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Exploring the long-term disability outcomes in Trauma patients: study protocol

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Abstract

Objectives Trauma registries are essential tools for improving trauma care quality and efficiency, but many fail to capture long-term patient-reported outcome measures (PROMs). Focusing on these outcomes is crucial for understanding the extent of disability patients experience and identifying potential post-discharge interventions to optimize recovery. Studies reflecting the experience from low- and middle-income countries in this area are limited. Therefore, we aim to develop a digital trauma registry in Pakistan to prospectively capture patient-reported outcome measures at one, three, six, and twelve months post-injury.

Methods We will develop and implement a digital trauma registry at two tertiary care facilities in Karachi, Pakistan: Aga Khan University Hospital and Jinnah Postgraduate Medical Center. The registry will include all admitted adult trauma patients (≥ 18 years). Data collection will be conducted digitally using tablets, with mortality, level of disability, functional status, and quality of life as primary outcomes. Follow-up data will be collected through telephone interviews with patients and caregivers. We will employ descriptive statistics to summarize participant's socio-demographic and clinical characteristics. Additionally, we will perform survival analysis using Kaplan-Meier curves and Cox proportional hazard models and utilize mixed-effects linear regression to adjust for potential confounders for primary outcomes.

Discussion The trauma registry will fill the current gap in knowledge regarding long-term outcomes among trauma patients in low- and middle-income countries (LMICs). This study will delineate future direction for capturing post-discharge data, enhancing our understanding of recovery, and informing the design of interventions aimed at improving long-term outcomes.

Keywords Patient reported outcome measures, Digital Trauma registries, Disabilities, Low- and middle- income countries

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Text box 1. Contributions to the literature

- The majority of injuries occur in LMICS. There is growing data on the mortality and short-term outcomes of injuries yet little is known about the long-term outcomes.
- Information about the level of post-injury disability is necessary to optimize post-hospital injury care and rehabilitation services.
- This study is among the few that address this knowledge gap and determine the patient-reported long-term outcomes.

Introduction

Trauma is a global public health concern [1]. Worldwide, injuries claim 4.4 million lives annually, comprising 3.16 million unintentional deaths and 1.25 million violence-related deaths [1]. Globally, injuries contribute to 8% of all deaths, are leading cause of death among youth, and account for 8% of the total years lived with disability [2]. According to the Global Status Report on Road Safety (GSRRS) 2023, approximately 1.19 million people die yearly from road traffic injuries worldwide, with 92% of these deaths occurring in low- and middle-income countries (LMICs) [3].

Trauma registries provide data essential for improving the quality and efficiency of trauma care. However, most registries are limited by a lack of long-term outcomes, such as survival rates, functional status, and disability levels. With improvement in trauma care in high-income countries, patient survival rates have increased, resulting in higher number of victims living with the long-term effects of their injuries [4, 5]. Unfortunately, little is known about the post-discharge outcomes of these survivors in LMICs. Understanding patients' levels of disability and identifying potential improvements in post-discharge care to maximize recovery necessitates a focus on long-term outcomes. However, longitudinal patient tracking is both challenging and resource-intensive [6].

Pakistan is situated in the WHO Eastern Mediterranean Region (EMRO), which faces a substantial injury burden. The WHO estimated 27,568 road traffic deaths in Pakistan (11.9 per 100,000 people) in 2021 [7]. Trauma registries have been piloted and implemented at various levels in Pakistan highlighting the burden, demographics, epidemiology and associated factors [8–10]. However, none of these registries have focused on long-term patient-reported outcomes. Determining these outcomes could bridge a significant knowledge gap, better inform clinical decision-making, and enhance quality improvement efforts. Currently, this crucial information is not available in Pakistan. This study aims to develop a digital trauma registry to prospectively capture patient-reported disability outcome measures (PROMs) at one-, three-, six- and twelve months post-injury in Pakistan.

Methods

Study design and setting

We will use a prospective cohort study design. Pakistan is the fifth most populated country in the world, with a population of around 240 million [11]. Karachi ranks as the twelfth most populous city worldwide [12]. The registry will be established in two large tertiary care teaching hospitals in Karachi, Pakistan: the Aga Khan University Hospital (AKUH), a fee-for-service private institution, and Jinnah Postgraduate Medical Centre (JPMC), a government supported facility. AKUH has 760 beds, while JPMC has 2,000 beds. Both hospitals serve a broad catchment area, encompassing Karachi, parts of Sindh and Baluchistan provinces. Both hospitals maintain dedicated emergency departments (ED), have full time attendings/residents in emergency medicine and accept trauma patients. JPMC's ED receives over 300,000 patients annually while AKUH's ED receives over 80,000. Besides emergency physicians, each institution is staffed with general surgeons, anesthesiologists, orthopedic surgeons, and neurosurgeons. Both have developed protocols for managing acute emergencies.

Planning, needs assessment and stakeholder engagement

We conducted an initial needs assessment to determine the current situation of injury data collection, defined specific data points to be collected, identified challenges/barriers in setting up the trauma registry, and identified solutions to overcome these challenges. Next, we identified and engaged key stakeholders, including hospital leadership, administrators, departments, and clinicians, to get their buy-in on the project.

The registry

We developed a digital trauma registry to assess short, medium, and long-term disability outcomes. We will recruit the admitted in-patients in person and, once enrolled, will administer the in-hospital trauma registry questionnaire. The data will be collected six days a week, from 9 a.m.-5:30 p.m. In addition, we will follow up with patients telephonically at one, three, six- and twelve months post-discharge.

The development of trauma registry questionnaire

The study team developed, refined, and finalized the trauma registry questionnaire. We primarily used the Collector Trauma Registry as a guideline to develop the in-hospital registry questionnaire. We added few variables (e.g., ethnicity, occupation) to better understand our population. We refined the questionnaire using multiple rounds of discussions with national and international experts (emergency medicine physicians, trauma surgeons, and public health experts). The experts gave input on selecting variables, sequencing, language, and

outcome measures. Based on the expert's feedback, outcomes, such as septic complications and duration of stay, were added. We pretested the questionnaire on twenty eligible trauma patients in AKUH. We assessed the individual questions and the overall design of the questionnaire. We identified the necessary changes in sequencing and language and updated the questionnaire. Finally, the modified questionnaire was again administered to a few more patients. The registry is simple, with clear and standardized fields, and uses drop-down menus to minimize errors. The complete set of variables in the in-hospital trauma registry questionnaire is shown in Table 1. (Insert Table 1 here).

Outcome measures

The outcome measures are discharge outcomes, in-hospital and post-discharge mortality, duration of stay, septic complications, functional status, quality of life (QoL), and post-traumatic stress disorder (PTSD).

We used the following questionnaires to record patient reported outcomes for functional limitations, quality of life, and PTSD at one, three, six-, and twelve-months post discharge follow-ups. The questionnaires were translated into Urdu and later back-translated into English by native Urdu speakers fluent in English and Urdu. We pretested the questionnaire to assess whether the words and terms used in the Urdu version were clear, relevant, and comprehensible.

- Functional Independence Measure (FIM): The Functional Independence Measure (FIM) tool is a fundamental measure of *patient disability*. The 18 items in the FIM instrument comprise six domains, as mentioned in Table 2. A scale of 1 (complete dependence) to 7 (complete independence) is used to rate each item; higher scores signify a higher level of functional independence (summed scores range from 18 to 126).
- Revised Trauma Quality of Life Instrument (RT-QoL): The revised trauma quality of life (RT-QoL) instrument measures trauma specific long-term quality of life outcomes. This is an , 18-item questionnaire, with the three domains specified in Table 2.
- Primary Care PTSD Screen for DSM: This questionnaire is used to assess post-traumatic stress disorder (PTSD). The questionnaire screens with an item which assesses lifetime exposure to traumatic events. If a respondent denies exposure, the PC-PTSD-5 is complete with a score of 0. However, if a respondent indicates that they have had any lifetime exposure to trauma, the respondent is instructed to respond to 5 additional yes/no questions about how that trauma exposure has affected them over the past month.

Personnel and training

The research team comprises a team lead, a research specialist who coordinates the day-to-day activities, and three medical officers who will collect data. They attended two days of training: one day in class and one-day on-site training. They received training on software use, ICD-10 coding, Abbreviated Injury Scale (AIS), Injury Severity Score (ISS), and Revised Trauma Score (RTS) training. We will also provide frequent refresher training (every 2–3 months) to address data collection challenges and train new data collectors.

Eligibility criteria

All admitted adult trauma patients (≥18 years) with one or more traumatic injuries, which is defined as the injury being severe enough to need hospitalization for at least 24 h will be included. The patients will be included from the inpatient wards (orthopaedics/general surgery/thoracic) Intensive Care Unit/High Dependency Unit. Patients under 18, those unable to communicate verbally without a proxy, and those released from hospital within 24 h will not be included.

Data collection, follow ups and data management

The data collector will be placed in the wards (orthopedics, general surgery, and thoracic) and surgical Intensive Care Unit (ICU)/ High dependency Unit (HDU). Data collectors will identify new admissions with the assistance of nurses, doctors, and admission registers. They will enroll patients in the study after obtaining informed consent and determining the eligibility criteria. Then, they will interview the patient at the bedside to collect the required basic information. If the patient cannot answer, the caregivers will be interviewed. Next, the data collector will extract detailed information from the medical records (labs, radiology reports, and discharge summary). Finally, at the time of discharge, the patient/caregiver will be re-interviewed to document discharge outcomes. If the patient leaves the hospital before being interviewed, they will be followed up telephonically within a week of discharge.

Patients enrolled in the study will be followed across the continuum of recovery. These will comprise twenty to twenty-five-minute telephone interviews. The interview will have an initial screening, verbal consent, and questions about his/her recovery. Patients will be approached at least twice a day for the next 3 days. After these attempts, if still unreachable, the patient will be considered lost to follow-up.

Table 1 Variables included in the in-hospital trauma registry questionnaire

Categories	Variables	Source of Information
Demographic Information		
	Name	Interview
	Age	Interview
	Medical registration number	Medical Record
	Gender	Interview
	Ethnicity	Interview
	Contact details	Interview
	Address	Interview
	Education	Interview
	Occupation	Interview
	Status of employment prior to the injury	Interview
	Arrived to the facility by	Interview
Past History		
	Comorbidities	Interview
	Disability status prior to the injury	Interview
	Functional health status prior to the injury	Interview
Injury Details		
	Injury date and time	Interview
	Cause of injury	Interview
	Nature of Injury	Interview
	Diagnosis	Medical Record
	Position of Vehicle	Interview
	Protective Devices	Interview
	Abbreviated Injury Scale (AIS)	Medical Record (Classification done by data collector)
	Injury Severity Score (ISS)	Medical Record (Classification by data collector)
	Trauma Score and Injury Severity Score (TRISS) score	Medical Record (Classification by data collector)
	International Classification of Diseases (ICD-10)	Medical Record (Classification by data collector)
Inter-hospital case management		
	Name of prior facility	Medical Record
	Arrival date at facility	Medical Record
	Arrival by	Interview
	Name of ambulance service	Interview
	Treatment if given in ambulance	Interview
	Referral	Medical Record
	Workup done at referring facility	Medical Record
	Treatment list/medication given in prior facility	Medical Record
	Procedures done in the prior facility	Medical Record
	Departure date	Medical Record
Data Related to Workup in ED		
	Date and Time	Medical Record
	Initial Assessment	Medical Record
	Vitals	Medical Record
Tracking of patients as he/she moves from ED to OT/HDU/ICU/wards		
	Location tracking	Medical Record/Interview
	Service tracking	Medical Record/Interview
Procedure Details		
	Radiological procedure	Medical Record
	Surgical procedures	Medical Record
	Medications	Medical Record
	Other procedures	Medical Record
	Blood Transfusions	Medical Record
Outcomes		

Table 1 (continued)

Categories	Variables	Source of Information
	Discharge outcome	Interview/Medical Record
	Date and Time	Interview/Medical Record
	Duration of stay	Interview/Medical Record
	Septic complications	Medical Record
	Disability status at discharge	Interview
	Functional health status at discharge	Interview

Table 2 In-hospital trauma registry questionnaire, follow-up questionnaires, content, data collection method, and time points (patient-reported outcomes)

Questionnaire	Content	Data Collection Method	Data Collection Time point
In-hospital Trauma Registry Questionnaire	Demographics, injury details, inter-hospital case management, tracking of patients as he/she moves from emergency (ED) to operation theatre (OT)/High dependency unit (HDU)/ Intensive Care Units (ICU)/ wards, Outcomes	Medical Records, In-person interviews	In-hospital and within one week of discharge
Follow-up questionnaires at one, three, six-, and twelve-months post discharge			
Functional Independence Measure (FIM)	Self-care, sphincter control, transfer, locomotion, communication, and social cognition	Telephone Interview with patient/proxy	Within one week of discharge, one, three, six-, and twelve-months post discharge
Revised Trauma Quality of Life Instrument (RT-QoL)	Emotional well-being, physical well-being, functional engagement	Telephone Interview with patient/proxy	One, three, six-, and twelve-months post discharge
Primary Care PTSD Screen for DSM	Post-traumatic stress disorder (PTSD)	Telephone Interview with patient/proxy	One, three, six-, and twelve-months post discharge

We will enter data through digital software (REDCap). It is a free-of-cost, secure web application for surveys and databases. Online data entry in REDCap is fast, flexible, and easy to use. We will build the project database on REDCap by uploading the data collection tools (trauma registry and follow-up questionnaires). To ensure that data collection tools look and work as we intend, we will create a few test records and enter some data for each tool.

Quality assurance

The data collectors will use an excel sheet to send daily updates of newly enrolled patients and the number of follow-ups calls through google docs. Only team members will have access to Google Docs. These forms, however, will report the ID numbers and will not contain any patient identifiers. This information will be stored on a password-protected computer. The research specialist (RS) will close out the cases on Google Documents after verifying them on REDCap. The PI will receive weekly updates and cross check the enrollments on a regular basis. A research specialist will make random visits weekly to oversee data collection, spot and address field problems, and ensure all eligible patients are enrolled in the study by comparing enrolled participants with admission lists and ensure quality checks at field site. The PI will monitor all entered data and check the data for data completeness and accuracy. We will compare the entered data elements with the patient's medical records for data accuracy. We will calculate the error rate for a subset of records to ensure data quality.

Anticipated barriers and challenges in the implementation of registry and follow-ups

Table 3 outlines the anticipated barriers and challenges and solutions to overcome them. These include barriers related to recruitment, medical records, and follow-ups. (Insert Table 3 here)

Data analysis

We will conduct a descriptive analysis to summarize the participant profile, clinical characteristics, and outcomes, including the median and interquartile range (IQR), mean and standard deviation, and proportions (95% confidence intervals). Kaplan Meir survival curves and means will be obtained, and the log-rank test will be used to test the hypothesis that survival curves are similar. The Cox Proportional Hazard model will be used to perform survival analysis. Assumptions of proportionality of hazards will be assessed. We will use mixed-effects linear regression model in order to adjust for potential confounders such as gender, education, ethnicity. Variables with an overall model p-value of <0.25 will be considered eligible for entering the model-building stage, and a likelihood ratio test will be performed at each step. Multicollinearity among the qualifying variables will be checked using correlation coefficients for quantitative variables and Kramer's V for categorical variables.

Table 3 Barriers and challenges in the implementation of registry and follow-ups

Barriers	Explanation	Solutions
Recruitment	Research team was stationed in ED to recruit the patients. However, most trauma patients got discharged after first aid, preventing long-term follow-up. Secondly, difficulty tracing patient movement post-admission.	We repositioned the research team to the wards, where all admitted patients were enrolled in the study.
Patient capture	The patients admitted on Sundays and public holidays may not be captured.	The data collector will attempt to enroll those patients on the next working day.
Limitations of Medical Records	The medical records lack information for some variables, such as socio-demographics, pre-hospital care, and injury details.	This information will be obtained from the patients or their caregivers during interviews.
Electronic entry and completion	Digital data entry depends on the availability of a reliable internet connection, and sometimes the RedCap server may not respond due to electricity or internet issues.	When the RedCap is not working, the research team collects data on hard copies.
Follow-ups	The medical records often lack contact numbers. Additionally, the patients' attendants are sometimes neighbors or friends who are not directly involved in the patients' care.	We take more than one contact numbers to overcome these issues.

Adjusted odds ratios (AOR) and 95% CI will be calculated. The significance level of all statistical tests will be considered at 0.05. Stata for windows version 14 will be used for analysis. For FIM, mean and standard deviation will be reported for one, three, and six months. For RT-QoL, the mean and standard deviation will be reported for all three sub-components, along with the mean and standard deviation for the overall score.

Discussion

The study aims to describe the design and methodology of setting up a digital trauma registry to capture long-term disability-related outcomes in Pakistan. It will also provide a comprehensive insight into trauma-related disabilities and how they affect injured patients by looking at their current level of disability. This will provide an opportunity for recommendations for incorporating PROMs into trauma registries in LMICs to maximize the rehabilitation and reintegration of the injured into society.

Strengths

This will be among the first studies in Pakistan to collect trauma-related long-term PROMs. This study employs a prospective cohort study design to capture estimates of disability among injured patients using validated instruments at one month, three months, six months, and twelve months following the injury in Pakistan. This study's large sample size increases the accuracy and generalizability of the findings. We will calculate the injury severity score and revised trauma score, which are important measures of severe injury. Also, we will assess PTSD that could directly impact outcomes related to disabilities.

Limitations

The study has some limitations. The study will be carried out in two trauma centres with different volumes, patient flow systems, and resource availability. This might not accurately represent the situation in other local trauma centres in the country. Due to practical reasons, we will not include paediatric trauma patients, missing a substantial proportion of the population contributing to the trauma burden. In addition, we will not fully account for the trauma burden (minor injuries, brought dead, and mortalities in the ED) because we will only include admitted patients. However, since we intend to recruit participants with whom we can follow up to learn more about long-term consequences, collecting the whole trauma burden is not the study's objective. Some patients will be missed since there will be only eight to ten hours of data collection per day, six days per week. Patients admitted on Sundays or holidays and those who pass away or leave against medical advice at night are a few examples. There may be differences between missed and admitted patients, and the generalizability may be limited. The extraction of data from medical records may pose certain challenges. Some of the variables in the medical records might be missing or have inconsistent data. Data entry is dependent on the availability of electricity and high-quality internet. There may be challenges related to telephonic follow-ups. Inaccurate phone numbers, inactive phone numbers, female patients' reluctance to participate, and non-response may pose follow-up barriers.

Conclusion

The high disability rates following trauma imposes a significant burden and cost on individuals and society. A trauma registry would fill this gap by capturing post-discharge long-term PROMs. Including long-term measures of disability in routine follow-ups will provide insights into physical, social, and policy barriers and help improve injury care and rehabilitation.

Abbreviations

PROMs Patient-Reported Outcome Measures
ED Emergency Department
AIS Abbreviated Injury Scale

ISS	Injury Severity Score
TRISS	Trauma Score and Injury Severity Score
QoL	Quality of Life
PTSD	Post-Traumatic Stress Disorder

Supplementary Information

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Supplementary Material 1

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Author contributions
NS, AAHM, and JR conceived the idea of this manuscript; NS, AAHM wrote the manuscript; NS, JR, AAH, and AH critically revised the paper and provided valuable feedback. All authors read and approved the final manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study was approved by both The AKUH Ethics Review Committee (ERC Reference No. 2021-6251-18973) and the JPMC Institutional Review Board Committee (Reference No. F.2–81/2021-GENL/70586/JPMC). The study complies with the Declaration of Helsinki. Informed verbal consent was obtained from all the participants before starting data collection. Participation was voluntary, and the right to ask any questions and to decline participation/leave the study at any time was emphasized during the data collection. Data was anonymized during data management, analysis, and reporting.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Disclaimer
None.

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