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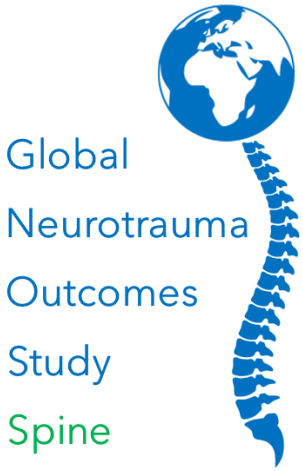
Global Neurotrauma Outcomes Study: Spine

GNOS Spine

An international, multi-centre, prospective, observational study on traumatic spine injury



Study Protocol

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Overview of Study

Background

Traumatic spinal injury (TSI) accounts for a significant proportion of disability and death worldwide, with the majority of this burden affecting individuals in low- to middle- income countries. Crucially, to date, the current disease profile of TSI has not been characterised globally. In addition, the global approach to the care of patients following TSI is inconsistent with considerable geographical differences in process of care reported, and limited data available on the impact of these variations on outcomes following TSI. A better understanding of case-mix and processes of care is urgently needed to underpin efforts to identify ways of improving outcome relevant to different socioeconomic settings globally.

Objectives

The primary objective of this study is to characterise the case-mix, processes of care and variations in non-operative and operative management strategies, including emergency, ward, ICU care, in patients presenting with traumatic spinal injury (TSI) between centres across low and high Human Development Index (HDI) countries. The secondary aims are to summarise current local resources and management pathways for TSI through validation of provider profiling data, describe differences in indications for nonoperative and operative management, and short-term outcomes following TSI. This study aims to identify gaps in processes of care to identify targets for future interventions to improve TSI care across high and low-resource settings.

Methods

A multi-centre, international, prospective, observational study. Any unit assessing patients with TSI worldwide will be eligible to participate. Each participating unit will form a study team responsible for gaining local approval, identifying patients for inclusion and conducting data collection. Data will be collected via a secure online platform in an anonymised form. Processes of care will be characterised by a detailed provider profiling exercise. A registry describing the case-mix and care of all adults presenting with radiologically confirmed TSI will be collected, in a given consecutive 30-day period during the study period starting in 2021.

Results

The dataset, developed through an iterative feedback process involving clinicians from low and high Human Development Index (HDI) countries, includes patient demographics, details of injury mechanism, local injury management and, if applicable, timing and nature of surgery, post-operative care and immediate post-operative complications. Outcome measures include Frankel grade at 6 weeks post-admission (or at discharge or death, whichever event occurs first), early mortality, peri-operative complications, adverse events of special interest, functional status and mobility. Descriptive analyses of case-mix and the variations

in processes of care will be conducted. Available resources, use of guidelines and variations in processes of care will be characterised using both provider profiling responses and patient-level data collected. Areas where known best practice is deficient or unavailable will be identified as potential targets for future implementation studies.

Conclusions

GNOS Spine aims to provide a global snapshot of the case-mix, management, processes of care and short-term outcomes of patients presenting with TSI. In addition, we aim to identify areas for further study, and establish a platform and clinical network to facilitate this future research in global neurotrauma and spinal surgery.

Background

Traumatic spinal injury (TSI) is an umbrella term for injuries to the spinal cord, nerve roots, osseous structures, and disco-ligamentous components of the spinal column[1]. Traumatic spinal cord injury (SCI) is a subset of TSI which is most commonly reported in literature. TSI represents a significant global disease burden, recently reported to be 1.6 times higher in low- to middle-income countries (LMICs) than high-income countries (HICs)[2]. Furthermore, ongoing indirect costs of severe disability secondary to TSI are a recognised socioeconomic burden, which may disproportionately affect LMICs[3,4].

Management of traumatic spinal injury (TSI)

Delays in the initiation of comprehensive management of TSI have been shown to add to the complexity of management, result in a higher incidence of complications, longer hospitalisation, added costs and poor outcomes[5]. The Lancet Commission on Global Surgery estimates that 5 billion people worldwide lack access to safe, affordable, accessible surgical care and this disparity extends to neurosurgical interventions[6]. Challenges to delivering emergency management of TSI in LMICs are often compounded by inadequate pre-hospital care, lack of infrastructure and trained manpower[7].

Neurosurgical research in low- to middle-income countries (LMICs)

Whilst the epidemiology of TSI has been described in a number of LMICs[8–11], there is limited literature describing current practice for the management of TSI in resource-limited settings. Additionally, a 2011 bibliometric review of all neurosurgical publications over 13 years found that in almost 70% of all published work the first author originated from one of only 5 high or upper-middle income countries[12]. The limited resources that clinicians work within in LMICs presents a challenge to adhere to latest practice guidelines that are developed in high-income countries (HICs)[3,13,14]. The discrepancy between management and available resources urges a need for up-to-date, context-specific clinical data collected directly from these countries to allow a better understanding of current practice, and future TSI guidelines to be tailored to the specific capabilities of the country. Variances in processes of care have even been identified between centres in HDI settings and are likely to be substantial at all stages of TSI care, including pre-hospital, emergency department, ward-based, operative and ICU phases. Characterisation of these variances may offer important opportunities to intervene across both high and low-resource settings.

Conclusion

We propose to conduct an international, multi-centre, prospective, observational study of outcomes following admissions for TSI. We believe this project will provide valuable insight into current practice to identify areas for future studies and establish a platform and clinical network to facilitate this future research in global neurotrauma and spinal surgery.

1. Objectives

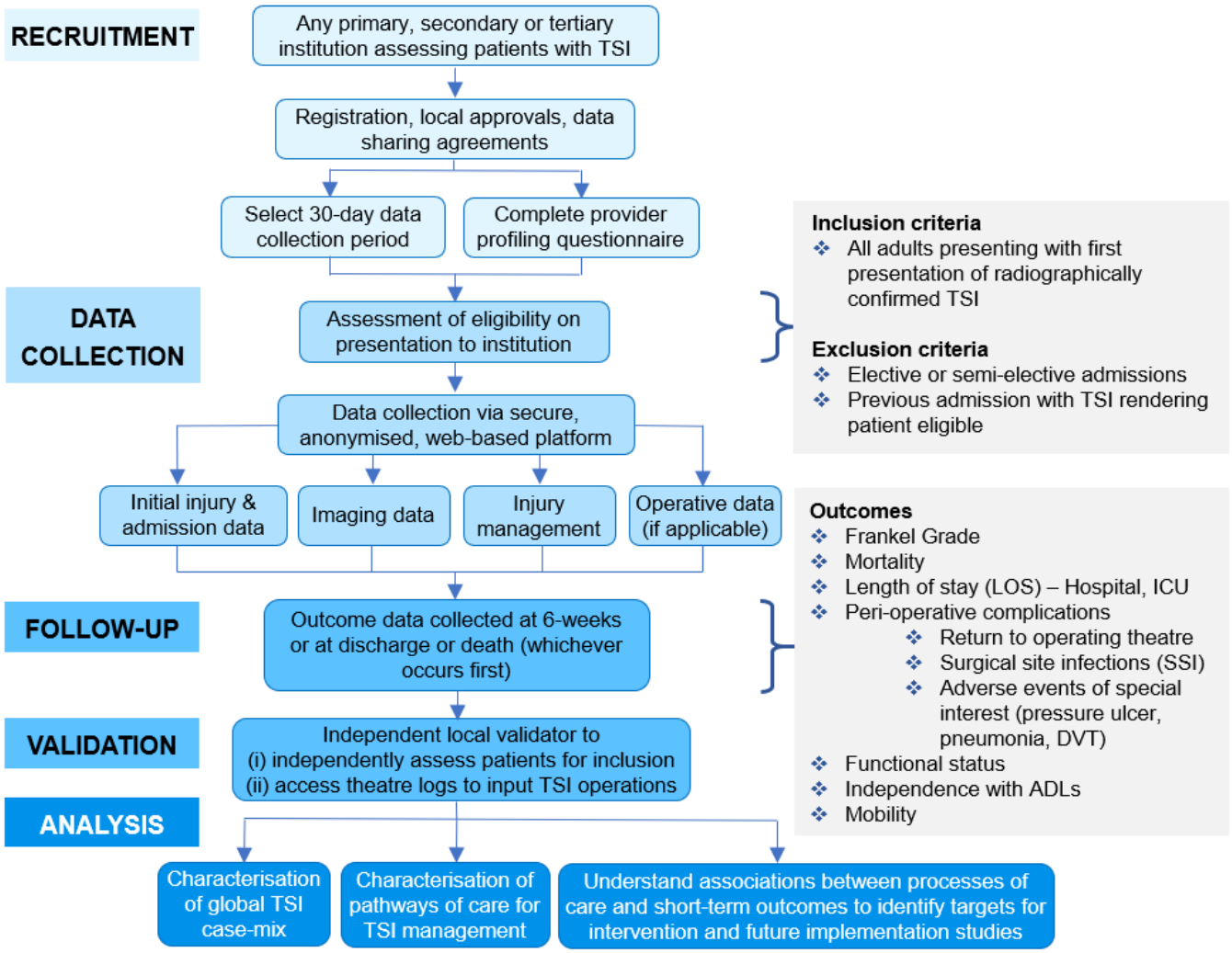
1.1 Primary Objective

- Characterise case-mix, processes of care and variations in nonoperative and operative management strategies, including emergency, ward, surgical and ICU care, in patients presenting with traumatic spinal injury (TSI) between centres across low and high Human Development Index (HDI) countries

1.2 Secondary Objectives

- Summarise the current resources and management pathways for patients presenting with suspected traumatic spinal injury worldwide, through validation of provider profiling data
- Describe differences in current (i) indications for conservative management vs surgery, and (ii) short-term outcomes (early mortality, functional, neurological, adverse events) following TSI worldwide.
- Identify gaps in implementation of current evidence-based best practice and explore possible reasons in specific settings.
- Identify targets for future global health, process of care or clinical interventions to improve outcomes across different settings.
- Obtain point-estimates of, and gain insights into local variations in the epidemiology of TSI.
- Define patient profiles which predict efficacy of specific interventions and pathways of care.
- Identify possible performance indicators to characterise TSI care across settings in preparation for a future consensus study.

2. Overview – Study Flowchart



3. Methods

3.1 Inclusion Criteria

3.1.1 Centre inclusion Criteria

Any primary, secondary or tertiary institution worldwide managing patients with TSI is eligible to participate. In many institutions, management for TSI may be provided by spinal surgeons – however, centres in which management for TSI is provided by general surgeons, trauma surgeons, general medical doctors or even non-physician clinicians are also eligible to participate.

3.1.2 Patient inclusion and exclusion criteria

3.1.2.1 Inclusion Criteria

All adult patients presenting to the participating institution with a first presentation of TSI confirmed radiographically, during the selected 30-day inclusion period are eligible for inclusion in the core study.

3.1.2.2 Exclusion Criteria

- Elective (planned) or semi-elective (patient initially discharged after emergency with planned intervention at a future date) admissions
- Patients who have previously had an admission for TSI rendering them eligible for inclusion in this study (regardless of whether they were included on the previous admission or not)

3.2 Provider Profiling

Before beginning patient-level data collection, each institution lead will be asked to fill out a provider profiling questionnaire on the local caseload, catchment populations, management frameworks and resources available at pre-hospital, emergency department, ward, surgical and ICU phases of TSI care.

3.3 Data Set

A data set will be collected on all adult patients admitted after TSI within the 30-day inclusion period. This will be split into five sections: (i) initial injury and admission data, (ii) imaging data, (iii) injury management, (iv) operative data (if applicable) and (v) outcome data. The dataset was developed and refined through iterative consultation with clinicians caring for TSI in low and high HDI countries.

3.4 Duration of Study

Local study teams may pick any 30-day period between the 6-month study period to conduct the study. Teams must follow patients for up to 6-weeks post-admission or until they are discharged or die (whichever event occurs first). For example, if a team selects 1/6/2021 as their start date, they must include all patients who meet the inclusion criteria between 1/6/2021 and 30/6/2021. Moreover, if a patient is admitted during the inclusion period on 30/6/2021 they should be followed up until the 11/8/2021 or until discharge or death (whichever event occurs first).

3.5 Study measures

The following categories of routine clinical data will be collected prospectively for all patients included in the study. The full data set is included in *Appendix A*.

Initial injury and admission data

- Baseline demographics e.g. age, gender
- Type and mechanism of injury
- Pre-hospital timeline, transfers and transportation
- Clinical presentation on arrival to hospital e.g. GCS, Kampala Trauma Score, Frankel grade
- Initial injury details
- Admission details

Imaging data

- Imaging modalities utilised for radiological characterisation of injury
- Injury classification e.g. AO Spine classification

Injury management data

- Intended injury management
- Injury management during transfer e.g. immobilisation
- Specialised therapies received e.g. physiotherapy, speech and language therapy

Operative management (where applicable)

Where included patients underwent operative management, these details will be collected prospectively. However, operative management is not a prerequisite for inclusion in the study.

- Details of the operating team
- Duration, location and type of operation

- Intra-operative course and complications
- Funding

Outcome Data

Outcomes will be measured up to 6-weeks or until death/discharge (whichever event occurs first). This follow-up period was selected after consultation with experienced clinicians from high and low HDI settings to balance the aim of capturing significant short-term outcome events with practicalities of robust data collection across centres. This is supported by literature suggesting that over half of patients are typically lost to follow-up, with significantly increased barriers to follow-up in LMICs, and that early outcomes assessed within shorter time frames, particularly in these settings, remain significant and useful[14,15]. A range of outcomes after traumatic spinal injury will be assessed including:

- Frankel grade at 6-weeks post-admission (or at discharge, whichever event occurs first). This has been demonstrated as a feasible measure to collect in both high and low resource settings[4, 12].
- 6-week mortality
- Length of stay (LOS)
    - Hospital
    - Intensive Care Unit
- Perioperative complications (where applicable)
    - Return to operating theatre during follow-up period
    - Surgical site infection (SSI)
    - Adverse events of special interest e.g. pressure ulcer, pneumonia, deep venous thrombus
- Functional status at 6-weeks or discharge
    - Independence with activities of daily living
    - Mobility

4. Data Capture and Validation

4.1 Data Capture

Collected data will be stored exclusively on a secure web-based system within the Outcome Registry Intervention and Operation Network (ORION) platform: https://orion.net/login. This will enable secure data collection, validation and storage in a standard format (SQL) which is compliant with National Health Service security standards (including the Information Governance Toolkit). All patient data will be transmitted and held anonymously. A pilot will be conducted using the platform to assess feasibility prior to rolling out the full study.

4.2 Data Validation

A number of steps have been taken to ensure validation of all data entered.

I. The dataset, web-based case report forms, and curation process has been designed according to DAQCORD principles[16].

II. Web-based forms in the ORION platform contain fixed options at the point of data entry to maximise the likelihood of accurate and complete data capture at the point of collection.

III. A local data validator independent to the local study team will be appointed at every participating institution. They will have access to a separate platform on Orion to ensure blinding to the rest of the data collected at their institution. They will be asked to complete a two-phase validation process, with a specific ORION validation user guide available to guide them through the process.

   a. Prospective Case Acquisition**:** During the selected 4-week inclusion period, the local data validator will be asked to independently identify and collect all patient cases suitable for inclusion in the study. For validation, they will be required to prospectively collect these cases, recording the admission date, age at admission and AO injury type. This will subsequently be correlated with the data collected by their local team by the central study team.

   b. Retrospective Operative Data: At 10 weeks from the start of the inclusion period (6-weeks following the end of the inclusion period), the local data validator will be asked to independently access operating theatre logs over the preceding 10 weeks. They will be required to document all the patients who have had an operation for TSI during this period and input the date and type of operation into the validation system where this corresponds to a patient admitted during the inclusion period. This will be used by the central study team to validate this specific cohort of their institution's cases.

5. Statistical Analysis

Anonymised data will be analysed by the central study team. Fundamentally the main analysis will consist of a quantitative description of case-mix and the variations in processes of care. Identification and description of areas where known best practice is lacking or unavailable will be performed. This will enable identification of potential targets for future implementation studies.

In addition, early outcomes will be assessed to identify case-mix and process factors that may form a substrate for intervention. Participating centres will be stratified based on their country into groups based on their Human Development Index (HDI). The Human Development Index is calculated for each country based on its life expectancy at birth, years of schooling and gross national income (GNI) per capita[17].

Specifically, after data validation and curation, the primary analysis will comprise of (1) statistical descriptive analysis of patient-level registry variables, (2) characterisation of processes of care using statistical descriptions of both provider profiling data and patient-level process variables followed by a description of typical process groupings. This will follow and extend methodologies that have previously been applied successfully to traumatic brain injury[18] . Case-mix and process analysis will be stratified in a nested way by site, country, and association with human development index (HDI).

Analysis for the secondary objectives will consist of a quantitative statistical summary of non-operative and operative management. Intra- and inter-site variances will be compared and associations with HDI and process of care factors sought.

Whilst only short-term outcomes can be obtained in this pragmatic point-study, outcomes analysis will be attempted for early mortality, functional status as assessed using the 5-point Frankel Grade, neurology, adverse events and trajectory from admission to 6 weeks post-injury (or discharge or death, whichever occurs first). These will be analysed by HDI group in an appropriate nested model accounting for random effects of site and country. Either ordinal models (for statistical power) or dichotomised models will be used depending on the statistical properties of the data and suitability of model assumptions. Mixed effects models will be used to assess the relationship between HDI and deterioration in functional status at 6 weeks while controlling for confounding variables.

Associations between patient factors and processes of care will be sought with recognised indicators of evidence-based good practice to identify patient profiles associated with efficacious treatment trajectories. Using methodology previously successfully applied to TBI, process of care variables from both the registry and provider profiling will be collated with estimates of variability to inform a future Delphi consensus process aimed at defining process of care performance indicators that are feasible, measurable, and globally relevant[19,20].

Provider profiling summary statistics will be compared with current evidence-based best practice to identify gaps and associations with process of care, case-mix, site and HDI will be explored using standard statistical approaches. Variability in guideline availability and any association with TSI care will be assessed by comparing provider profiling and registry data using methodology conducted previously for TBI[21].

The data, along with catchment area data from provider profiling will be used to obtain point estimates with confidence intervals to provide a high-level description of the epidemiology of TSI across the sites studied using routinely available population data. A similar methodology that has been applied to the study of chronic subdural haemorrhage will be utilised[22].

A *p*-value of less than 0.05 will be considered statistically significant, correction for multiple comparisons will not be undertaken. A median odds ratio approach will be used to compare variations in outcomes between sites correcting for explanatory features discovered in the descriptive part of the analysis.

6. Limitations

This pragmatic, prospective, observational study has been designed with the aim of obtaining estimates of the current global case-mix, management and processes of care for patients who present with TSI at a single point in time. Long-term follow-up is therefore not appropriate or feasible across all settings. This protocol has not been designed to investigate or provide:

- Worldwide epidemiological data of all TSI
- Indications for or efficacy of specific management for patients with TSI
- Long-term outcomes following TSI

7. Approval

GNOS Spine will not collect any patient identifiable data, with all data entered directly into an anonymised form on our secure, online platform. The aim of GNOS Spine is to measure current practice worldwide, with no intended changes to standard management of TSI to be introduced using the findings of this study.

The United Kingdom National Health Service Health Research Authority tool classifies this study as service evaluation, rather than original research, and hence, it does not require formal approval by a Research Ethics Committee with the United Kingdom. This has been confirmed by the South East Scotland Research Ethics Service.

Local teams should follow local protocol and guidance to obtain approval from either their service evaluation, clinical audit, research department or head of department, prior to commencing any data collection for this study. Where local institutions require approval from their Research Ethics Committee, we would advise seeking an expedited review or ethical waiver if deemed appropriate locally, in view of only anonymised routine clinical data being collected. Written confirmation will be requested from each institution before local study teams are able to access the online, data-collection platform.

If classified locally as research, local study teams should follow local protocol, which may involve consenting all patients involved to participate in this study. Example participant information leaflets and participant consent forms can be found on the study website (www.globalspinetrauma.com) or requested via email (info@globalspinetrauma.com). These are available in English, and so should be translated where required.

8. Roles, responsibilities, and publication

8.1 Roles and Responsibilities

A team of investigators from the United Kingdom, Asia, Africa, Australia and America are responsible for running this study on behalf of the NIHR Global Health Research Group on Neurotrauma. At each participating unit, there will be a local study team who will conduct local data collection and validation. Local teams may consist of a mix of fully trained surgeons, physicians, trainees, and medical students.

Local collaborators will gain access to their own data upon completion of the study, to compare their practice to international practice. Members of the local study team may request access to a subset of the data to answer a defined research question through post-hoc analyses.

8.2 Publication

All main multicentre publications that result from the GNOS Spine Study utilising data from substantially all participating centres will include in the authorship designation, “on behalf of the Global Neurotrauma Outcomes Study Spine Collaborators”. The international committee of medical journal editors (ICMJE) guidelines for authorship will determine the authors who will be fully named on the by-line of publications resulting from this study along with the principal and chief investigators as below.

Every member of the local study team and independent validators at each institution will be listed as PubMed citable collaborator status authors on all publications resulting from this study, along with other individuals who contribute substantially to the study under the following headings.

Co-Chief Investigators (Rikin Trivedi, Peter Hutchinson)

Co-Principal Investigators (Saniya Mediratta, Jibin Francis)

Protocol Development Group (G Balamurali, Karol Budahoski, Ari Ercole, Alexis Joannides, Tariq Khan, Radek Kindl, Colum Nolan, Abenezer Tirsit, Sara Woodrow)

Honorary Advisory Panel (TBC)

Writing Group (TBC)

Dissemination Group (TBC)

9. Support and Funding

This study has the support of the World Federation of Neurological Societies (WFNS), European Association of Neurosurgical Societies (EANS) and Society of British Neurological Surgeons (SBNS). Funding for the administrative costs of this study are being provided by the National Institute of Health Research (NIHR) Global Health Research Group on Neurotrauma.

10. Appendix A – Data Fields

10.1 Initial Injury & Admission data

ORION Unique Patient Identifier	
Gender	Male, Female
Date of Birth	dd/mm/yyyy
Date/Time of Injury	dd/mm/yyyy HH:MM

Type of Injury	● Blunt
	  ○ Low energy
	  ○ High energy
	● Penetrating
	  ○ Low energy
	  ○ High energy

Mechanism of Injury	Road Traffic Collision (RTC) ● RTC Pedestrian ● RTC Cyclist ● RTC Motorcyclist ● RTC Motorcyclist (passenger) ● RTC Car (driver) ● RTC Car (passenger) ● RTC other vehicle (driver) ● RTC other vehicle (passenger) Fall ● Fall standing height ● Fall from height Assault ● Assault – no weapon ● Assault – blunt instrument ● Assault – sharp instrument ● Assault – firearm Other ● Self-harm ● Other violence ● Animal attack ● Explosion ● Industrial accident (outside categories listed above) ● Sport/recreational activity
Date/Time of admission to hospital	dd/mm/yyyy HH:MM
Was the patient directly transferred from the site of the accident to the current institution?	● Yes ● No
Mode of transport to primary institution	● Air ambulance (helicopter) ● Land ambulance (paramedic staffed) ● Land ambulance (not paramedic staffed) ● Public Transport ● Police ● Private vehicle ● By foot ● Other (specify _____)
Method of transport to the current institution	● Air ambulance (helicopter) ● Land ambulance (paramedic staffed) ● Land ambulance (not paramedic staffed) ● Police ● Private vehicle ● By foot ● Other (specify _____)

GCS on arrival to your institution (if intubated on arrival, lease state pre-intubation GCS)	● Eye Response
	  ○ Open spontaneously - 4
	  ○ Open to verbal command - 3
	  ○ Open to pain - 2
	  ○ No eye opening - 1
	● Verbal Response
	  ○ Oriented - 5
	  ○ Confused - 4
	  ○ Inappropriate words - 3
	  ○ Incomprehensible sounds - 2
	  ○ No verbal response - 1
	  ○ Intubated - T

	● Motor Response
	  ○ Obeys commands - 6
	  ○ Localising pain - 5
	  ○ Withdrawal from pain - 4
	  ○ Flexion to pain - 3
	  ○ Extension to pain - 2
	  ○ No motor response - 1

Kampala Trauma Score	● Age
	  ○ 5-55
	  ○ <5 or >55
	● SBP (mmHg)
	  ○ >89
	  ○ 50-89
	  ○ 1-49
	  ○ Undetectable
	● Respiratory rate (/min)
	  ○ ≤9
	  ○ 10-29
	  ○ ≥30
	● Neurological status
	  ○ Alert
	  ○ Responds to verbal stimuli
	  ○ Responds to painful stimuli
	  ○ Unresponsive
	● Serious injuries
	  ○ None
	  ○ 1
	  ○ 2 or more

Frankel Grade at initial assessment	● A: Complete motor and sensory loss ● B: Complete motor loss, incomplete sensory loss ● C: Incomplete motor loss without practical use ● D: Incomplete motor loss, able to ambulate with or without walking aids ● E: Free of neurological symptoms
Major intracranial injury (defined as requiring hospital admission in its own)	● Yes ● No
Site of PRIMARY spinal cord injury	● Occipital condyle to S1: ● Unknown
Primary vertebral fracture Level	● Occipital condyle to S1: ● Unknown
Deformity	● Yes ● No
Any other injury (can select multiple)	● Chest ● Abdomen ● Pelvis ● Long bones
Admission location	• General wards • HDU • ITU
Admitting Team	● Orthopaedics ● Neurosurgery ● General Surgery ● Medicine ● Emergency Department

10.2 Imaging Data

Date/Time of first imaging	dd/mm/yyyy HH:MM
Most advanced type of imaging performed	● Plain film radiograph ● Non-contrast CT Scan ● Contrast CT Scan ● MRI Scan
Anatomical area of spine included on imaging (Can select multiple)	● Cervical ● Thoracic ● Lumbar ● Sacral
Level of fracture	● Upper cervical ● Subaxial ● Thoracolumbar ● Sacral ● No injury
AO Classification of Injury	
Subluxation/Translation	● Yes ● No
Traumatic herniated nucleus pulposis (not required if only plain radiograph available)	● Yes ● No If Yes: ● Please specify level: ● Cord compression: Yes/No
Haematoma (not required if only plain radiograph available)	● Yes ● No

10.3 Injury Management

What was the **intended** injury management?	● No intervention ● Non-operative ● Operative
Was there immobilisation during transfer?	● Nothing ● Collar ● Trauma board ● Bed
Did the patient have surgical bedrest?	● Nothing ● Bedrest, no logroll ● Bedrest + logroll ● Collar only
Traction?	● Yes ● No
Did the patient receive any specialist therapy as an inpatient	Yes No If Yes, what type of therapy was provided? - Speech and Language Therapy - Tracheostomy care - Physiotherapy - Occupational therapy - Alternative therapy – Ayurveda etc - Other (specify _____)
Was spinal surgery performed?	● Yes, performed at this institution ● Yes, transferred to a different institution for surgery ● No

10.4 Operative Data (If "Yes, performed at this institution" to 'Was spinal surgery performed?')

Grade of most senior surgeon present in the operating theatre	● Fully qualified spinal surgeon ● Other qualified surgeon ● Surgical trainee ● Medical doctor
Type of anaesthesia	● General ● Local ● None
Grade of most senior anaesthesia provider present in the operating theatre	● Fully qualified anaesthetist with medical qualification ● Anaesthetist in training with medical qualification ● Not medically qualified anaesthesia provider ● Anaesthetic administered by the surgeon
Date of Operation	dd/mm/yyyy
Duration of operation	● Less than 1 hour ● 1-5 hours ● 5-10 hours ● Over 10 hours
Were pre-incision prophylactic antibiotics given?	● Yes ● No
Class of surgical wound	● I Clean ● II Clean-contaminated ● III Contaminated ● IV Dirty-infected
Location of surgery	● Cranio-cervical ● Cervical ● Thoracic ● Lumbar ● Sacral
What was the main procedure undertaken? *If >1 procedure undertaken, refer to the main one ** Flow-Chart on ORION Platform **	● Open a. Approach: Anterior/Posterior/360 b. Minimally invasive surgery? Yes/No c. Open Reduction? Yes/No d. Direct decompression? Yes/No e. In situ fusion? Yes/no f. Fusion? Yes/No ▪ Type of instrumentation ● None ● OC ● C1/2 ● Lateral mass ● Pedicle ● Anterior plating ● Bone graft ● Interbody fusion ● Lateral plating ○ Fluoroscopy used: Yes/No ● Closed ○ Gardener Wells vs Halo ○ Mechanism of Maintenance: Collar vs Halo vs Bedrest
Funding (Select all who contributed)	● Patient ● Family ● Government ● Insurer ● Hospital ● NGO

	● Other (specify _____)
Did the patient experience a hypotensive episode (systolic BP<90mmHg for >5 minutes) during the surgical procedure?	● Yes ● No
Did the patient experience a hypoxic episode (SpO_2< 90% for > 5 minutes) during the surgical procedure?	● Yes ● No
Optional further comments regarding the procedure	Free text
Intraoperative complications (please select all that occurred)	● None ● Incorrect level of surgery ● Misplacement of metalwork ● Incidental durotomy ● Death ● Other (specify _____)

10.5 Outcome Data

Death within the 6-week follow-up period?	● Yes ● No If Yes: • Date of death: dd/mm/yyyy • In ICU at time of death? Yes/No
Discharged within the 6-week follow-up period?	• Yes • No If Yes: • Date of discharge: dd/mm/yyyy • Destination of discharge: ○ Transfer to another hospital ○ Transfer to a rehabilitation unit ○ Usual place of residence/Home ○ Absconded ○ Other (specify _____)
Was the patient admitted to intensive care at any point during the 6-week follow up period?	● Yes ● No If Yes: • Date of admission to ICU: dd/mm/yyyy • Was the patient discharged from ICU during the 6-week follow up period? Yes/No If Yes: • Date of discharge from ICU: dd/mm/yyyy
Was the patient intubated during admission?	● Yes ● No
Did the patient require a tracheostomy?	● Yes ● No
Was the patient requiring ventilatory support at time of death/the end of the 6-week follow up period (whichever event occurs first)?	● Yes ● No
Did any adverse events of special interest occur in the 6-week follow-up period? (Select all that apply)	● None ● Pressure Ulcer ● Pneumonia ● Pulmonary embolism ● Deep venous thrombosis ● Decubitus Ulcer

<table>
<tr><td></td><td>● Urinary tract infection ● Symptomatic haematoma</td></tr>
<tr><td>Did any surgical site infections occur in the 6-week follow-up period?</td><td>● Yes
● No

If Yes:
● Required antibiotics only
● Required debridement
● Required removal of metalwork</td></tr>
<tr><td>Did the patient return to the operating theatre for spinal surgery during the current admission?</td><td>● Yes - planned
● Yes - unplanned
● No

If Yes: Was the re-operation at:
● Same level
● Different level</td></tr>
<tr><td>Did the patient survive to the end of the follow up period (6 weeks post-admission or until they were discharged from hospital, whichever came first)?</td><td>Yes
No

Was the patient still an inpatient at the end of 6 weeks post-admission?
- Yes
- No</td></tr>
<tr><td>Frankel Grade at the end of the 6-week follow up period or at time of death/discharge (whichever event occurs first)?</td><td>● A: Complete motor and sensory loss
● B: Complete motor loss, incomplete sensory loss
● C: Incomplete motor loss without practical use
● D: Incomplete motor loss, able to ambulate with or without walking aids
● E: Free of neurological symptoms</td></tr>
<tr><td>How independent is the patient in the following activities of daily living at the end of the follow up period or at time of discharge?</td><td>
<table>
<tr><th></th><th>Unaided</th><th>With Aid</th><th>Completely Dependent</th></tr>
<tr><td>Feeding</td><td></td><td></td><td></td></tr>
<tr><td>Grooming</td><td></td><td></td><td></td></tr>
<tr><td>Bathing</td><td></td><td></td><td></td></tr>
<tr><td>Dressing – upper body</td><td></td><td></td><td></td></tr>
<tr><td>Dressing – lower body</td><td></td><td></td><td></td></tr>
<tr><td>Toileting</td><td></td><td></td><td></td></tr>
<tr><td>Swallowing</td><td></td><td></td><td></td></tr>
<tr><td>Bladder management</td><td></td><td></td><td></td></tr>
<tr><td>Bowel management</td><td></td><td></td><td></td></tr>
<tr><td>Transfers</td><td></td><td></td><td></td></tr>
<tr><td>Climbing stairs</td><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>What is the patient using to mobilise at the end of the follow up period or at time of discharge (whichever event occurs first)?</td><td>● Mobilising independently
● Use of one walking stick / crutch
● Use of two walking sticks / crutches
● Use of a frame
● Wheelchair
● Not mobilising (bed-bound)</td></tr>
</table>

11. Appendix B – Registration Form

To register your institution to participate in the GNOS Spine study, please complete the online registration form, which can also be found on the website www.globalspinetrauma.com.

Please note that the information provided in this registration form will not affect your eligibility to participate in this study.

Name of Institution	
Address of Institution	
Members of the local study team	Local Study Lead (Mandatory) Full name: Email: Contact number: Do you own a smartphone? Yes/No Additional local team members (Optional – up to 2) Full name: Email: Full name: Email: Local data validator (Mandatory) Full name: Email:
Does this institution maintain a logbook of all admissions (electronic or paper-based)?	Yes No
Does this institution maintain a logbook of all operations (electronic or paper-based)?	Yes No
Does this institution maintain a logbook of all radiological imaging (electronic or paper-based)?	Yes No

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