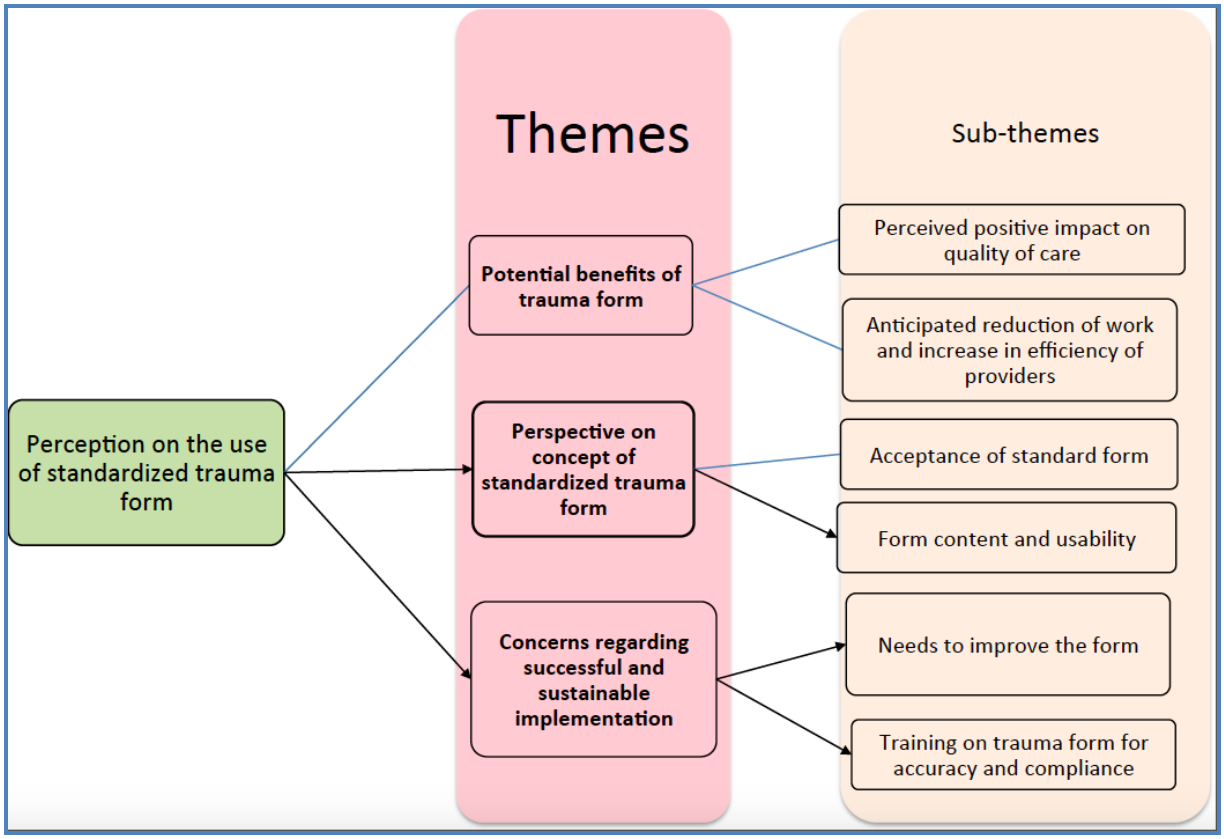
TABLES

Table 10. Hospital Roles of Study Participants

Hospital Role	Interview, N=33 n (%)	Gender: male %	Prior use of trauma form %
Nurse	6 (18.2)	83.3	16.7
Medical Officer	8 (24.2)	75	37.5
Assistant Medical Officer	5 (15.2)	80	0
Clinical Officer	6 (18.2)	83.3	0
Specialist Doctor			0
Emergency Physician	1 (3)	100	100
Orthopaedic/Trauma Specialist	1 (3)	100	0
Surgery Specialist	1 (3)	100	0
Administrator	2 (6.1)	50	0
HMIS Officer	2 (2.1)	50	0
ICT Officer	1 (3.0)	100	0

Figure 4. Analytical themes and sub-themes



Discussion of the paper

Supplementary methods

Participants

Purposive sampling technique was employed by the Principal Investigator to enrol participants based on their involvement in the care of trauma patients and having used the standardised form. In each EU, a sample size of 7 participants was estimated based on the available staff. The participants were invited to take part in the semi-structured interviews and informed of the right not to participate as well as the right to withdraw their participation at any moment.

Data collection and analysis

Interviews were semi-structured with mainly open-ended questions that focused on exploring the perceptions of the health care providers in utilising the standardised trauma form for clinical care of patients, and trauma burden documentation. Using an interview guide (**Appendix 2.5**) the principal investigator led with some baseline questions related to the participant's demographics, past and previous experience with management and documentation of care of trauma patients. During the interview, participants were provided with an opportunity to review and document on the form (**Appendix 2.6**), based on a patient scenario that the principal investigator provided. The scenario allowed the investigator to determine if the providers had an understanding of different aspects of trauma variables, and how they link to the form. The participants estimated the average time that it would take for them to complete such a trauma form, and were asked to expressed their opinions and ideas about the usability of the form and if they had suggestions for improvement. The interviews were carried out in a designated space outside the clinical areas to ensure maximum cooperation and limiting the interruptions. After all the interviews, the Principal Investigator reviewed the key changes proposed by the participants and revised it accordingly, prior to piloting and implementation.

Supplementary results

In addition to analytical themes and sub-themes presented in the main study, the following additional information was revealed in the course of interviews that were conducted.

Familiarity with a Trauma form

During the interviews the respondents were asked about their familiarity with a the standardised trauma form. There were a variety of responses, with some providers noting prior experience with the form at Muhimbili National Hospital were they had previously worked at, and some reporting that they had encountered the form in a research environment:

...I have a slight idea on this form, I saw it at Muhimbili, when I sent a referral patient, it was on a big book and the doctors use it to document for the patients…[Participant no.4]

Another participant explained that:

...yes I know about it because I saw it in use at Muhimbili [National hospital] when I was an intern, this form has checkbox that guide you through the history taking, physical examination and management….we used to document on it, it makes life easy but here at[name of hospital] we don't have, only for research…[Participant no.6]

Current system of trauma documentation

The participants were asked about their individual practice of trauma documentation in their facilities, as well as the overall flow of patients who had sustained trauma. This revealed a highly variable documentation practice between the EUs, as well as between different kinds of patients:

...the documentation of trauma patients is done on a standard casualty card which is like a continuation form and the doctor documents important information and management…….[Participant no.4]

...the registry issues a card that the patient comes with and we [doctor] document on that card, if the patient is admitted the card go [with] the patient, and if[the patient] is discharge the card goes to the registry…[Participant no.7]

....documentation varies from patient to patient, sometimes there are patients who are not documented because they are not very sick and the doctor is very busy with many patients, so they will just dress the wounds and discharge…[Participant no.2]

Supplementary limitations

In addition to the limitations described in the study, the provision of standardized form to study participants for review and documentation practices during interview might have elicited perspectives related to this particular version of the form. However, participants were made aware that the sample form being shared is intended as an example, and the interview we are seeking their general perspective on introducing a context appropriate standardised trauma form for care and clinical documentation in their facilities. Furthermore, our study was conducted on a sample of regional hospitals, which limits its generalisability to the entire health care system of Tanzania. However, the diversity of study participants and their roles in daily management of trauma patients provides some avenue for applicability of the perceptions that have been revealed in the course of interviews to other sites and providers.

Chapter conclusion

In this chapter, we found that the implementation and utilisation of standardised trauma documentation form is acceptable and adaptable at regional hospitals. While health care providers raised some reservations regarding utilisation of standardised trauma documentation, there was overwhelming acceptance by providers for moving towards this intervention, with perceptions of a positive impact on both quality of trauma care and injury data capture. In Chapter 6, we combine the information gathered in chapters 4 and 5 to inform the development, pilot implementation and impact of standardised trauma form on the capture of injury variables at the EUs of regional hospitals.

Chapter 6: Development, structure and implementation of a context appropriate standardised trauma form

Reference:

Sawe HR, Reynolds TA, Weber EJ, Mfinanga JA, Coats TJ, Wallis LA. Development and pilot implementation of a standardised trauma documentation form to inform a national TR in a low-resource setting: lessons from Tanzania. BMJ Open 2020;10:e038022. doi:10.1136/bmjopen-2020-038022

Declaration from author and co-authors:

The following co-authors contributed to the paper: Hendry R. Sawe, Teri A. Reynolds, Ellen J Weber, Juma A. Mfinanga, Timoth J Coats, and Lee A Wallis. In the case of Chapter 6, contribution by authors to the work was as follow:

HRS contributed to the conception and design of the study, acquired, analysed and interpreted the data, and drafted original manuscript and revised the manuscript. JAM contributed to the design of the study, data validation, and analysis and read, revised, and approved of the final manuscript. TAR, EJW, TJC and LAW contributed to the design of the study, assisted with data interpretation, and read, revised, and approved of the final manuscript.

Extent of contribution:

4. Dr. Hendry R. Sawe: 70%,
5. Dr. Juma A. Mfinanga: 10%
6. Prof. Lee A. Wallis: 5%
7. Prof. Ellen J Weber: 5%,
8. Prof. Teri A. Reynolds: 5%
9. Prof. Timoth J Coats: 5%

19th April 2021

Hendry R. Sawe Date

Declaration by co-authors

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other author of the publication according these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from date indicated below

Location of stored data:

Data set analysed during the current are stored on the authors (HRS) encrypted Research Electronic Data Capture (RedCap) account allocated through the Emergency Medicine Association of Tanzania, research portal.

16th April 2021

Prof. Lee A. Wallis — Date

14th April 2021

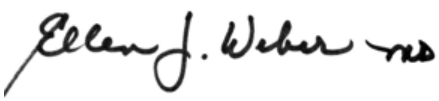
Dr. Juma A. Mfinanga — Date

20th April 2021

Prof. Timothy Coats — Date

29th April 2021

Prof. Teri A. Reynolds — Date



23rd April 2021

Prof. Ellen J Weber — Date

Main findings

- This participatory action research generated context appropriate standardised trauma documentation form incorporating the WHO DSI with dual functions of serving as the clinical chart and a source of injury data to inform the development of TR.
- The pilot implementation of contextually appropriate, standardised trauma documentation form was successful in yielding marked improvement in the capture of essential WHO DSI data points to inform the TR.

Motivation for conducting the study

The development of a TR is largely dependent on the availability of a set of injury variables so that information can be combined from multiple sites. Standardised variables for trauma are largely non-existent in most LMICs. In Tanzania, like most LMICs, there is no formal TR, with initial efforts to establish a registry being confined to a single hospital, with limited wider spread across the country (23). The WHO DSI was developed to support member countries and other interested stakeholders who wish to standardise the documentation of care of injured patients, as well as secure necessary injury variables to inform a TR (85). In our preliminary studies, we evaluated the documentation practices at a sub-group of regional hospitals in Tanzania, focusing on how frequently WHO DSI variables were documented, and where we found poor capture rate of variables in documentation in these facilities (195). Subsequently, we explored the barriers and facilitators of current trauma documentation practices and how these factors that may affect implementation of a standardised trauma form at regional hospitals in Tanzania (175). The results of these studies provided potential way forward for improving trauma data capture at these sites. In this study, we ought to describe how this participatory action research was used to develop, pilot and implement a standardised trauma documentation form that is based on an adaptation and utilization of the WHO DSI as the first step in the development of a national TR in our country.

Aim

The aim of this project was to develop and pilot a context-appropriate standardised trauma form for clinical documentation and to supply data to a national TR.

Objectives

1. To describe the process of development, structure and implementation of a context appropriate standardised trauma for clinical documentation and use in a national TR.
2. To determine the change in proportion of variables of Data Set for Injury captured after implementation of a standardised trauma documentation form

A copy of the published paper follows over the next twenty pages.

Copy of published paper

Development and Pilot Implementation of a Standardised Trauma Documentation Form to Inform a National Trauma Registry in a Low-Resource Setting: Lessons from Tanzania

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Abstract

Objectives: Trauma registries are an integral part of a well-organized trauma system. Tanzania, like many low and middle-income countries, does not have a trauma registry. We describe the development, structure, implementation and impact of a context appropriate standardised trauma form based on the adaptation of the World Health Organization Data Set for Injury (DSI), for clinical documentation and use in a national trauma registry.

Setting: Our study was conducted in emergency units of five regional referral hospitals in Tanzania.

Procedures: Mixed methods participatory action research was employed. After an assessment of baseline trauma documentation, we conducted semi-structured interviews with a purposefully selected sample of 33 health care providers from all participating hospitals to understand, develop, pilot and implement a standardised trauma form. We compared the number and types of variables captured before and after the form was implemented.

Outcomes: Change in proportion of variables of DSI captured after implementation of a standardised trauma documentation form.

Results: Piloting and feedback informed the development of a context appropriate standardised trauma documentation paper form with carbonless copy that could be used as both the clinical chart and data capture. Among 721 patients (seen by 21 clinicians) during the initial 30-day pilot, overall variable capture was 86.4% of required variables. After modifications of the form and training of health care providers, the form was implemented for seven months, during which the capture improved to 96.3% among 6302 patients (seen by 31 clinicians). The providers reported the form was user-friendly, resulted in less time documenting, and served as a guide to managing trauma patients.

Conclusions: The development and implementation of a contextually appropriate, standardised trauma form was successful, yielding increased capture rates of injury variables. This system will facilitate expansion of the trauma registry across the country and inform similar initiatives in Sub Saharan Africa.

Strengths and limitations of this study

- This participatory action research generated a model form for capturing all variables required for the World Health Organization Data Set for Injury that may be used and adapted in other low-resource settings working to develop trauma registries.
- The development of a structured, paper-based data form that could also be used as the chart demonstrated a feasible and sustainable method for providing data for a registry, while also improving the quality of injury care and documentation, provides

a model for developing a trauma registry in other limited resource countries.

- This study was conducted at a selected sample of regional level hospitals, which limits the generalisability to the whole healthcare system, as regional level hospitals tend more have human and infrastructural resources than lower level facilities.
- There is a possibility that providers demonstrated a substantial improvement in capture of injury variable due to their awareness of being observed; however, capture remained significantly higher even at seven months a point at which we would expect that the "Hawthorne effect" would no longer be at play. Subsequent follow up is planned.

BACKGROUND

Trauma is responsible for approximately 5.8 million deaths annually, accounting for 10% of all deaths worldwide (141). Ninety percent of these deaths occur in low- and middle-income countries (LMICs) (196). Evidence from high-income countries suggests that improving trauma care systems could substantially reduce trauma-related morbidity and mortality in LMICs. Trauma care systems in most LMICs are under-developed and, in places where they exist, high volume of trauma leaves systems under-resourced and over-burdened (11).

Trauma registries are critical to both prevention of traumatic injuries, and the development and improvement of trauma care (51). Trauma registries are databases that contain prospectively collected information on trauma patients, including demographics, injury mechanisms and severity, treatment and disposition. Registries allow the health care system to assess the quality of trauma care, apportion resources, monitor the impact of performance improvement on quality of care and public health interventions to prevent injuries (13,27).

Trauma registries form an integral component of the trauma care system in most high-income countries. However, trauma registries in LMICs are largely non-existent (197). In the few hospitals where registries exist, they are developed in short-term research projects that are not sustainable (120,198), and they are not linked at a national level, preventing evaluation of the system as a whole (16,121). Tanzania does not have a national trauma registry. The first Tanzanian effort to develop a trauma registry was at the Muhimbili National Hospital (MNH) in Dar es Salaam, and it has been very successful for capturing trauma data seen at this referral hospital (23); however thus far these efforts have been limited to MNH. These experiences have since informed the development of World Health Organization (WHO) clinical form(199). The Ministry of Health (MoH) utilises a purpose-designed Health Management Information System (HMIS) register, which gathers information on all patients visiting health facilities throughout Tanzania (21). HMIS documentation is performed by the treating clinicians, in addition to their clinical charts, and

then data aggregation is performed by a clerk at each facility and submitted to MoH. HMIS data entry creates an additional burden in time and costs for the physician and hospital, which affects the quality and volume of data reported (107,200).

To provide guidance on the establishment of trauma registries in LMIC's, the World Health Organization proposed the Data Set for Injury (DSI)(85), a minimum set of variables needed for a centralised trauma registry as well as a standardised clinical form for trauma patients(199). However, when we studied the capture of these variables in routine clinical documentation we found a poor capture of variables documented. In a mixed-methods study of documentation for trauma patients in five regional hospitals in Tanzania, we found poor availability of requisite data and a very low capture (33.6%) of DSI variables using existing documentation methods, as well as potential barriers and facilitators to complete documentation (195,201). Results of these studies were, paradoxically, encouraging as they suggested vast potential and a way forward for improving trauma data capture.

To facilitate implementation of a sustainable trauma registry in Tanzania, a contextually appropriate mechanism of collecting relevant data is needed. This study describes the development, piloting and implementation of a low-burden system based on an adaptation and utilization of the WHO DSI as the first step in the development of a national trauma registry in our country. The primary aims of the project were to ensure all eligible trauma patients are included and maximizing the capture of variables within the standardised trauma form.

METHODS

A participatory action research study was conducted between 1st February 2018 and 30th September 2019 at five regional referral hospitals in Tanzania (Morogoro, Arusha, Mwananyamala, Coastal and Tanga) (195).

The process of development and implementation of a system to collect standardised trauma variables was guided by Susan and Evereds' cyclic process of inquiry for action research (202) (**Figure 1**). The first two phases of this process ("diagnosis" and "action planning") were previously undertaken during the aforementioned needs assessment studies (195,201,203), and are briefly described here.

Diagnosis

First, we conducted a prospective, observational cross-sectional study to evaluate capture of the variables in the WHO DSI amongst all trauma patients presenting to the EUs. This revealed poor capture (33.6%) of the recommended variables (195). Following this analysis, we conducted a qualitative study using focus groups at these five hospitals to understand the

barriers and facilitators for capturing required data (201). Among the barriers were provider knowledge, and the burden of dual documentation.

Action planning

During these discussions, the investigators and participants determined that a solution to the barriers identified in diagnosis phase would be a standardised trauma data collection tool that could also be used as a chart, and created a plan to develop and pilot test it. The development of the tool was further informed by semi-structured interviews with providers at the EU's, aimed at understanding their perception and attitudes towards using a standardised chart with pre-specified variables for providers to complete for all trauma patients (203).

Action taking

The "diagnosis and action planning" phases led to the design of context-appropriate standardised trauma documentation form based on the adaptation of the WHO DSI and clinical form (199). Usability of the form was evaluated by health care providers at all EUs, after which semi-structured interviews were again conducted to assess perceptions and attitudes of healthcare providers regarding utilisation of the form, and soliciting input on the design and variables within the form and how it could be implemented without dual documentation. This feedback was reviewed and incorporated into a final draft of the form (203).

The current report summarizes further steps in "action taking" followed by "evaluation" and "specifying learning," the final two stages of the cyclic process of inquiry for action research.

Training of HCPs

Two clinical care leads (a nurse and a physician) from each EU were invited to participate in a two-day training of trainer (ToT) course, conducted at MNH. The ToT course focused on basic components of the primary trauma care (204), importance and definition of each DSI variable, associated documentation in the standardised trauma form including practice on filling out the form using different scenarios of pre-prepared hypothetical trauma cases**,** and how the variables will link with registry. After the ToT, the clinical leads conducted one-on-one training of clinicians in their respective EUs who are involved in the care of trauma patients. The one-on-one training involved filling out the proposed standardised clinical documentation form on a sample of patients who presented at EU during clinical shift. The ToT reviewed the clinical charts and provided feedback in real time to clinicians on different aspects of completing the form, including explaining any variables or components that were not clear to the clinicians. The trained clinical leads were also used as the key personnel (super-users) supporting day-to-day queries on use of the standardised trauma form at their respective EUs.

Pilot testing and modification of the form

After providers had been trained at all EU's, we conducted a one-month pilot in January 2019. The form was printed with a carbonless copy, and clinicians were expected to document their clinical care and trauma variables on the form. Then, the top copy could be removed to become part of the patient's chart, while the bottom copy was retained to inform the registry. In each EU, research assistants - clinical officers (middle level providers with diploma in clinical medicine) and nurses received extensive training on how to capture data electronically, and prior to this phase of the study, they all had participated in data collection for the baseline observational study (195), reported in the diagnostic phase.

The research assistant collected the bottom copy of the clinical form and entered the data to an online Research Electronic Data Capture (REDCap) software (© REDCap, San Francisco, CA, USA). For each variable, the research assistant entered the documentation of the physician and the REDCap version of the form had options to indicate for each variable whether it was documented, and whether there was an error in the documentation. Errors were defined as documenting data that didn't match the variable requested. Data from REDCap were exported to Statistical Package for Social Science (SPSS) (version 22.0, IBM, Ltd, Carolina, USA) and analysed.

The number of patients for whom forms were completed was compared with the main hospital register, and the capture of each variable was calculated as the number of variables documented divided by the total of variables for each patient. The proportion of errors were calculated as number of documented variables with errors divide by the number of documented variables.

The principle investigator (a specialist emergency physician, HS) provided feedback to the providers in the EUs on the results. HS then conducted consultative interviews with trauma care providers in each EU to obtain feedback on the understandability and usability of the form, and challenges to its completion. Interview participants at each EU were purposefully selected based on their involvement in the trauma care process and to maximize the variation in cadres and work experience of the interviewees. The challenges identified in the interviews were then addressed by modification of the form and online REDCap variables, additional one-on-one informal training, feedback to individual providers on their documentation, and enlisting the hospital administration to advocate during clinical meetings for accurate use of the form for clinical documentation of all trauma patients.

Implementation of the standardised trauma documentation form

The refined standardised trauma documentation form (clinical chart) was launched for a seven-month period from end of February 2019 to September 2019. We conducted a pre-

planned interim analysis of data 30 days into the implementation to ensure the revised form was working well, with improved capture of variables and fewer errors. As in the pilot, all trauma patients who presented to the EU and seen by clinicians were supposed to have documentation completed using the standardised trauma form. Process for data collection and analysis was the same as after the pilot, with one copy of the form becoming part of patient's medical chart, and the other used for data entry in the trauma registry by the research assistant. The research assistants entered the data into REDCAP both with regard to whether the data was present and whether there was an error in the documentation.

Evaluation

During the seven-month implementation period, the Principal Investigator reviewed a random sample of the paper form and the entry of data and notation of errors into the REDCap by the research assistant. If the research assistant marked something as an error that wasn't, or failed to spot an error, the PI corrected the entry in Redcap. The PI provided feedback to clinical leads of each site and the research assistants on the observed variable capture as well as supporting to trouble-shoot any challenges that are related to data collection and entry. After quality check, data from REDCap system were exported to SPSS and analysed. The capture of each variable was calculated as the total number of variables documented or documented as not done or documented as unknown divided by the total of variables for each patient. Then, the proportion of documented DSI variables during the study period were compared to the proportion captured during the initial needs assessment (when the standardised form did not exist and only existing records were evaluated) (195). DSI variables were aggregated into five main categories to demonstrate the change in the proportion of variables completed from baseline to seven months post-implementation.

Specifying learning

The authors reflect on key lessons on engagement, development and implementation of standardised trauma documentation form in the discussion.

Patient and Public Involvement

The development of standardised form to inform a national trauma registry is in response to the public health need of preventing injury and improving care of the injured by acquiring better evidence. Patients and the public were not involved in the design of the study. The results of our study will be disseminated through open access publications.

RESULTS

Action taking

Pilot testing and modification of the standardised trauma documentation form

During the pilot in January 2019, 21 clinicians across the five EUs of the regional hospitals

saw 721 trauma patients. The proportion of variables completed, and errors showed marked variation by variable. Patient name was documented 100%, whereas others were poorly documented **(Table 11).** Documentation of mental status (AVPU) was 61.3% complete with 30.5% errors among those entries; a key DSI variable "Mechanism of Injury" was missing in 28% of cases with 12.3% having errors **(Table 12).** There was also evidence of bias in the data that was missing, as most of the 11.5% of patients who did not have a disposition recorded were in fact discharged.

Thirty-three health care providers who had previously been interviewed for the design of the form were again interviewed after the first pilot (**Table 13**), their demographics are discussed elsewhere (203). These interviews revealed the need to collect additional information critical for the Tanzanian context, and necessary for clinical care, including medico legal data points. Suggested changes included:

- Expansion of the demographics section to ensure that the mode of arrival captures traditional means of travel in Tanzania,
- Designated spaces for documenting: chief complaints; results; reassessment of patients, including vital signs prior to patients exiting EU; and mass casualty incident occurrences,
- Additional check boxes to indicate mass casualty incidents, normal assessment for all primary and secondary survey, and for the most common investigations,
- Removal of the pain scale assessment (as this is not in their routine clinical care and they are not conversant with the scale), and
- Adjustment of font to at least 12 point.

Using this provider input, we updated the form (**Appendix 2.6)**.

In addition to improvements in the form, the interviews revealed that some EU providers needed greater clarity on some of trauma variables, as well as means of distinguishing lack of documentation (missing data) from something that could not be done due to lack of resources, process or expertise to perform the intervention. An adjustment was made to allow the providers to document not done (ND) or unknown in all variables that were not done in the EU or information is unavailable from patient so as to distinguish the lack of documentation (missing data) from something that can not be done due to lack of resources, process or expertise to perform the intervention (for example a blood pressure was recorded ND if there was no equipment to make the measurement), and all were analysed as documented. All EUs went on to conduct additional one-no-one internal training to clinicians by clinical care leads, as well as daily advocacy to improve understanding of the form's relevance to clinical care and data.

Evaluation

The final form was implemented from end of February 2019. The pre-planned interim analysis 30 days after implementation included 925 patients seen by 23 clinicians, and found overall data completion and errors improved substantially across all categories (**Figure 6**). The overall documentation increased from baseline in the diagnostic phase (33.6%) in July 2018 (195), to 96.3% at 7-month post implementation a substantial improvement from 33.6% observed during the "diagnostic" phase, and improvement was across all categories (**Table 11**). Details of injury (from 20.7% to 96.2%), initial clinical condition (from 26% to 96.5%), and injury examination (from 27.5% to 94.6%) had the largest improvements in documentation (**Table 11**). Age, activity at time of injury and disposition plan were documented in all patients post implementation. Some variables remained below 100% capture, including injury intent (8.9% missing), injury anatomical location (7.9% missing), injury type (7.4% missing), and interventions in EU (7.3% missing).

The use of the option for not done (ND) or unknown highlighted several gaps in the ability or processes of these departments to manage trauma patients. These variables included the setting of the injury and activity at the time, and vital sign data, which was, marked ND in 9.6% – 18.5% of cases (**Table 11**). However, the use of ND did not fully account for the improvement in documentation.

DISCUSSION

Countries that have no trauma registries are limited in their capacity to correctly define the burden of injury, reduce injury rates, and develop contextually-appropriate strategies to improve care processes (198). This participatory action research generated a model form for capturing DSI variables that may be replicable in other low-resource settings working to develop trauma registries. Inclusion of DSI variables will allow for comparison with other countries.

High quality documentation of trauma cases can serve several crucial purposes both at national and hospital level (179). Trauma registries have provided the ability to better understand sources of injury and patient outcomes, and to make inter-hospital or regional comparisons that potentially indicate best practices. Trauma registry data in HIC have demonstrated impact of trauma care re-organization on overall patient mortality over a period of ten years, and more recently enabled recognition of a demographic shift of age and injury mechanisms among trauma victims (205,206). Such detailed information is desperately needed in most low and middle-income countries, given the need to apportion our limited resources to maximize patient outcomes.

However guaranteeing sustainable quality data from facilities requires an understanding by all staff and institutional management as to why documentation can impact outcomes (115) as well as to provide a feasible way to do it. It is likely that numerous factors led to the successful implementation of the form at different EUs. Its development relied on substantial groundwork, including a needs assessment to evaluate baseline capture of DSI variables, and evaluation of facilitators and barriers to implementation as well as education as to the value of the data. The engagement of health care providers and administrators at all stages in diagnosis, development and implementation yielded valuable input to modify the tool and promoted wide acceptance. Iterative pilot testing was crucial for refinement, as were feedback interviews. Furthermore, this feedback identified additional reasons for lack of documentation that could be addressed by additional training of providers on primary trauma care (207). As one of the first locally developed trauma forms to incorporate WHO DSI variables, the final tool we developed can now been used to inform the implementation of WHO International Registry for Trauma and Emergency Care(86) using data from Tanzania.

Inevitably, we encountered several challenges. The form's development involved introduction of WHO DSI variables, most of which were not routinely documented by the providers. Robust training was necessary to not only teach HCPs how to use the form, but also reinforce its value and alter negative perceptions surrounding its implementation. Changing clinicians' mind-sets required strong support from administration, and a willingness to use its authority and supervision to ensure compliance. Because providers frequently rotate in and out of departments, sustainability of the process was aided by the train of trainers program, so that each EU could perform it's own training as needed. The variability in providers' training and experience meant training had to be tailored to non-emergency physicians, to ensure all providers understood variables and documented them correctly. Similar to previous observations (127,208), we found most EUs had limited equipment and consumables to support the provision of high quality emergency care. This was identified as one of the reasons why some variables were poorly captured. In our training, and formatting of the standardised form, we added a component to indicate that a particular assessment, investigation or intervention was not done, or is unknown to help distinguish lack of documentation from inability to perform the evaluation. It was notable that the variables most likely to have an ND were those of assessment of vital signs, which is a fundamental need in all trauma cases. This suggests a gap that requires additional training and resources to appropriately care for patients. The use of unknown for name, age and address of patient may suggest the inability patient to respond due to either being altered or brought in with fatal injuries, as trauma patients in our settings may be brought to EU by good samaritan, or police from the scene of injury (22). Similarly for activity being

performed at the time of the injury, and setting, may suggest either a failure to ask the question or the inability of the patient to respond.

A key to the sustainability of the form, and support from providers is that it does not contribute to existing strains in their roles (13,16,27,177). Prior to the development of the tool, providers had to endure dual documentation to report each case in the HMIS register (21). Reducing the amount of documentation at facility level has been shown in similar settings to improve compliance, data capture, and reduce provider fatigue (162). Most registries use dual documentation systems, which require an additional clerk around the clock to ensure complete capture (16,209), which would not be feasible in our setting. In high-income countries, prior to electronic charts, carbonless copies were frequently used in emergency units to support clinical documentation and billing. In our setting, they support and improve capture of injury variables in LMICs without dual documentation. If electronic records are eventually adopted throughout Tanzania the data could be directly imported into a trauma registry while also serving as a clinical record.

Nevertheless, long term consistency of data collection is a challenge in most settings (198). In this study, seven months after implementation of the form, capture were still very high, though there was a slight decline from the interim analysis at 30-days post implementation. Several factors might have contributed to this decline, including knowledge retention issues, staff turnaround and changes in-patient flow through EUs. Additional research is necessary to identify best practices for mitigating these issues.

Limitations

Our study had several limitations. We conducted the study at selected sample of regional hospitals in Tanzania, which may not represent the whole healthcare system of the country, as regional hospitals tend to have more resources and preferentially qualified providers than lower facilities. There was only one assessor for each chart at each site, and thus inter-ratter reliability of the data input and assessment of errors by research assistants could not be assessed; the PI reviewed a selected sample of charts and made only few correction to the online data, however inter-ratter reliability was not assessed. Future initiatives will focus on assessing the quality of variable captured, as well as consistency at each site so as to ensure high quality data for trauma reporting. Our capture post pilot was determined using all documentation (including the use of ND and unknown for variables documented as not done due to lack of resources, process or expertise), which limit generalizability to settings with more resources for care that may require more documentation of performed assessment or interventions. Furthermore, there is a possibility that providers in the EU demonstrated a significant improvement in documentation due to their awareness of being observed (210);

however, capture remained significantly higher than baseline even at seven months, a point at which we would expect that the "Hawthorne effect" would no longer be at play. Subsequent follow up is planned.

Conclusion

Through participatory action research a contextually appropriate, standardised trauma documentation form was successfully developed and implemented, yielding marked improvement in the capture of essential injury variables. This system will facilitate expansion of the trauma registry across the country and inform similar initiatives in other countries in Sub Saharan Africa. Future work should focus on expanding the existing registry to broader network of hospitals, utilisation of the existing dataset to inform on the burden of injury in the region, and addressing challenges associated with long-term consistency of the registry.

DECLARATIONS

Ethics approval and consent to participate

The study protocol was reviewed and approved by the Institutional Review Board of the Muhimbili University of Health and Allied Sciences (MUHAS) and The Ministry of Health, Community Development, Gender, Elderly and Children of Tanzania issued a permission to survey all of the hospitals (Ref.No.HB.209/450/01A/135). As no patient or provider identifying details were kept, and no patient contact was made, no patient consent was required.

Consent to publish

Not applicable.

Data availability statement

Extra data are available on reasonable request. For those who would like to request additional data, they can e-mail to (hsawe@muhas.ac.tz).

Competing interests

The authors declare no conflicts of interest.

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This was a non-funded project; the principal investigators used their own funds to support the data collection and logistics.

Author contributions

HRS contributed to the conception and design of the study, acquired, analysed and interpreted the data, and drafted original manuscript and revised the manuscript. TAR contributed to the design of the study, assisted with data interpretation, and read, revised, and

approved of the final manuscript. EJW contributed to the design of the study, assisted with data interpretation, and read, revised, and approved of the final manuscript. JAM contributed to the design of the study, data validation, and analysis and read, revised, and approved of the final manuscript. TJC contributed to the design of the study, assisted with data interpretation, and read, revised, and approved of the final manuscript. LAW contributed to the design of the study, assisted with data interpretation, and read, revised, and approved of the final manuscript.

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TABLES OF RESULTS

Table 11. Capture of DSI variables before, during pilot and after seven-month implementation phase of standardised trauma documentation form

Variable	Injury variable capture			
	Pre-implementation (N=2891)	Pilot (N=721)	Post-Implementation* (N=6302)	ND or Unknown** (N=6302)
Patient Demographics	%	%	%	%
Name of the patient	99.3	100	100	4.3
Age or date of birth	82.0	84.9	97.3	3.8
Gender	69.7	84.2	99.3	0
Address of the patient	83.8	89.9	95.4	5.4
Injury Geographical location	14.1	95.6	94.5	3.3
Initial clinical condition				
Referral status	8.3	85.6	94.1	3.7
Date of EU care	80.9	91.4	99.8	0
UE arrival mode	23.6	83.9	99.7	5.9
Signs of life	31.2	89.2	94.8	0
Time of first vital signs	32.2	96.3	95.6	6.5
Initial Heart rate	24.5	93.5	95.8	9.6
Initial SBP	18.7	90.3	97.1	15.2
Respiratory rate	18.0	88.2	99.7	11.1
Saturation of oxygen	13.1	84.2	98.5	18.5
Initial GCS/AVPU	3.1	61.3	92.1	2.0
First provider assessment time	32.2	91.4	94.1	0
Details of injury				
Mechanism of injury	45.0	72.0	95.5	1.3
Mass casualty event	0.5	82.2	94.5	0.2
Injury event date	52.2	74.5	96.3	0
Injury settings	5.3	84.6	98.9	8.0
Activity at time of injury	3.3	87.2	100	8.9
Injury intent	6.8	84.5	91.1	2.1
Protective Devices	32.0	80.0	97.3	7.6
Injury Examination				
Type of injury	72.1	87.4	92.6	0
Injury anatomical location	9.2	79.9	92.1	0
Defined Serious Injuries	1.3	90.3	99.1	2.2
Emergency Unit details				
Interventions done at EU	33.0	90.4	92.7	4.9
Time of EU departure	15.3	93.3	95.2	2.1
EU disposition	62.9	88.5	100	1.1

**Field was filled with data or Not done (ND) or Unknown*

*** Variables documented as not done (ND) or Unknown*

Table 12. Documentation error in variables during pilot and implementation of the standardised trauma documentation form

	Pilot (N=721)		Implementation (N=925)*	
	Variable	Errors identified	Variable	Errors identified
Patient Demographics	n	%	n	%
Name of the patient	721	3.3	925	0.1
Age or date of birth	612	6.4	900	0.0
Gender	607	0.0	925	0.0
Address of the patient	648	11.0	925	0.0
Injury Geographical location	689	2.4	924	0.1
Initial clinical condition				
Referral status	617	2.8	924	0.4
Date of EU care	659	2.5	924	0.6
UE arrival mode	605	1.1	925	0.0
Signs of life	643	8.6	921	0.3
Time of first vital signs	694	7.8	923	0.2
Initial Heart rate	674	6.1	925	0.0
Initial SBP	651	6.2	921	0.2
Respiratory rate	636	5.4	923	0.0
Saturation of oxygen	607	0.0	923	0.0
Initial AVPU	442	30.5	922	1.9
First provider assessment time	659	2.5	923	0.2
Details of injury				
Mechanism of injury	519	12.3	925	0.1
Mass casualty event	593	6.5	916	1.0
Injury event date	537	1.4	921	0.9
Injury settings	610	16.6	925	0.0
Injury intent	609	5.4	923	0.1
Protective Devices	577	13.9	922	0.0
Care prior to EU	625	0.6	913	0.1
Injury Examination				
Type of injury	630	3.3	918	0.5
Injury anatomical location	576	16.2	918	0.2
Defined Serious Injuries	651	8.5	925	0.1
Emergency Unit details				
Interventions done at EU	652	6.2	921	0.2
Time of EU departure	673	7.6	925	0.0
EU disposition	638	7.4	925	0.0

** During the first 30 days post implementation*

Table 13. Demographics of healthcare workers in semi-structured interviews

Hospital Role	Interviewed (n, %)
Nurse	6 (18)
Medical officer	8 (24)
Assistant Medical Officer	5 (15)
Clinical Officer	6 (18)
Specialist Physicians	
Emergency Specialist Physician	1 (3)
Orthopaedic/Trauma Specialist Physician	1 (3)
Surgery Specialist Physician	1 (3)
Administrator	2 (6)
HMIS officer	2 (6)
Information and Communications Technology Officer	1 (3)

Figure 5: Five steps of participatory action research for development and implementation of the standardised trauma documentation form, based on Susman & Evereds' cyclic process of inquiry for action research.

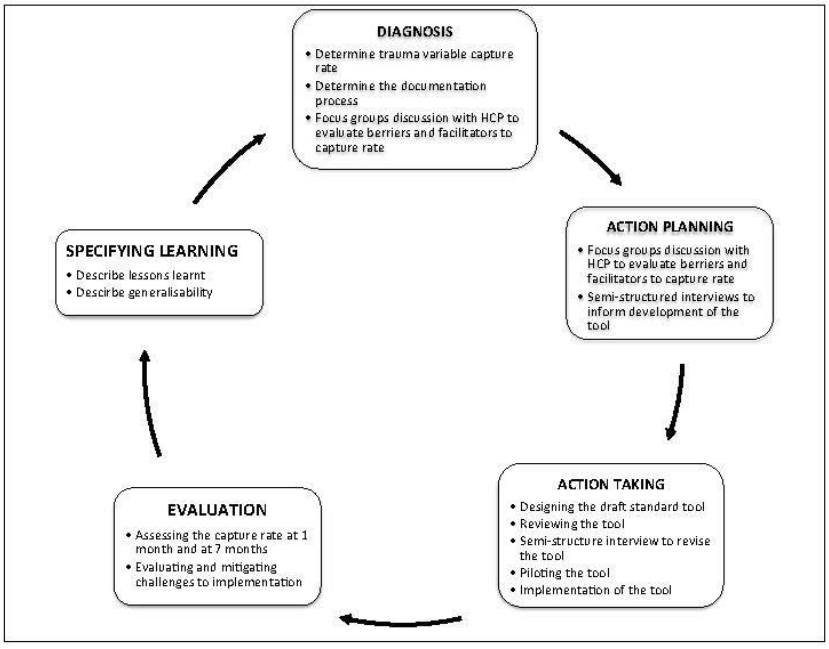
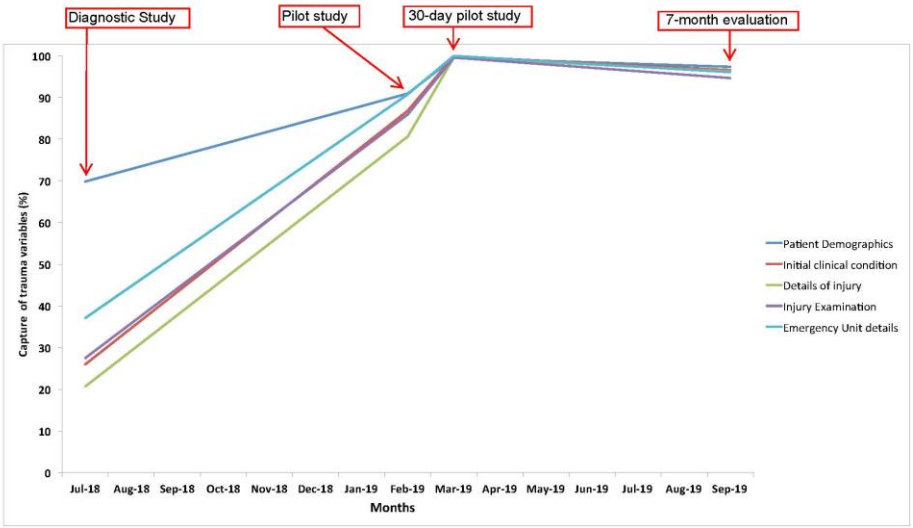


Figure 6. Capture of trauma variable categories over seven-month implementation phase of standardised trauma documentation form



Discussion of the paper

Supplementary methods

Setting

Clinical documentation of all cases in EUs is done by treating clinical officers (mid-level providers with a diploma in clinical medicine), Assistant Medical Officers (mid-level provider with an Advanced Diploma in clinical medicine) or General Practitioners (five years of medical school training). The registration of patients in all hospitals participating in the study is done electronically, however clinical documentation for trauma patients was paper-based at four facilities: plain unformatted paper (Tanga and Arusha), patient-bought exercise books (Morogoro), plain manila card (Mwananyamala), while documentation was performed on using both plain paper and electronic unstructured free-text documentation on a computer at the fifth (Coastal).

Susman and Evered's cyclic process of inquiry

As described in the study, this participatory action research was guided by the Susman and Evered cyclic process of *diagnosis, action planning, action taking, evaluation, and specifying learning.*

Step 1. Diagnosis

In addition to the description provided in the study, we conducted an evaluation of each facility's HMIS register to determine all patients who were seen during the course of the study, allowing us to determine the proportion of patients captured in HMIS vs. clinical documentation, as well as evaluating the utility of variables captured through the HMIS (195).

Step 2 Action planning- Planning the process for development and implementation

The information gathered during baseline assessment of injury variables as well as our analysis of focus group discussions of the barriers and facilitators to injury variable capture, led us to believe that the standardised trauma documentation form was the best solution for improving the documentation and capture of injury variables. The availability of WHO DSI, and a standard template chart was identified as the starting point, and could be adapted and modified to suit the existing context. The principal investigator used the input (on types of variables, patient flow, and disposition) to customize the existing template into an initial draft that can be presented to the EU providers for input and initial piloting. Since the execution of this study, WHO has published the final version of this standardised trauma documentation form for injured patients, which is accessible for adaptation and could lead to further changes in the form (199).

Step 3. Action taking-Development and pilot implementation

The principal investigator adopted and customised the WHO DSI standard documentation template using the EU providers' input provided during FGDs. The Principal investigator received input on the content of the draft form from three specialist emergency physicians, four residents in emergency medicine and two general practitioners working in the emergency medicine department of Muhimbili National Hospital (where the principal investigator is based) (113). All these providers have had prior experience with use of standardised documentation forms at MNH, previously on paper and now in an electronic version. This input from MNH clinicians was used to finalise the draft form before it was presented to the EUs of the participating regional hospitals. The draft form was presented to a purposefully selected sample of EU providers in all five regional hospitals, and we conducted interviews to assess their perception and attitudes regarding the utilisation of the form (211), soliciting input on the design, the variables requested within the form, and how it could be implemented without dual documentation. This feedback was reviewed and incorporated into a final draft of the form (203). The implementation of the form was preceded with training of super-users from each of the EUa, for which two clinical care leads (a nurse and a physician) from each EU were invited to undergo a two-day training of trainers, with the aim of ensuring there is oversight at each facility. The clinical care leads where then responsible for one-on-one trainings, as well as running the refresher trainings when new providers were recruited or rotating in their respective EUs. The form was then piloted in each of the sites, and the principal investigator used the Research Electronic Data Capture (*RedCap*) dashboard to query the quality of data capture, which formed the basis of regular feedback and subsequent discussions, one-on-one training (clinical leads and providers) informal training, feedback to individual providers on their documentation as well as discussion with hospital administration (principal investigator and head of department) to enlist them in advocating for the process of clinical documentation. After one month of piloting and modification of the form, the standardised trauma documentation was launched at each of the sites at the end of February 2019. The principal investigator reviewed the dashboard regularly to visualise the capture rate of the variables and completion rate, then provided feedback to the sites through communications with clinical leads and research assistants.

Step 4. Evaluation

The evaluation process was focused on assessing the DSI variables for the proportion of their documentation, as well as comparing this with the baseline proportion of capture found in the aforementioned diagnosis phase (195).

Step 5. Specifying learning

The authors reflection of key lessons included the process of engagement, development and implementation of a standardised trauma documentation form.

Supplementary results

Pre-and-post implementation capture of DSI variables at each EU

The pre and post implementation capture of DSI variables improved substantially for most of categories of the standardised chart but varied among sites. The largest improvement for patient demographics was observed in the Arusha EU, increasing from 65% pre to 92% post implementation, while Mwananyamala had the highest observed change in capture for the variable initial clinical condition (9% to 87%), details of injury (19% to 92%) and injury examination (22% to 95%). Morogoro EU had the highest improvement in capture for Emergency Unit details (34% to 94%). However, the documentation of variables for vital signs remained below 90% in all sites except for Arusha EU where documentation of two vitals: heart rate (92.4%) and respiratory rate (91.8%) were above ninety **(Table 14).**

Proportion of variables marked unknown or not done in each EU

Allowing EU providers to document ND or Unknown for measurements or interventions not done or un available at EU enabled us to distinguish between the lack of documentation and the lack of resources for trauma care. This approach revealed several gaps in the care of trauma patients and ability of EUs to adequately manage patients. **Table 15** indicates the proportion of variables that were labelled not done (ND) or unknown at each EU. Overall, the variables for medical history and history of present illness were unknown in the majority of cases: 94% in Coastal to 97% in Arusha and 94% in Coastal to 97% in Mwananyamala, respectively. Similarly, a large proportion of variables for patient reassessment at EU was marked as ND, (ranging from 42% in Tanga to 77% in Morogoro). Morogoro had the highest proportion of patients whose name was unknown (9.6%), while in Arusha, the variable for age was labelled unknown or ND, adult or child in 22.6% of cases. Across all EUs, occupation was marked as unknown in the majority of patients, ranging from 53.3% in Tanga to 89.9% in Mwananyamala. Morogoro had the highest proportion for variables of triage acuity marked ND (21.0%) while Tanga had the lowest proportion (7.1%). The vital sign variables marked with most ND across all EUs were initial SBP (7.1% Mwananyamala to 22.% in Arusha), and saturation of oxygen (11.0% in Tanga to 24.4% in Morogoro).

Table 14: Pre and post implementation capture of DSI variables at each EU

	Mwananyamala		Coastal		Tanga		Arusha		Morogoro	
Regional Hospitals	**Pre**	**Post***	**Pre**	**Post***	**Pre**	**Post***	**Pre**	**Post***	**Pre**	**Post***
Variable	**N=764**	**N=1829**	**N=555**	**887**	**N=211**	**736**	**N=950**	**1917**	**933**	**N=411**
Patient Demographics	%	%	%	%	%	%	%	%		%
Name of the patient	99.7	96.6	98.6	95.0	99.1	97.8	99.1	96.7	100.0	90.9
Age or date of birth	98.0	87.8	75.5	89.2	91.0	95.1	66.9	75.2	91.2	88.1
Gender	73.4	99.2	76.8	99.1	86.7	99.7	62.6	99.0	60.6	99.9
Address of the patient	98.7	92.8	82.3	90.4	83.9	91.8	67.8	90.8	91.5	80.6
Injury Geographical location	25.4	95.0	11.7	92.8	11.4	92.4	11.2	88.8	4.6	89.6
Initial clinical condition										
Referral status	1.8	91.6	11.4	93.8	23.2	92.2	5.6	85.9	15.1	92.3
UE arrival mode	0.7	93.4	18.6	92.0	11.4	99.5	50.8	92.3	16.5	94.9
Signs of life	0.7	97.0	9.9	97.7	4.7	97.1	73.8	89.8	31.9	95.9
Time of first vital signs	40.8	86.0	32.1	91.5	39.3	85.3	15.7	92.4	50.6	89.2
Initial Heart rate	1.8	81.3	31.4	82.1	32.2	86.8	31.6	92.4	37.2	86.2
Initial SBP	1.4	74.8	18.4	85.3	18.3	77.9	27.9	89.0	29.9	80.7
Respiratory rate	1.3	86.1	17.3	92.3	16.8	84.8	27.5	91.8	28.5	86.5
Saturation of oxygen	0.1	81.8	8.6	83.7	9.1	88.6	23.1	75.7	21.9	75.3
Initial GCS/AVPU	0.1	91.4	10.6	66.0	8.7	99.7	0.6	99.1	1.5	96.2
First provider assessment time	40.8	86.0	32.1	91.5	39.3	85.3	15.7	92.4	50.6	89.2
Details of injury										
Mechanism of injury	44.8	93.9	42.3	93.8	50.7	93.9	46.9	95.8	41.8	92.7
Mass casualty event	0.0	93.9	1.3	93.8	0.5	93.9	95.8	95.8	1.7	92.7
Injury event date	46.0	95.7	58.0	98.0	53.6	94.2	54.9	96.6	49.0	97.0
Injury settings	5.9	89.5	4.3	91.9	2.4	93.9	6.0	91.1	5.4	90.0
Activity at time of injury	2.5	91.6	2.3	93.5	2.4	91.4	4.0	89.9	3.3	90.0
Injury intent	3.9	91.3	7.4	90.9	4.3	84.1	8.3	86.9	9.5	90.9
Protective Devices	31.8	90.9	38.2	89.8	23.2	86.2	30.6	88.7	31.9	91.3
Injury Examination										
Type of injury	61.0	94.0	80.7	96.2	95.2	95.0	67.8	88.2	78.8	93.7
Injury anatomical location	3.1	94.0	17.7	94.8	17.1	93.6	9.4	87.9	4.4	93.1
Defined Serious Injuries	1.3	96.1	1.6	98.8	1.4	96.5	0.6	94.2	2.2	96.5
Emergency Unit details										
Interventions done at EU	30.2	88.5	22.4	88.5	64.9	85.6	34.8	87.8	31.8	88.8
Time of EU departure	14.8	94.0	21.1	94.0	15.2	90.8	13.7	92.6	11.9	93.2
EU disposition	61.9	98.1	77.1	97.6	59.2	100	58.0	99.3	58.4	100

**Field was filled with data*

Table 15: Proportion of variables marked unknown or not done in each EU

Regional Hospitals	Mwananyamala	Coastal	Tanga	Arusha	Morogoro
Variable (N=6302)	**1829**	**887**	**736**	**1917**	**933**
Patient Demographics	%	%	%	%	%
Name of the patient	3.4	5.0	2.2	3.3	9.1
Age or date of birth	8.7	6.9	2.9	22.6	10.2
Address of the patient	3.9	6.5	3.4	4.0	12.0
Occupation	89.9	69.6	53.3	79.1	64.1
Initial clinical condition					
Triage	13.4	9.6	7.1	19.8	21.0
UE arrival mode	6.4	7.8	0.3	7.3	4.8
Initial Heart rate	14.9	12.3	11.8	4.3	6.1
Initial SBP	22.6	12.6	20.0	7.1	16.3
Respiratory rate	13.8	7.4	14.8	8.0	13.0
Saturation of oxygen	15.6	15.2	11.0	22.7	24.4
Medical History					
Past medical history	97.5	93.3	99.6	98.1	95.6
Past surgical History	96.9	93.0	99.0	97.3	95.4
History of allergies	98.8	97.5	98.4	97.3	92.7
Vaccination status	94.6	92.9	87.4	96.1	93.9
History of present illness					
Hours since last meal	94.6	93.1	96.6	95.5	95.9
Alcohol use	99.5	94.3	97.7	98.4	96.8
Patient reassessment					
Heart rate	57.0	75.0	41.3	64.3	76.6
SBP	57.6	77.6	41.8	66.1	77.4
Respiratory rate	59.4	76.3	42.5	65.9	76.5
Emergency Unit details					
Interventions done at EU	4.8	4.5	6.0	4.7	5.0

Supplementary limitations

As described in our study, our capture of variables post pilot was determined using all documentation (including the use of ND and unknown for variables documented as not done due to lack of resources, process or expertise), which might limit the utility of missing variables that were captured as not done (example assessment of vital signs due to lack of resources). Furthermore, the study did not ask clinicians to document the exact nature, circumstances or factors around the lack of resources or information. This would have been helpful in determining whether lack of data is due to lack of resources, lack of provider knowledge or time pressures. Future studies will focus on improving the quality of data through asking for additional information from providers on exact reasons for documenting ND or Unknown in some of the crucial DSI variables so as to better understand how to mitigate these gaps. This will not only help improve the quality of data captured but potentially identify resource and educational needs at these sites.

Chapter conclusion

The development of TRs in low resource settings is dependent on developing a system that can sustainably ensure the capture of injury variables in the context of existing patient flow, resource availability, providers' knowledge, and level of workload associated with care of patients and documentation (13). This tudy utilised participatory action research to understand, develop, and pilot a standardised trauma documentation form at selected regional hospitals in Tanzania, resulting in a marked improvement in the documentation of DSI variables, that can be used for a national TR. The engagement of providers at all levels of development and piloting has provided essential insight into factors and flow processes for trauma patients that are crucial to consider when setting up such a system. **In chapter 7,** we use the prospectively collected injury data from these five regional hospitals to characterise the burden of injury.

Chapter 7: Characterising the burden of injury using Trauma Registry data

Reference

Sawe HR, Wallis LA, Weber EJ, Mfinanga JA, Coats TJ, Reynolds TA. The burden of trauma in Tanzania: Analysis of prospective TR data at regional hospitals in Tanzania. Injury [Internet]. 2020 Sep [cited 2020 Oct 9]; Available from: https://linkinghub.elsevier.com/retrieve/pii/S0020138320307713

Declaration from author and co-authors:

The following co-authors contributed to the paper: Hendry R. Sawe, Lee A Wallis, Ellen J Weber, Juma A. Mfinanga, Timoth J Coats, and Teri A. Reynolds. In the case of Chapter 7, contribution by authors to the work was as follow:

HRS contributed to the conception and design of the study, acquired, analysed and interpreted the data, and drafted original manuscript and revised the manuscript. JAM contributed to the design of the study, data validation, and analysis and read, revised, and approved of the final manuscript. TAR, EJW, TJC and LAW contributed to the design of the study, assisted with data interpretation, and read, revised, and approved of the final manuscript.

19th April 2021

Hendry R. Sawe Date

Declaration by co-authors

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other author of the publication according these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from date indicated below

Location of stored data:

Data set analysed during the current are stored on the authors (HRS) encrypted Research Electronic Data Capture (RedCap) account allocated through the Emergency Medicine Association of Tanzania, research portal.

16th April 2021

Prof. Lee A. Wallis — Date

14th April 2021

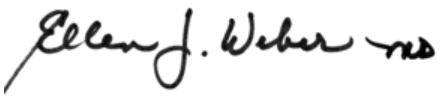
Dr. Juma A. Mfinanga — Date

20th April 2021

Prof. Timothy Coats — Date

29th April 2021

Prof. Teri A. Reynolds — Date



23rd April 2021

Prof. Ellen J Weber — Date

Main findings

- The pilot implementation of a standardised trauma form has informed the development of a regional TR that has provided an opportunity to describe the burden of injury at a representative sample of five regional hospitals in Tanzania.
- Most of our findings, such as males being more prone to trauma and RTAs being the most common cause, aligned with prior studies, suggesting that the data had good quality. However, there are differences between regions on mechanism of injury, mode of arrival to hospital and severity.
- The availability of standardised variables of injury provides an opportunity for assessing and implementing quality improvement measures at the health facility level, as well as instituting measures aimed at injury prevention.

Motivation for conducting the study

The pilot implementation of a standardised trauma documentation incorporating the WHO DSI resulted in improved data capture for most variables of injury compared to the previous system of injury documentation. **In chapter 6**, we described how participatory action research was used to inform the development and pilot implementation of the standardised TR at the EUs of five Regional Hospitals. The success of this implementation provided an opportunity for streamlining the clinical documentation of injured patients, while at the same time gathering injury data that can inform a regional injury registry. In this chapter, we sought to use this improved documentation to characterise the burden of trauma seen at five regional hospital Emergency Units in Tanzania using data from this new TR.

Aim

The aim of this project was to use the newly implemented TR to characterise the burden of injury from the five regional hospitals in Tanzania.

Objectives

1. To describe the demographic characteristic of trauma patients presenting to the five regional Hospitals
2. To describe the injury mechanisms and mode of arrival of trauma patients presenting to the five regional Hospitals.
3. To determine the injury severity and outcomes of trauma patients presenting to the to the five regional Hospitals.

A copy of the published paper follows over the nineteen pages.

The Burden of Trauma in Tanzania: Analysis of Prospective Trauma Registry Data at Regional Hospitals in Tanzania

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ABSTRACT

Background: Trauma contributes significantly to the burden of disease and mortality in sub-Saharan Africa (SSA). Like most of SSA, Tanzania lacks prospective trauma registries (TRs), resulting in poor and inconsistent availability of injury data. A model TR was implemented at five representative regional hospitals in Tanzania; the TR incorporates the variables recommended by the World Health Organization (WHO) Data Set for Injury. This study characterises the burden of trauma seen at five regional hospital Emergency Units (EUs) in Tanzania using data from this new TR.

Methods: This prospective descriptive study used TR data from EUs of five regional Hospitals in Tanzania between February 2019 to September 2019. Descriptive statistics were calculated for mechanism of injury, injury severity, disposition and mortality. Injury severity scores were calculated. We determined relative risk for mortality by injury type.

Results: Over a seven-month period, 6,302 (9.6%) patients presented to these EUs with trauma-related complaints. They had a median age of 27 (IQR: 19-37) years and 71.3% were male. Most patients (76.6%) were self-referred and presented to EU on motorized (two or three-wheeler) vehicle (55.9%). Road traffic accidents (RTAs) 3786 (60.3%) were the most common mechanism of injury. Most patients (63.3%) presented with injuries to the upper and lower extremities, while few (2.0%) had injuries to the chest. The overall mean Injury Severity Score (ISS) was 9 (Interquartile Range (IQR): 4-13], and varied by hospital. Total 24-hour mortality was 3.3% and 126 (2.1%) patients died while receiving care at the EU. Among those who died, 156 (81.7%) had an intracranial injury; relative risk of death was [13.3 ($CI_{95\%}$: 9.3 -19.1), $p<0.0001$] for intracranial injuries compared to other injury patterns.

Conclusions: TR from these five Tanzanian regional hospitals has provided an opportunity to more accurately describe the country's burden of injury. Having sufficient data for ISS and other key trauma variables allows us to compare the burden and outcomes of trauma in Tanzania with other countries, which will help to quantify an accurate burden of injury, inform quality improvement initiatives, and suggest where to focus preventative measures.

Keys words: Trauma registry, Trauma burden, emergency care, Tanzania, Africa

BACKGROUND

Trauma contributes significantly to the burden of disease and mortality throughout the world, particularly in low- and middle-income countries (LMICs) (212). Globally, injuries cause over five million deaths annually; this is 32% more than deaths due to HIV, tuberculosis and malaria combined (213). Ninety percent of injury-related deaths occur in LMICs, where there are inadequate resources to provide the appropriate care to optimise patient outcomes (214).

Trauma care systems are known to decrease mortality and improve functional outcomes for injured patients (7). In most high-income countries (HICs), these systems are well developed and resourced to care for patients throughout the injury continuum, from the scene of injury to acute care facilities (including emergency, operative, and intensive care) through to rehabilitation and recovery (215). In HICs, trauma care systems are informed by formal trauma registries (TRs), which provide aggregate data to inform improvements in quality of care and deployment of necessary preventive measures against injuries.

Most LMICs do not have functioning trauma care systems and TRs are virtually non-existent; in places where they have been implemented, they have been rudimentary and unsustainable (11). Trauma data in these countries are largely derived from limited single hospital reports or temporarily installed registers that are cost-intensive and challenging to sustain beyond initial research periods (9).

Tanzania is among the sub-Saharan African countries that face a major burden of morbidity and mortality due to traumatic injuries (216). Despite the large burden of trauma, Tanzania lacks a formal, nation-wide TR, and most prior studies of trauma are based on individual hospital-based trauma registries, health surveys, surveillance reports and police data (149). The Ministry of Health (MoH) maintains a country-wide Health Management Information System (HMIS) that gathers information from all health facilities within Tanzania (21). However, the HMIS does not collect dedicated patient-level trauma data, but rather, gathers higher level data, such as aggregated diagnoses from outpatient departments (21). The lack of a formal TR has substantially limited the ability to accurately document burden of disease, inform processes and quality of trauma care, and adequately measure clinical outcomes across Tanzania.

As a first step in developing a sustainable national TR for Tanzania, a TR was implemented at five representative regional hospitals in Tanzania; the TR incorporates the variables recommended by the World Health Organization (WHO) Data Set for Injuries (DSI) (85). The data collection tool serves as both a clinical chart and registry record. It is a template form that prompts healthcare providers to perform appropriate care and also ensures capture

of key standardised data points. Compared to data collection prior to implementation, the TR has markedly increased capture of variables at these hospitals, thus allowing a more complete and accurate set of data (195). This study aimed to characterise the burden of trauma seen at five regional hospital Emergency Units (EUs) in Tanzania using data from this new TR.

METHODS

We conducted a prospective, descriptive study of TR data for all trauma patients presenting to EUs at five regional hospitals in Tanzania between February 2019 and September 2019.

Setting

Tanzania has seven Geopolitical zones, 25 administrative regions and 159 districts (217). The healthcare system has a pyramidal structure, with three levels of service provision: primary, secondary and tertiary levels (118). The primary level constitutes dispensaries, health centres and district hospitals; the secondary level is composed of regional hospitals. The tertiary level contains zonally, national and consultant hospitals. Each level serves as a referral hospital to its immediate level below. There are 25 regional hospitals, and these serve as the main hospital for a particular administrative region. The regional hospitals are expected to offer multispecialty services (including orthopaedic, traumatology and neurosurgical), however none of them have neurosurgical, dialysis or intensive care units with full ventilatory capabilities. This necessitates referral of patients with these needs to National and consultant hospitals. Five regional hospitals were chosen for implementation of a TR based on their geographic variation and the different stages of emergency medicine development they represent (195).

Morogoro Regional Hospital, located in central Tanzania, serves a catchment area of approximately 2.3 million people, and has an EU that operates 24 hours a day with care provision overseen by one specialist emergency physician. Arusha Regional Hospital provides tertiary level care for Northern Tanzania Region of Arusha, one of the busiest, and urbanised city with a great deal of motorcycle traffic. The EU operates 24 hours and has one specialist emergency physician, who is also the head of EU. Mwananyamala Regional Hospital in Dar es Salaam city has a catchment population of approximately 1.1 million, this hospital refers most of their critically ill patients to Muhimbili National Hospital (113). Coastal Regional Hospital, serves approximately 1.2 million people; its location near to the Tanzania's North-south highway makes it a centre for receiving injury victims for road traffic accidents (RTAs) (20). The Tanga Regional Hospital, located near the northwest coast of Tanzania, is the regional hospital for Tanga Region and serves a catchment population of 2.0 million. Critically injured patients from these regional hospitals requiring advanced

neurosurgical and trauma care may be transferred to the main National Hospital in Dar es salaam (113).

Study population

All patients (adult and child) who presented to any of the five aforementioned regional hospital EUs between February 2019 and September 2019 after sustaining injuries from the scene of an accident, or transferred from lower health facilities with injuries were eligible for enrolment. Patients who returned to EU after initial care for a follow up of injury care (example: removal of stitches, removal of plaster cast or change of bandage) were not eligible for enrolment. Patients who were brought in dead were included in total counts of patients and descriptive data (to the extent feasible). They were excluded from the 24-hour mortality analysis.

Data source

A paper-based standardised trauma documentation tool was developed and implemented through a participatory action research project that was guided by Susman and Evereds' cyclic process (202). The process involved key personnel at the five regional referral hospitals who contributed to design, piloting and implementation of a context-appropriate standardised trauma form based on the WHO DSI (85). The standardised tool served as the clinical record and had a total of 12 sections: Demographics and mode of arrival, chief complaint, vitals and triage acuity, primary survey, history of presenting illness, past medical history, secondary survey and details of injury, plan and intervention, laboratory and radiographic investigations, final emergency unit diagnosis, consultation, disposition and provider signature. The standardised tool had a carbonless paper copy, allowing duplicates of the same information to be kept for input into the TR. The copy was used to abstract data and upload into an online Registry hosted through data capture software (© REDCap version 7.2.2, Vanderbilt, Nashville, TN, USA).

Research assistants received extensive training on how to abstract the data from standardised trauma form to REDCap. In each EU, we conducted training for all clinicians on how to use the standardised trauma form in documenting the care of injured patients prior to launching of the form. Two clinical care leads (a nurse and a physician) participated in an additional training of trainers course, and served as key personnel (super-users) on the ground supporting day-to-day queries, and providing additional one-on-one training for any new clinicians recruited in the EU.

Procedures

In all EU, for each injured patient, clinicians were expected to document their clinical care on the standardised trauma form. After patient care and documentation of the care provided,

research assistants collected the bottom copy of the form and abstracted data into the REDCap database. The number of patients entered was compared with the Hospital patient registers (which record all patients received in each EU) to determine the proportion of eligible patients captured in the paper-based standardised trauma documentation. All patients who were enrolled into the data capture software were followed up in person if admitted or, if not admitted, telephoned.

Data Analysis

The data was exported from REDCap into Statistical Package for Social Science (© SPSS version 22.0, IBM, Ltd, Carolina, USA) for analysis. The dataset was subsequently cleaned, and outliers were removed. Descriptive statistics were summarised by frequency distribution tables of patient demographics, and mean and standard deviation or median and interquartile range (IQR), as appropriate. EU diagnoses were coded using International Classification of Diseases (ICD) 10. Two study authors, both Emergency Medicine specialist physicians, calculated the Abbreviated Injury Scale categorisation and calculation of Injury Severity Scores (ISS) from the anatomic description of the injuries on the trauma documentation tool. Any ISS >15 was considered a severe injury. ISS were compared across various patient dispositions. The Mann-Whitney U test was used to compare the median ISS between different patients disposition from the EU. Relative risks of death for each type of injury were calculated. Patients who arrived without signs of life to the EUs were not included in the 24-hour mortality analysis or risk factors for death.

RESULTS

Patient Characteristics

A total of 65,852 patients were seen in all EUs, of which 9.6% (n = 6,302) presented with trauma-related complaints (**Figure 7**). Based on a comparison with main hospital registers, 96% of patients with trauma-related complaints were captured in the TR. The median age was 27 (IQR: 19-37) years; 71.3% (n = 4,492) were male. (**Table 16**) Most patients (n = 4,829; 76.6%) were self-referred, and presented to EU on motorized (two or three-wheeler) vehicle (n=3,525; 55.9%). Tanga had the highest proportion of referred patients (45.1%), and Mwananyamala had the highest proportion of those who came in motorized vehicles (91%), while Arusha had the highest proportion of patients brought in by police (32.9%). Ambulance arrival (4.3%) was uncommon and usually occurred in cases of transfer from another hospital.

Injury mechanism and intent

RTAs accounted for the majority of injuries (n = 3,786; 60.3%), and were the most common mechanism of injury in four of the five hospitals (**Table 17**); at Tanga Regional Hospital, RTA (41.4%), and fall from height (40.9%) were near equally common. Among RTA patients, motorcycle injuries were most common (n = 2015; 53.2%), while bicycle injuries were the least 206 (5.4%). Unintentional injuries were far more frequent that intentional; Tanga had the highest proportion of intentional injuries (15.4%). Alcohol use was poorly documented with no information in more than 90% of patients (**Table 17**).

Predominant body region of injury

Table 18 provides a breakdown of injury by anatomical location. Most patients (63.3%) had injuries to upper and lower extremities, and/or pelvic girdle. 1,804 (28.6%) had head or neck injuries while 2.0% of patients had injuries to the chest.

EU diagnosis

Intracranial injury was reported in 24.8% of patients. Femur fractures accounted for 13.2% of injuries, and fracture of lower leg (below femur) accounted for 11.7%. Injury of unspecified body region was diagnosed in 7.9% of cases. Sexual abuse accounted for all 194 (3.1%) maltreatment syndrome cases (**Table 19**).

Severity of injuries

The median ISS among all trauma patients was 9 [Interquartile Range (IQR) 4-13]; 83% of patients had an ISS of less or equal to 15. The proportion of severely injured patients varied among hospitals: there was a higher proportion (21%) of patients with ISS > 15 at Morogoro regional hospital compared to the other hospitals (**Table 20**.)

Patient outcomes and injury severity score

A total of 211 (3.3%) patients had no signs of life on arrival to the EU (dead on arrival) (**Figure 16**). Among the other patients, over half (n = 3,095; 51.4%) were discharged from EU; there was no statistically significant difference in the median ISS among those who were admitted to the regional hospital (9) and those who were discharged (9). The median ISS of those who were transferred to another facility for a higher level of care was 15.

A total of 126 (2.1%) patients died while receiving care at the EU; their corresponding median ISS (25; IQR: 25-34) was significantly higher ($p<0.0001$) than patients who survived to leave the EU (**Figure. 8**). Among the 5896 patients who survived to leave the EU, 243 (4.1%) could not be traced (lost to follow-up) after 24 hours (**Figure. 7**). The overall 24-hour mortality (including those who died while receiving care in the EU) was 3.3% (n = 191), and 81.7% of this group had a diagnosis of intracranial injury. Those with intracranial injury

were far more likely to die than those without (risk ratio 13.3 ($CI_{95\%}$: 9.3-19.1); $p<0.0001$) (**Table 19**).

DISCUSSION

Although the trauma burden is disproportionately high in most LMICs, there is a known mismatch between data reported by these governments and estimates by the WHO. This is especially true in regard to the number of patients injured and mortality resulting from injuries (218). These discrepancies are largely attributed to a lack of contextually-appropriate methods of collecting standardised trauma data on a large scale across the country. The ability to collect data using a TR at multiple hospitals can make an important contribution to understanding the epidemiology of injuries, informing hospital resources and prevention strategies. This study is the first to report on the burden of injury from analysis of prospectively collected data in a regional TR that includes the variables specified in the WHO data set for injury.

We found a substantial burden of trauma in all regional hospitals, with young males being the majority of victims. Most patients presented to EU on a motorized (two or three-wheeler) vehicle as self-referral. This mode of arrival is different from studies in South Africa, which found that most patients presented to EU by ambulances (219). In our study, less than five percent of patients were brought into the EU by ambulance, reflecting the absence of a formal pre-hospital care system in Tanzania (220). RTA was the most common mechanism of injury, usually as a result of motorcycle. Motorcycle taxis are very common in Tanzania: they provide a means of employment (especially for youth) and are used by many citizens as a cheap, convenient means of transport to navigate traffic in the country's congested cities. Unlike other EUs included in this study, where road traffic accidents accounted for the majority of injuries, Tanga Regional Hospital had an equal proportion of RTAs and falls. This finding is likely due to the cultural-economic life of most residents of Tanga, where harvesting fruit from trees is a major source of livelihood (221). Mwananyamala Hospital had twice the proportion of patients with burns compared to the other UEs. While we did not look into the details of the environment surrounding the cause of burn, previous studies of burns in Tanzania have found domestic accidents are the major cause of burns, and children are disproportionally affected (222). Thus, these data suggest a need to more closely assess the homes of people in this area for unsafe conditions. In general, the variation among hospitals shows how a TR can highlight the need for different allocation of resources and prevention activities in different regions.

Over half of patients presenting with assault as mechanism of injury were sexually abused. There is limited data on the magnitude of sexual abuse in Tanzania, with most studies focusing on qualitative evaluation of sexual assault victims in the community (223). Our

findings have quantified the problem and can provide an impetus and baseline for setting up and evaluating interventions that can prevent such incidents, especially in vulnerable populations.

Intracranial injury has been identified as the major cause of mortality in patients with trauma (224). In all EUs and across all age groups in our study, intracranial injury was the leading cause of mortality, accounting for over 80% of all trauma-related deaths. Tanzania has only one centre with capacity to provide high quality neurosurgical trauma care (225). However, contextual challenges, the lack of a formal prehospital system, and a referral system that is dependent on availability of a functional facility-owned ambulance, time of day and ambiguous protocols of who should referred – often lead to patients not receiving timely care and access to this specialised centre. Simple interventions performed pre-hospital and at lower level facilities have been shown to impact outcomes of head injury patients (226). In this study, we did not evaluate the interventions performed in the regional hospitals. To improve outcomes of head injured patients, future studies could evaluate the quality of these interventions.

Similar to previous studies in Tanzania, the majority of patients had ISS less than 15 (227). This has also been found in high-income countries (228). Given the lack of pre-hospital care in our country, this is not reassuring, as we know that most people die at the scene. A study by Boniface et al involving road traffic victims conducted at the main orthopaedic hospital and three city hospitals in Tanzania, found that many severely injured patients did not survive to be cared for in hospitals, while those with minor injuries were hospitalized (20). Studies in other LMIC's support the concern that the most severely injured patients never reach the hospital (229).

There is no clear guideline to inform transfer of patients to higher facilities, however the ISS for patients transferred to other facilities was higher than those who were discharged, indicating that providers in these facilities are able to distinguish which patients need a higher level of care. Interestingly, we found no statistically significant difference in ISS among patients who are admitted and those discharged. This could be due to multiple factors including clinical acumen, availability of resources or determining admission on need for a specific hospital-based treatment rather than severity of injury.

Strengths of this study

Prior studies of injury in Tanzania have reported data from single hospitals, with limited information that lacked key injury variables (230). This new TR has provided the opportunity to assess patient injury severity and outcomes, as well as care provision. Most previous studies lacked the details of variables to characterise these key data points, hence

reporting mostly on outcomes without linking them to any standardised injury severity score (216). Unlike most previous studies, our documentation of clear diagnosis, with capacity to code into ICD-10 diagnosis, lends comparability (224) with other sites. This comparability is crucial for understanding the common indicators of quality of care, as well as interventions that can be replicated in the Tanzanian setting. While a countrywide dissemination of the registry will provide a complete picture of injury burden in Tanzania, these initial data can serve to provide an interim assessment of the burden of injury and a model for wider implementation.

Limitations

This study was conducted in five selected regional hospitals in Tanzania, which has a pyramidal referral system for all patients (118). The referral pattern of patients in these facilities may not reflect the reality in all regional hospitals in Tanzania. Furthermore, Tanzania lacks a formal pre-hospital system (231), hence it is not known how many injured patients do not make it to the level of regional referral hospitals for care. Future studies of trauma should focus on evaluation of interventions that can impact care of patients in pre-hospital settings. There was also a low clinical inquiry to alcohol use among trauma patients, which precluded analysis of the effect of alcohol use in trauma. Furthermore, the scoring of ISS by principal investigators using secondary survey clinical information may have led to underestimates of ISS.

Conclusion

A TR from these five Tanzanian regional hospitals has provided an opportunity to more accurately describe the country's burden of injury. Most findings, such as males being more prone to trauma and RTAs being the most common cause, aligned with prior studies. However, there are differences between regions on mechanism of injury, mode of arrival to hospital and severity. Having sufficient data for ISS and other key trauma variables allow us to compare the burden and outcomes of trauma in Tanzania with other countries, as well as inform quality improvement initiatives, resource distribution and preventative measures.

Consent to publish

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are presented as additional supporting files alongside this manuscript.

Competing interests

The authors declare no conflicts of interest.

TABLES OF RESULTS

Table 16: Patient demographics

Regional Hospitals	Overall	Morogoro	Arusha	Mwananyamala	Coastal	Tanga
Demographics*	N=6302	933	1917	1829	887	736
Sex	n (%)	%	%	%	%	%
Male n (%)	4492 (71.3)	66.2	66.6	71.4	77.2	82.3
Age**	N=5360	822	1455	1591	793	699
Median (IQR) years	27 (19-37)	28 (20-40)	24 (12-35)	27 (22-35)	27 (18-38)	29 (19-43)
Age Group		%	%	%	%	%
< 5 Years	445 (8.3)	4.1	17.7	3.0	8.1	5.9
5-15 years	591 (11.0)	12.9	11.3	8.4	13.0	12.0
16-55 years	3938 (73.5)	74.2	63.5	85.0	71.8	69.1
> 55 years	386 (7.2)	8.8	7.5	3.6	7.2	13.0
Referral status	N=6302	933	1917	1829	887	736
Self referral	4829 (76.6)	63.7	84.6	92.5	64.7	47.3
Referred	1101 (17.5)	30.8	7.0	3.6	31.8	45.2
Unknown	372 (5.9)	5.6	8.5	3.9	3.5	7.5
Mode of arrival	N=6302					
Motorcycle	2267 (36.0)	20.9	29.4	53.3	34.3	31.1
Tricycle	1258 (19.9)	12.6	12.8	37.7	16.2	8.3
Police	727 (11.5)	6.1	32.9	0.3	2.1	2.0
Private Car	637 (10.1)	10.2	5.7	1.8	16.5	34.4
Commercial car	610 (9.7)	19.9	8.8	2.2	13.9	12.5
Walked	451 (7.2)	19.4	5.1	1.0	11.4	7.3
Ambulance	269 (4.3)	8.8	4.2	3.3	3.7	1.8
Bicycle	62 (1.0)	1.6	0.7	0.1	1.6	2.3
Unknown	21 (0.3)	0.4	0.4	0.2	0.3	0.3

**All patients including those who were dead on arrival*

*** Exact Age was missing 6.5% cases, and documented as adult in 8.3% and as child 0.1%*

Table 17: Mechanism and intent of injury of trauma patients presenting at five regional hospitals in Tanzania

Regional Hospitals	Overall (N=6281)*	Morogoro (N=924)	Arusha (N=1912)	Mwananyamala (N=1828)	Coastal (N=881)	Tanga (N=736)
Mechanism of injury	n (%)	%	%	%	%	%
Road Traffic Crash	3786 (60.3)	61.3	63.9	63.1	61.4	41.4
Fall from height	1161 (18.5)	16.3	14.5	13.2	21.5	40.9
Burn	427 (6.8)	5.4	3.5	12.9	5.1	4.2
Assault	337 (5.4)	6.3	6.3	3.7	5.9	5.3
Stab	191 (3.0)	2.3	3.8	4.3	1.2	1.2
Hit by falling object	139 (2.2)	3.6	2.5	0.7	1.8	4.2
Poisoning	76 (1.2)	0.8	2.1	1.0	0.9	0.3
Animal bite	54 (0.9)	2.3	0.8	0.1	1.0	0.8
Hanging	12 (0.2)	0.1	0.1	0.2	0.2	0.5
Drowning	11 (0.2)	0.1	0.1	0.3	0.1	0.3
Gunshot	6 (0.1)	0.0	0.2	0.1	0.1	0.1
Miscellaneous	81 (1.3)	1.6	2.2	0.7	0.7	0.7
Intent of injury						
Unintentional	5649 (89.9)	93.5	88.5	91.1	91.9	84
Intentional	561 (8.9)	5.2	10.3	8	6.5	15.4
Unknown	71 (1.1)	1.3	1.3	0.9	1.6	0.7
Alcohol						
No information on alcohol	6205 (98.8)	98.1	99.6	100	95.8	98.2
Suspected-alcohol use	55 (0.9)	1.0	0.4	0	3.3	1.4
Confirmed-alcohol use	21 (0.3)	1.0	0	0	1.1	0.4

** Details of injuries were missing in 21 patients*

Table 18: Anatomical locations of injuries for trauma patients presenting at five regional hospitals in Tanzania

Regional Hospitals	**Overall (N=6302)**
Injury anatomical location	n (%)
Extremities or pelvic girdle	3994 (63.3)
Head or neck (including cervical spine)	1804 (28.6)
External injury	1664 (26.4)
Face (including skeleton, nose, mouth, eyes and ears)	840 (13.3)
Abdomen or pelvic contents	479 (7.6)
Chest (including thoracic spine and diaphragm)	128 (2.0)

Table 19: ICD 10 diagnoses and 24 hours mortality

International Classification of Diseases (ICD) 10 Diagnosis	All patients (N=6302)	24 hours mortality (N-191)	RR (95% CI)	p-value
Intracranial injury	1565 (24.8)	156 (81.7)	13.3 (9.3-19.1)	<0.001
Fracture of femur	833 (13.2)	20 (10.4)	0.8 (0.5-1.2)	0.235
Fracture of lower leg, including ankle	736 (11.7)	5 (2.6)	0.2 (0.1-0.4)	<0.001
Injury of unspecified body region*	500 (7.9)	0	0.03 (0.002-0.5)	0.013
Burn and corrosion, body region unspecified	414 (6.6)	9 (4.7)	0.7 (0.4-1.3)	0.281
Open wound of unspecified body region	373 (5.9)	5 (2.6)	0.4 (0.2-1.0)	0.055
Fracture of shoulder and upper arm	311 (4.9)	8 (4.2)	0.8 (0.4-1.7)	0.606
Fracture of forearm	242 (3.8)	8 (4.2)	1.1 (0.5-2.2)	0.823
Maltreatment syndromes	194 (3.1)	0	0.1 (0.01-1.3)	0.077
Unspecified multiple injuries	172 (2.7)	5 (2.6)	0.9 (0.4-2.3)	0.9034
Injury of intra-abdominal organs	171 (2.7)	9 (4.7)	1.8 (0.9-3.4)	0.091
Open wound of head	148 (2.3)	0	0.1 (0.01-1.7)	0.115
Superficial injuries involving multiple body regions	108 (1.7)	0	0.2 (0.01-2.4)	0.1769
Fracture of lumbar spine and pelvis	85 (1.3)	4 (2.1)	1.5 (0.6-4.1)	0.3764
Fracture of skull and facial bones	62 (1.0)	0	0.3 (0.02-4.1)	0.338
Sequelae of injuries of neck and trunk	56 (0.9)	0	0.3 (0.02-4.5)	0.375
Dislocation, sprain and strain of joints and ligaments of shoulder girdle	55 (0.9)	0	0.3 (0.02-4.6)	0.382
Other and unspecified injuries of thorax	52 (0.8)	0	0.3 (0.02-4.9)	0.403
Dislocation, sprain and strain of joints and ligaments of knee	50 (0.8)	0	0.3 (0.02-5.1)	0.419
Open wounds of wrist and hand	44 (0.7)	0	0.4 (0.02-5.7)	0.472

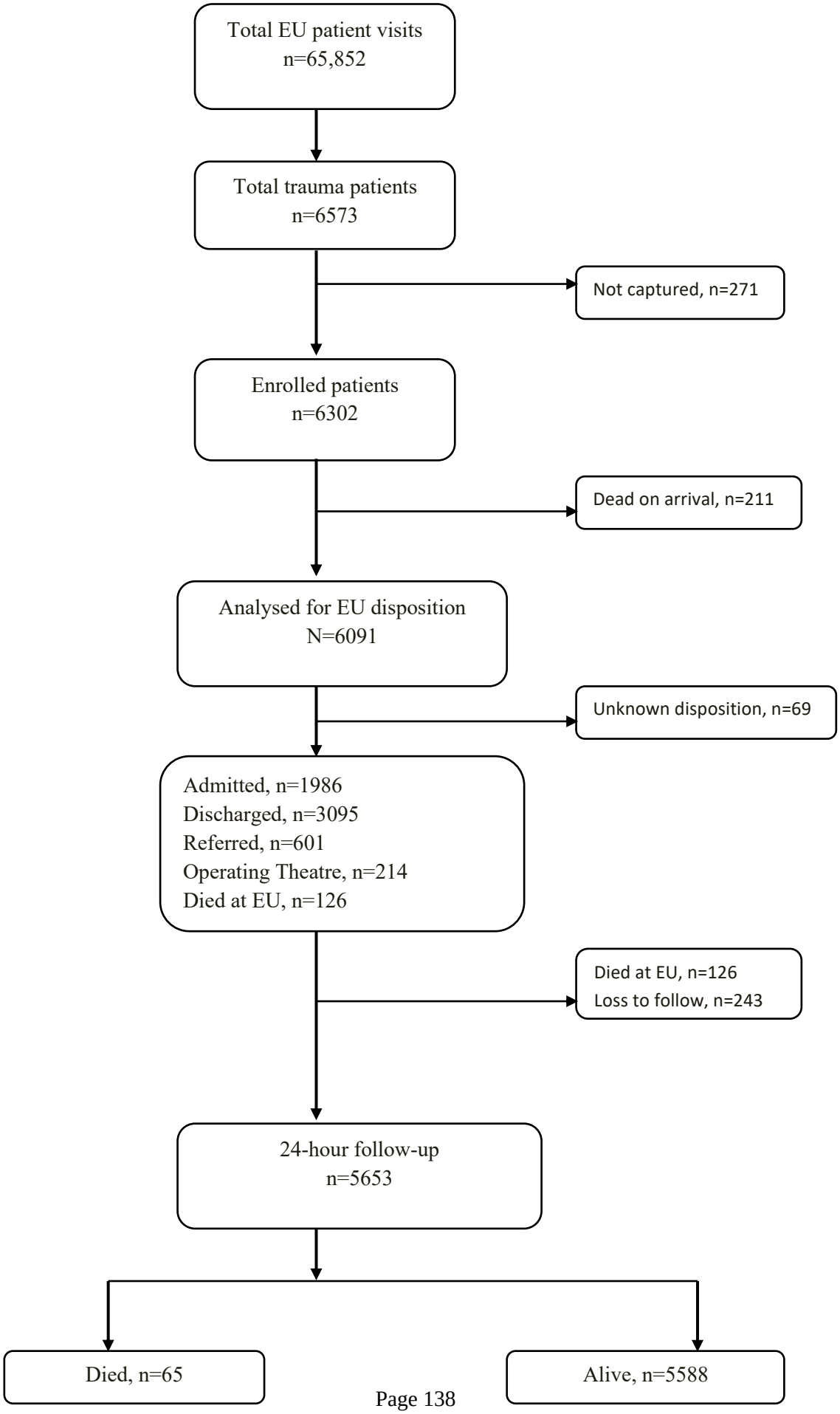
**Includes sprain, soft tissue injuries and bruises*

Table 20. Injury severity scores for trauma patients

Regions	ISS	ISS ≤15	ISS>15
	Median (IQR)	%	%
All hospitals (N=6107)*	9 (4-13)	83	17
Morogoro (N=922)	9 (4-15)	79	21
Arusha (N=1827)	9 (4-13)	81	19
Mwananyamala (N=1755)	9 (4-13)	86	14
Coastal (N=874)	9 (4-15)	84	16
Tanga (N=729)	9 (4-14)	84	16

**ISS calculation could not be done on 195 patients due to missing details of injuries*

Figure. 7: Flow Diagram of Study Enrolment



Discussion of the paper

Supplementary methods

In each EU, we had a dedicated research coordinator who was a clinical lead who supported the clinicians as well as follow-up as well as the follow up of patients in each site. The site research coordinators received training of trainers course on trauma using primary trauma care modules, to enable them to better understand the WHO DSI variables and how they are linked to the trauma care.

As previous described in the published paper, data was exported from REDCap into Statistical Package for Social Science (© SPSS version 22.0, IBM, Ltd, Carolina, USA) for analysis, and EU diagnoses were coded using International Classification of Diseases (ICD) 10. Patients who arrived without signs of life to the EUs were not included in the 24-hour mortality analysis or risk factors for death. The Mann-Whitney U test was used to compare the median ISS between different patients' disposition from the EU.

Supplementary results

Injury anatomical location by each EU

Overall, injuries to upper and lower extremities (61.3%) constituted the most frequent, with Coastal having the most frequent (71.8%), while Mwananyamala and Arusha having the least (52.3% versus 62.6% respectively). While the injuries to the chest and thorax (3.0%) had the least frequency, Coastal accounted for the highest frequency (3.6%) among all EUs. In Arusha EU 40.2% of patients had injuries to the head of neck compared to 22.0% observed in Coastal **(Table 21).**

Investigations performed in the EU

Overall, most patients (25.1%) had X-ray of the long bones taken as part of care they received in EU, while only 0.4% received X-ray of the Cervical Spine. Tanga had most patients (6.9%) who received chest X-ray as part of their investigations (**Table 22).**

Treatment and interventions performed at the EU

In the EU, intravenous fluid bolus were given to (59.6%) of trauma patients overall. A total of 3583 patients (56.9%) received analgesics for pain, with Morogoro (61.8%) having the highest proportion of those who received the analgesics. Tetanus Toxoid was administered to 9.4% of trauma patients across all EUs. Prophylactic antibiotics were administered to 14.1% of trauma patients, with Coastal (16.0%) and Mwananyamala (10.5%) having the highest and lowest proportion of patients who received antibiotics respectively **(Table 23).**

Splinting of fracture (12.2%) was the most common intervention performed in all EUs, while foreign body removal (0.7%) was the least.

Table 21: Injury anatomical location by each EU

Regional Hospitals	Overall	Mwananyamala	Coastal	Tanga	Arusha	Morogoro
	N=6297	1829	887	736	1916	929
Anatomical location	%	%	%	%	%	%
Head or neck incl. cervical spine	29.8	23.2	22.0	27.7	40.2	30.4
Face injury	14.2	16.0	13.0	12.0	15.7	10.3
Chest thorax and spine injury	3.0	1.2	3.6	2.4	3.7	4.8
Abdominal injury	7.1	3.7	11.4	11.5	6.1	8.1
Extremity and pelvic injury	61.3	52.3	71.8	63.5	62.6	64.6
External injury	17.9	9.9	34.4	37.9	12.6	13.1

Table 22: **Investigation performed at the UE**

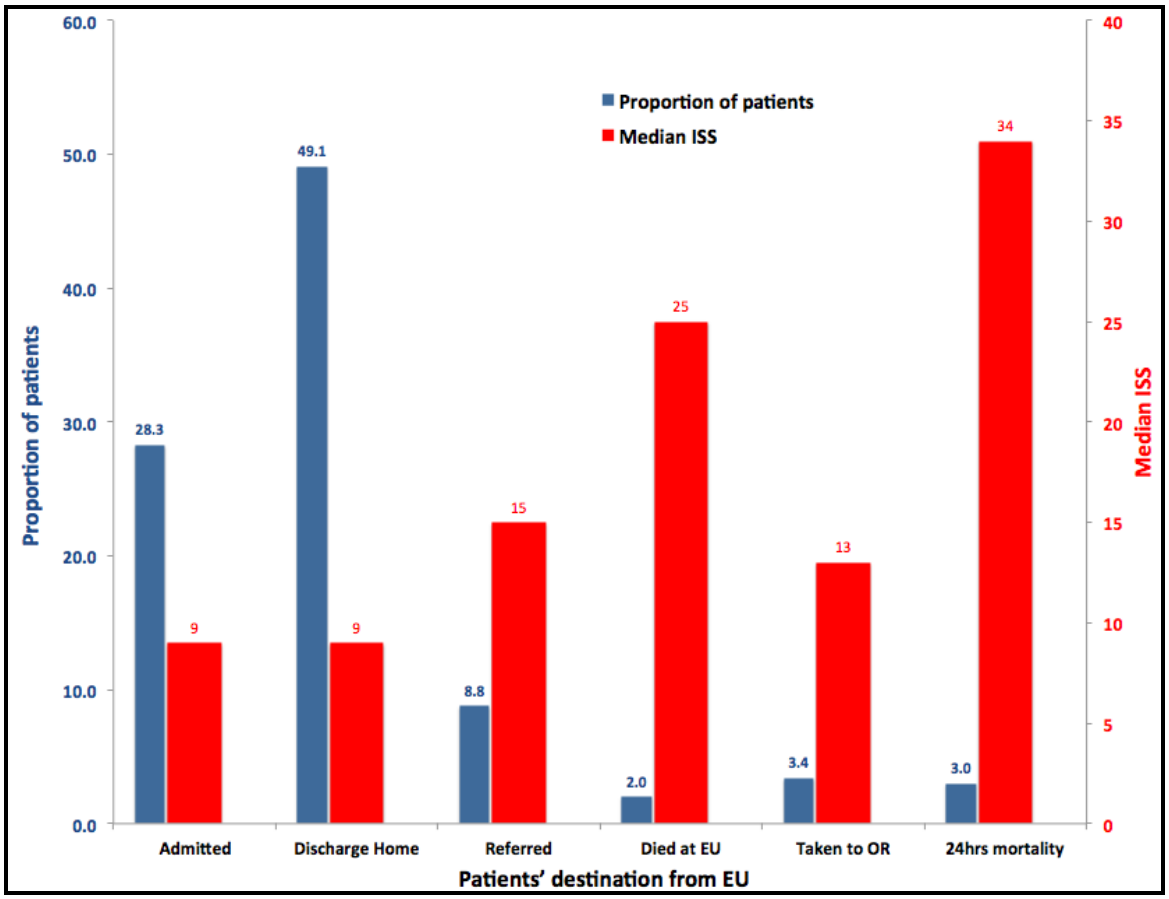
Regional Hospitals	Overall	Mwananyamala	Coastal	Tanga	Arusha	Morogoro
	N=6297	1829	887	736	1916	929
Imaging investigations	%	%	%	%	%	%
CXR	3.7	4.0	2.7	6.9	3.0	2.8
Long bone X-ray	25.1	23.7	24.7	28.0	26.1	23.8
C-Spine X-ray	0.4	0.3	0.1	1.9	0.3	0.1
Other X-ray*	0.2	0.1	0.5	0.1	0.2	0.0

**Included Pelvic and Skull X-ray*

Table 23*:* Interventions performed at the EU

Regional Hospitals	Overall	Mwananyamala	Coastal	Tanga	Arusha	Morogoro
	N=6297	1829	887	736	1916	929
Fluid and Medication given at EU						
Intravenous Fluid	59.6	54.2	54.9	56.3	66.7	62.3
Blood products	0.7	1.0	0.0	0.7	0.7	1.2
Analgesia	56.9	54.6	56.0	45.8	61.4	61.8
Tetanus Toxoid	9.4	7.1	11.7	3.0	14.6	5.9
Antibiotics	14.1	10.5	16.0	18.9	11.5	21.3
Procedures done at EU						
Chest tube placement	0.7	0.6	0.5	0.8	0.9	1.0
Splinting of fracture	12.2	12.4	12.1	21.6	9.0	10.9
Fracture reduction	3.9	6.0	8.2	2.2	1.9	1.1
Laceration repair	8.9	13.0	5.4	4.5	8.8	7.9
Foreign body removal	0.7	1.1	0.2	0.3	0.6	0.8

Figure 8: Median ISS scores and disposition



Supplementary limitations

In addition to the limitations pointed out in the manuscript, the use of ISS to inform on different categories of severity required the trained emergency physician to code the injuries to specific severity based on the information provided in the secondary survey assessment. This practive might limit the generalisability of using ISS in settings that may not have the specialised personnel to review and code for appropriate severity scoring. Furthermore, the use of providers to indicate the severity and number of injury will require training to ensure consistency and reliability of the scoring if ISS is to be used in most LMIS settings. However the standardized trauma form which was implemented, has necessary variables which offers the opportunity to compute and document other validated tools for injury severity scoring, including the Kampala Trauma Score. The lack of formal pre hospital system might have led to underestimation of the mortality of patients, given that not all patients make it to the regional hospital level after injury, and in some cases those who are brought dead to the regional hospitals may be taken straight to the mortuary by passing the EU.

Chapter conclusion

In this study, the utilization of standardised trauma documentation form at five regional hospitals provided unique opportunity for collecting injury variables that have been used to inform the development of TR. TR implementation has enabled the characterisation of regional injury burden that will help inform quality improvement initiatives, as well as injury prevention strategies across the country. Future initiatives will focus on using the experience gained in the implementation and data collection to inform both the expansion of injury registry at other sites as well as ensuring quality of data from each of the sites.

Chapter 8: Limitations, conclusion, and recommendations

Limitations

This thesis and work in designing and implementation of a standardised trauma form at Regional Hospitals is associated with several limitations. The studies in this thesis were conducted at a selected sample of five regional hospitals in Tanzania, which have variable resources, patient flow and volume. This may limit the generalisability of our results to sites and centres that have different flow patterns of patients, resources, as well as clinical practice.

In auditing the capture of injury variables at baseline, we used the full set of WHO DSI variables (85) for all patients with injury related complaints, regardless of nature, size or severity. This design was chosen to gain an understanding of the general picture of patient presentation as well as the flow patterns and variables that can be captured so as to inform the development of standardised trauma documentation form. This approach might have resulted in low documentation rates for some variables, particularly those patients who are not severely injured or those who are judged by treating providers as having need for expanded documentation due to the nature of their injuries. However, we performed a subgroup analysis of patients who might have had a likelihood of serious injuries (admitted, died in EU and referred) and found similar low rates of documentation, that is, no better than that observed in patients who had injuries that might be considered less serious. The assessment of baseline capture did not include variables related to care given prehospital or in other facilities, nor did we include variables related inpatient care. This limits the generalisability of these findings to these other phases of care setting, as well as limiting the generalisability of our data to other TRs, as most registries include the data from prehospital and inpatient settings (28). Most TRs reports on clinical pathways (operating theatre, intensive care and rehabilitation unities) mortality and functional outcomes of patients (87), all of which requires follow-up of patients beyond the EU.

In **chapter 4**, we conducted focus group discussions in a purposefully selected sample of providers who were involved in trauma care. Hence, the generalisability of their views to a wider health care system, and providers of Tanzania, might be limited. The FGDs were conducted in the local language (Swahili), which was then transcribed verbatim, and then translated into English language for the final analysis, which might have introduced some errors or misinterpretations. We tried to counteract this effect by using bilingual moderators to conduct the FGDs as well as to translate the scripts. We acknowledge that the moderator's reflexivity is a potential limitation to the views provided by the participants. Linda Finlay has emphasised the importance of considering reflexivity in qualitative research, and we attempted to navigate the potential impact to ensure trustworthiness, transparency, and accountability of our qualitative research outcomes (174).

The generalisability of semi-structured interviews in **chapter 5** is limited by the small sample of healthcare providers from the five sites. However, the diversity of study participants and their roles in daily management of trauma patients provided some avenue for wider applicability of the perceptions that have been revealed in the course of interviews.

The study in **chapter 6** had several limitations as highlighted in the main study; we had only one assessor for each chart at each site, and thus inter-rater reliability of the data input and assessment of errors by research assistants could not be assessed; the PI reviewed a selected sample of charts and made only few correction to the online data, however inter-rater reliability was not assessed. Also, the capture post pilot was determined using all documentation (including the use of ND and unknown for variables documented as not done due to lack of resources, process or expertise), which limit generalizability to settings with more resources for care that may require more documentation of performed assessment or interventions. Furthermore, there is a possibility that providers in the EU demonstrated a significant improvement in documentation due to their awareness of being observed (210); however, capture remained significantly higher than baseline even at seven months, a point at which we would expect that the "Hawthorne effect" would no longer be at play. Subsequent follow up is planned.

The description of injury burden in **chapter 7** is based on patients from five selected regional hospitals in Tanzania, which has a pyramidal referral system for all patients (118). The referral pattern of patients in these facilities may not reflect the reality in all regional hospitals in Tanzania. Furthermore, Tanzania lacks a formal pre-hospital care system (231), hence it is not known how many injured patients do not even survive to reach the level of regional referral hospitals for care.

Conclusion

TR is an integral component of a well functioning trauma care system as it can facilitate appropriate resource allocation, quality improvement initiatives, injury prevention, and policy development (12). In LMICs, despite having a disproportionately high burden of injury, there are no well-developed trauma care systems, and no TRs to inform efforts to decrease injuries, improve care or document the impact of trauma in the general community (11). In these settings, the trauma data for epidemiology, trauma quality improvement, and intervention planning is mostly reliant on single site, hospital-based chart reviews or mortuary-based data logs. Several efforts have been made to develop and implement TRs in hospitals in LMICs with varying levels of success (15–18). While TRs have been successfully implemented in LMICs through research initiatives, sustaining and expanding them beyond the research period has proven difficult. This thesis has contributed to literature with five peer-reviewed publications that describe a step-wise approach toward developing a standardised trauma documentation tool which incorporates the World Health Organization (WHO) data set for injury, that can serve as the basis for a sustainable National TR in Tanzania, and potentially other low resource settings.

In **chapter 2**, a literature review to provide a critical appraisal of the existing body of knowledge related to the development and implementation of TRs in LMICs, highlighting the process, types, sustainability, cost and challenges associated with maintain such registries. In light of knowledge gained in literature search, **chapter 3,** using a WHO DSI template, we found inadequate documentation of the minimum trauma variables as well as poor documentation of the variables in the Ministry of Health Information Management System register. In **chapter 4**, multiple barriers related to providers, volume of documentation, resource availability for care, and facility care flow processes were unveiled in the process, however, several facilitators to this implementation process have also been found. An implementation of standardised trauma documentation form was jointly agreed as key measure to ensure sustainable documentation of trauma variables.

In **chapter 5**, we unveiled a wide acceptance of moving towards standardised clinical documentation for trauma patients, with providers citing the potential benefits of improving quality of care, reducing workload and increasing efficiency in trauma care. Potential barriers to successful and sustainable implementation of the form were also noted. **Chapter 6,** using a participatory action research a contextually appropriate standardised trauma documentation form was successfully developed and pilot implemented, yielding marked improvement in the capture of essential injury variables. **In chapter 7,** in characterising the burden of injury most findings, such as males being more prone to trauma and RTAs being the most common cause, aligned with prior studies. This data will support initiatives to

improve the quality of trauma care as well as providing opportunity for instituting injury preventive measures in Tanzania, and other similar settings.

Recommendations for further research

This thesis focused on the development and pilot implementation of a standardised trauma form at regional hospitals, using pre-defined WHO DSI variables of injury, to inform a national trauma registry. The initial focus was at regional hospitals; these hospitals are towards the top of the pyramidal referral system, and tend to have a higher patient volume, and more resources than hospitals at lower tiers. Hence the utility of the standardised trauma form at health facilities below regional hospitals (District hospitals, health centre and dispensaries) is beyond the scope of this work. A future area of work is supporting and testing implementation of the standardised documentation form at lower level health facilities. As regional health facilities in Tanzania are transitioning to an electronic medical record system, there is also potential for incorporating and customising the standardised trauma into these system, and study its performance and utility in comparison to the current paper-based documentation.

One key area of intervention to improved trauma care and outcome is a well functioning pre-hospital care system. In the current standardised trauma documentation form, we did not assess the documentation of injury variables available during pre-hospital care. In future research, a focus on capturing the injury variables and care process in the pre-hospital environment is required.

The documentation of variables of injury for inpatient care as well as overall outcome of patients who have been admitted to inpatient services is important to inform key outcome measures, such as the mortality and morbidity. In this thesis we did not document the care process and outcome beyond 24-hours of patient's care, and hence future research and implementation should incorporate the assessment of care and outcomes for patients who have been admitted to the hospital, so as to gain a full understanding of the health facility outcome of patients.

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Addenda

Appendix 1. HREC and IRB approvals

Appendix 1.1 MUHAS Institutional Review Board original Approval for phase I

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR OF RESEARCH AND PUBLICATIONS

P.O. Box 65001
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E-mail: drp@muhas.ac.tz

Ref. No. 2017-12-06/AEC/Vol.XII/88

06th December, 2017

Dr. Hendry R. Sawe,
Department of Emergency Medicine,
School of Medicine,
MUHAS.

Re: Approval for Ethical Clearance for a study titled "Injury Burden and Capture Rate for Variables within WHO Datasets for Injury in Regional Hospitals in Tanzania"

Reference is made to the above heading.

I am pleased to inform you that the Chairperson, has on behalf of the University Senate, approved ethical clearance of the above mentioned study, on recommendation of the Senate Research and Publications Committee meeting.

The validity of this ethical clearance is one year effective from **23rd November, 2017** to **22nd November, 2018.** You will therefore be required to apply for renewal of ethical clearance on a yearly basis if the study is not completed at the end of this clearance.

You will also be expected to provide adverse events reports where applicable, six monthly progress report and final project upon completion of your study.

Dr. Fredirick Mashili
Acting Chairperson, Senate Research and Publications Committee

Muhimbili University of Health and Allied Sciences ★ DIRECTOR ★ Research & Publications ★ Box 65001 ★

Appendix 1.2. MUHAS Institutional Review Board original Approval for phase II

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR OF RESEARCH AND PUBLICATIONS

P.O. Box 65001
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Ref. No.DA.282/298/01.C/31

07th August, 2018

Dr. Hendry R.Sawe
Department of Emergence Medicine
School of Medicine
MUHAS.

Re: Approval for Ethical Clearance for a study titled "Factors affecting current trauma documentation practices and the implementation of a standardized trauma form in charting of trauma patient information at regional hospitals in Tanzania"

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above mentioned study, on recommendations of the Senate Research and Publications Committee Meeting.

The validity of this ethical clearance is one year effective from **30th July, 2018** to **29th July, 2019.** You will therefore be required to apply for renewal of ethical clearance on a yearly basis if the study is not completed at the end of this clearance.

You will be expected to provide adverse events report where applicable, six monthly progress reports and a final project report upon completion of your study.

Muhimbili University of Health and Allied Sciences
DIRECTOR Research & Publications
Box 65001

Dr. Bruno Sunguya
Ag.Chairperson, Senate Research and Publications Committee

Appendix 1.3. University of Cape Town HREC original approval for phase I

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

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

07 September 2017

HREC REF:632/2017

Prof L Wallis
c/o Ms A Maas
Division of Emergency Medicine
E52.27 OMB

Dear Prof Wallis

PROJECT TITLE: BUILDING A MODEL FOR DEVELOPMENT OF A NATIONAL TRAUMA REGISTRY: ESTABLISHING BASELINE MEASURES OF TRAUMA VARIABLES DATA DOCUMENTATION AND THE INJURY BURDEN IN REGIONAL HOSPITALS IN TANZANIA (PHD CANDIDATE - DR H SAWE)

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

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

Approval is granted for one year until the 30 September 2018.

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)

We acknowledge that the student: - Dr H Sawe will also be involved in this study.

Please quote the HREC REF in all your correspondence.

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.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

HREC 632/2017

Appendix 1.4. University of Cape Town HREC original approval for phase II

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

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

10 August 2018

HREC REF: 472/2018

Prof Lee Wallis
Emergency Medicine
F51, OMB

Dear Prof Wallis

PROJECT TITLE: BUILDING A MODEL FOR DEVELOPMENT OF A NATIONAL TRAUMA REGISTRY: DETERMINING FACTORS AFFECTING CURRENT TRAUMA DOCUMENTATION PRACTICES, AND THE IMPLEMENTATION OF A STANDARDISED TRAUMA FORM IN CHARTING OF TRAUMA PATIENT INFORMATION AT REGIONAL HOSPITALS IN TANZANIA (SUB-STUDY LINKED TO 632/2017) (PHD CANDIDATE - DR H SAWE)

Thank you for submitting your response to the Faculty of Health Sciences Human Research Ethics Committee dated 6 August 2018.

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

Approval is granted for one year until the 30 August 2019.

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 quote the HREC REF in all your correspondence.

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, Dr Henry Sawe will also be involved in this study.

Yours sincerely

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

HREC 472/2018

Appendix 2: Data collection tools

Appendix 2.1 DSI Variable Capture Audit Tool

Confidential

Dsi Variable Capture Audit Tool

Record ID	_____
Subject ID number in the project	_____
Patient Initials in File	_____
Name of the Facility	◯ Mwananyamala Hospital ◯ Tumbi Hospital ◯ Bombo Hospital ◯ Mt. Meru Hospital ◯ Morogoro Regional Hospital
Hospital Registration Number	◯ Not Documented ◯ Documented
PATIENT DEMOGRAPHICS	
Patient's Name	◯ Not Documented ◯ Documented
Mass Casualty Status	◯ Not Documented ◯ Documented
Patient's Address	◯ Not Documented ◯ Documented
Age or Date of Birth	◯ Not Documented ◯ Documented
Sex	◯ Not documented ◯ Documented
Occupation	◯ Not Documented ◯ Documented ◯
Injury Geographical Location	◯ Not Documented ◯ Documented

REDCap

INITIAL CLINICAL CONDITION	
Date of EU Care	◯ Not Documented ◯ Documented
Time of EU Care	◯ Not Documented ◯ Documented ◯
Time of First Vital Signs	◯ Not Documented ◯ Documented
Referral Status	◯ Not documented ◯ Documented
Name of the referring facility	◯ Not Documented ◯ Documented
EU Mode of Arrival	◯ Not Documented ◯ Documented
Patient's Signs of Life	◯ Not Documented ◯ Documented
Assessment of Signs of Life at EU	◯ Not Done ◯ Done
Patient Ambulatory Status	◯ Not Documented ◯ Documented ◯
Contact Person's name	◯ Not Documented ◯ Documented
Contact Person's address	◯ Not Documented ◯ Documented ◯
Contact Person's phone	◯ Not Documented ◯ Documented
Triage	◯ Not Done ◯ Done
Triage Status	◯ Not Documented ◯ Documented
Chief Complaint	◯ Not Documented ◯ Documented

VITALS	
SBP	◯ Not Documented ◯ Documented
SBP Measurement	◯ Not Done ◯ Done
DBP	◯ Not Documented ◯ Documented
DBP Measurement	◯ Not Done ◯ Done
Pulse	◯ Not Documented ◯ Documented
Pulse Measurement	◯ Not Done ◯ Done
Respiratory Rate	◯ Not Documented ◯ Documented
Respiratory Measurement	◯ Not Done ◯ Done
Saturation of Oxygen	◯ Not Documented ◯ Documented
Saturation of Oxygen Measurement	◯ Not Done ◯ Done
Temperature	◯ Not Documented ◯ Documented
Temperature Measurement	◯ Not Done ◯ Done
Weight	◯ Not Documented ◯ Documented
Weight Measurement	◯ Not Done ◯ Done
Pain Score	◯ Not Documented ◯ Documented
Pain Score Assessment	◯ Not Done ◯ Done

AVPU status Assessment	◯ Not Done ◯ Done
AVPU score	◯ Not Documented ◯ Documented
GCS status Assessment	◯ Not Done ◯ Done
GCS score	◯ Not Documented ◯ Documented
Ultrasound for patient while in EU	◯ Not Done ◯ Done
Ultrasound results	◯ Not Documented ◯ Documented

DETAILS OF INJURY

Injury Anatomical location	◯ Not Documented ◯ Documented
Past Medical History	◯ Not Documented ◯ Documented
Past Surgical History	◯ Not Documented ◯ Documented
History of Allergies	◯ Not Documented ◯ Documented
Patients Safety at Home	◯ Not Documented ◯ Documented
Last Normal Menstrual Period	◯ Not Documented ◯ Documented
Social History	◯ Not Documented ◯ Documented
Vaccination status	◯ Not Documented ◯ Documented
Family History	◯ Not Documented ◯ Documented
Date of Injury	◯ Not Documented ◯ Documented
Time of Injury	◯ Not Documented ◯ Documented
Injury Settings	◯ Not Documented ◯ Documented

Activity at Time of Injury	◯ Not Documented ◯ Documented
Mechanism of Injury	◯ Not Documented ◯ Documented
Patient MTA position	◯ Not Documented ◯ Documented ◯ Not MTA
Patient safety in MTA	◯ Not Documented ◯ Documented
Details of Incident	◯ Not Documented ◯ Documented
Type of Injury	◯ Not Documented ◯ Documented
Injury Acuity Status	◯ Not Documented ◯ Documented
Injury Intent	◯ Not Documented ◯ Documented
Hours Since Last Meal	◯ Not Documented ◯ Documented
Alcohol use status	◯ Not Documented ◯ Documented
SECONDARY SURVEY	
General Examination of Patient	◯ Not Documented ◯ Documented
HEENT Examination	◯ Not Documented ◯ Documented
Neck Examination	◯ Not Documented ◯ Documented
Neurological Examination	◯ Not Documented ◯ Documented
Chest Examination	◯ Not Documented ◯ Documented
Cardiovasculr Examination	◯ Not Documented ◯ Documented
Abdominal Examination	◯ Not Documented ◯ Documented

Pelvic Examination	◯ Not Documented ◯ Documented
Genital Urinary Examination	◯ Not Documented ◯ Documented
Back Examination	◯ Not Documented ◯ Documented
Musculoskeletal Examination	◯ Not Documented ◯ Documented
Patient Assessment and Plan	◯ Not Documented ◯ Documented
Laboratory Investigation at EU	◯ Not Done ◯ Done
Laboratory Investigation orders	◯ Not Documented ◯ Documented
EU INTERVENTIONS	
Imaging of Chest at EU	◯ Not Done ◯ Done
Imaging of Chest	◯ Not Documented ◯ Documented
Imaging of long bones at EU	◯ Not Done ◯ Done
Imaging of long bones	◯ Not Documented ◯ Documented
IV Fluids at EU	◯ Not given ◯ Given
IV Fluids	◯ Not Documented ◯ Documented
Blood Products at EU	◯ Not given ◯ Given
Blood Products	◯ Not Documented ◯ Documented
Analgesics at EU	◯ Not given ◯ Given
Analgesics	◯ Not Documented ◯ Documented
Sedation at EU	◯ Not given ◯ Given

Sedation	◯ Not Documented ◯ Documented
Tetanus Toxoid at EU	◯ Not given ◯ Given
Tetanus Toxoid	◯ Not Documented ◯ Documented
Antibiotics at EU	◯ Not given ◯ Given
Antibiotics	◯ Not Documented ◯ Documented
Paralytics at EU	◯ Not given ◯ Given
Paralytics	◯ Not Documented ◯ Documented
Chest Tube Insertion at EU	◯ Not Done ◯ Done
Chest Tube Insertion	◯ Not Documented ◯ Documented
Splinting of Fracture or Dislocation at EU	◯ Not Done ◯ Done
Splinting of Fracture or Dislocation	◯ Not Documented ◯ Documented
Fracture Reduction at EU	◯ Not Done ◯ Done
Fracture Reduction	◯ Not Documented ◯ Documented
Laceration Repair at EU	◯ Not Done ◯ Done
Laceration Repair	◯ Not Documented ◯ Documented
Foreign Body Removal at EU	◯ Not Done ◯ Done
Foreign Body Removal	◯ Not Documented ◯ Documented
Periocardiocentesis at EU	◯ Not Done ◯ Done

Periocardiocentesis	◯ Not Documented ◯ Documented
Intubation at EU	◯ Not Done ◯ Done
Intubation	◯ Not Documented ◯ Documented
Cricothyrotomy at EU	◯ Not Done ◯ Done
Cricothyrotomy	◯ Not Documented ◯ Documented
Open thoracotomy at EU	◯ Not Done ◯ Done
Open thoracotomy	◯ Not Documented ◯ Documented
Other Procedures at EU	◯ Not Done ◯ Done
Other Procedures	◯ Not Documented ◯ Documented
Patient Reassessment at EU	◯ Not Documented ◯ Documented
Time of Patient Reassessment	◯ Not Documented ◯ Documented
VITALS	
Temperature_2	◯ Not Documented ◯ Documented
SBP_2	◯ Not Documented ◯ Documented
DBP_2	◯ Not Documented ◯ Documented
Pulse_2	◯ Not Documented ◯ Documented
Respiratory Rate_2	◯ Not Documented ◯ Documented
Saturation of Oxygen_2	◯ Not Documented ◯ Documented

EU DETAILS	
Patient's Condition after reassessment	◯ Not Documented ◯ Documented
Diagnosis at EU	◯ Not Documented ◯ Documented
Number of Serious Injuries	◯ Not Documented ◯ Documented
Patient's Disposition	◯ Not Documented ◯ Documented
ED Disposition	☐ Admitted to ward ☐ Admitted to ICU ☐ Admitted to OT ☐ Discharged home ☐ Transferred to another facility ☐ Died at ED ☐ Others
Other Explain	_____
Name of the Referrals Facility	◯ Not Documented ◯ Documented
Cause of Death	◯ Not Documented ◯ Documented
EU Departure Date	◯ Not Documented ◯ Documented
EU Departure Time	◯ Not Documented ◯ Documented

Appendix 2.2: HMIS variable Audit tool

Confidential

Hmis Varible Audit Tool

Record ID _____

HMIS AUDIT TOOL	
Patient's record on HMIS	◯ Not Documented ◯ Documented ◯ Not in HMIS book
Patients Registration number in HMIS	◯ Not Documented ◯ Documented ◯ Not in HMIS book
Date of EU Care in HMIS	◯ Not Documented ◯ Documented ◯ Not in HMIS book
Name in HMIS	◯ Not Documented ◯ Documented ◯ Not in HMIS book
Address in HMIS	◯ Not Documented ◯ Documented ◯ Not in HMIS book
Age in HMIS	◯ Not Documented ◯ Documented ◯ Not in HMIS book
Gender in HMIS	◯ Not Documented ◯ Documented ◯ Not in HMIS book
Weight in HMIS	◯ Not Documented ◯ Documented ◯ Not in HMIS book
Height in HMIS	◯ Not Documented ◯ Documented ◯ Not in HMIS book ◯
EU Dignosis on HMIS	◯ Not Documented ◯ Documented ◯ Not in HMIS book

REDCap

Investigation on **HMIS**	◯ **N**ot Documented ◯ Documented ◯ **N**ot in **HMIS** book
EU treatment on **HMIS**	◯ **N**ot Documented ◯ Documented ◯ **N**ot in **HMIS** book
Outcome on **HMIS**	◯ **N**ot Documented ◯ Documented ◯ **N**ot in **HMIS** book
Remarks on **HMIS**	◯ **N**ot Documented ◯ Documented ◯ **N**ot in **HMIS** book

Appendix 2.3: Heath Facility EU Tool

Confidential

Heath Facility EU Tool

Record ID	_____
Facility	◯ Mwananyamala ◯ Tumbi ◯ Morogoro ◯ Tanga ◯ Arusha
Total number of hospital beds	_____
Total number of EU beds	_____
Total number of Operating Theatre	_____
Total number of ICU beds	_____
Total number X-ray machine	_____
Total number CT-Scan machine	_____
Total number Ultrasound machine	_____
Clinician- Emergency Physician	_____
Clinician- General Surgeon	_____
Clinician-Orthopaedic Surgeon	_____
Clinician-Urologist	_____
Clinician-Medical Officer	_____
Clinician-Assistant Medical Officer	_____
Clinician-Clinical Officer	_____
Clinician-Others	_____

REDCap

Others-specify	_____
Clinician per day shift	_____
Clinician per night shift	_____
Number of **R**egistered **N**urses	_____
Number of **E**nrolled **N**urses	_____
Number of **H**ealth Attendant	_____
Number of nurses per day shift	_____
Number of nurses per night shift	_____

Appendix 2.4: Focus Group Guide: Emergency Unit Providers

Part I

- **Tell them**: Thank you for taking time out from your busy schedule to do this interview.
- **Inform them:** About the norms of FGDs: *Talk by showing a hand, to listen to others, not laughs at others opinions, not character assassinate, and mutual respect to each other's opinions.*
- **Provide:** Each participant will be provided identity number for coding purposes.
- **Inform them**: That there identities will be kept confidential throughout the investigation.
- **Inform them**: Initial analysis of the capture rate for each of the variables of the WHO minimum data set for injury among trauma patients at *[Hospital]* indicates that the capture rate of trauma variables is well for (*demographics*) and very low for (*vital signs* and *patients complains*, *FAST examinatio*n, *injury intent, mechanism of injury, re-assessment, ED disposition, and final diagnosis*). Our aim is to understand how trauma patient are cared for in emergency unit (EU), and explore barriers and facilitators to capturing all variables within the WHO minimum dataset for injury at [*Hospital*].
- **Introduction**: As active members of EU here at [*Hospital*] I would value your opinions on care of trauma patients, barriers and facilitators capturing all variables within the WHO minimum dataset for injury. This interview will be recorded for transcription purposes, but we will not record any identifying information. At the conclusion of the study, the digital recordings will be destroyed.
- **Let them**: Read and sign the informed consent form if they agree to do.
- Remember to thank them after the interview.

Part II

1. **Trauma care and documentation process:**
   (i). What is the whole patient care process for trauma patients presenting to [*Hospital*]?
   (ii). How is the documentation of the clinical care of patients done at this Emergency unit?
   (iii). What parts of this process are easy or efficient? (**Probe**: why do you think this part is easy or efficient?)
   (iv). Which parts of this process are difficult or time-consuming? (**Probe**: why do you think this part is difficult?)
2. **Trauma data processing and management:**

(i). Which information do you normally abstract from charts as part of the Hospital required statistics and / quality assurance? (**Probe**: why this information?)

(ii). Which information do you normally abstract for filling in to the Ministry of Health, health information management system? (**Probe 1**: How often do you do this?) (**Probe 2**: Is there a designated person for this role?)

(iii). Do you normally do quality assurance on the documentation of the clinical chart for the department? (**Probe**: Do you get feedback from the ministry of health on the submitted information from the charts?)

3. Current trauma documentation:

(i). Why is the documentation of demographics good in your current documentation?,

(ii). Why is the documentation of vital signs and patient's chief complaint poor?

(iii). Why is the documentation of vital signs mechanism of injury and injury intent poor?

(iv). Why is the documentation of ED diagnosis and disposition poor?

(v). Why is the documentation of FAST poor?

4. Concept of standardised trauma form:

(i). What do you think is important information to know about trauma patients

(ii). Would you be interested to know the pattern of injuries that come to [*Hospital*]? (**Probe:** why or why not?)

(iii). Do you think it would be helpful to have a standardised charting specifically for trauma patients? (**Probe**: why and why not?)

(iv). Do you think a standardised charting will have impact on overall documentation process? (**Probe:** Why and why not?)

(v). In your opinion do you think implementation of standardised charting will be successful? (**Probe:** why and why not?)

(vi). In your opinion do you think implementation of standardised charting will have any challenges? (**Probe:** why and why not?)

(vii). In addition to standardised charting, what other accompanying measures can help improve the documentation of the trauma patients?

(viii). Is there anything you would add the best way to perform implementation of standardises documentation at your unit?

(ix). If you were to design a standardised trauma form, what would it look like?

Appendix 2.5: Semi-structured interview guide

Part I:

- **Tell him/her**: Thank you for taking time out from your busy schedule to do this interview.
- **Inform him/her**: That his/her identity will be kept confidential throughout the investigation.
- **Inform him/her**: Initial analysis of the capture rate for each of the variables of the WHO minimum data set for injury among trauma patients at *[Hospital]* is not consistently well done. Our aim is to improve the capture rate of all variables within the WHO minimum dataset for injuries through development of a standardised documentation chart.
- **Introduction**: As a key personnel of the emergency unit here at [*Hospital*] I would value your personal input in the design and piloting of a trauma chart for the [*hospital*] emergency providers. This document could be utilised to document trauma patients during care and collect information on injury coming through your facility. The interview should take approximately 45 minutes, we will ask a few questions and then show you a draft of the trauma chart for your suggestions and comments. All your responses will remain anonymous, and you are free to terminate the interview at anytime. We will record this interview for transcription purposes.
- **Let him/her**: Read and sign the informed consent form if they agree to do.
- Remember to thank him/her after the interview.

Part II:

Personal details and professional experience:

(i). What is your position at the emergency unit?
(ii). How long have you worked as a provider, post graduation?
(iii). How many years of experience do you at the emergency department?
(iv). Where did you train?
(v). Have you worked in other hospitals other than *[Hospital]?*

Past and current trauma charting:

(i). Have you ever used a trauma form? (**Probe:** Why or why not?)
(ii). Are you currently using a form? (**Probe:** Why or why not?)
(iii). If not, how do you currently chart trauma patients?
(iv). When do you normally do your charting (during treatment, patient still in emergency unit, after stabilized)?

After reviewing the proposed Form:

(i). How usable is this form? Would you and other providers at [*Hospital*] use it?
(ii). Does it capture the needed information? (**Probe:** If not, what is missing?)
(iii). What makes this form useful?
(iv). What makes this form difficult? (**Probe:** what would be the challenges with using the form)?
(v). Is there anything you would add or subtract from the proposed draft form?

After piloting testing the form:

(i). How usable is this form?
(ii). Does the form simplify your charting of the trauma patients (**Probe:** why/why not)
(iii). What makes this form difficult to use? (**Probe**: why?)
(iv). Which aspects of the form would you like to be changed (**Probe**: why?)

Appendix 2.6: Standardised trauma form

REGIONAL REFERRAL HOSPITAL CASUALTY TRAUMA FORM □ Mass Casualty

Hospital Registraon Number: | Date: / / | Time of Arrival: __ __ :__ __ (24h)

Paent Surname:_____
First Name:_____

Date of Birth: / / | Age: _____ INFANT / CHILD / ADULT
Sex: M / F | Weight: _____ kg

Arrival Mode: □Ambulance □ Car (*circle* private or Taxi) □ Walk-in □ Motorcycle □Tricycle (*circle* private or Taxi) □ Public transport □ Police □ Bicycle □Other

□Self Referral □Referred from: _____

Occupation:_____ □ Unknown
Residenal address:_____ □ Unknown

Contact Person:_____
Phone:_____ Relation:_____

CHIEF COMPLAINT:_____

Triage Category: □ Emergency □ Priority □ Queue

□ Dead on arrival

INITIAL VITAL SIGNS: at _____:____(24h format) **BP:** ____/_____ **HR:**_____ **RR:**_____ **SpO_2:**_____ **% on**___ **Temp:**_____°C

PRIMARY SURVEY

	Physical findings	Interventions done
Airway □ NORMAL	□ Angioedema □ Stridor □ Voice changes □ Oral/Airway burns **Obstructed by**: □ Tongue □ Blood □ Secreons □ Vomit □ Foreign body	**Airway Manipulation:** □ Repositioning □ Suction **Airway:** □Oral Airway □Nasal Airway □ laryngeal mask airway □ Endotracheal intubaon **Cervical collar:** □None needed □Placed before arrival □Placed at casualty
Breathing □ NORMAL	**Spontaneous Respiration:** □ Yes □ No **Chest Rise:** □Shallow □Retracons □Paradoxical **Trachea:** □ Midline □Deviated to □L □R **Breath Sounds:** Abnormal: □ L____ □R____	**Given Oxygen:** _____ L □Nasal Cannula □Mask □Non-rebreather mask □Bag valve Mask □CPAP □Venlator; **Chest tube/Needle** (circle): □ Le –Size: _____ Depth: _____ cm □ Right–Size: _____ Depth: _____ cm
Circulation □ NORMAL	**Skin:** □ Warm □ Dry □ Pale □ Cyanoc □ Moist □ Cool **Capillary refill:** □ <2 sec □ ≥2 sec **Pulses:** □ Weak □ Asymmetric_____ **Jugular Venous Distension:** □ Yes □ No	□ Bleeding controlled (bandage, tourniquet, direct pressure) **Access:** □Intravenous Locaon _____ cannula Size _____G □Central Line Locaon _____ Size _____G □Intraosseous Line: Locaon _____ Size _____G **□Intravenous Fluid:**_____mL □NS □RL □DNS □Dextrose □Blood ordered □Pelvic binder placed
Disability □ NORMAL **E**xposure □ NORMAL	**Blood glucose**: _____mmol/l □ Glucose given **Responsiveness:** □ A □ V □ P □ U **GCS**:____/15 (E_____ V_____M_____) **Moves Extremities:** □ LUE □RUE □LLE □RLE **Pupils:** L___mm→___mm R___mm→___m □ **Patient has been Exposed completely**	**Focused Assessment with Sonography in Trauma (FAST)** **F**AST □ NORMAL □ Not Indicated □ Not done; **Peritoneum** □ Negave □ free fluid □ Indeterminate **Chest** □ Negave □ Indeterminate □ Pneumothorax _____ (Right/le) □ Pleural fluid _____ (Right/le) □ Pericardial fluid

HISTORY OF PRESENT ILLNESS **Date of Injury:** ____/____/_____

Place of injury: _____□Unknown
Patient's activity at time of injury: _____ □Unknown
Mechanism of injury:
□Road traffic incident: □ Driver □ Passenger □ Pedestrian □ Airbag □ Seat belt □ Other vehicle restraint □ Helmet □ Extricated Vehicle involved: _____ □ Ejected Crashed with: _____
□Fall from: _____ □Hit by falling object: _____
□Stab/Cut □Gunshot □Sexual Assault
□Other blunt force trauma (struck/hit): _____
□Suffocaon, choking, hanging
□Drowning: _____ Flotaon device: Y / N
□Burn caused by: _____
□Poisoning/Toxic Exposure:_____
□Unknown □Other: _____

First care sought before arrival at the Casualty
□ None □ Layperson first aid □ Health care provider
Care given:_____
Other Details of Incident
□Loss of Consciousness □<5 min □5-29 min □30-24hr □>24 hr
□ Head trauma Yes / NO □ Neck trauma Yes / NO
□ Other:_____
Hours since last Meal:_____□ Unknown
Intent: □ Unintenonal or accidental □ Intenonal: □Self harm □ Legal process, polical unrest or war □ Unknown
□ Assault [**Assaulted by:**_____]
Substance use within 6 hours of injury:
□ Unknown □ None □ Reported □ Evidence (posive test or clinical findings) □ Alcohol □ Others:_____

PAST MEDICAL HISTORY

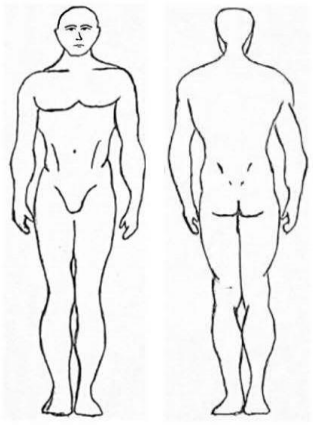
History of: □ Hypertension □ Diabetes □ COPD □ HIV
□Other:_____□None □Unknown
Current Medications:_____□None □Unknown
Past Surgeries: _____□None □Unknown
Any Known Allergies:_____□None □Unknown

Pregnant: □ Yes □ No □ Not Applicable (N/A)
Vaccinations up to date? □Yes □No _____
Substance Use: □Tobacco □Alcohol □ Drugs □ IV Drugs
Safe at home? _____

PHYSICAL EXAMINATION (SECONDARY SURVEY)

□ NORMAL	**General**	
□ NORMAL	**Head, Eyes, Ears Nose and Throat (HEENT)**	
□ NORMAL	**Neuro Exam**	
□ NORMAL	**Neck**	
□ NORMAL	**Respiratory**	
□ NORMAL	**Cardiovascular**	
□ NORMAL	**Abdominal**	
□ NORMAL	**Pelvis**	
□ NORMAL	**Genital urinary**	
□ NORMAL	**Back exam**	
□ NORMAL	**Musculoskeletal**	

Label any details of injury



EU PLAN AND INTERVENTIONS

Fluids and Medications Given at EU

□**IV Fluids:** □ NS_____mL |□RL _____mL | □_____mL □ None given
□**Blood Transfusion** □ WB_____U |□ PRBC____U| □ Others___U □ None given
□**Analgesia**_____ □ None given
_____
□**Antibiotics**_____□ None given
_____
□**Tetanus toxoid**_____ □ None given
□ **Sedation and Paralytics**:_____ □ None given
□ **Other**:_____

EU Procedures done

□ Splinting: _____
□ Fracture Reduction_____
□ Pelvic Stabilisation on: _____
□ Foreign Body Removal:_____
□ Simple / Complex Laceration Repair: _____
□ Intubation: _____
□ Chest Tube: _____
□ Others: _____
_____

LABORATORY TEST AND RESULTS

□ **Urine for pregnancy** □ Not done □ posi. ve □ Nega ve
□ **Haemoglobin:** _____g/dl □ pending □ Not done
□ **Blood grouping:**_____ □ pending □ Not done
□**Others:**_____

RADIOLOGICAL/IMAGING INVESTIGATIONS AND RESULTS

□ **X-Ray of**_____
□Pneumothorax □Pleural Fluid □Rib Fracture □Pulmonary Opacity
□ C-spine fracture □ Extremity Fracture □ Pelvic Fracture
□ Wide medias. num □ Other:_____

FINAL CASUALTY DIAGNOSIS: 1:_____**2:**_____
3:_____ **Number of serious injures** (circle): 0 or 1 or ≥ 2

CASUALTY CONSULTATION: □ **None needed** □ **Done to:**_____
Recommendation from consult:_____

FINAL CASUALTY REASSESSMENT at _____:____(24h format) **BP:** ____ /_____ **HR:**_____ **RR:**_____ **SpO_2:**____ **% on**___ **Temp:**____°C
PATIENT CONDITION: □ Same □ Changed:_____

□ **ADMITTED TO:** □ Ward _____ □ ICU □ Operating Theatre
□ **REFERRED to:** _____
□ **DAMA**

□ **DISCHARGE HOME**
□ **DIED OF** _____

Name of the attending Clinician	Cadre (MD, AMO, CO, Intern)	Signature and Date and time
		_____ ____ /____ /_____| : hrs

Appendix 2.7: RedCap Case report form

Trauma Case Report Form

Record ID	_____
Name of the facility	◯ Mwananyamala Hospital ◯ Tumbi Hospital ◯ Bombo Hospital ◯ Mt. Meru Hospital ◯ Morogoro Regional Hospital
Site Data Coordinator	◯ Ms.Simphorosa ◯ Dr. Siaely ◯ Dr. Banda ◯ Dr. Makona ◯ Dr. Clement
Mass Casualty	◯ No ◯ Yes ◯ Unknown
Hospital Registration Number	_____
Patient's initials	_____
Address	_____
Date of birth documented	◯ No ◯ Yes
Date of Birth	_____ (Use the calendar or DAY-MONTH-YEAR)
Age (if no age, adult or child)	_____
Sex	◯ Male ◯ Female ◯ Not documented
Date of ED care documented	◯ No ◯ Yes
Date of ED Care	_____ (Use the calendar or DAY-MONTH-YEAR)
Time of ED care documented	◯ Yes ◯ No
Time of arrival	_____

Referral Status	◯ Referred ◯ Self referral ◯ Unknown
Name of the referring facility	_____
Status of a patient	◯ ◯ Alive on arrival ◯ Dead on arrival or brought dead
EU Mode of arrival	◯ Private car ◯ Police ◯ Commercial vehicle ◯ Ambulance ◯ Self ◯ Bicycle ◯ Motorcycle ◯ Tricycle ◯ Unknown
Contact Person's name	_____
Contact Person's Address	_____
Contact Person's phone	_____
Occupation	◯ Public/Private sector ◯ Unemployed ◯ Petty trader ◯ Student ◯ Other
Other (specify)	_____
Chief Complaint	_____

VITALS

SBP	_____
DBP	_____
PULSE	_____
RR	_____

SPO2	_____
TEMPERATURE	_____
Weight (kgs)	_____
Pain scale	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ Not assessed/Not documented

PRIMARY SURVEY AND INTERVENTIONS

Airway assessment	☐ Not documented ☐ Normal/ Patent ☐ Obstructed by tongue ☐ Obstructed by blood ☐ Obstructed by secretions ☐ Obstructed by vomit ☐ Obstructed by foreign body ☐ Stridor ☐ Angioedema ☐ Oral/ Airway burns
Management of compromised airway	☐ Repositioning ☐ Suction ☐ OPA ☐ NPA ☐ LMA ☐ BVM ☐ ETT ☐ Cervical collar ☐ Not documented ☐ None
Breathing assessment	☐ Not documented ☐ Normal ☐ Paradoxical chest movement ☐ Deviated trachea ☐ Abnormal breath sounds
Management on abnormal breathing	☐ Oxygen therapy ☐ Needle thoracostomy ☐ Chest tube ☐ Pleural tap ☐ Other ☐ Not documented ☐ None

Oxygen delivery mode	○ None ○ NC (nasal canuler) ○ Mask ○ NRM (Non rebreather mask) ○ BVM ○ CPAP/ BIPAP ○ Ventilator ○
Circulation assessment	☐ Not documeted ☐ Normal ☐ Dry skin ☐ Pale ☐ Cyanotic ☐ Cap refill >2sec ☐ Weak pulse ☐ JVD
Management on abnormal circulation	☐ IO ☐ IV ☐ CVL ☐ IVF ☐ FFP ☐ PRBC ☐ Whole blood ☐ Not documented ☐ None
Exposure Completely	○ Yes ○ No
RBG	_____
AVPU score	_____
GCS Eye opening	_____
GCS Verbal response	_____
GCS Motor Response	_____
Total GCS at EMD	_____
FAST/ EFAST	○ Not documented ○ Negative ○ Abnormal
EFAST results	☐ Free fluid ☐ Pericardial effusion ☐ Pneumothorax ☐ Pleural fluid ☐ Indeterminate

Details of area of injury	☐ Head or neck injury including cervical spine ☐ Face including the facial skeleton, nose, mouth, eyes and ears ☐ Chest-Thoracic spine and diaphragm ☐ Abdomen or pelvic contents-abdominal organs and lower spine ☐ Extremities or pelvic girdle -pelvic skeleton ☐ External
Past Medical History	○ None ○ Significant ○ Unknown
Past Medical History (specify)	_____
Past surgeries	○ Yes ○ No ○ Unknown
Past Surgeries (specify)	_____
History of allergies	○ Yes ○ No ○ Unknown
Allergies (specify)	_____
Safety at home	○ Yes ○ No ○ Unknown
Last normal menstrual period	_____
Social history	☐ Not documented ☐ Tobacco ☐ Alcohol ☐ Drugs ☐ IV drugs ☐ None
Vaccination up to date	☐ Not documented ☐ No ☐ Yes
Family history	_____
Date of injury documented	○ Yes ○ No
Date of Injury	_____

Time of injury documented	○ Yes ○ No
Time of injury	_____
Place of injury	○ Private home ○ School ○ Street ○ Public building/ office ○ Other ○ Unknown
Patient's activity at time of injury	○ Work ○ Leisure ○ Education ○ Travel ○ Sport ○ Walking to school ○ Unknown ○ Other
Mechanism of injury	☐ MTA ☐ Fall ☐ Hit by Falling Object ☐ Stab ☐ Gun Shot ☐ Assault ☐ Suffocation ☐ Burn ☐ Poisoning ☐ Animal Bite ☐ Hanging ☐ Unknown ☐ Others ☐ Not documented
MTA position	○ Motorcycle rider ○ Motorcycle passenger ○ Vehicle driver ○ Vehicle occupant ○ Pedestrian ○ Bicyclist ○ Bajaj occupant
Vehicle involved	○ Motorcycle ○ Car ○ Truck ○ Bus/Daladala ○ Bajaj ○ Bicycle ○ Others
Patient wearing Helmet	○ No ○ Yes
Patient wearing Seat belt	○ No ○ Yes

Intent of injury	○ Unintentional ○ Intentional ○ Unknown
Alcohol use within 6 hours of injury	○ Suspected ○ Confirmed ○ No information

Physical examination

General	○ Normal ○ Abnormal ○ Not done ○
Describe	_____
HEENT	○ Normal ○ Abnormal ○ Not done ○
Describe	_____
Chest thorax and Spine	○ Normal ○ Abnormal ○ Not Done
Describe	_____
Abdomen	○ Normal ○ Abnormal ○ Not Done
Describe	_____
Pelvis	○ Normal ○ Abnormal ○ Not Done
Describe	_____
Genital Urinary	○ Normal ○ Abnormal ○ Not Done
Describe	_____

Back	○ Normal ○ Abnormal ○ Not Done
Describe	_____
MUSCULOSKELETAL AND SKIN	○ Normal ○ Abnormal ○ Not Done
Describe	_____

Lab results

UPT	○ Positive ○ Negative ○ Not done ○ Not applicable
Hemoglobin	○ Normal ○ Low ○ Not done
Blood type	○ Ordered ○ Not ordered
Imaging at EU	☐ CXR ☐ Long bones ☐ C-spine ☐ Pelvic ☐ Other

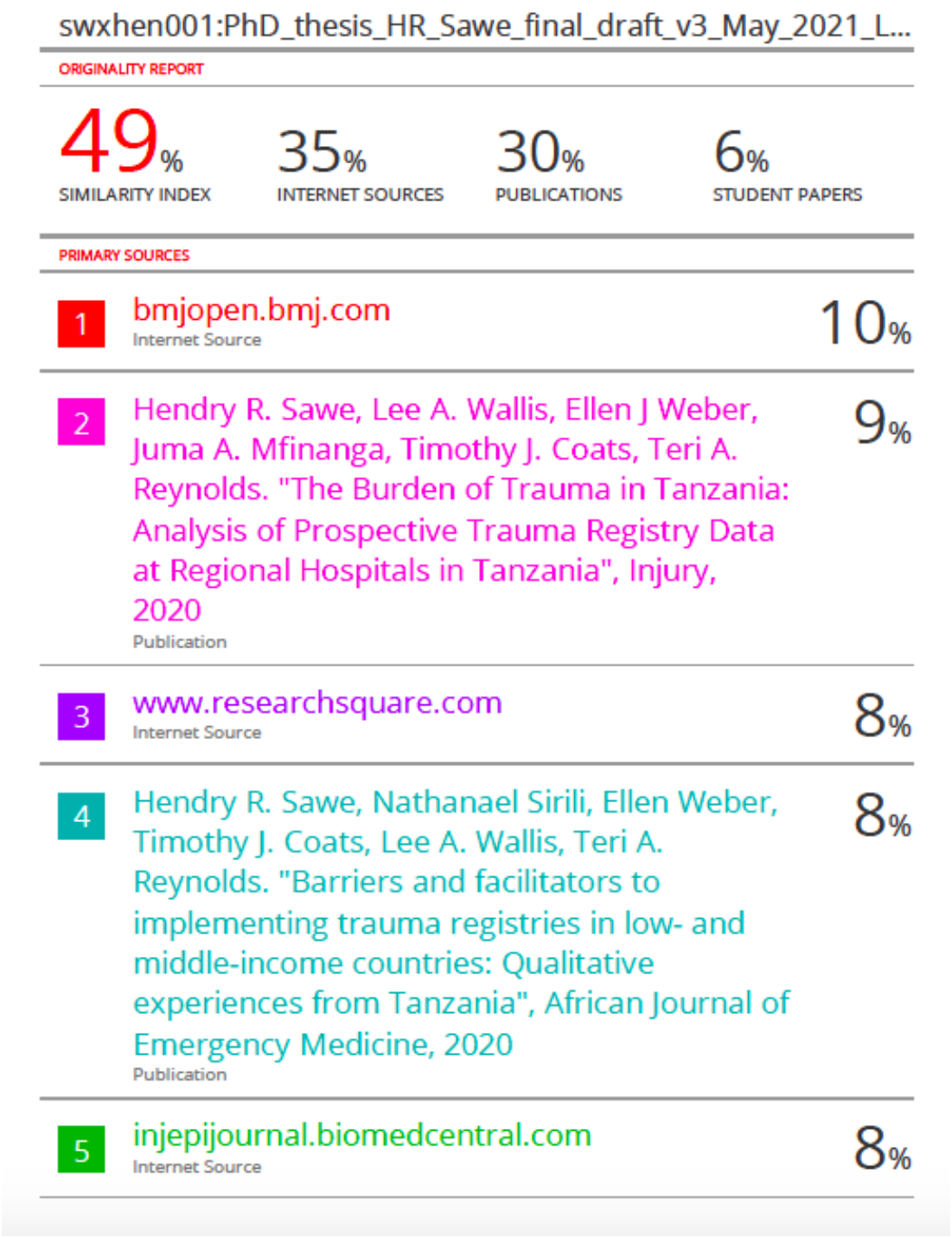
Additional Interventions

Fluid and Medications given at EU	☐ Intravenous Fluid (NS, DNS, RL) ☐ Blood Products ☐ Analgesia ☐ Sedation ☐ Tetanus Toxoid ☐ Antibiotics ☐ Paralytics ☐ Others
Procedures at EU	☐ Chest tube ☐ Splinting ☐ Fracture reduction ☐ Simple/Complex laceration repair ☐ Foreign body removal ☐ Pericardiocentesis ☐ Intubation ☐ Cricothyroidotomy: Open / Needle ☐ Open thoracotomy ☐ Other

REASSESSMENT	
Patient reassessment done at EU	○ Not documented ○ Done ○ Not done
TEMP	_____
SBP	_____
DBP	_____
HR	_____
RR	_____
SPO2	_____
Describe condition after reassessment	○ Same ○ Change ○ Not described
ED Diagnosis-1	_____
ED Diagnosis-2	_____
ED Diagnosis-3	_____
Number of Serious Injuries	○ 0 ○ 1 ○ 2 ○ >2 ○ Not Assessed
ED Disposition	○ Admitted to ward ○ EU Observation ○ Admitted to OT ○ Discharged home ○ Transferred to another facility ○ Died at EU ○ Brought dead ○ DAMA ○ Unknown
Name of the facility transferred to	_____
Date of ED departure documented	○ Yes ○ No

Date of ED departure	_____
Time of ED departure documented	◯ Yes ◯ No
Time of ED departure	_____
24 hours follow up	◯ Alive ◯ Died ◯ Unknown
30 days follow up	◯ Alive ◯ Died ◯ Unknown

Appendix 2.8: Turnitin originality report.



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