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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: We ought to describe the of process of development, structure, implementation and impact of a dual-functions standardized trauma form that incorporates the World Health Organisation (WHO) dataset for injury (DSI), to serve as the basis for a novel national trauma registry in Tanzania.

Settings: Our study was conducted in emergency units (EU) of five regional referral hospitals in Tanzania.

Participants: A mixed methods participatory action research was employed to conduct semi-structured interviews on a purposefully selected sample of 33 health care providers from each hospital to develop and implement the form. We then used a developed form to collect prospective trauma data from all patients presenting with trauma related complaints at each EU over a period of 7 months.

Outcomes: Implementation of standardized trauma form was used to test improvement in clinical documentation and capture rate of WHO variables of DSI.

Results: Piloting and feedback results informed the development of a draft standardised trauma documentation form with 12 sections, printed on a carbonless A3 paper format that could be used as a clinical chart and checklist for patient care. Among 721 patients seen during form's initial 30-day pilot, overall variable capture rate was 86.4%; this improved significantly to 99.7% among 925 patients seen in the second 30-day post-refinement pilot ($P<0.0001$). Providers reported the form was user-friendly, resulted in less time documenting, as well as serving as guide to managing trauma patients. During the 7-month implementation of the finalised form, 6302 patients were seen with 96.3% capture rate.

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

Strengths and limitations of this study

- This participatory action research generated a dual-functions model form for capturing comparable data set for injury variables that may be replicable in other low-resource settings working to develop trauma registries.
- The dual-function model form demonstrated a significant and sustainable improvement in quality of injury care documentation providing data set for injury variables to inform development of comparable regional trauma registries.
- This study was conducted at selected sample of regional level hospitals, which limits the generalisability to the whole healthcare system, as regional level hospitals tend more human and infrastructural resources than lower level facilities.
- There is a possibility that providers demonstrated a significant improvement in capture rate to injury variable due to their awareness of being observed; however, the fact that capture rates remained significantly higher even at seven months, without observation, suggests this was not a major issue.

BACKGROUND

Trauma is responsible for approximately 5.8 million deaths annually, and accounting for 10% of all deaths worldwide (1). Ninety percent of this mortality occurs in low- and middle-income countries (LMICs) (2); these disproportionately high rates of morbidity and mortality are largely due to road traffic crashes, suicide, homicide and war are the main contributors to the from trauma these regions. Evidence from high-income countries (HICs) suggests that improving trauma care systems could substantially reduce trauma-related morbidity and mortality in LMICs. Trauma care systems in most LMICs are underdeveloped and, in places where they exist, high volumes of trauma leave systems under-resourced and over-burdened (3).

Trauma registries (TRs) are critical to both prevention of traumatic injuries, and the development and improvement of trauma care (4). TRs are databases that serve to monitor quality and performance improvements in trauma care and public health interventions aimed at addressing injury prevention in a specified geo-political region (5–7). In most HICs, trauma registries form an integral component of the trauma care system (8).

Trauma registries in LMICs are largely non-existent. In the few hospitals where they do exist, TRs are based on short-term research projects that are not sustainable (9,10), and they are not linked to the national level to inform trauma care quality and injury prevention initiatives on a wider scale (11–13). Tanzania does not have a national TR. The first Tanzanian effort to develop such a registry was at the Muhimbili National Hospital (MNH) in Dar es Salaam (14); however, its success has been limited to MNH. The Ministry of Health (MoH) utilises a purpose designed Health Management Information System (HMIS) register, which gathers specific information on all patients visiting health facilities throughout Tanzania (15). The HMIS documentation is then aggregated by a clerk at each facility and submitted. This system creates an additional burden in time and costs for the physician and hospital, which affects the quality and volume of data reported (16,17). The result has been unreliable and incomplete information for addressing the burden of trauma in Tanzania (16).

To help guide the development of these registries, the WHO has established a dataset for injury (DSI) to guide systematic facility-based data collection on injury that can be centralised and analysed in a trauma registry (18). A 2018 mixed-methods needs assessment conducted in five regional hospitals in Tanzania identified poor availability of requisite data and a very low capture rate (33.6%) of DSI variables in existing documentation methods (19). The study used a first draft of the form to identify potential facilitators, including MoH requirements for accurate burden of disease data, and documentation requirements for insurance reimbursement and police cases. It also highlighted barriers to capture of DSI variables and to potential implementation of a form, including lack of knowledge surrounding DSI variables, poor patient filing systems, high documentation burden, physical and human resource shortages, and variability in expertise and attitudes of providers. Results of this study were motivating, as they suggested vast potential for improvement in trauma data capture and incentives for facilitating such improvements. It is important that challenges were identified, so that they could be factored into development and implementation plans.

To facilitate implementation of a sustainable TR in Tanzania, a contextually appropriate mechanism of collecting relevant data is needed. This study describes the development, piloting and implementation of a low-burden standardised trauma documentation form to generate MoH and DSI information for a national TR.

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 (19,20), with the aim of designing a standardised trauma documentation form that captures both MoH and DSI variables.

The process of development and implementation of a standardised documentation form was guided by Susman and Evereds' cyclic process of inquiry for action research (21) (**Figure 1**). Note that the first two phases of this process ("diagnosis" and "action planning") were previously undertaken during the aforementioned needs assessments (19,22,23). Phase three ("action taking") also began during this needs assessment: a context-appropriate standardised trauma documentation form that incorporated the WHO DSI based on existing trauma documentation forms and needs assessment input was designed (23). Usability of the form was evaluated by clinicians at all EUs, after which semi-structured interviews were used to assess perceptions and attitudes of healthcare providers (HCPs) and other staff surrounding the form and its potential implementation.

In this study, the "action taking" phase was continued, followed by the final two stages of the cyclic process of inquiry for action research ("evaluation" and specifying learning").

Action taking

Drafting a standardised trauma documentation form

Feedback from previous focus group discussions, covering utilisation of the form, and input on the design and variables within the form, was reviewed and incorporated into a final draft of the form (23).

Training of HCPs

In order to ensure sustainability of knowledge about the documentation form beyond the research period, we conducted training in two phases: first, a training-of-trainers (ToT) was conducted with a group of clinicians and nurses from all regional hospitals participating in the study at a central location. The training focused on the basic components of primary trauma care (24), importance of each DSI variable, associated documentation in the standardised trauma documentation form, and how the form links with the WHO metadata that is used to inform the registry. After the ToT, trainers returned to disseminated this information in their respective EUs.

Pilot testing and modification of the form

Pilot testing of the form was a conducted at all participating site for one month in January 2019. The variables collected for each patient were compared with the registry metadata

summary for errors. Form complete rates and accuracy of data were assessed, after which feedback was provided to HCPs and interviews were conducted with to receive feedback on the form. The form was subsequently adjusted to improve efficiency of completion and capture rate of variables.

A more robust training and advocacy strategy was generated. All EUs went on to conduct internal ToTs, and research assistants conducted addition training and advocacy efforts to improve understanding the form's relevance to care and improve support. A second one-month pilot in February 2019 was conducted after these trainings, using the iteratively amended form.

Implementation of the standardised trauma documentation form

The refined standardised trauma documentation form was then launched for a seven-month period at all sites. The form was placed in a large book using A3 originals with carbon-less copy paper; providers would complete the form, with one copy kept in the book and one taken for later quality checks by investigators. Research assistants entered forms into a database via the Research Electronic Data Capture (REDCap) software (© REDCap, San Francisco, CA, USA). These research assistants also trained to provide guidance on use of the form, and were available at all sites to do so. They also observed data collection and documented any clinical care performed by HCPs.

Evaluation

Authors performed a quality check for accuracy of data entry, reviewing at least 25% of randomly selected cases captured at each site during the 7-month period. Research assistant notes on clinical interventions were also reviewed to determine accuracy of capture rates for HCP-performed clinical interventions. Proportion of documented DSI variables during the study period were compared to those captured in during the needs assessment period (when the standardised form did not exist and only existing records were evaluated).

DSI variables were aggregated into five main categories (**Table 1**) to calculate the time series of capture rate from baseline to seven months post-implementation.

Specifying learning

The authors reflected on key lessons on engagement, development and implementation of standardised trauma documentation form.

Patient and Public Involvement

The development of standardized form with injury variables to inform the national trauma registry has been largely in response to the public health need of preventing injury and improving care of the injured through better understanding of evidence based trauma care. Patients and the public were not involved in the design of the study, however the developed form is explicitly oriented towards better and standard care for all patients. The results of our study will be disseminated through open access publications.

RESULTS

Action taking

Training of HCPs

Five clinicians and five nurses, one of each from each regional hospital, participated in the ToT course.

Pilot testing and modification of the standardised trauma documentation form

Total of 721 patients were seen across all EUs during the one-month pilot. Completion and error rates varied across variables when data from the beginning and end of the pilot were compared (**Table 1**). A key DSI variable - mechanism of Injury - was missing in 28% of cases, with a 12.3% error rate compared with HMIS data. There was also evidence of bias in the missing data, as most of the 11.5% of patients who did not have a disposition recorded were in fact discharged.

The draft-standardised form was presented during interviews with 33 stakeholders (**Table 2**) to gather feedback after the implementation period. Some of these suggestions were made based on elements not included in the DSI but critical for the Tanzanian context, including medicolegal datapoints. 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 ass 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 of the to at least text to be of 12-font size.

Using this provider input, we updated the form to its final draft prior to piloting. The pilot form had a total of 12 sections, as described in **Supplementary File 1**.

All EUs went on to conduct internal ToTs, and research assistants conducted addition training and advocacy efforts to improve understanding the form's relevance to care and improve support. During the second pilot period, 925 patients presented to EUs. Overall data completion and error rates and improved significantly across all form categories (**Table 1**).

Evaluation.

During the 7-month implementation phase, 6302 patients were seen among the participating hospitals. The overall capture rate for variables increased to 96.3% from 33.6% observed during the initial needs assessment phase (prior to any form implementation), and all variable

improved significantly (**Table 3**). The overall documentation rate increased from baseline (36.2%) in July 2018, to 99.6% at 30-days post-implementation (February 2019), though later studies indicated that, 7 months post-implementation, this rate had decreased to 96.1%. 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 top three highest rate of change in documentation (**Figure 2**). Age and gender, activity at time of injury and disposition plan were documented in all patients post implementation. Some variables remained below 100% capture rate, including injury intent (8.9% missing), injury anatomical location (7.9%), injury type (7.4%), and interventions in EU (7.3%).

Specifying learning

Key lessons on engagement and future research

The engagement of health care providers and administrators in the process of developing the standardized trauma documentation tool yielded valuable input to modify the tool and allow wide acceptance for clinical utilization, and capture of data (96.1% at 7 months post implementation) to inform injury burden. However, the slight decrease of capture rate of injury variables from 99.6% (at 30-days post-implementation) to 96.1% (7 months post-implementation) provides an opportunity for future follow-up studies to utilising the existing dataset demonstrate factors associated with long-term consistency of the registry.

DISCUSSION

Tanzania has no TR (10), limiting the capacity to correctly define the burden of injury, reduce injury rates, and develop contextually-appropriate strategies to improve care processes. This study generated a model form for capturing DSI variables that may be replicable in other low-resource settings working to develop TRs. The form serves dual functions of improving quality of injury care documentation and providing standardised variables that can inform national TR. Furthermore, inclusion of DSI variables will allow for comparison with other countries.

It is likely that numerous factors led to the successful implementation of the form at five unique EUs. Its development relied on substantial groundwork, including a needs assessment to evaluate baseline capture rates of DSI variables, and evaluation of facilitators and barriers to implementation. The participatory nature of this study was key to form adoption: buy-in from all stakeholders was likely improved by their engagement at all stages of the form's development and implementation. Iterative pilot testing was crucial for refinement, as were feedback interviews.

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' mindsets required strong support from administration, and a willingness

to use its authority and supervision to ensure compliance. So as to ensure the long-term sustainability of the form despite providers rotating in and out of departments, the selected trainers were established EU personnel and EU-based training was developed to be rapidly conducted at the beginning or end of shifts. The variability in providers' training and experience meant training had to be balanced, to ensure all providers understood variables and documented them correctly. Similar to previous observations (25,26), we found most EUs had limited equipment and consumables to support the provision of high quality emergency care. Consequently, 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 the component to indicate that a particular assessment, investigation or intervention was not done, to help distinguishing lack of documentation and performance.

Collectively, these efforts resulted in a standardised trauma documentation form that led in a significant, clinically important increase in the capture rate of DSI variables across five regional hospitals in Tanzania. Given the checklist nature of the form, it is likely that trauma care will also improve, since providers are prompted to conduct and document specific assessments and interventions as they progress through the form.

Providers and administrators at all facilities indicated a strong support for the implementation of a form that will enhance the clinical documentation quality, while not contributing to existing strain to their roles. During planning, we aimed to develop a form that becomes an integral part of the trauma care process. In doing so, it was important to focus on a concern that many HCPs expressed in pre-implementation interviews: that the form would be unsustainable if it was time- or resource-intensive (5,6,11,27). The new form removes the requirement for dual documentation that providers had to endure in reporting each clinical case in HMIS registers (15). Reducing the amount of documentation at facility level has been shown in similar settings to improve compliance, data capture rate, and reduce provider fatigue (28). Most registries use dual documentation systems, which require an additional clerk around the clock to ensure complete capture (11,29,30). To the best of our knowledge, this is the first study that describes utilising this technique of carbonless copies to support and improve capture rate of injury variables in LMICs without dual documentation. Eventually, if such documentation can be done within an electronic record such as a mobile phone app, there would be a simpler way to enter the data into a TR.

Long term consistency of registries is a challenge in most settings (10). In this study, seven months after implementation of the form, capture rates were still very high, though there was a slight decline from the original 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 (some facilities opened dual-entry systems, with multiple triage areas, concurrent to this study). Additional research is necessary to identify best practices for mitigating these issues.

As one of the first locally developed trauma forms to incorporate WHO DSI variables, outcomes were used to inform ongoing refinement of the WHO trauma form.

Limitations

Our study was conducted 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. Further more, there is a possibility that providers in the EU demonstrated a significant improvement in capture rate to injury variable due to their awareness of being observed (31); however, the fact that capture rates remained significantly higher even at seven months, without observation, suggests this was not a major issue.

Conclusion

The development and implementation of a contextually appropriate, standardised trauma documentation form was successful, yielding increased capture rates of injury variables. Though there is no national Tanzanian TR, there is WHO DSI platform that could be used to capture data from our standardised trauma documentation form. This system may facilitate the next step in this process, expansion of the TR across the country. 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.

FIGURE LEGENDS

Figure 1: 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 2. Capture rate of trauma variable categories over seven-month implementation phase of standardised trauma documentation form at five regional hospital EUs in Tanzania.

Supplementary File 1. Standardised trauma documentation form

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.

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

Table 1: Capture rates of DSI variables before and after one-month pilot phase of standardised trauma documentation form at five regional hospital EUs in Tanzania.

	Pilot (N=721)		30 days after Pilot (N=925)	
Variable	**Data completion**	**Errors identified**	**Data completion**	**Errors identified**
Patient Demographics	%	%	%	%
Name of the patient	100	3.3	100	0.1
Age or date of birth	84.9	6.4	97.3	0.0
Gender	84.2	0.0	100.0	0.0
Address of the patient	89.9	11.0	100.0	0.0
Injury Geographical location	95.6	2.4	99.9	0.1
Initial clinical condition				
Referral status	85.6	2.8	99.9	0.4
Date of EU care	91.4	2.5	99.9	0.6
UE arrival mode	83.9	1.1	100.0	0.0
Signs of life	89.2	8.6	99.6	0.3
Time of first vital signs	96.3	7.8	99.8	0.2
Initial Heart rate	93.5	6.1	100.0	0.0
Initial SBP	90.3	6.2	99.6	0.2
Respiratory rate	88.2	5.4	99.8	0.0
Saturation of oxygen	84.2	0.0	99.8	0.0
Initial AVPU	61.3	30.5	99.7	1.9
First provider assessment time	91.4	2.5	99.8	0.2
Details of injury				
Mechanism of injury	72.0	12.3	100.0	0.1
Mass casualty event	82.2	6.5	99.0	1.0
Injury event date	74.5	1.4	99.6	0.9
Injury settings	84.6	16.6	100.0	0.0
Injury intent	84.5	5.4	99.8	0.1
Protective Devices	80.0	13.9	99.7	0.0
Care prior to EU	86.7	0.6	98.7	0.1
Injury Examination				
Type of injury	87.4	3.3	99.2	0.5
Injury anatomical location	79.9	16.2	99.2	0.2
Defined Serious Injuries	90.3	8.5	100.0	0.1
Emergency Unit details				
Interventions done at EU	90.4	6.2	99.6	0.2
Time of EU departure	93.3	7.6	100.0	0.0
EU disposition	88.5	7.4	100.0	0.0

* $p < 0.001$ for the percentage difference of overall completion rate in each main categories during pilot and at 30 days.

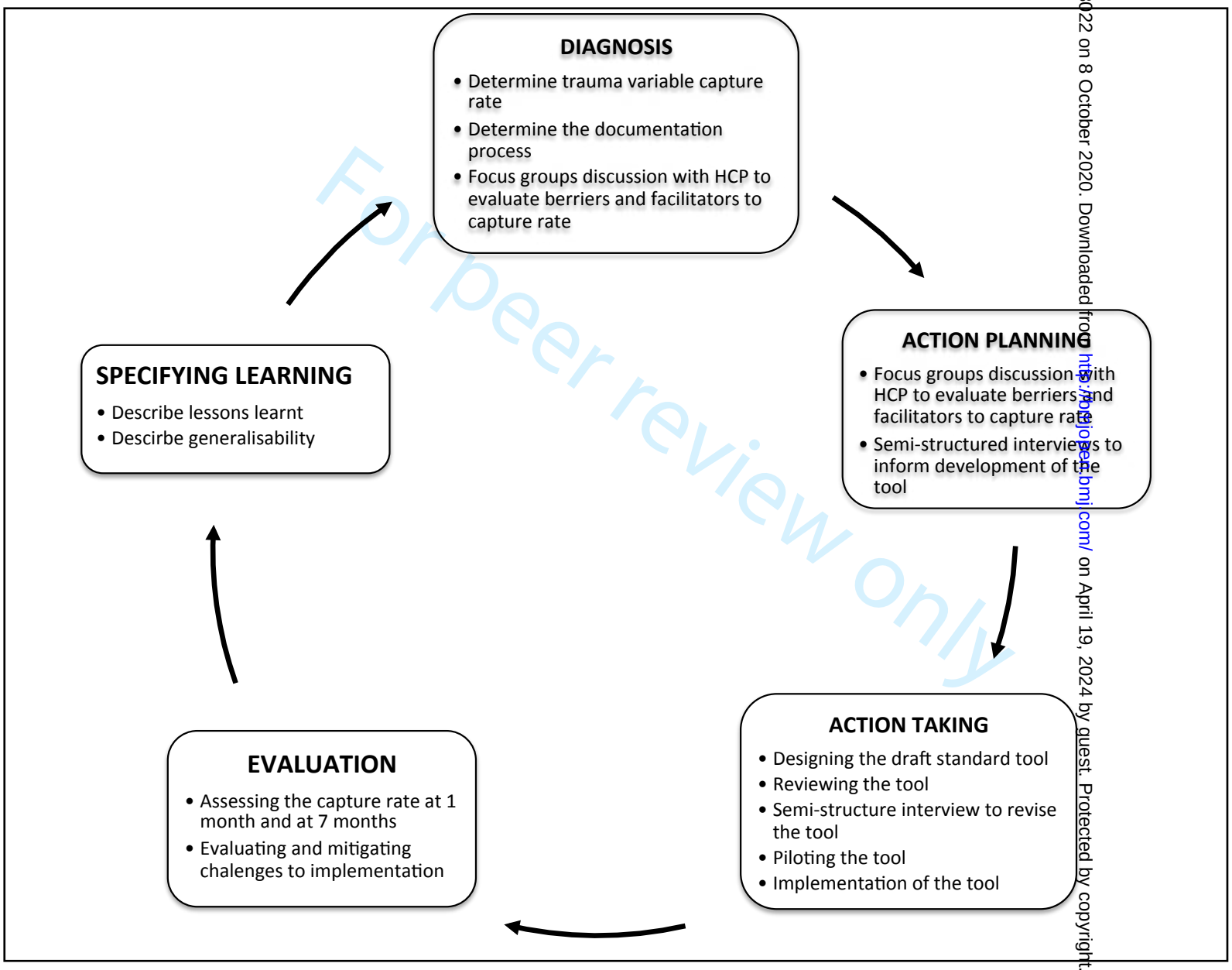
Table 2. Demographics of healthcare workers in semi-structured interviews

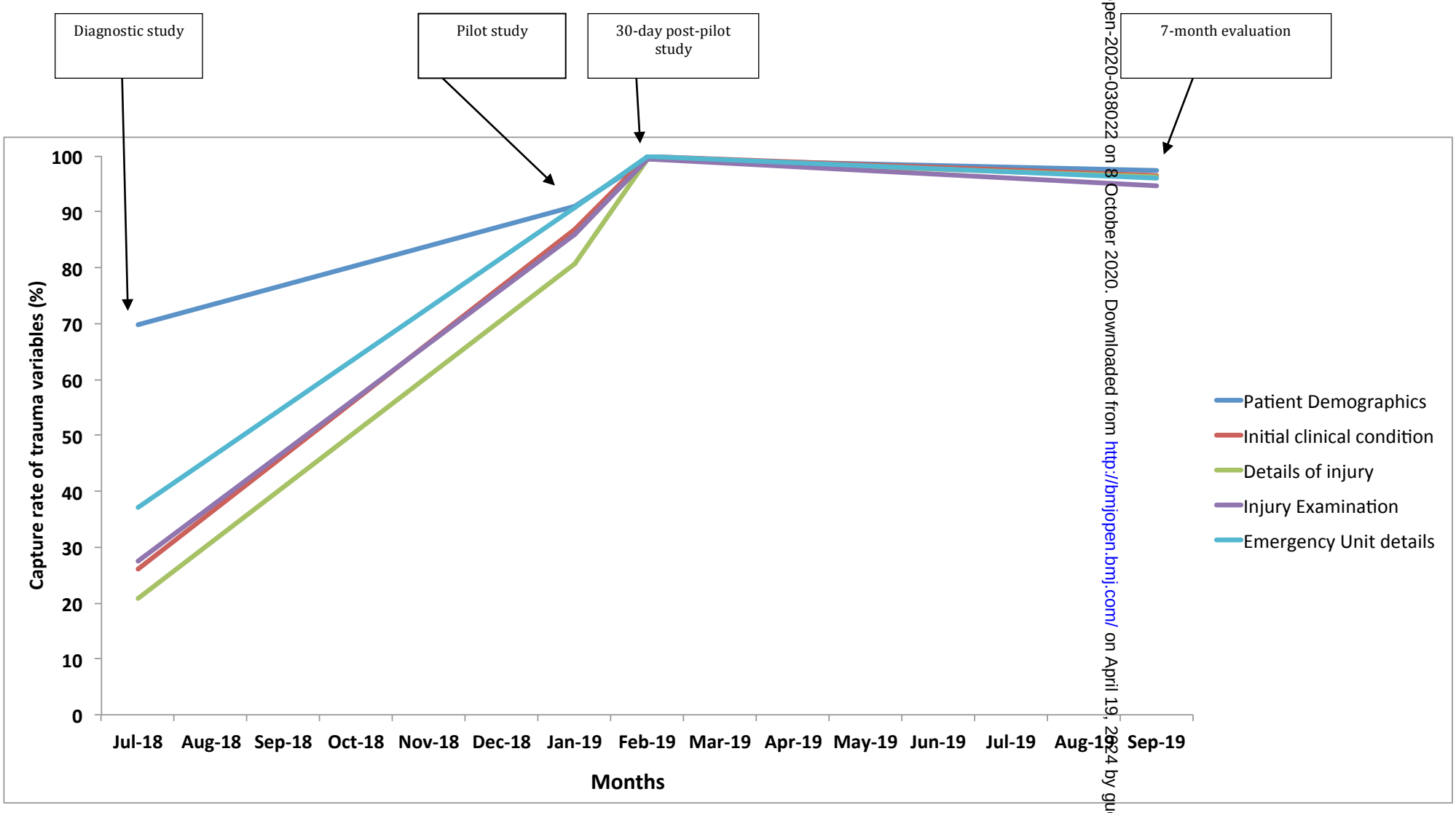
Hospital Role	Interviewed (n, %)
Nurse	6 (18.2)
Medical officer	8 (24.2)
Assistant Medical Officer	5 (15.2)
Clinical Officer	6 (18.2)
Specialist Physicians	
Emergency Specialist Physician	1 (3.0)
Orthopaedic/Trauma Specialist Physician	1 (3,0)
Surgery Specialist Physician	1 (3.0)
Administrator	2 (6.1)
HMIS officer	2 (6.1)
Information and Communications Technology Officer	1 (3.0)

Table 3. Capture rates of DSI variables before and after six-month implementation phase of standardised trauma documentation form at five regional hospital EUs in Tanzania.

Variable	Injury variable capture rate		
	Pre-implementation (N=2891)	Post-implementation (N=6302)	Percentage change*
Patient Demographics	%	%	
Name of the patient	99.3	100	0.7
Age or date of birth	82.0	97.3	15.3
Gender	69.7	99.3	29.6
Address of the patient	83.8	95.4	11.6
Injury Geographical location	14.1	94.5	80.4
Initial clinical condition			0
Referral status	8.3	94.1	85.8
Date of EU care	80.9	99.8	18.9
UE arrival mode	23.6	99.7	76.1
Signs of life	31.2	94.8	63.6
Time of first vital signs	32.2	95.6	63.4
Initial Heart rate	24.5	95.8	71.3
Initial SBP	18.7	97.1	78.4
Respiratory rate	18.0	99.7	81.7
Saturation of oxygen	13.1	98.5	85.4
Initial GCS/AVPU	3.1	92.1	89
First provider assessment time	32.2	94.1	61.9
Details of injury			0
Mechanism of injury	45.0	95.5	50.5
Mass casualty event	0.5	94.5	94
Injury event date	52.2	96.3	44.1
Injury settings	5.3	98.9	93.6
Activity at time of injury	3.3	100	96.7
Injury intent	6.8	91.1	84.3
Protective Devices	32.0	97.3	65.3
Injury Examination			0
Type of injury	72.1	92.6	20.5
Injury anatomical location	9.2	92.1	82.9
Defined Serious Injuries	1.3	99.1	97.8
Emergency Unit details			
Interventions done at EU	33.0	92.7	59.7
Time of EU departure	15.3	95.2	79.9
EU disposition	62.9	100	37.1

* $p < 0.05$ for the percentage change in each category





REGIONAL HOSPITAL TRAUMA FORM

Hospital Registration Number: | Date: DD/MM/YY | Time of Arrival: : AM/PM

Patient Name (Surname, First): | Arrival Mode: □Walk □Non-motorized vehicle □Private vehicle □Motorized 2- or 3-wheeler □Taxi □Public transport □Police □Ambulance □ Aeromedical □Unknown □Other: _____

Occupation:

Date of Birth: DD/MM/YY | Age: _____

Sex: M / F | Weight: kg | INF / CH / AD

prior facilities: ____ Referred from: _____

Patient Residence (at least City and Sub-district): | □Ambulatory Non Ambulatory: □ Acute □ Chronic

Sub-district where injury occurred: | Contact Person: Phone: Relation:

CHIEF COMPLAINT: | **Triage Category:** _____ □ Mass Casualty

INITIAL VS: **Time:** : AM/PM | □ **Dead on arrival**

Temp: _____ **BP:** _____ /_____ **HR:**_____ **RR:**_____ **SpO_2:**_____ **% on**___L

Pain score (on a scale of 1-10, see Reference Card for details): _____

FIRST PROVIDER EXAM:
Date: DD/MM/YY Time: : AM/PM

PRIMARY SURVEY (see Reference Card for normal findings, only mark NML if all key elements are normal):

Airway □ NML
- □ Angioedema □ Stridor □ Voice changes □ Oral/Airway burns
- **Obstructed by**: □ Tongue □ Blood □ Secretions □ Vomit □ Foreign body
- **Airway Manipulation:** □ Repositioning □ Suction
- **Airway:** □ OPA □ NPA □ LMA □ BVM □ ETT
- **Cervical collar:** □None needed □Placed before arrival □Placed in EU (none needed = not altered, no pain or TTP, no distracting injury)

Breathing □ NML
- **Spontaneous Respiration:** □ Yes □ No
- **Chest Rise:** □Shallow □Retractions □Paradoxical
- **Trachea:** □ Midline □Deviated to □L □R
- **Breath Sounds:** Abnormal: □ L_____ □ R_____
- **Oxygen:** _____ L □NC □Mask □NRB □BVM □CPAP/BIPAP □Ventilator
- **Chest needle / tube** (circle): □ L – Size: _____ Depth: _____ cm; □ R – Size: _____ Depth: _____ cm

Circulation □ NML
- **Skin:** □ Warm □ Dry □ Pale □ Cyanotic □ Moist □ Cool
- **Capillary refill:** □ <2 sec □ ≥2 sec
- **Pulses:** □ Weak □ Asymmetric_____
- **JVD:** □ Yes □No
- □ Bleeding controlled (bandage, tourniquet, direct pressure)
- **Access:** □IV: Loc _____ Size _____ □CVL: Loc _____ Size _____ □IO: Loc _____ Size _____
- **□IV:**_____mLs □NS □LR □Other_____
- □Blood ordered □Pelvic binder placed

Disability □ NML
- **Blood glucose**: _____ □Glucose
- **Responsiveness:** □ A □ V □ P □ U □Naloxone
- **GCS**:_____ (E_____ V_____M_____)
- **Moves Extremities:** □ LUE □RUE □LLE □RLE
- **Pupils:** L____mm→____mm R____mm→____mm
- □ Exposed completely

Exposure □ NML

□ Not Indicated

FAST □ NML
- **Peritoneum:** □ Negative □ Indeterminate
- □ Free Fluid: _____
- **Chest:** □ Negative □ Indeterminate
- □ Pneumothorax (R/L): _____
- □ Pleural fluid (R/L): _____
- □ Pericardial effusion

MEDICAL HISTORY

Medications:

Allergies:

Past Medical: □ HTN □ Diabetes □ COPD □ Psychiatric □ Renal Disease Other:

Pregnant: □ Yes □ No
Vaccinations up to date? □Yes □No _____
Substance Use: □Tobacco □Alcohol □ Drugs □ IV Drugs
Last Menstrual Cycle:_____□ N/A **G**___**P**___ □ N/A
Safe at home? _____

Past Surgeries (type & date):

HISTORY OF PRESENT ILLNESS

Date of Injury: DD/MM/YY Time: : AM/PM

Enter exact term from Reference Card for the following:
Place of injury: _____
Prehospital care: _____
Patient's activity of time of injury: _____

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): _____
□Suffocation, choking, hanging
□Drowning: _____ Flotation device: Y / N
□Burn caused by: _____
□Poisoning/Toxic Exposure:_____
□Unknown □Other: _____

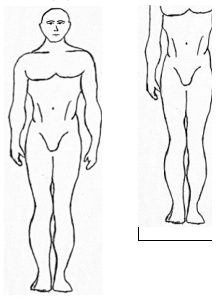
Intent: □ Unintentional or accidental □ Intentional: □Self harm □Assault □ Legal process, political unrest or war □ Unknown
Assaulted by (see Reference Card): _____
Hours since last meal: _____ HR
Substance use within 6 hours of injury:
□ Unknown □ None □ Reported □ Evidence (positive test or clinical findings)
□ Alcohol □ Other Substance (if known): _____

Details of Incident:
□ LOSS OF CONSCIOUSNESS: <5 min/ 5-29 min/ 30-24 hr/ > 24 hr
□ TRAUMA: □ Head □ Neck □ Chest

PHYSICAL EXAM: (See Reference Card for normal findings. Do NOT mark NML unless all key elements are normal.)

□NML	**General**	
□NML	**HEENT**	
□NML	**Neuro**	
□NML	**Neck**	
□NML	**Pulm/Chest**	
□NML	**Cardiac**	
□NML	**Abdominal**	
□NML	**Pelvis**	
□NML	**GU/Rectal**	
□NML	**Back**	
□NML	**MSK/Skin**	

Detail area of injury:



LAB RESULTS:

UPT: □ Positive □Negative
Hgb: _____ □ Result pending
Blood type: _____
Other:

IMAGING RESULTS:

□ Pneumothorax □ Pleural Fluid □ Rib Fracture □ Pulmonary Opacity
□ C-spine fracture □ Extremity Fracture □ Pelvic Fracture
□ Wide mediastinum
□ Other:

ADDITIONAL INTERVENTIONS:

Fluids and Medications Given (include time)
□ IVF:_____mLs □NS □LR □Other
□ Blood products (specify number of units given):
Whole Blood_____ PRBC___
FFP_____ Platelets____
□ Opioid Analgesia:_____
□ Other Analgesia:_____
□ Sedation and Paralytics:_____
□ Antibiotics:_____
□ Tetanus: _____
□ Other:_____

Procedures (include time and outcome)
□ Cricothyroidotomy: Open / Needle_____
□ Intubation: _____
□ Chest Tube: _____
□ Pericardiocentesis: _____
□ Open Thoracotomy: _____
□ Splinting: _____
□ Fracture Reduction/Pelvic Stabilisation: _____
□ Foreign Body Removal:_____
□ Simple / Complex Laceration Repair: _____
□ Other: _____

ASSESSMENT (include summary and differential) **AND PLAN** (imaging, meds/interventions, consults, etc):

Consultants (time called, time arrived, recommendations):

REASSESSMENT at ____:____AM/PM. **Condition:** □ Same □ Changed: _____
Temp HR BP / RR SpO_2: % on L

DISPOSITION Checklist completed: □ Y □ N ED departure (date & time): DD/MM/YY : AM/PM

Diagnoses/Impressions (list all): **Number of serious injuries (circle): 0 1 ≥2**

□ **Admit to:** □ Ward _____ □ ICU □ OT
□ **Discharge** Plan discussed with patient?: □ Yes □ No
□ **Transferred to**: _____ Accepting Provider: _____
□ **Died of** (specify cause-NOT cardiopulmonary arrest): _____
□ **Left without being seen** □ **Left without complete treatment**

Provider	Role	Signature and Date

STROBE checklist for study titled: *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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Funding		10

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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 in 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 standardized trauma form, incorporating the World Health Organisation (WHO) dataset 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 standardized 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 standardized trauma documentation form.

Results: Piloting and feedback informed the development of a standardised trauma documentation paper form with carbonless copy that could be used as both the clinical chart and trauma 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 and training this improved to 99.7% among 925 patients (seen by 23 clinicians) during the first month of the implementation. Providers reported the form was user-friendly, resulted in less time documenting, and served as guide to managing trauma patients. During the entire seven-month implementation of the finalised form, 6302 patients were seen with 96.3% capture rate for DSI.

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 WHO 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 human and infrastructural resources than lower level facilities.
- There is a possibility that providers demonstrated a significant improvement in capture of injury variable due to their awareness of being observed; however, capture remained significantly higher even at seven months, without observation, which suggests this was not a major issue.

BACKGROUND

Trauma is responsible for approximately 5.8 million deaths annually, accounting for 10% of all deaths worldwide [1]. Ninety percent of these deaths occur in low- and middle-income countries (LMICs) [2]. 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 [3].

Trauma registries are critical to both prevention of traumatic injuries, and the development and improvement of trauma care [4]. 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 [5–7].

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 [8]. In the few hospitals where registries exist, they are developed in short-term research projects that are not sustainable [9,10], and they are not linked at a national level, preventing evaluation of the system as a whole [11,12]. 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 [13]; however, its success has been limited to patients seen MNH. 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 [14]. 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. This system creates an additional

burden of entering data into this system in time and costs for the physician and hospital, which affects the quality and volume of data reported [15,16].

To provide guidance on the establishment of trauma registries in LMIC's, the World Health Organisation proposed the Data Set for Injury (DSI), a minimum set of variables needed for a centralised trauma registry [17]. However, we previously identified that capture of these variables, as well as clinical documentation in general, was insufficient. 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 rate (33.6%) of DSI variables using existing documentation methods, as well as potential barriers and facilitators to complete documentation [18,19]. Results of these studies were, oddly, 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 for standardised trauma documentation as the first step in the development of a national trauma registry in our country. The primary aims were to ensure all eligible trauma patients are included and maximizing the capture of variables within the standardized 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) [18].

The process of development and implementation of a system to collect standardised trauma variables was guided by Susman and Evereds' cyclic process of inquiry for action research [20] (**Figure 1**). The first two phases of this process ("diagnosis" and

"action planning") were previously undertaken during the aforementioned needs assessment study, and are briefly described here [18,19,21].

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 [18]. 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 [19]. 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 standardized 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 [21].

Action taking

The "diagnosis and action planning" phases led to the design of context-appropriate standardised trauma documentation form that incorporated the WHO DSI. 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 [21].

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 [22], importance of each DSI variable, associated documentation in the standardised trauma form, 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 trained clinical leads were also used as the key personnel (super-users) supporting day-to-day queries on use of the standardized trauma form at their respective EUs.

Pilot testing and modification of the form

After providers had been trained at all the 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. This form was also built into an online Research Electronic Data Capture (REDCap) software (© REDCap, San Francisco, CA, USA). Data from paper-based forms was entered to REDCap, then 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 proportion and variables entered for each patient was determined using the master list of variables in the REDCap software for comparison. Errors were also recorded. Errors were defined as documenting data that didn't match the variable requested. The principle investigator (a specialist

emergency physician, HS) provided feedback to the providers in the EUs on the results. HS then conducted 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 for based on their involvement in the trauma care process and to maximize the variation in cadres and work experience of the interviewees. Interviews were conducted until no new information was disclosed [23]. 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 the hospital administration instructed the advocacy to be done during clinical meetings to ensure there is 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 at all sites from middle of February 2019 to the end of 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 standardized 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 flagged variables that were missing from the paper form, as well as errors in documentation.

Evaluation

During the seven month implementation period, the Principal Investigator performed a quality check for accuracy of data entry to online REDCap software, reviewing at least 25% of randomly selected cases captured at each site by

comparing the paper-based standardized trauma form variables with the entry in REDCap. After this quality check, data from REDCap system were exported to SPSS and analysed. As in the pilot assessment, the number of completed variables divided by the total number of variables was considered the proportion of variables completed. Then, proportion of documented DSI variables during the study period were compared to the proportion captured in during the initial needs assessment (when the standardised form did not exist and only existing records were evaluated) [18].

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 standardized 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% of the time with no errors), whereas others were poorly documented **(Table 1).**

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. 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 2**), their demographics are discussed elsewhere [21]. These interviews revealed the need to collect additional information critical for the Tanzanian context, and necessary for clinical care, including medicolegal 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 (**Supplementary File 1)**.

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. All EUs went on to conduct additional internal ToTs, and research assistants conducted additional training and advocacy efforts to improve understanding the form's relevance to care and improve support.

Evaluation

The final form was implemented in February 2019. The pre-planned interim analysis 30 days after implementation began included 925 patients seen by 23 clinicians, and found overall data completion and errors improved significantly across all categories (**Table 1**). The overall documentation rate increased from baseline in the diagnostic phase (33.6%) in July 2018 [18], to 99.6% at 30-days post-implementation.

During the entire 7-month implementation phase, 6302 patients were seen among the participating hospitals. Overall 96.3% of variables were completed, a significant improvement from 33.6% observed during the "diagnostic" phase, and improvement was across all categories (**Table 3**). 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 (**Figure 2**). Age and gender, activity at time of injury and disposition plan were documented in all patients post implementation. Some variables remained below 100% capture rate, including injury intent (8.9% missing), injury anatomical location (7.9% missing), injury type (7.4% missing), and interventions in EU (7.3% missing).

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 [10]. This participation 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 [24]. Trauma registries have provided the ability to better

understand sources of injury and patient outcomes, and to make interhospital or regional comparisons that potentially indicate best practices. Trauma registry data in high income countries 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 [25,26]. 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 of all staff and institutional management as to why documentation can impact outcomes [27] 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 five unique EUs. Its development relied on substantial groundwork, including a needs assessment to evaluate baseline capture rates 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 [28]. As one of the first locally developed trauma forms to incorporate WHO DSI variables, the final tool we developed has now been used to inform on-going refinement of the WHO trauma form.

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' mindsets 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 [29,30], 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, to help distinguish lack of documentation from inability to perform the evaluation. .

A key to the sustainability of the form, and support from providers is that it does not contribute to existing strains in their roles [5,6,11,31]. Prior to the development of the tool, providers had to endure dual documentation to report each case in the HMIS register [14]. Reducing the amount of documentation at facility level has been shown in similar settings to improve compliance, data capture rate, and reduce provider fatigue [32]. Most registries use dual documentation systems, which require an additional clerk around the clock to ensure complete capture [11,33], which would not be feasible in our setting. In high-income countries, prior to electronic charts, carbonless copies were frequently used in emergency departments 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 [10]. In this study, seven months after implementation of the form, capture rates 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 was conducted 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. Furthermore, there is a possibility that providers in the EU demonstrated a significant improvement in documentation due to their awareness of being observed [34]; 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.

FIGURE LEGENDS

Figure 1: 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 2. Capture rate of trauma variable categories over seven-month implementation phase of standardised trauma documentation form at five regional hospital EUs in Tanzania.

Supplementary File 1. Standardised trauma documentation form

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.

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

Table 1: Capture of DSI variables before and after one-month pilot phase of standardised trauma documentation form at five regional hospital EUs in Tanzania.

	Pilot (N=721)		30 days after Pilot (N=925)	
Variable	**Data completion**	**Errors identified**	**Data completion**	**Errors identified**
Patient Demographics	%	%	%	%
Name of the patient	100	3.3	100	0.1
Age or date of birth	84.9	6.4	97.3	0.0
Gender	84.2	0.0	100.0	0.0
Address of the patient	89.9	11.0	100.0	0.0
Injury Geographical location	95.6	2.4	99.9	0.1
Initial clinical condition				
Referral status	85.6	2.8	99.9	0.4
Date of EU care	91.4	2.5	99.9	0.6
UE arrival mode	83.9	1.1	100.0	0.0
Signs of life	89.2	8.6	99.6	0.3
Time of first vital signs	96.3	7.8	99.8	0.2
Initial Heart rate	93.5	6.1	100.0	0.0
Initial SBP	90.3	6.2	99.6	0.2
Respiratory rate	88.2	5.4	99.8	0.0
Saturation of oxygen	84.2	0.0	99.8	0.0
Initial AVPU	61.3	30.5	99.7	1.9
First provider assessment time	91.4	2.5	99.8	0.2
Details of injury				
Mechanism of injury	72.0	12.3	100.0	0.1

Mass casualty event	82.2	6.5	99.0	1.0
Injury event date	74.5	1.4	99.6	0.9
Injury settings	84.6	16.6	100.0	0.0
Injury intent	84.5	5.4	99.8	0.1
Protective Devices	80.0	13.9	99.7	0.0
Care prior to EU	86.7	0.6	98.7	0.1
Injury Examination				
Type of injury	87.4	3.3	99.2	0.5
Injury anatomical location	79.9	16.2	99.2	0.2
Defined Serious Injuries	90.3	8.5	100.0	0.1
Emergency Unit details				
Interventions done at EU	90.4	6.2	99.6	0.2
Time of EU departure	93.3	7.6	100.0	0.0
EU disposition	88.5	7.4	100.0	0.0

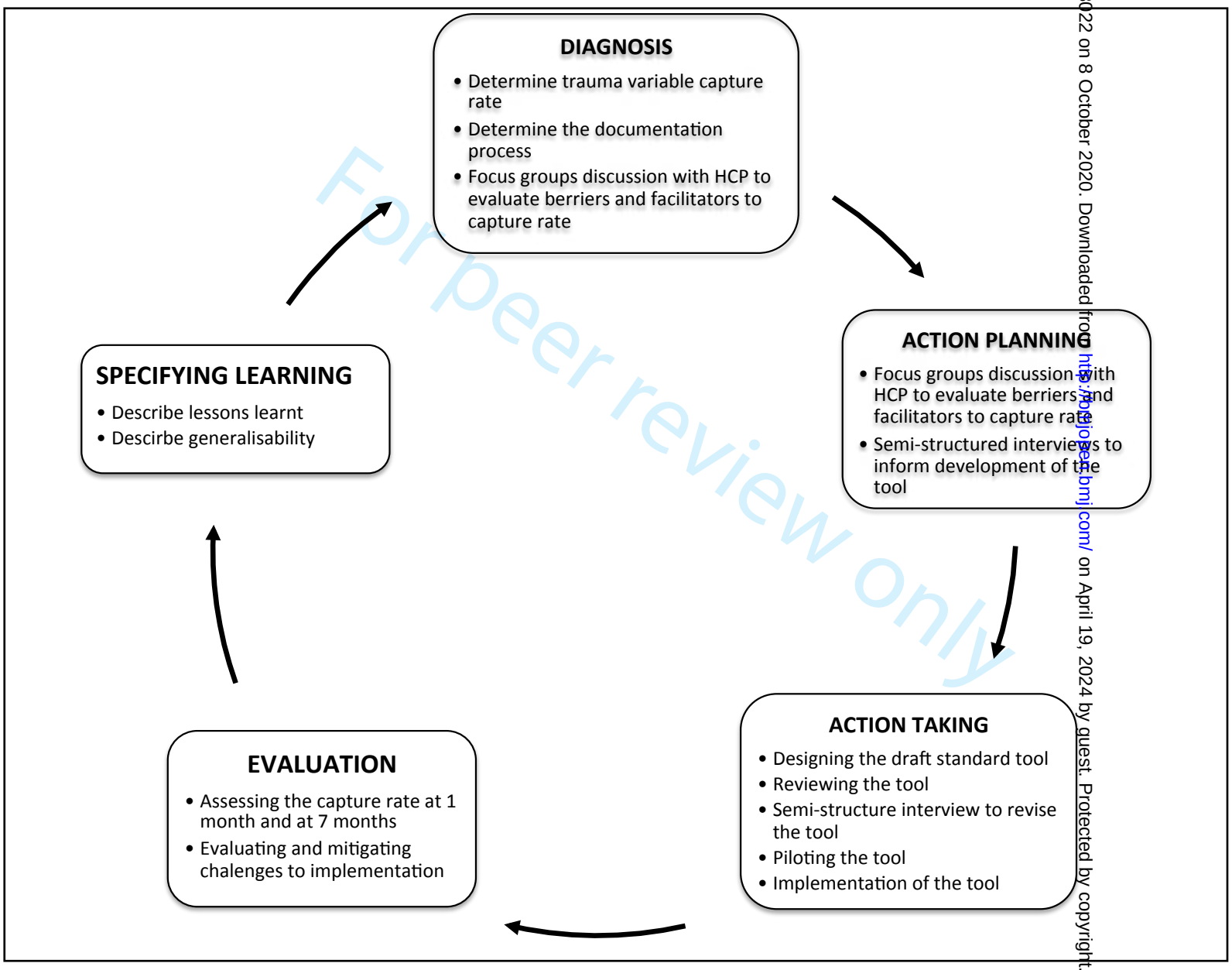
Table 2. Demographics of healthcare workers in semi-structured interviews

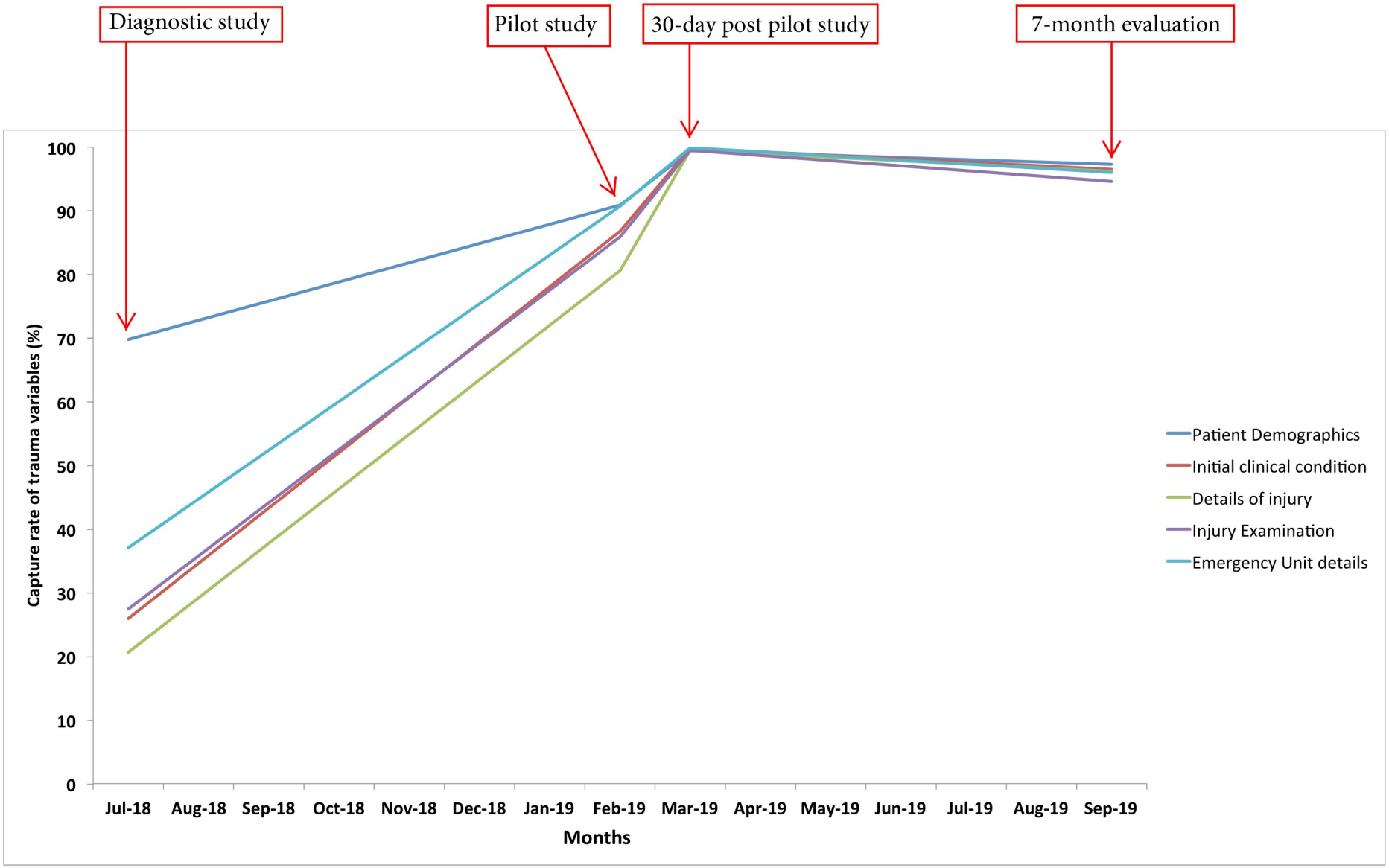
Hospital Role	Interviewed (n, %)
Nurse	6 (18.2)
Medical officer	8 (24.2)
Assistant Medical Officer	5 (15.2)
Clinical Officer	6 (18.2)
Specialist Physicians	
Emergency Specialist Physician	1 (3.0)
Orthopaedic/Trauma Specialist Physician	1 (3,0)
Surgery Specialist Physician	1 (3.0)
Administrator	2 (6.1)
HMIS officer	2 (6.1)
Information and Communications Technology Officer	1 (3.0)

Table 3. Capture rates of DSI variables before and after seven-month implementation phase of standardised trauma documentation form at five regional hospital EUs in Tanzania.

Variable	Injury variable capture rate		
	Pre-implementation (N=2891)	Post-implementation (N=6302)	Percentage change*
Patient Demographics	%	%	
Name of the patient	99.3	100	0.7
Age or date of birth	82.0	97.3	15.3
Gender	69.7	99.3	29.6
Address of the patient	83.8	95.4	11.6
Injury Geographical location	14.1	94.5	80.4
Initial clinical condition			
Referral status	8.3	94.1	85.8
Date of EU care	80.9	99.8	18.9
UE arrival mode	23.6	99.7	76.1
Signs of life	31.2	94.8	63.6
Time of first vital signs	32.2	95.6	63.4
Initial Heart rate	24.5	95.8	71.3

Initial SBP	18.7	97.1	78.4
Respiratory rate	18.0	99.7	81.7
Saturation of oxygen	13.1	98.5	85.4
Initial GCS/AVPU	3.1	92.1	89
First provider assessment time	32.2	94.1	61.9
Details of injury			
Mechanism of injury	45.0	95.5	50.5
Mass casualty event	0.5	94.5	94
Injury event date	52.2	96.3	44.1
Injury settings	5.3	98.9	93.6
Activity at time of injury	3.3	100	96.7
Injury intent	6.8	91.1	84.3
Protective Devices	32.0	97.3	65.3
Injury Examination			
Type of injury	72.1	92.6	20.5
Injury anatomical location	9.2	92.1	82.9
Defined Serious Injuries	1.3	99.1	97.8
Emergency Unit details			
Interventions done at EU	33.0	92.7	59.7
Time of EU departure	15.3	95.2	79.9
EU disposition	62.9	100	37.1





REGIONAL HOSPITAL TRAUMA FORM

Hospital Registration Number: | Date: DD/MM/YY | Time of Arrival: : AM/PM

Patient Name (Surname, First): | Arrival Mode: □Walk □Non-motorized vehicle □Private vehicle □Motorized 2- or 3-wheeler □Taxi □Public transport □Police □Ambulance □ Aeromedical □Unknown □Other: _____

Occupation:

Date of Birth: DD/MM/YY | Age: _____

Sex: M / F | Weight: kg | INF / CH / AD

prior facilities: ____ Referred from: _____

Patient Residence (at least City and Sub-district): | □Ambulatory Non Ambulatory: □ Acute □ Chronic

Sub-district where injury occurred: | Contact Person: Phone: Relation:

CHIEF COMPLAINT:

Triage Category: _____ □ Mass Casualty

INITIAL VS: **Time:** : AM/PM

□ **Dead on arrival**

Temp: _____ **BP:** _____ /_____ **HR:**_____ **RR:**_____ **SpO_2:**_____ **% on**___L

Pain score (on a scale of 1-10, see Reference Card for details): _____

FIRST PROVIDER EXAM:
Date: DD/MM/YY Time: : AM/PM

PRIMARY SURVEY (see Reference Card for normal findings, only mark NML if all key elements are normal):

Airway □ NML
- □ Angioedema □ Stridor □ Voice changes □ Oral/Airway burns
- **Obstructed by**: □ Tongue □ Blood □ Secretions □ Vomit □ Foreign body
- **Airway Manipulation:** □ Repositioning □ Suction
- **Airway:** □ OPA □ NPA □ LMA □ BVM □ ETT
- **Cervical collar:** □None needed □Placed before arrival □Placed in EU (none needed = not altered, no pain or TTP, no distracting injury)

Breathing □ NML
- **Spontaneous Respiration:** □ Yes □ No
- **Chest Rise:** □Shallow □Retractions □Paradoxical
- **Trachea:** □ Midline □Deviated to □L □R
- **Breath Sounds:** Abnormal: □ L_____ □ R_____
- **Oxygen:** _____ L □NC □Mask □NRB □BVM □CPAP/BIPAP □Ventilator
- **Chest needle / tube** (circle): □ L – Size: _____ Depth: _____ cm; □ R – Size: _____ Depth: _____ cm

Circulation □ NML
- **Skin:** □ Warm □ Dry □ Pale □ Cyanotic □ Moist □ Cool
- **Capillary refill:** □ <2 sec □ ≥2 sec
- **Pulses:** □ Weak □ Asymmetric_____
- **JVD:** □ Yes □No
- □ Bleeding controlled (bandage, tourniquet, direct pressure)
- **Access:** □IV: Loc _____ Size _____ □CVL: Loc _____ Size _____ □IO: Loc _____ Size _____
- **□IV:**_____mLs □NS □LR □Other_____
- □Blood ordered □Pelvic binder placed

Disability □ NML
- **Blood glucose**: _____ □Glucose
- **Responsiveness:** □ A □ V □ P □ U □Naloxone
- **GCS**:_____ (E_____ V_____M_____)
- **Moves Extremities:** □ LUE □RUE □LLE □RLE
- **Pupils:** L____mm→____mm R____mm→____mm
- □ Exposed completely

Exposure □ NML

□ Not Indicated

FAST □ NML
- **Peritoneum:** □ Negative □ Indeterminate
- □ Free Fluid: _____
- **Chest:** □ Negative □ Indeterminate
- □ Pneumothorax (R/L): _____
- □ Pleural fluid (R/L): _____
- □ Pericardial effusion

MEDICAL HISTORY

Medications:

Allergies:

Past Medical: □ HTN □ Diabetes □ COPD □ Psychiatric □ Renal Disease
Other:

Pregnant: □ Yes □ No
Vaccinations up to date? □Yes □No _____
Substance Use: □Tobacco □Alcohol □ Drugs □ IV Drugs
Last Menstrual Cycle:_____□ N/A **G**___**P**___ □ N/A
Safe at home? _____

Past Surgeries (type & date):

HISTORY OF PRESENT ILLNESS

Date of Injury: DD/MM/YY Time: : AM/PM

Enter exact term from Reference Card for the following:
Place of injury: _____

Prehospital care: _____
Patient's activity of time of injury: _____

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): _____
□Suffocation, choking, hanging
□Drowning: _____ Flotation device: Y / N
□Burn caused by: _____
□Poisoning/Toxic Exposure:_____
□Unknown □Other: _____

Intent: □ Unintentional or accidental □ Intentional: □Self harm □Assault □ Legal process, political unrest or war □ Unknown
Assaulted by (see Reference Card): _____

Hours since last meal: _____ HR

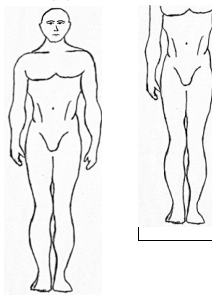
Substance use within 6 hours of injury:
□ Unknown □ None □ Reported □ Evidence (positive test or clinical findings)
□ Alcohol □ Other Substance (if known): _____

Details of Incident:
□ LOSS OF CONSCIOUSNESS: <5 min/ 5-29 min/ 30-24 hr/ > 24 hr
□ TRAUMA: □ Head □ Neck □ Chest

PHYSICAL EXAM: (See Reference Card for normal findings. Do NOT mark NML unless all key elements are normal.)

□NML	**General**	
□NML	**HEENT**	
□NML	**Neuro**	
□NML	**Neck**	
□NML	**Pulm/Chest**	
□NML	**Cardiac**	
□NML	**Abdominal**	
□NML	**Pelvis**	
□NML	**GU/Rectal**	
□NML	**Back**	
□NML	**MSK/Skin**	

Detail area of injury:



LAB RESULTS:

UPT: □ Positive □Negative
Hgb: _____ □ Result pending
Blood type: _____
Other:

IMAGING RESULTS:

□ Pneumothorax □ Pleural Fluid □ Rib Fracture □ Pulmonary Opacity
□ C-spine fracture □ Extremity Fracture □ Pelvic Fracture
□ Wide mediastinum
□ Other:

ADDITIONAL INTERVENTIONS:

Fluids and Medications Given (include time)
□ IVF:_____mLs □NS □LR □Other
□ Blood products (specify number of units given):
Whole Blood_____ PRBC___
FFP_____ Platelets____
□ Opioid Analgesia:_____
□ Other Analgesia:_____
□ Sedation and Paralytics:_____
□ Antibiotics:_____
□ Tetanus: _____
□ Other:_____

Procedures (include time and outcome)
□ Cricothyroidotomy: Open / Needle_____
□ Intubation: _____
□ Chest Tube: _____
□ Pericardiocentesis: _____
□ Open Thoracotomy: _____
□ Splinting: _____
□ Fracture Reduction/Pelvic Stabilisation: _____
□ Foreign Body Removal:_____
□ Simple / Complex Laceration Repair: _____
□ Other: _____

ASSESSMENT (include summary and differential) **AND PLAN** (imaging, meds/interventions, consults, etc):

Consultants (time called, time arrived, recommendations):

REASSESSMENT at ____:____AM/PM.
Temp HR BP / RR SpO_2: % on L
Condition: □ Same □ Changed: _____

DISPOSITION Checklist completed: □ Y □ N ED departure (date & time): DD/MM/YY : AM/PM

Diagnoses/Impressions (list all):

Number of serious injuries (circle): 0 1 ≥2

□ **Admit to:** □ Ward _____ □ ICU □ OT
□ **Discharge** Plan discussed with patient?: □ Yes □ No
□ **Transferred to**: _____ Accepting Provider: _____
□ **Died of** (specify cause-NOT cardiopulmonary arrest): _____
□ **Left without being seen** □ **Left without complete treatment**

Provider	Role	Signature and Date

STROBE checklist for study titled: *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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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 standardized trauma form based on the adaptation of the World Health Organisation 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 standardized 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 standardized 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 Organisation 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 [1]. Ninety percent of these deaths occur in low- and middle-income countries (LMICs) [2]. 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 [3].

Trauma registries are critical to both prevention of traumatic injuries, and the development and improvement of trauma care [4]. 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 [5–7].

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 [8]. In the few hospitals where registries exist, they are developed in short-term research projects that are not sustainable [9,10], and they are not linked at a national level, preventing evaluation of the system as a whole [11,12]. 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 [13]; however thus far these efforts have been limited to MNH. These experiences have since informed the development of World Health Organisation (WHO) clinical form[14]. 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 [15]. 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 [16,17].

To provide guidance on the establishment of trauma registries in LMIC's, the World Health Organisation proposed the Data Set for Injury (DSI)[18], a minimum set of variables needed for a centralised trauma registry as well as a standardized clinical form for trauma patients[14]. 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 [19,20]. 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 standardized 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) [19].

The process of development and implementation of a system to collect standardised trauma variables was guided by Susman and Evereds' cyclic process of inquiry for

action research [21] (**Figure 1**). The first two phases of this process ("diagnosis" and "action planning") were previously undertaken during the aforementioned needs assessment studies [19,20,22], 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 [19]. 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 [20]. 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 standardized 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 [22].

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 [14]. 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 [22].

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 [23], 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 invoved filling out the proposed standardized 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 standardized 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 [19], 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 standardized 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 entred 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 troube-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) [19]. 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 standardized 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 1).** 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 2).** 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 3**), their

demographics are discussed elsewhere [22]. These interviews revealed the need to collect additional information critical for the Tanzanian context, and necessary for clinical care, including medicolegal 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 (**Supplementary File 1)**.

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 substatially across all categories (**Figure 2**). The overall documentation increased from baseline in the diagnostic phase (33.6%) in July 2018 [19], 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 1**). 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 1**). 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 1**). 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 [10]. 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 [24]. 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 high income countries 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 [25,26]. 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 [27] 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 [28]. 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[29] 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' mindsets 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 [30,31], 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 brough to EU by good samaritan, or police from the scene of injury [32]. 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 [5,6,11,33]. Prior to the development of the tool, providers had to endure dual documentation to report each case in the HMIS register [15]. Reducing the amount of documentation at facility level has been shown in similar settings to improve compliance, data capture, and reduce provider fatigue [34]. Most registries use dual documentation systems, which require an additional clerk around the clock to ensure complete capture [11,35], which would not be feasible in our setting. In high-income countries, prior to electronic charts, carbonless copies were frequently used in emergency departments 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 [10]. 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-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-reater 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 varibles 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 perfomed 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 [36]; 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.

FIGURE LEGENDS

Figure 1: 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 2. Capture of trauma variable categories over seven-month implementation phase of standardised trauma documentation form

Supplementary File 1. Standardised trauma documentation form

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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Table 1. 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 2. 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

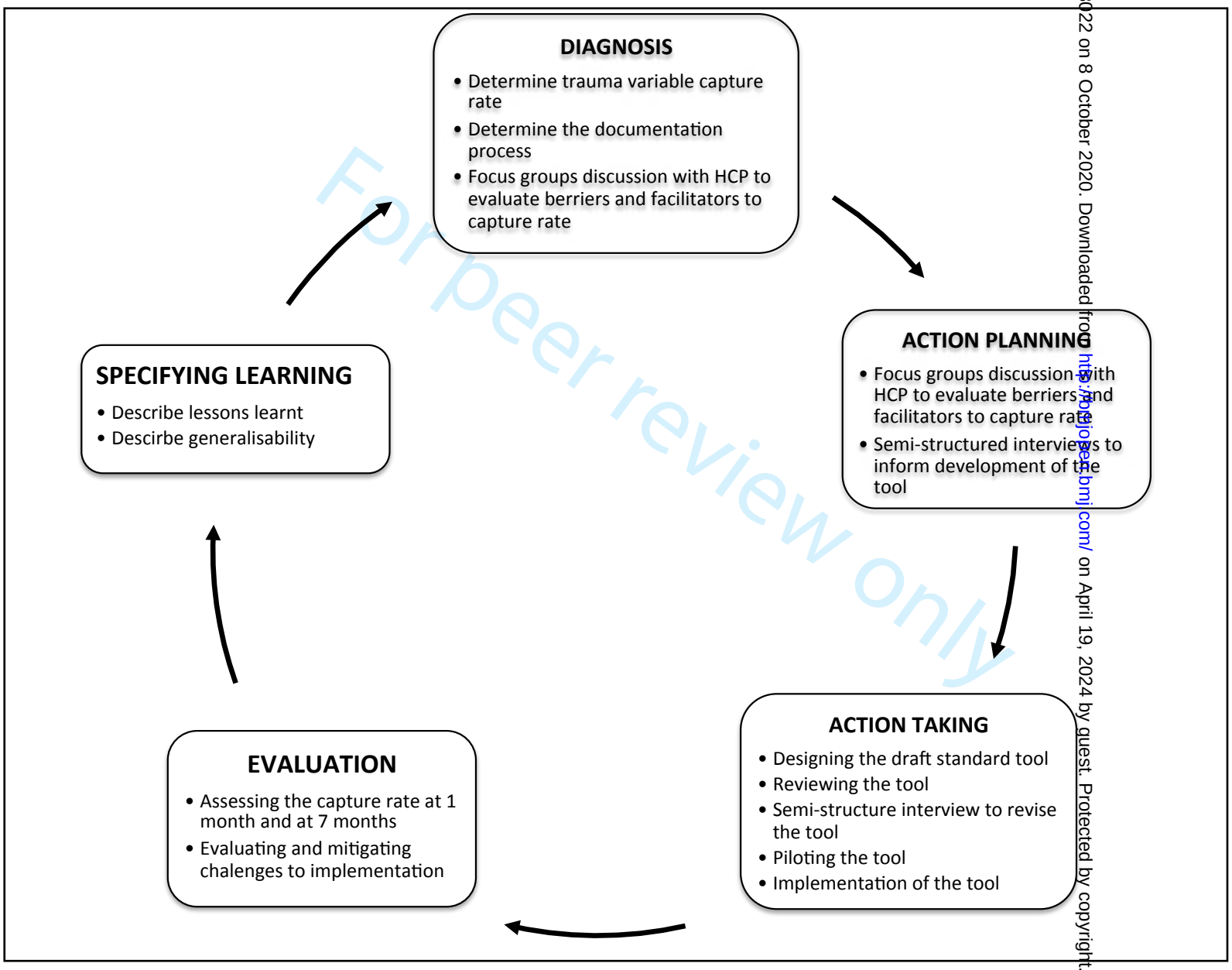
Initial clinical condition				
Referral status	617	2.8	924	0.4
Date of EU care	659	2.5	924	0.6
UE arrival mode	605	1.1	925	0.0
Signs of life	643	8.6	921	0.3
Time of first vital signs	694	7.8	923	0.2
Initial Heart rate	674	6.1	925	0.0
Initial SBP	651	6.2	921	0.2
Respiratory rate	636	5.4	923	0.0
Saturation 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

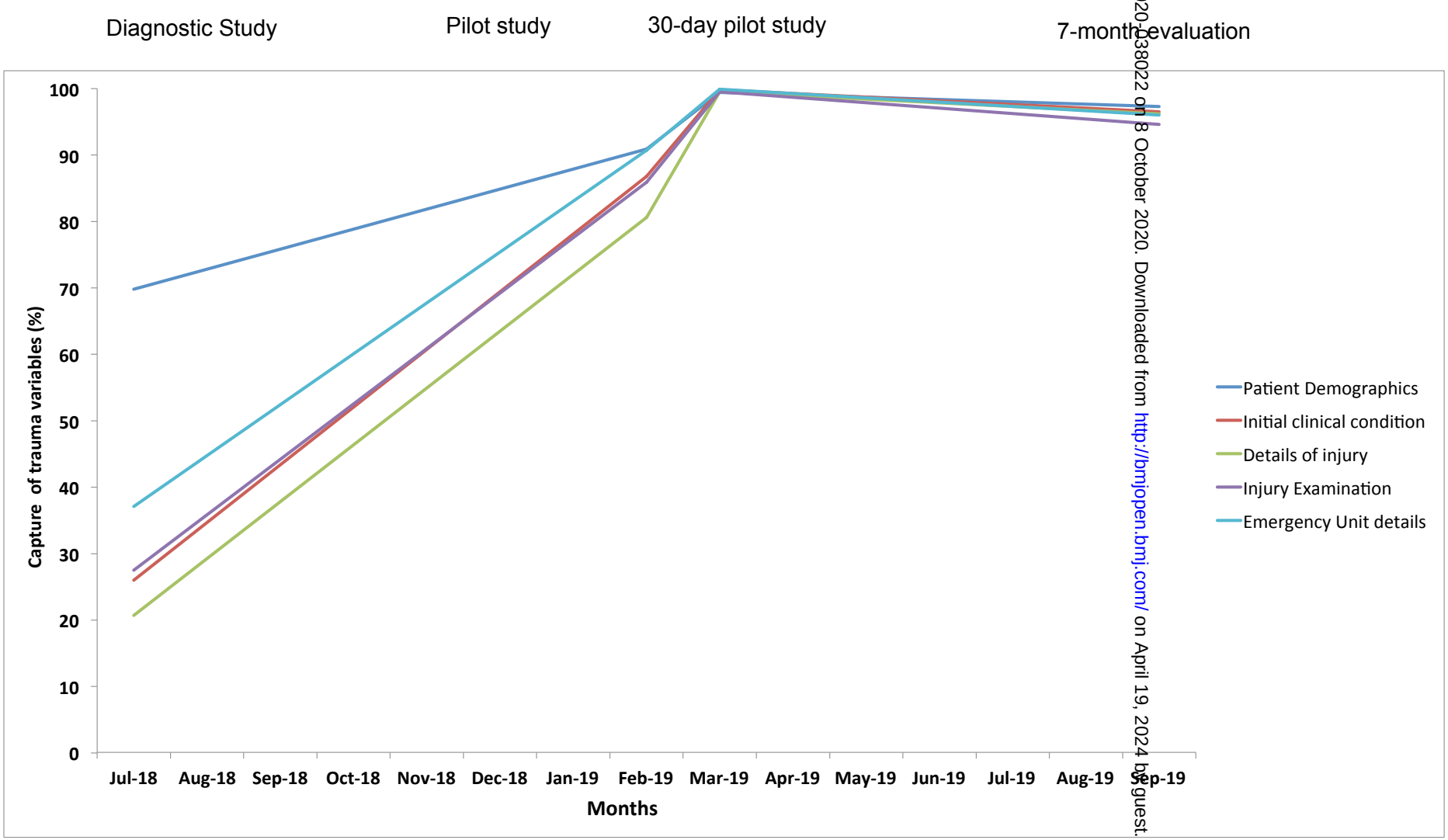
** During the first 30 days post implementation*

Table 3. 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)





REGIONAL REFERRAL HOSPITAL CASUALTY TRAUMA FORM

□ Mass Casualty

Hospital Registraon Number:

Date: / /

Time of Arrival: __ __ :__ __ (24h)

Paent Surname:_____

First Name:_____

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

Date of Birth: / /

Age: _____

INFANT / CHILD / ADULT

Sex: M / F

Weight: _____ kg

□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:_____ºC**

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

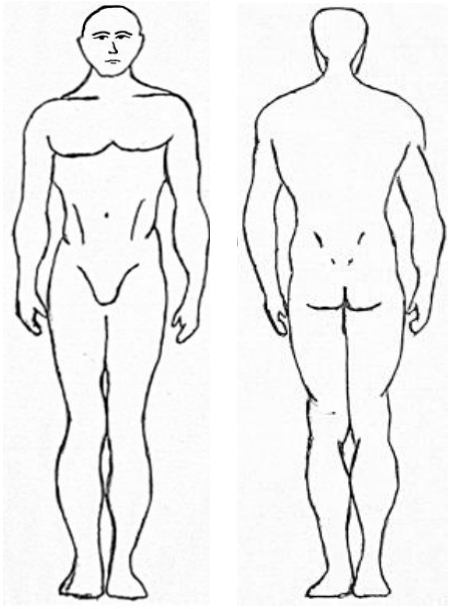
History of: □ Hypertension □ Diabetes □ COPD □ HIV
□Other:_____□None □Unknown
Current Medications:_____□None □Unknown
Past Surgeries: _____□None □Unknown
Any Known Allergies:_____□None □Unknown

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

STROBE checklist for study titled: *Development and Pilot Implementation of a Standardised Trauma Documentation Form to Inform a National Trauma Registry in a Low-Resource Setting: Lessons from Tanzania*

Item	Item No	Recommendation	Page No
Title and abstract	1	a) Indicate the study's design with a commonly used term in the title or the abstract	1
		b) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any pre-specified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	Give the eligibility criteria, and the sources and methods of selection of participants	5
Variables	7	Clearly define all outcomes of the study	8
Data sources/measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8

Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	*(a)* Describe all statistical methods, including those used to control for confounding *(b) Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	8
Results			
Participants	13	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7-8
Descriptive data	14	(a) Give characteristics of study participants (e.g demographic, clinical, social) and information on exposures and potential confounders	7-8
Outcome data	15	*Cross-sectional study*—Report numbers of outcome events or summary measures	7-8
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for	8-10

		and why they were included	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding		Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13