GEO-TBI

Global Epidemiology and Outcomes following Traumatic Brain Injury

An international registry for supporting care and research excellence

in traumatic brain injury

NIHR Global Health Research Group on Acquired Brain and Spine Injury

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National Institute for Health Research

Global Health Research Group on Acquired Brain and Spine Injury, and

NIHR | Brain Injury MedTech Co-operative

Brain Injury MedTech Co-operative

Endorsed by

World Federation of Neurosurgical Societies

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Registry overview

Background

Traumatic brain injury (TBI) is estimated to affect 69 million people annually[1]. It is the most common cause of traumatic morbidity and mortality[2], and accounts for approximately a third of all trauma-related mortality[3]. Furthermore, the current worldwide rise in the incidence of TBI is projected to continue, especially in low-to-middle income countries (LMICs) concurrently with increasing and aging populations[4]. Even though 86% of injury-related mortality occurs in LMICs[5], more than 80% of TBI research used to inform standards of care originates in high-income countries (HICs)[6].

The Global Neurotrauma Outcomes Study has recently highlighted the global disparity in the demographics, pathology, management and outcomes of surgically treated TBI[7]. However, in light of the study population and the study's snapshot design, the factors underlying these differences, including intervention effectiveness, remain unclear[8]. Establishing a more accurate global picture of the burden of TBI represents a challenging task requiring systematic and ongoing data collection of TBI patients across all management modalities.

Aims and implementation

The Global Epidemiology and Outcomes following Traumatic Brain Injury (GEO-TBI) registry aims to support care and research excellence in the field of traumatic brain injury.

In particular, the registry will provide a robust infrastructure for high-quality data collection, archiving, and analysis for:

1. Enabling clinical audit, benchmarking against best practice, and driving ongoing quality improvement initiatives
2. Identifying unmet clinical need in TBI and its prioritisation for health policy development and future research
3. Providing robust epidemiological data and enabling identification and recruitment of specific patient groups for further research and follow-up.

The registry objectives, dataset, and implementation were established and refined through an international consensus-based approach[9]. The registry is funded by the UK National Institute of Health Research Global Health Research Group on Neurotrauma (NIHR GHRGN), hosted on a digital platform by OrionMedTech CIC (a not-for-profit organisation), and endorsed by the World

Federation of Neurosurgical Societies (WFNS). Data ownership remains with individual contributing centres, with appropriate permissions sought to allow collaborative analysis on pooled, anonymised data. Participating centres have unrestricted access to their own aggregate data, and the registry platform also supports extension of the core dataset to support bespoke studies. The participating centres are able to compare their data to registry-wide anonymised aggregate dataset reports provided automatically at fixed intervals.

Workflow

The operational structure of the registry is outlined in Figure 1 – any centre treating TBI is eligible to join. Upon registering to participate in the GEO-TBI registry, the centres are asked to appoint a local registry team, return a provider profile questionnaire (Appendix 1), and obtain local institutional approval where required. The local team will include a local independent data validator, who validates the local dataset by returning a quarter-yearly validation questionnaire (Appendix 2) and using independent sources where available.

Inclusion criteria

- Clear history of recent trauma leading to TBI

AND at least one of:

- Neurosurgical admission with TBI
- Intensive care unit (ICU) admission with TBI
- Neurosurgical procedure(s) for TBI

The ownership and ability to fully utilise local data remains with the participating centre. An anonymised, fixed-period, registry-wide aggregate dataset of the basic registry variables will be made available to all participating centres for benchmarking purposes (Figure 2).

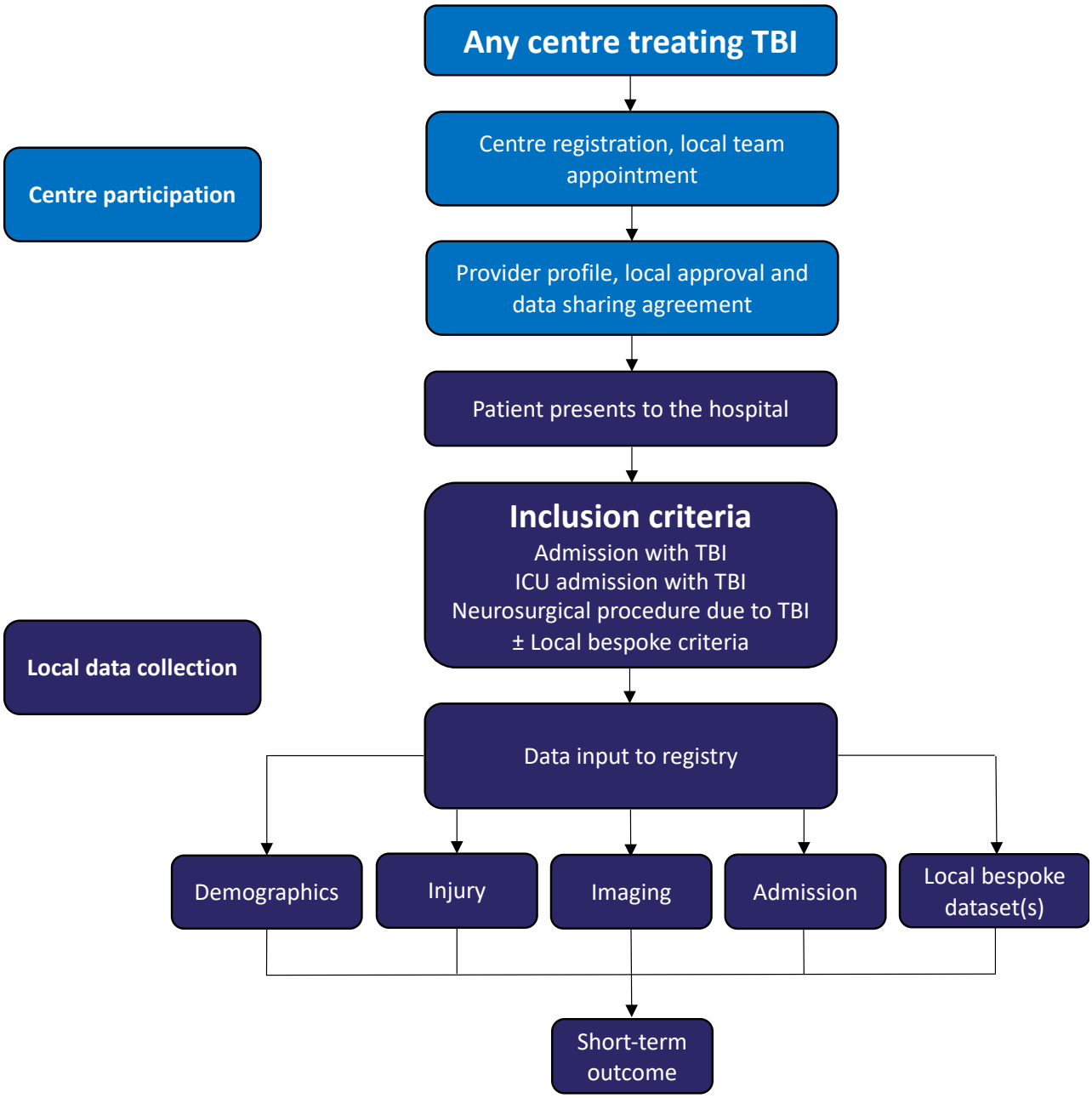

Figure 1. Global Epidemiology and Outcomes following Traumatic Brain Injury (GEO-TBI) registry flowchart.

Dataset

Demographic data

- Date of birth
- Sex

Injury data

- Date and time of injury
- Mechanism of injury
- Primary intracranial injury
- Secondary intracranial injury
- Presence of major extracranial injury
- Systemic disease (ASA grade)
- Secondary transfer
- Admission (or pre-intubation) GCS
- Pupil reactivity
- Focal neurological deficit
- Systolic blood pressure prior to resuscitation
- Oxygen saturation prior to resuscitation

Imaging data

- Date of initial CT head
- Imaging pathology
- Date of initial CT head
- Imaging pathology
- Midline shift
- Obliteration of basal cisterns

Admission data

- Date of admission
- Pre-hospital intubation
- Neurosurgical operation details
- Intracranial infection during admission
- Date of intubation
- Date of extubation/tracheostomy
- Date of ICU admission
- Date of ICU discharge
- In-hospital mortality
- GCS on hospital discharge
- Glasgow Outcome at Discharge Scale (GODS)
- Date of hospital discharge

Outcome data

- Date of assessment
- GOSE

A detailed registry dataset (Case Report Form) is provided in Appendix 3.

Data management and governance

The collected dataset will be stored exclusively on a secure web-based system (ORION; www.orion.net). The ORION platform enables secure data collection, validation and storage in a standard format (SQL), which is compliant with UK Data Protection and National Health Service security standards (including the Data Security and Protection Toolkit). All patient data will be transmitted and stored in encrypted form. In addition to dedicated collection, patient data may be input locally as part of medical training and imported via interfacing from existing sources and databases (Figure 2).

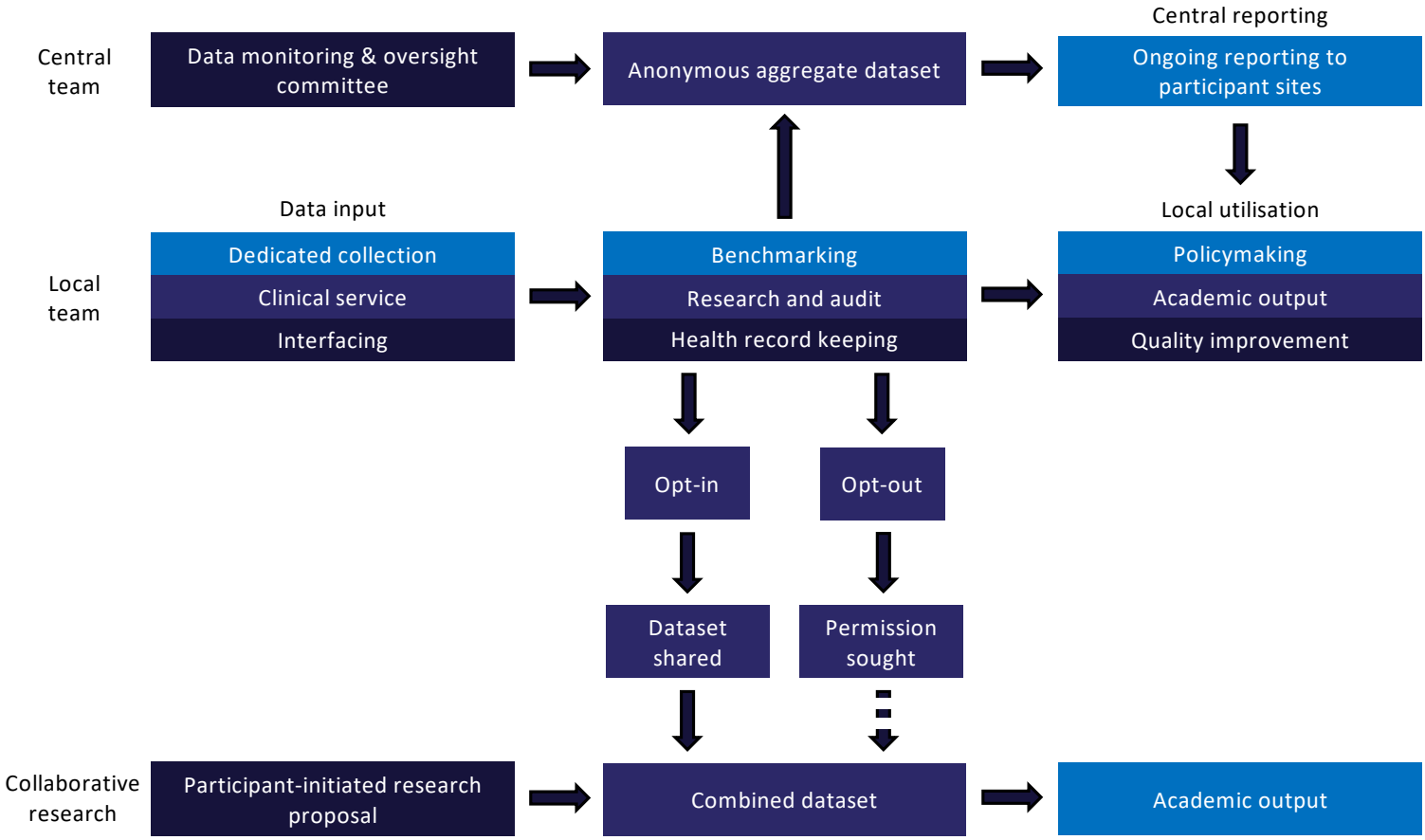

Figure 2. Global Epidemiology and Outcomes following Traumatic Brain Injury (GEO-TBI) registry operational and governance structure.

Non-identifiable data collection

The GEO-TBI registry is fully compliant with anonymous data collection – identifiable data collection is not required for registry participation but can be used by participating centres for their exclusive use (e.g. facilitating recording of follow-up data). The GEO-TBI registry is a tool for healthcare audit with direct input from local treating teams. The decision for local ethical approval will depend on local and national regulations, but support materials are available centrally to support any such applications.

Identifiable data collection

Local centres may wish to use the GEO-TBI registry for health data archiving, benchmarking and service evaluation, where retrospective access to patient data may be desired. Where necessary for local data utilisation, participating centres may include identifying data to their dataset at their discretion as long as this is covered by local institutional approval. Any identifiable data is not accessible to the central study team or other registry participant sites, and the ownership and non-restricted capability to utilise the data

remains with the participating centres. Collection of identifiable data may require local ethical approval depending on local policies and regulations.

Local teams will be able to access the ORION platform having provided the central GEO-TBI team with written confirmation of local institutional approval.

Collaboration strategy and permissions model

A benchmarked report based on the core GEO-TBI dataset will be distributed to all participating centres on an ongoing basis to enable local service evaluation against international standards, and an aggregate registry-wide report across all centres will be regularly published.

Participant-initiated research

Participating centres will have the option to participate in collaborative research projects initiated by other centres participating in the GEO-TBI registry – if they wish to do so, sites will have the ability to share their anonymised dataset with other centres via the ORION platform. At the time of site registration, each site will have the option to participate in such projects without explicit approval sought for each study (opt-in), or with explicit approval sought by the initiating site from the participant sites for each collaboration (opt-out) (Figure 2).

Furthermore, local data may be exported from the GEO-TBI registry as needed. As such, individual centres are able to utilise and combine their data outside of the ORION platform at their own discretion, including bespoke collaborations with other centres. In this case, it is expected that the GEO-TBI registry will be acknowledged in any publications arising from the data.

Authorship

The GEO-TBI registry follows the International Committee of Medical Journal Editors criteria for authorship. In addition, all members of the local study teams will be listed individually as PubMed-citable GEO-TBI collaborators in any central reporting output. In any other manuscripts arising from the GEO-TBI dataset (such as participant centre-initiated projects), members of the local teams who participated in the corresponding project should be listed as authors or PubMed-citable collaborators. In any publications arising from GEO-TBI-based data, it is expected that the GEO-TBI collaboration is acknowledged.

Ethical considerations and approval

Registry approval

The GEO-TBI registry is aimed to measure current TBI practice and epidemiology with no direct implications to clinical patient care. As such, the registry may be regarded as a service evaluation tool rather than research, and in some cases, Research Ethics Committee approval may therefore be waived if permitted by local protocols. Participating centres should follow local guidelines and pathways to obtain approval of the GEO-TBI registry. Proof of local approval will be required in finalising the centre registration process.

Patient consent

Written consent (Appendix 4 or local equivalent) to be included in the registry should be obtained from the patients when permitted by clinical circumstances. However, as the registry will only be used for ongoing data collection without direct impact on patient care, the patients will not be contacted or undergo any additional procedures due to the registry, and only routinely collected data will be used, their consent to be included may be assumed if written consent can not be obtained due to clinical circumstances.

Data ownership and access

Local data ownership remains with the respective participating centre, who may utilise the data for their own purposes at their own discretion in accordance with local regulations. The central registry committee only has access to anonymous aggregate data to provide fixed-period ongoing reporting to participating centres. The current GEO-TBI collaborators are:

- Co-Principal Investigators – Peter Hutchinson, Angelos Kolias and Alexis Joannides
- Study Research Fellow – Tommi Korhonen
- Protocol Development Group – Thomas Bashford, Ronnie Baticulon, David Clark, Indira Devi Bhagavatula, Ignatius Esene, Anthony Figaji, Beverly Cheserem, Tariq Khan, Tzegaseab Laeke, David Menon, Midhun Mohan, Wellingson Paiva, Kee Park, Andres Rubiano, Vijaya Sekhar, Hamisi Shabani, Kachinga Sichizya, Davi Solla, Abenezer Tirsit, Sara Venturini, Deepak Gupta, Manjul Tripathi, Rocio Fernandez-Mendez, Myat Thu, Michael Martin
- Honorary Advisory Panel – Bart Depreitere, Corrado Iaccarino, Laura Lippa, Andrew Reisner, Gail Rosseau, Franco Servadei, Rikin Trivedi, Vicknes Waran

The GEO-TBI team warmly welcomes all neurotrauma professionals to join the GEO-TBI working group via an expression of interest (e-mail geotbi@orion.net, or via https://geotbi.org). All working group members will be listed on the GEO-TBI website.

Contact e-mail geotbi@orion.net.
Website www.geotbi.org & www.neurotrauma.world/projects/global-neurotrauma-registry

Appendix 1. Participant site profile questionnaire

Centre details	
Institution name:	
Institution address:	
Institution country:	
Local registry team members	Local registry lead/contact person Full name: E-mail: Contact number: Local data validator Full name: E-mail: Contact number: Full names and e-mails of other local team members:
Centre characteristics	
Healthcare level of your centre:	Primary/Secondary/Tertiary
Do you consider your hospital rural or urban?	Rural/Urban
Does your centre manage only adults, only children, or both?	Adults only/Children only/Both
Do patients have to pay for the care they receive at your centre?	Yes, all of it/Yes, some of it/No, none of it
Early management of TBI	
How do TBI patients arrive to your hospital?	Ambulance (including HEMS), staffed by doctor(s) Ambulance (including HEMS), staffed by paramedics Ambulance (including HEMS), staffed by non-medical practitioners Car, staffed by non-medical practitioners Other, what?
Does your centre have a trauma team who immediately assesses seriously injured patients upon their arrival to your hospital?	All of the time Most of the time Some of the time Never
Do you have at least one CT scanner in your hospital?	Yes No
Is there constant access to a CT scanner in your hospital?	Yes No If no: is there a nearby institution you can send patients to for emergency CT imaging? Yes No
In your hospital, TBI is managed by: (tick all that apply)	Neurosurgeons General surgeons NCCU/ICU/anaesthetists General practitioners Other, who?

Operative management of TBI				
How many fully trained neurosurgeons are employed by your institution?				
How many cranial neurosurgical procedures are performed in your institution per year?				
Do you have access to the following in cranial neurosurgery?	Yes, for all cases	Yes, for most cases	Yes, for some cases	Never
High-speed drill				
Diathermy (monopolar and/or bipolar)				
Haemostatic agents				
Perioperative management of TBI				
Does your centre have an intensive care unit (ICU)?	Yes No			
Number of ICU beds for adult neurosurgery patients (if your institute only treats paediatric patients, enter 0)				
Number of ICU beds for paediatric neurosurgery patients (if your institute only treats adult patients, enter 0)				
How would you best describe the ICU that TBI patients are admitted to in your institution?	Neurosurgical ICU Neurotrauma ICU Neurological/neurosciences ICU Trauma ICU Surgical ICU Medical ICU General ICU			
Does your institution have a separate paediatric ICU?	Yes No, paediatric TBI patients are managed in the same ICU as adult patients We do not manage paediatric TBI			
Do you have access to an ultrasound machine in your ICU?	Yes No			
How ofter are the following available for the treatment of TBI patients in your hospital?	All of the time	Most of the time	Some of the time	None of the time
Mechanical ventilator				
Invasive blood pressure (arterial line)				
Central venous pressure (central line)				
End-tidal CO_2 monitoring (capnography)				
Intravenous fluids				
Hyperosmolar therapy (e.g. mannitol, hypertonic saline)				
Tranexamic acid				
Sedatives				
Muscle relaxants				
Opiates				
Anticonvulsants				
Vasopressors				
Inotropes				

Red blood cell transfusion				
Platelet transfusion				
Arterial blood gas testing				
Blood electrolyte testing				
Full blood count				
Clotting tests				
Chest radiograph				
Parenteral feeding				
Enteral feeding (NGT or PEG)				
TBI rehabilitation				
Do TBI patients have access to the following during their rehabilitation phase?	All of the time	Most of the time	Some of the time	None of the time
Physiotherapist				
Occupational therapist				
Neuropsychologist				
Speech and language therapist				
Dietician				
Rehabilitation medicine physician				
Do TBI patients undergo follow-up in your hospital?	Yes No If Yes, how many TBI patients are followed up? 0-25% 25-50% 50-75% 75-100%			
Who conducts TBI patients' follow-up?	Neurosurgeons NCCU/ICU/anaesthetists Trauma surgeons General surgeons Neurologists General practitioners Other, who?			
Volume data				
Catchment population				
Catchment area	km^2			
Estimated admissions per year due to: Mild TBI Moderate TBI Severe TBI Estimated operations per year due to TBI:				

Appendix 2. Data validation form

To ensure the epidemiological quality of the GEO-TBI data, the local data validator is requested to fill the below fields using an alternative information source such as hospital records, theatre logbooks or institutional reports.

Centre name:	
Number of admissions due to TBI during the year:	
Number of operations due to TBI during the year:	
Source of information:	

Appendix 3. Case Report Form

Demographic data	
Name	Surname, forename
Date of birth	dd.mm.yyyy
Sex	Male/female
Unique patient ID number	CHI number/NHS number/National patient identifier
Hospital	Choose from participating hospitals
Injury data	
Date and time of injury	dd.mm.yyyy, hh:mm
Mechanism of injury	Select one: Fall: level/<2m/≥2m Vehicle collision: car/motorcycle/pedestrian/bicycle/other Assault: firearm/blade/blunt Blast Not otherwise specified: occupational/recretional/self-harm/other/unknown
Primary intracranial injury	Select one: Scalp injury Fracture of skull vault Base of skull fracture Compound fracture of skull Concussion Diffuse brain injury Focal brain injury or contusion Extradural haematoma Acute subdural haematoma Chronic subdural haematoma Traumatic subarachnoid haemorrhage Traumatic intraventricular haemorrhage Injury to cranial nerve Unspecified injury to head No secondary intracranial injury
Secondary intracranial injury	
Presence of major extracranial injury	Yes/No
Admission (or pre-intubation) GCS	Eye, Verbal, Motor: 1–4, 1–5, 1–6, respectively
Pupil reactivity at presentation	Left, right: Yes/No/Unassessable
Focal neurological deficit	Yes/No/Unassessable
ASA grade	I–V
Secondary transfer	Yes/No

sRR prior to resuscitation	Millimetres of mercury, option for unknown
SpO2 prior to resuscitation	%, option for unknown
Imaging data	
No imaging performed	Tick if no imaging
	If imaging performed:
Date of initial CT head	dd.mm.yyyy
Imaging pathology present	Select if present: Extradural haematoma Subdural haematoma Contusion Fracture Intraventricular blood Traumatic subarachnoid haemorrhage
Midline shift on initial CT	Millimetres
Obliteration of basal cisterns	Select one: Normal Compressed Absent
Admission data	
Date and time of hospital admission	dd.mm.yyyy, hh:mm
Pre-hospital intubation	Yes/No
Treatment	Non-operative management only If operatively managed, select if conducted: Washout or debridement (including penetrating injury) ICP monitoring EVD Burrhole(s) Fracture elevation Craniotomy Craniectomy Posterior fossa decompression Other surgical procedure
Intracranial infection during admission	Yes/No

Intubation*	Yes/No If Yes: Dates of intubation & extubation or tracheostomy (dd.mm.yyyy) Extubation Tick one: Independent ventilation/tracheostomy/terminal
Intensive care unit admission	Yes/No If Yes: Dates of ICU admission & discharge dd.mm.yyyy
In-hospital mortality	Yes/No If No: Glasgow Coma Scale on hospital discharge Eye, Verbal, Motor: 1–4, 1–5, 1–6, respectively
Glasgow Outcome at Discharge Scale (GODS)	1–8
Date of hospital discharge	dd.mm.yyyy
Outcome data	
Date of assessment	dd.mm.yyyy
GOSE	1–8

*Intubation other than solely for surgery. For example, if the patient was only intubated for intraoperative anaesthesia (e.g. surgery of subdural and epidural haematomas causing only mild neurological impairment). If the patient was kept intubated postoperatively, they should be recorded as intubated.

Appendix 4. Patient information leaflet

What is the Global Epidemiology and Outcomes following Traumatic Brain Injury (GEO-TBI) registry?

GEO-TBI is an international database established in 2017 for recording the occurrence and outcomes of traumatic brain injury (TBI). It aims to provide reliable data to inform better service provision in TBI and drive research into the condition. You have been contacted as you have recently sustained a traumatic brain injury.

What are the benefits of the GEO-TBI registry?

- It provides accurate independent information to patients, carers, healthcare regulators and head injury management professionals about the frequency and outcomes after traumatic brain injury.
- It enables the identification of best practices and encourages professionals to develop their practices towards a global standard.
- It helps medical professionals and researchers to identify patient groups for further study and/or unmet needs in head injury care.
- It helps give up-to-date information on the changing worldwide trends of traumatic brain injury occurrence.

Who will have access to my information?

Your treating team will record basic demographic information such as your name, date of birth, and medical record identifier to reliably identify your record for future research purposes. We will collect data on the time and type of injury you had, details of the possible operations, and short-term outcome data.

Data will be kept confidential at all times. Your personal data will only be accessible to your local team. Authorised persons working for the GEO-TBI registry will have access to your data in anonymised form for analysis, from which you cannot be identified.

Is my information safe?

Keeping your information safe is of the highest importance. All those involved in the GEO-TBI comply with the requirements of the UK Data Protection Act 2018, the General Data Protection Regulation (GDPR) and NHS Act 2006. Only your medical team will have access to your identifiable information. All personal information is securely stored in encrypted form, and there are strict procedures in place to ensure only those authorised will be able to view your records. Your personal information will not be shared or passed onto any third party unless required by law.

What if I have further questions about the GEO-TBI registry?

Your treating team should be able to provide you with information about the registry. If you would like to find out more information, you can contact us via e-mail at geotbi@orion.net or write to The GEO-TBI Registry, Orion MedTech CIC, Heron Suite, Middle Court, Copley Hill Business Park, Cambridge, CB22 3GN.

Permission

I **understand** that my information will be stored on the ORION database for the purpose of participating in the GEO-TBI registry.

I **agree** for my medical record identifier to be used for linking my data to other data sources for research around the quality and efficacy of my treatment	☐ Yes	☐ No
I would like to be **informed** about future relevant research that I may be eligible for	☐ Yes	☐ No

Signed:…….. **Date:**……...

Name:……

*If signing on behalf of a child or young person by a person with **parental responsibility***:

Relationship to patient: ……

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