

Global Neurotrauma Outcomes Study (GNOS)

Outcomes following emergency surgery for traumatic brain injury – a prospective, multi-centre, international cohort study



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GNOS Study Protocol Version 9.0.



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1. Overview of study

Objectives

Traumatic brain injury (TBI) accounts for a significant amount of death and disability worldwide and the majority of this burden affects individuals in low-and-middle income countries. Despite this, considerable geographical differences have been reported in the care of patients following TBI. On this background, we aim to provide a comprehensive international picture of the management and outcomes of patients undergoing emergency surgery for traumatic brain injury (TBI) worldwide.

Design

Multi-centre, international, prospective cohort study.

Subjects

Any unit performing emergency surgery for TBI worldwide will be eligible to participate. All TBI patients who receive emergency surgery in any given consecutive 30-day period beginning between 1st of October 2018 and 1st of April 2019 in a given participating unit will be included.

Methods

Each participating unit will form a study team responsible for gaining local approval, identifying patients and conducting data collection. Data will be collected via a secure online platform in anonymised form.

Results

Data related to initial presentation, operative intervention and short-term outcomes will be collected. The dataset developed through an iterative feedback process involving clinicians from both high and low HDI index countries includes patient demographics, details of injury mechanism, timing and nature of surgery, post-operative care and immediate post-operative complications. The primary outcome measures for the study will be 14-day mortality.

Conclusions

The GNOS study aims to provide a global picture of the management and outcomes of patients undergoing emergency surgery for TBI. In addition, this will establish a platform and clinical network facilitate future research in global neurotrauma and neurosurgery.

2. Background

Injuries are estimated to be responsible for approximately 5 million deaths per year worldwide, 9% of all mortality (1), greater than deaths from HIV, malaria and tuberculosis combined. Traumatic brain injury (TBI) accounts for the largest proportion of these deaths – estimates suggest one third of all injury-related mortality (2). 89% of injury-related deaths occur in low-and-middle income countries (1) and in-hospital mortality following TBI is known to be significantly higher in LMICs compared to high-income countries (3).

Emergency surgery for traumatic brain injury

According to the US National Trauma Data Bank, 3.6% of all patients with a head injury require surgical intervention (4) but this value is significantly higher in patients with severe TBI (GCS 8 or less on admission), the subset of TBI which has the worst outcome (5). Timely and adequate evacuation of intracranial haematomas has long been known to dramatically improve outcome (6-9). As such, multiple global health organisations recognise neurosurgical procedures, such as burr holes for the evacuation of traumatic intracranial haematomas and the elevation of depressed skull fractures, as essential to be available on an emergency basis to all worldwide (10, 11). However, 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 (12).

Neurosurgical research in low-and-middle income countries

There has been a relative paucity of neurosurgical research conducted in low-and-middle income countries. 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 (United States, Japan, Germany, United Kingdom and China) (13). Moreover, guidelines for the surgical management of TBI typically advocate the use of expensive technology such as invasive intracranial pressure monitoring which is typically unavailable in low-resource settings (14, 15). As such, context-specific research is urgently required to determine best practice for delivering effective care for traumatic neurological injuries in low-and-middle income countries where the burden of disease is greatest.

Conclusion

We propose to conduct an international multi-centre study of outcomes following emergency surgery for traumatic brain injury. We believe such a project would provide valuable information to advance the care of patients globally with traumatic brain injuries and be feasible with the proposed methodology.

3. Objectives

3.1 Primary objective

- Compare outcomes for emergency surgery for traumatic brain injury (TBI) between high and low Human Development Index (HDI) countries

3.2 Secondary objectives

- Describe differences in patient demographics, baseline clinical characteristics, indications for surgery, choice of procedure, perioperative and postoperative care in emergency surgery for TBI worldwide
- Compare practise globally to the currently accepted standards of care for surgical management of TBI
- Compare typical resources available for essential and emergency neurosurgical care between high and low HDI countries
- Establish a network of providers of neurotrauma and neurosurgical care in high and low HDI index countries interested in participating in research studies to improve outcomes internationally

4. Roles, responsibilities and authorship

4.1 Roles and responsibilities

A team of lead investigators from the NIHR Global Health Research Group on Neurotrauma from the UK, Africa, Asia and South America will be responsible for running this study. In addition, at each participating institution there will be a local study lead, up to 2 additional members of the local study team who will assist with data collection and an independent data validator. The data validator will work independently to the rest of the local study team performing validation of their data as per the process outlined in section 6.2. Local teams can consist of a mix fully trained surgeons, physicians, trainees and/or medical students.

4.2 Authorship

Fully named authors on the byline of publications resulting from this study will be those that satisfy the International Committee of Medical Journal Editors (ICMJE) guidelines for authorship. In addition, 'on behalf of the Global Neurotrauma Outcomes Study Collaborators' will be listed on the byline. The local study lead, additional members of the local study team and independent data validator at each participating site will be listed as PubMed citable collaborator status authors on all publications resulting from this study. Individuals that contribute significantly to the study in other ways will also be listed as PubMed citable collaborator status authors and will be acknowledged on all manuscripts under the following headings based on their contributions (names in each category are listed in alphabetical order) –

- Principal investigator (Peter Hutchinson)
- Co-Principal Investigators (David Clark, Alexis Joannides and Angelos Kolias)
- Protocol Development Group (Omar Ibrahim Abdallah, Amos Olufemi Adeleye, Abdul Hafid Bajamal, Tom Bashford, Indira Devi Bhagavatula, Arnold Bhebe, Hagos Biluts, Karol Budohoski, David Clark, Tony Figaji, Deepak Kumar Gupta, Peter Hutchinson, Ali Ilunga, Alexis Joannides, Mathew Joseph, Tariq Khan, Angelos Kolias, Tsegazeab Laeke, Vickneswaran Mathaneswaran, Rocio Fernandez Mendez, David Menon, Kee Park, Andres Rubiano, Youssuf Saleh, Franco Servadei, Hamisi Shabani, Kachinga Sichizya, Manoj Tewari, Abenezzer Tirsit, Myat Thu, Manjul Tripathi, Rikin Trivedi, Sofia Villar)
- Writing Group – to be confirmed.
- Dissemination Group – to be confirmed.
- Advisory Panel – to be confirmed.

Local collaborators will be given access to their own data after the study has finished so they can compare local to international practise. Named collaborators will be able to request access to the entire data set or a subset of the data to perform post-hoc analyses to answer a defined research question.

5. Methods

5.1 Inclusion criteria

5.1.1 Centre inclusion criteria

Any hospital or clinic worldwide performing emergency surgery for traumatic brain injury is eligible to participate. In the majority of institutions, emergency surgery for TBI is provided by neurosurgeons – however, centres in which emergency surgery for TBI is provided general surgeons, trauma surgeons, general medical doctors or even non-physician clinicians are also eligible to participate.

5.1.2 Patient inclusion and exclusion criteria

5.1.2.1 Inclusion criteria

All adult and paediatric patients admitted to the participating institution with a traumatic brain injury for which they receive emergency surgery during the selected 30-day inclusion period are eligible for inclusion in the core study.

4.1.3 Exclusion criteria

- Patients who ONLY have an external ventricular drain or intraparenchymal wire (or other monitoring device) inserted for the diagnosis and/or management of intracranial hypertension.
- Patients who undergo procedures for chronic subdural haematoma(s), including burr holes or mini-craniotomies.
- Elective (planned admission) or semi-elective (where patient initially admitted as an emergency, then discharged from hospital, and re-admitted at later time for surgery) procedures.
- Patients who have previously had emergency cranial surgery for traumatic brain injury rendering them eligible for inclusion in this study (regardless of whether they were included)

5.2 Data set

A data set (appendix A) will be collected on all adult or paediatric patients receiving emergency surgery for TBI in the inclusion period. The data set is split into 3 sub-sections – injury/admission data, operative data and outcome data. The data fields were inspired by the International Mission for Prognosis and Analysis of Clinical Trials in TBI (IMPACT) Common Data Elements, the UK Traumatic and Audit Research Network (TARN) and Collaborative European NeuroTrauma Effectiveness Research in TBI (CENTER-TBI) data sets and refined through iterative consultation with clinicians caring for TBI in both high and low HDI index countries.

Finally, each institution lead will be asked to fill out a questionnaire on resources available for neurotrauma care and related pathologies.

5.3 Duration of study

Local study teams can pick any 30-day period the 1st of October 2018 and the 1st of April 2019 to start their study. From the date of their surgery, teams must follow patients up for 14-days or when they are discharged or die – whichever of these comes first. For example, if a team selects the the 1st of March 2018 as their start date then they must include all patients who meet the inclusion criteria between then and the 31st of March 2018. Moreover, if a patient receives surgery during the inclusion period on the 31st of March 2019, they should be followed up until the 14th of April 2019 or when they are discharged or die – whichever of these comes first.

5.4 Outcome measures

5.4.1 Primary outcome

The primary outcome measure will be 14-day mortality. The Corticosteroid Randomisation after Significant Head Injury (CRASH) trial demonstrated this is a feasible outcome measure to collect in TBI research in both high and low-resource settings (3).

5.4.2 Secondary outcome

- Return to operating theatre during follow up period
- Length of stay in hospital
- Length of stay in intensive care
- Surgical site infection (SSI)
- Glasgow Coma Score at discharge (GCS-D)

6. Data capture and validation

6.1 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://orioncloud.org/>). The platform enables the secure data collection, validation and storage in a standard (SQL) format and is compliant with NHS security standards (including the Information Governance toolkit). All patient data will be transmitted and held anonymously. An internal pilot will be conducted using the platform to assess feasibility prior to roll out of the full study.

6.2 Data validation

Data validation will occur by 2 mechanisms.

- Web-based forms in the ORION platform will contain fixed options at the point of data entry to maximise the likelihood of accurate and complete data capture from the outset.
- A local data validator independent to the local study team will be appointed at every participating site. After the study period has ended, each data validator will be asked to retrospectively identify all patients that received emergency surgery for TBI in their centre's study period to assess case ascertainment and collect data on 2 variables for those receiving surgery – the operation they received and date it took place.

7. Statistical analysis

Statistical advice has been provided by the MRC Biostatistics Unit at the University of Cambridge.

7.1 Sample size

Sparse data exists in the literature on differences in outcome following emergency surgery for TBI between high and low HDI index countries, which enhances the rationale for the proposed study but also limits our ability to perform accurate sample size calculations. Data from HICs suggests the majority of surgery for TBI occurs in patients with severe TBI (GCS 3-8) (4, 5). A post-hoc analysis of the CRASH trial results (the largest trial conducted in TBI to date) demonstrated mortality at 6 months following severe TBI was 30% in HICs but 51% in LMICs (18). Similarly, a systematic review by Georgoff et al. in 2010 of differences in outcome following severe TBI worldwide at a variety of time points demonstrated a similar disparity between 'developed' and 'developing' countries (19). In our study, we plan to stratify countries into 2 groups based on Human Development Index – high and low HDI index, categories which are very similar to the aforementioned methods of dichotomising countries based on socioeconomic status. As such, if we assume 14-day mortality following emergency surgery for TBIs in high HDI index countries is 50% and 30% in low HDI index countries then at least 91 patients would be required in each group to demonstrate this difference (80% power and 5% type I error).

To account for case mix, a logistic regression model will be constructed examining the effect of a country's HDI index on 14-day mortality while adjusting for confounders (age, Glasgow Coma Score, pupillary reactivity and major extracranial injury). If we assume there is a 0.7 correlation between the confounders and the HDI index of the country, then a further 87 patients are needed in each group (178 in each group, 356 patients in total).

7.2 Analysis

Participating centres will be stratified based on their country into two groups based on their Human Development Index (HDI) rank, similar to the approach successfully used by the GlobalSurg studies (16, 17). The Human Development Index is calculated for each country based on its life expectancy at birth, years of schooling, years of schooling and gross national income (GNI) per capita (<http://hdr.undp.org/en/composite/HDI>). For the purposes of this study, countries classified as 'very high human development' and 'high human development' by the UN will be categorised as 'high HDI index' countries and those classified as 'medium human development' and 'low human development' will be categorised as 'low HDI index' countries. 14-day mortality rate will be reported for high and low HDI index countries and compared using the Pearson chi square test.

8. Standard of care

Audit standards have been derived from existing guidelines and, where appropriate guidelines are unavailable, consensus-derived standards based on the published literature.

8.1 Process of care measures

8.1.1 Time to CT head

Audit standards

- For moderate and severe TBI cases, CT head performed within 1 hour of arriving in the emergency department

Basis

The United Kingdom National Institute of Clinical Excellence (NICE) produces guidelines for investigation of suspected clinically significant acute head injuries (20). For patients with moderate (GCS 8-12) and severe (GCS 3-8) TBI, NICE advises that patients should have a CT head within 1 hour after being assessed. In a high functioning health system, such patients should be assessed on arrival in the emergency department and as such CT head should be performed within 1 hour of arrival.

8.1.2 Time to surgery for evacuation of extradural and subdural haematomas

Audit standards

- <4 hours from time of trauma to skin incision
- <3 hours from time of arrival in ED to skin incision

Basis

According to level 2 evidence, temporal delays in performing trauma craniotomies for acute extradural and subdural haematomas have been associated with a significantly less favourable outcome (6-9). As such, the Brain Trauma Foundation (BTF) guidelines for the Surgical Management of TBI advise that surgical evacuation of traumatic mass lesions (acute extradural haematomas – EDH - and acute subdural haematomas - ASDH) be performed 'as soon as possible'. In the case of ASDH, Seelig et al. found in their landmark paper that mortality in patients who underwent surgery within 4 hours of trauma was 30% compared with 90% if performed after 4 hours (6). As such, we have specified that no more than 4 hours should elapse between trauma and skin incision.

Moreover, data from trauma systems in high HDI index countries suggests that time from arrival in ED to skin incision (including patients that present to other hospitals first) varies from 95 to 150 minutes (21-24). As such, we have determined that no more than 3 hours should elapse between arrival in ED and skin incision.

Haselberger et al. found that for ASDH if time from onset of coma to surgery was less than 2 hours then mortality was 47% compared with 80% mortality where surgery occurred after 2 hours (7). For EDH, Haselberger et al. found that a delay of less than 2 hours between onset of coma and surgery yielded a mortality of 17% and after 2 hours of 65% (7). As such, we have specified that no more than 2 hours should elapse between onset of coma and skin incision.

8.2 Outcome measures

8.2.1 Mortality

8.2.1.1 Mortality following surgery for acute subdural haematoma

Audit standards

- Mortality <15% for craniotomy for evacuation of ASDH
- Mortality <45% for decompressive craniectomy for evacuation ASDH

Basis

In a systematic review published in 2017 of studies comparing outcomes for craniotomy (CR) versus decompressive craniectomy (DC) for ASDH by Phan et al., overall mortality following CR for ASDH was 13.7%. In contrast, overall mortality following DC for ASDH was 40.5% (25). A significant proportion of this discrepancy is due to differences in case mix (patients selected for DC are more likely to have a worse baseline status), which we will also take account of in our analysis.

8.2.1.2 Mortality following surgery for acute epidural haematoma

Audit standards

- Mortality <15% for evacuation of acute epidural haematoma

Basis

Numerous studies have been published that reported the mortality for all patients receiving surgery for EDH. Overall mortality is approximately 10% (26).

8.2.2 Infection

8.2.2.1 Post-craniotomy surgical site infection (SSI) and meningitis

Audit standards

- Surgical site infection rate <10%
- Organ/deep space infection rate <5%

Basis

From the recent literature, rates of post-craniotomy surgical site infection vary from 5.6-7.7% (27-29) and rates of post-craniotomy organ/deep space infection vary from 0.5-3.2%. (27, 30-34).

9. Limitations

The recently published Lancet Commission on Traumatic Brain Injury identified a number of critical areas where research is desperately needed to improve our understanding of TBI, including surgical intervention (35). This study has been designed specifically to provide an overview of the management of patients who receive emergency surgery for TBI globally. Specific topics that this study has NOT been designed explicitly to investigate include:

- The epidemiology of all TBI worldwide
- Indications for surgical intervention in patients with TBI
- The management of severe TBI in intensive care, including indications for and use of ICP monitoring

To investigate topics like the above and more, a World Federation of Neurosurgical Societies (WFNS) sponsored consensus-based international neurotrauma registry is currently being designed by the NIHR Global Health Research Group on Neurotrauma (NIHR GHRGN). Updates will be posted on the NIHR GHRGN website at www.neurotrauma.world.

9. Approval

This study will measure current practice and no changes to standard patient management will be introduced. According to the United Kingdom National Health Service Health Research Authority tool, this study is considered a clinical audit rather than research and, as such, does not require approval by a Research Ethics Committee. We have also approached the Research and Development office at Cambridge University Hospitals who have confirmed this project is an audit rather than research. Local teams are expected to seek approval from either their clinical audit or research department prior to commencing the study, depending on which is the most appropriate locally. Where these departments do not exist, teams should follow the local procedure for obtaining approval for a study of this nature (e.g. a letter from the Head of the Department). Written confirmation of local approval must be submitted electronically prior to local study teams being granted access to the online data entry system and commencing data collection.

10. Support and funding

This study has the support of the World Federation of Neurological Surgeons (WFNS). 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.

11. Appendix A – Data Fields

11.1 Injury / admission data

ORION unique patient identifier	...	
Gender	- Male - Female	
Age (in years at time of admission)	... (option for 'Unknown')	
Mechanism of injury	<p><i>Road traffic collision (RTC)</i></p> <ul style="list-style-type: none"> - RTC Pedestrian - RTC Cyclist - RTC Motorcyclist - RTC Motorcyclist (passenger) - RTC Car (driver) - RTC Car (passenger) - RTC other type of vehicle (driver) - RTC other type of vehicle (passenger) <p><i>Fall</i></p> <ul style="list-style-type: none"> - Fall standing height - Fall from height <p><i>Assault</i></p> <ul style="list-style-type: none"> - Assault (without a weapon) - Assault blunt instrument - Assault knife - Assault firearm <p><i>Other</i></p> <ul style="list-style-type: none"> - Self Harm - Other violence - Animal attack - Explosion - Industrial accident (that does not fit into the categories listed above) - Sport/recreational activity - Unknown - Other 	
Date / time of injury	... (option for 'Unknown')	
Date / time of admission to hospital where surgery is taking place	...	
Was the patient directly transferred from the accident scene to the hospital where surgery is taking place?	- Yes - No	
Method of transport to the hospital where surgery is taking place	- Helicopter (air ambulance) - Land ambulance (staffed by paramedics) - Land ambulance (not staffed by paramedics) - Police - Private vehicle - By foot - Other (specify)	
American Society of Anaesthesiologists (ASA) Physical Status Classification	I – completely healthy fit patient II – mild systemic disease III – severe systemic disease that is not incapacitating IV - incapacitating disease that is a constant threat to life V – a moribund patient who is not expected to live 24 hour with or without surgery	
Glasgow Coma Score on admission (or last documented GCS off sedation if sedated on admission)	GCS total ... / 15 Eyes score ... / 4 Verbal score ... / 5 (option for 'T' if intubated) Motor score ... / 6 (option for 'Unknown')	
	Left	Right
Fixed and dilated pupil at any time point pre-operatively?		
Unreactive pupil at any point pre-operatively?		
Did the patient have an episode of hypoxia at any point prior to surgery?	- Yes - No - Not measured prior to surgery	
Did the patient have an episode of hypotension (systolic BP <90mmHg*) at any point prior to surgery?	- Yes - No - Not measured prior to surgery	

* Note that the lower limit of systolic BP differs for children with age according to the formula $90 + (2 \times \text{age in years})$	
Major extra-cranial injury (defined as requiring hospital admission in its own right)?	- Yes - No
Was a CT Head performed before the operation?	- Yes - No

11.1A CT data (if answered 'Yes' to 'Was a CT head performed before the operation?')

Date / time of first available CT head for review	...	
Midline shift in mm?	- 0-5mm - 5-10mm - >10mm	
Basal cisterns	- Open - Compressed/obliterated - Unknown	
Traumatic subarachnoid haemorrhage?	- Yes - No	
Is there a depressed skull fracture?	- Yes - No <i>If yes, are any of the fragments depressed >1cm relative to the rest of the skull on CT?</i> - Yes - No <i>If yes, is there any evidence of pneumocephalus on CT?</i> - Yes - No <i>If yes, is there evidence of a compound depressed skull fracture on examination of the patient?</i> - Yes - No	
	<i>Left</i>	<i>Right</i>
Supratentorial extradural haematoma?	- No - 0-10mm - 10-20mm - >20mm - Unknown	- No - 0-10mm - 10-20mm - >20mm - Unknown
Supratentorial subdural haematoma?	- No - 0-10mm - 10-20mm - >20mm - Unknown	- No - 0-10mm - 10-20mm - >20mm - Unknown
Supratentorial traumatic parenchymal lesion	- No - Small - Large (>50cm ³ volume) - Unknown	- No - Small - Large (>50cm ³ volume) - Unknown
Is there a traumatic posterior fossa haemorrhage?	- Yes - No	

11.2 Operative data

Grade of most senior surgeon present in the operating theatre	- Fully qualified neurosurgeon - Neurosurgeon-in-training - Other qualified surgeon - Other surgeon in training - Medically qualified but not in a surgical training programme - Not medically qualified surgical provider
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 - Other (specify) - No anaesthesia provided
Type of anaesthesia	- General - Local - None
Date / time operation started?	...
Date / time operation finished?	...

Were pre-incision prophylactic antibiotics given?	<ul style="list-style-type: none"> - Yes - No
Class of surgical wound	<ul style="list-style-type: none"> - Clean - Clean-contaminated - Contaminated - Dirty-infected
Location of surgery	<ul style="list-style-type: none"> - Left - Right - Bilateral - Midline
<p>What was the main procedure undertaken?</p> <p>* if > 1 procedure undertaken, select the main one</p>	<ul style="list-style-type: none"> - Exploratory burr holes <p>If selected 'Exploratory burr holes', what were the intraoperative findings?</p> <ul style="list-style-type: none"> - Extradural haematoma - Acute subdural haematoma - Chronic subdural haematoma - ICH/contusion - No significant findings <p>If selected 'Exploratory burr holes', how did you proceed given the intraoperative findings?</p> <ul style="list-style-type: none"> - No further operative steps, wounds closed - Proceeded to craniotomy - Proceeded to decompressive craniectomy <p><i>Supratentorial craniotomy/craniectomy for traumatic mass lesion</i></p> <ul style="list-style-type: none"> - Evacuation of supratentorial EDH - Evacuation of supratentorial ASDH - Evacuation of supratentorial traumatic parenchymal haemorrhage <p>If selected an option under 'supratentorial craniotomy for mass lesion', what was done with the bone flap at the end of the procedure?</p> <ul style="list-style-type: none"> - Replaced and fixed - Replaced and left floating/hinged - Removed and placed in abdomen - Removed and stored - Removed and discarded <p><i>Infratentorial craniotomy/craniectomy for traumatic mass lesion</i></p> <ul style="list-style-type: none"> - Evacuation of posterior fossa EDH - Evacuation of posterior fossa ASDH - Evacuation of posterior fossa traumatic parenchyma haemorrhage <p><i>Operations to decrease intracranial pressure</i></p> <ul style="list-style-type: none"> - Decompressive craniectomy to control raised intracranial pressure (no significant haematoma evacuated) - Posterior fossa decompression (no significant haematoma evacuated) - Cisternostomy <p><i>Other operation for cranial trauma</i></p> <ul style="list-style-type: none"> - Elevation of depressed skull fracture/other operation for depressed skull fracture - Surgical debridement of penetrating injuries <p>If selected 'Elevation of depressed skull fracture/other operation for depressed skull fracture' OR 'Surgical debridement of penetrating injuries', was there a dural tear?</p> <ul style="list-style-type: none"> - Yes - No <p>If selected 'Elevation of depressed skull fracture/other operation for depressed skull fracture' OR 'Surgical debridement of penetrating injuries', was there an associated venous sinus injury?</p> <ul style="list-style-type: none"> - Yes - No

	<p>If selected 'Elevation of depressed skull fracture/other operation for depressed skull fracture' OR 'Surgical debridement of penetrating injuries', were postoperative prophylactic antibiotics prescribed to prevent infection?</p> <ul style="list-style-type: none"> - Yes - No
<p>Did the patient have an episode of hypotension (systolic BP <90mmHg) at any point during their surgery?</p> <p>* Note that the lower limit of systolic BP differs for children with age, as above.</p>	<ul style="list-style-type: none"> - Yes - No - Unknown
<p>Did you have to perform a lobectomy?</p>	<ul style="list-style-type: none"> - Yes - No <p><i>If yes, what was the anatomical location of the lobectomy? Tick all that apply.</i></p> <ul style="list-style-type: none"> - Right frontal - Left frontal - Right temporal - Left temporal - Other anatomic region
<p>Was a duraplasty performed?</p>	<ul style="list-style-type: none"> - Yes, apposition of dural edges and watertight closure - Yes, rough approximation of dural edges with sutures but not watertight closure - Yes, autologous graft with watertight closure - Yes, autologous graft laid on top of dura with no watertight closure - Yes, non-autologous graft with watertight closure - Yes, non-autologous graft laid on top of dura with no watertight closure - No - Unknown
<p>Did the patient have a wound drain placed?</p>	<ul style="list-style-type: none"> - Yes, subdural - Yes, extradural - Yes, subgaleal - No
<p>Did the patient have an intracranial pressure (ICP) monitor in place for postoperative ICP monitoring?</p>	<ul style="list-style-type: none"> - Yes, intraparenchymal - Yes, ventricular - No
<p>Further comments regarding the procedure</p>	<p>...</p>
<p>Intraoperative death</p>	<ul style="list-style-type: none"> - Yes - No

11.4 Outcomes

<p>Was the patient admitted to intensive care after the operation at any point during the 14-day follow up period?</p>	<ul style="list-style-type: none"> - Yes - No <p>If yes, date of admission to ICU ...</p> <p>If yes, was the patient discharged from ICU during the 14-day follow up period?</p> <ul style="list-style-type: none"> - Yes - No <p>If yes, date of discharge from ICU ...</p>
<p>Surgical site infection</p>	<ul style="list-style-type: none"> - Yes - No <p><i>If yes, was it a superficial/deep incisional infection (i.e. scalp wound) or organ/space infection (i.e. bone flap osteitis, meningitis and/or empyema/abscess)?</i></p> <ul style="list-style-type: none"> - Superficial or deep incisional infection - Organ/space infection <p><i>If yes, how was it diagnosed? Tick all that apply.</i></p> <ul style="list-style-type: none"> - Symptoms - Signs on examination - Blood tests - Imaging - Wound swab microscopy

	<ul style="list-style-type: none"> - Wound swab Gram stain - Wound swab culture - CSF microscopy - CSF Gram stain - CSF culture - Surgical diagnosis
Did the patient return to the operating theatre for cranial surgery during the current admission?	<ul style="list-style-type: none"> - Yes - No <p>If yes, what was the re-operation?</p> <ul style="list-style-type: none"> - Re-evacuation of ipsilateral haematoma - Infection (wound washout) - Infection (removal of bone flap) - Craniectomy - Cranioplasty - Evacuation of contralateral haematoma - Other neurosurgical procedure
Did the patient survive to the end of the follow up period (14 days post-operatively or until they were discharged from hospital, whichever came first)?	<ul style="list-style-type: none"> - Yes - No <p>Was the patient still admitted to hospital on the 14th day post-operatively?</p> <ul style="list-style-type: none"> - Yes - No
Date of death or discharge from your institution (as applicable)	...
Discharge destination (if applicable)	<ul style="list-style-type: none"> - Transfer to another hospital - Transfer to rehabilitation unit - Usual place of residence - Absconded - Other (state)
Glasgow Coma Scale at discharge or at the end of the follow up period if not discharged at 14 days post-operatively (if applicable)	<p>GCS total ... / 15</p> <p>Eyes score ... / 4</p> <p>Verbal score ... / 5 (option for 'T' if intubated or tracheostomy)</p> <p>Motor score ... / 6</p> <p>(option for 'Unknown')</p>

13. Appendix B – Registration form

To register your institution to participate in the GNOS study, please either complete this form and send it with the necessary attachments (evidence of local approval of this study AND a signed copy of the data sharing agreement) to gnos@globalneurotrauma.com or fill out the online form and upload the attachment at: https://cambridge.eu.qualtrics.com/jfe/form/SV_4NikC0kQfabggax.

What is the name of your institution?	...
What is the address of your institution?	
What will be the start date for your 30-day study period?	...
Have you obtained local approval to run this study from the appropriate department/committee?	- Yes - No
Does your institution keep a logbook of all neurosurgical cases that are performed (electronic or paper-based)?	- Yes - No
Who are the members of your local study team?	<p>Local study lead (required) Forename ... Surname ... E-mail ...</p> <p>Additional local team members (up to 2 - optional) Forename ... Surname ... E-mail ...</p> <p>Forename ... Surname ... E-mail ...</p> <p>Local data validator (required, unless no institutional logbook of neurosurgical cases available) Forename ... Surname ... E-mail ...</p>
Do you own a smartphone?	- Yes - No

15. Appendix C – Guidance for successful participation in the study

This document is a guide to help you participate in the GNOS study successfully. There is no need to follow the guidance in this document exactly as each institution will differ slightly in its setup. As long as the requirements for the study are met, the data from your institution can be included in the study and your local study team will be cited as PubMed-citable collaborator status authors on all subsequent publications. However, we advise you read this entire guide prior to deciding to partake in this study so you know what will be required for successful participation in GNOS. If you have any questions or problems, please e-mail gnos@globalneurotrauma.com.

15.1 Prior to the study

15.1.1 Create a local study team

The first step is to appoint a local study lead. This individual will be responsible for coordinating the study at their institution including recruiting and managing the local study team, ensuring the study has been approved locally, registering their site, ensuring the site questionnaire has been completed and verifying the accuracy of all data submitted. Next, up to 2 additional local study team members can be appointed to assist the local study lead with collecting all data. We advise that there should be at least one qualified doctor in each local study team and ideally, at least one neurosurgical attending/consultant or resident/trainee where available. This will make it much easier to fill out certain sections of the data set (e.g. entering details on CT heads) and the site questionnaire. In addition to the above, an independent data validator should be appointed.

15.1.2 Select a 30-day inclusion period to run the study at your institution

Any 30-day period can be selected to include patients receiving emergency surgery for TBI starting between 1st of October 2018 and 1st March 2019. The team should select a period where most, if not all, of the team will be working in the department on most days and not on holiday or on leave. The independent data validator will complete their tasks in the weeks after your selected 30-day inclusion period has finished so you should bear this in mind when appointing this individual.

15.1.3 Obtain local approval for the study

The local study lead should obtain appropriate local approval prior to applying to register their site with us. We anticipate that this study will be considered by most institutions worldwide as an audit and as such will not require formal review by an ethics committee. However, some institutions may consider this project a service evaluation or even original research. If it is unclear, the local study lead should discuss with senior colleagues and/or their institution's audit and/or research departments. Once approval is obtained, written confirmation of approval should be acquired as it will be necessary to upload this document to register your site.

15.1.4 Sign the data sharing agreement

In addition, you will need to sign the data sharing and use agreement. You will need to fill out the form with the name of your institution, the address of your institution, the local Principal Investigator (this should be the local study lead) and your department. The 'Originator' section should be signed by the local Principal Investigator (again, this would be whoever is the local study lead) and the 'Data Provider' section should be signed by someone appropriate from the institution that employs the Originator, such as the Head of the Department.

15.1.5 Register your site

Once the above is done, go to <https://tinyurl.com/y6v5j4uc> and register your site! You will need to upload evidence of local approval and the signed data sharing and use agreement so please have these ready. Alternatively, you can fill out the form in appendix B and send it (along with evidence of local approval of the study AND a signed copy of the data sharing agreement) to gnos@globalneurotrauma.com. After you have registered by either route, we will generate user accounts for your entire study team to access the ORION platform and send you a link to complete the online site questionnaire.

15.1.6 Familiarise yourself with the test system

Log on to <https://test.orioncloud.org/gnos> and log in with user ID: gnos1 and password: gnosuser. This will allow you to become familiar with the ORION data capture platform by entering dummy/test patients (note that you should not enter REAL patient data into this platform).

15.2 During the study period – advice for local lead and additional team members

15.2.3 Enter all patients receiving emergency surgery for TBI

To identify patients, we recommend pursuing some or all of the following strategies during the inclusion period –

- Daily attendance at departmental morning handover to identify patients who have been admitted with TBI overnight
- Daily attendance at the intensive care unit morning handover to identify patients who have been admitted with TBI overnight
- Daily review of ward and intensive care unit handover sheets
- Daily review of operating theatre lists and/or theatre logbooks

Once identified, you should then create an entry for them on the ORION platform. You will need to create a unique patient identifier for every patient you enter into the study. Note that this should NOT

be the same as the patient's local medical records number. However, you should keep a secure record (electronic or paper) at your institution linking the unique patient identifier you generate for each patient for the study with their local medical records number. This record should be deleted when the data collection period is over. After this, you should complete the 'Injury/admission data' and 'Operative data' sections of the data set – please ensure this data is correct, as you cannot change it once entered.

15.2.4 Follow up patients daily

Once you have entered a patient who has received emergency surgery for TBI, we advise following them up daily. At the end of the 14-day follow up period (or when they are discharged from your institution – whichever comes first), you will need to complete the 'Outcomes' section of the data set for each patient. For some of the data fields in this section, it may be easier for you to collect data prospectively for each patient rather than retrospectively. This is particularly true if medical record keeping at your institution is not always very detailed. For example, one of the outcome measures is whether the patient returned to the operating theatre during the follow up period. We advise familiarising yourself with the entire data set (appendix A) and explanation of data fields (appendix F) before starting the study so you know what data you will need to collect for each patient and can formulate strategies for the best way to do so beforehand.

15.2.5 For all patients, complete the 'Outcomes' section of the data set at discharge (or the end of the 14-day post-operative follow up period, whichever comes first),

15.2.7 Ensure you have completed and submitted the site questionnaire

After you have completed entering all patient data required for the study into the ORION platform, you will also have to complete a site questionnaire detailing local resources available for neurotrauma management and related conditions. When you first registered for the study, you will have been sent a link to an online survey which contains the site questionnaire. You need to complete this survey before your site can be included in the study and the members of the local study team included as PubMed-citable collaborator status authors on publications resulting from the study. Teams who have not completed the survey will be sent periodical reminders to do so to ensure their data can be included. We advise you start completing the questionnaire early, as it will likely involve liaising with a number of departments and clinicians in your institution involved in the care of critically unwell neurological patients including possibly surgeons, intensivists, anaesthetists, emergency physicians, radiologists, theatre staff and nurses.

15.3 After the study period – advice for data validator

After the study period has finished, the data validator at each site should, independent to the rest of the study team, retrospectively identify all patients who received emergency surgery for TBI. The easiest way to do so will be by review of electronic or paper operating theatre logbooks. After these

patients have been identified, the validator should also note down the surgery they received and the date of the surgery (both these data points should be available from operating theatre logbooks). All data will then need to be entered into an Excel spreadsheet that we will send you after registration.

We thank you for participating in our study, wish you the best of luck and look forward to working with you on future projects.

16. Appendix D – Glossary of Terms for the Data Fields

16.1. Injury/admission data proforma

Unique patient identifier: A unique ID that YOU generate for each patient that you enter into the study. Note that this should not be the same as the patient's local medical records number, but you should keep a secure record (electronic or paper) at your institution linking the unique ID you generate for each patient with their local medical records number. This record should be deleted when the data collection period is over.

Gender, Age (in years at time of admission): Self-explanatory.

Mechanism of injury: Self-explanatory.

Date of injury: Self-explanatory. If the date of injury is not known, it is possible to specify 'Unknown'.

Time of injury: Self-explanatory. If there is uncertainty as to the time of the injury, try to provide an estimate to the nearest hour if possible. If you cannot specify the nearest hour with a reasonable degree of confidence, specify 'Unknown'.

Date of admission to hospital where surgery is taking place: Self-explanatory.

Time of admission to hospital where surgery is taking place: Self-explanatory.

Was the patient directly transferred from the accident scene to the hospital where surgery is taking place?: The patient may have been taken to a different hospital without the ability to perform emergency surgery for TBI first and subsequently transfer was arranged to your facility for further care – if this is the case, answer 'No' here. Similarly, the patient may have delayed seeking appropriate medical attention and not gone directly from the accident scene to your institution – again, in this case, answer 'No' here.

Method of transport to hospital where surgery is taking place: Self-explanatory. If the patient was transferred directly from the accident scene, enter the method of transport between the scene and your institution. If the patient presented to another hospital prior to yours and was transferred directly from there to your institution, enter the method of transport between their hospital and yours. If the patient

American Society of Anaesthesiologists (ASA) grade:

1. Normal healthy patient.
2. Patient with mild systemic disease
3. Patient with severe systemic disease
4. Patient with severe systemic disease that is a constant threat to life
5. Moribund patient not expected to survive without the operation

Glasgow Coma Score on admission: The patient's Glasgow Coma Score (GCS) admission to your institution should be recorded if they are not sedated (which they may be, particularly if they have been intubated and ventilated by a pre-hospital care team or if they were taken to another hospital before they arrived at your institution). If they are sedated on arrival to your institution, document the most recent GCS documented when they were not on sedation.

Fixed and dilated pupil at any point pre-operatively?: A fixed and dilated pupil (FDP) can be defined as a pupil greater than or equal to 4mm in size that is not reactive to light (38). You should document if the patient developed a FDP on the left, right or bilaterally pre-operatively. This includes situations where a FDP is temporary, for example where a FDP develops but resolves spontaneously or resolves with the administration of neuroprotective measures (for example, a bolus of mannitol).

Unreactive pupil at any point pre-operatively?: This field is similar but slightly different to the one above. If the patient has a FDP, that pupil is also unreactive. However, in some situations, the patient may have one or more normal or small pupils which are unreactive to light. In this case, the pupil is not dilated but it is 'fixed' (i.e. unreactive).

Did the patient have an episode of hypoxia (oxygen saturations <90%, PaO₂ <60mmHg or 8.0kPa or witnessed episode of prolonged apnoea or cyanosis) at any point prior to surgery?: Hypoxia in the context of severe TBI has been associated with a significant increase in mortality (39-41). Answer 'yes' if the patient had an episode of hypoxia documented prior to their surgery. The above definition of hypoxia (SpO₂ <90%, PaO₂ <60mmHg or 8.0kPa or witnessed episode of prolonged apnoea or cyanosis) is based on studies which demonstrate these parameters, particularly in the pre-hospital period, are associated with a significantly less favourable outcome in adults with severe TBI (39, 41). The same definition of hypoxia applies to children with severe TBI (42). If there is no documentation whatsoever of oxygen status in the pre-operative phases of the patient's care (pre-hospital and emergency department/ward) then select 'Not measured prior to surgery'.

Did the patient have a sustained episode of hypotension (systolic BP <90mmHg*) at any point prior to surgery?: Hypotension in the context of severe TBI has been associated with a significant increase in mortality (43, 44). The above cut off for the lower acceptable limit of BP (systolic BP <90mmHg) is based on studies which demonstrate that documented evidence of this parameter in the initial phase of the patient's care results in a significantly worse outcome (43, 44). We accept that emerging evidence suggests that episodes of systolic BP between 90 and 110mmHg may also increase the risk of a less favourable outcome in severe TBI (45), which is reflected in the current BTF guidelines, but feel that investigating this area further is outwith the scope of this study and therefore have opted to set a systolic BP of <90mmHg as our lower limit. If there is no documentation whatsoever of systolic blood pressure in the pre-surgery phases of the patient's care (pre-hospital and emergency department) then select 'Not measured prior to surgery'.

* The lowest limit of systolic BP for children (< or = 18 years) with severe TBI (as recommended by the Guidelines for the Acute Medical Management of Severe Traumatic Brain Injury in Infants,

Children and Adolescents) varies with age according to the following formula – $90 + (2 \times \text{age in years})$).

Major extracranial injury: This refers to any extracranial injury for which the patient would require admission to hospital if it was the sole injury. For example, if the patient had a limb fracture that required admission to hospital for open reduction and internal fixation then you should answer ‘Yes’ to this question. However, if the patient had a limb fracture which could be splinted in the emergency department and the patient then sent home to be seen in the outpatient clinic at a later date – you should answer ‘No’.

Was a CT head performed before the operation?

- We anticipate that for the majority of patients receiving an operation for emergency surgery for TBI, they will have a CT head prior to their operation. However, in certain situations in rural or low-resource environments, a CT head may not be possible to obtain pre-operatively. As such, the local clinical team may proceed with exploratory burr holes (or even a craniotomy) on the basis of clinical signs alone (depressed conscious level, mydriasis, hemiparesis). If this is the case, you should answer ‘No’ to this question and there is an option to specify the patient received ‘Exploratory burr holes’ in the ‘Operative data’ section.
- The interpretation of the CT head for this study should be performed by an individual who regularly looks at such images and is confident in identifying pathology on them, such as a neurosurgeon or neurosurgical trainee. In most institutions, a report by a radiologist will accompany a CT head and this may help to answer the questions below.

Date/time of first available CT head for review: Self-explanatory.

Midline shift (MLS): Midline shift is an indicator that an intracranial space-occupying lesion is exerting mass effect on the brain. There are various methods of calculating MLS, but one method involves drawing a line between the anterior and posterior attachments of the falx and measuring the deviation from this line of the septum pellucidum (see figure 1 below). Further guidance can be found at: <https://radiopaedia.org/articles/midline-shift>.

Basal cisterns: Compression or obliteration of the basal cisterns is associated with raised intracranial pressure and a less favourable prognosis. Clinicians experienced in the management of TBI may be able to categorise the basal cisterns on a CT scan into open or compressed/obliterated. However, if there is any doubt, we advise using the following method: at the level of the midbrain, the CSF cisterns can be divided into 3 limbs – 1 posteriorly and 2 laterally (see figure 1). The basal cisterns can then be classified as open (all limbs open), compressed (one to two limbs are absent) or obliterated (all 3 limbs are absent).



Figure 1 – The 3 limbs of the basal cisterns at the level of the midbrain.

Traumatic subarachnoid haemorrhage: Self-explanatory.

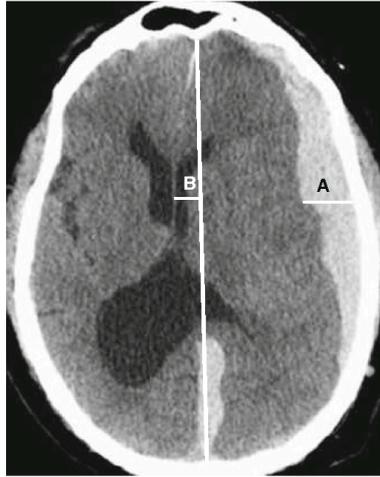
Is there a depressed skull fracture: This question asks whether there is one or more depressed skull fractures (DSFs) anywhere on the calvarium.

- If you answer 'Yes' to the above, you will be prompted to specify whether any fragment of any DSF is depressed >1cm relative to the rest of the skull.
- If you answer 'Yes' to the above, you will be prompted to specify whether there is any evidence whatsoever of pneumocephalus (intracranial air).
- If you answer 'Yes' to the above, you will be prompted to specify if there is evidence of a 'compound' depressed skull fracture – this means there is a break in the skin over the site of the fracture and is determined by physical examination of the patient (even though it is in the 'CT' section).

The following questions should be answered for both the left and right side:

Supratentorial extradural haematoma (EDH): If no evidence of EDH, answer 'No'. Otherwise, specify the thickness of the EDH. The thickness of an EDH should be measured from the inner table of the skull to the point where the haematoma extends maximally into the intracranial space (see figure 2).

Supratentorial acute subdural haematoma (ASDH): If no evidence of ASDH, answer 'No'. Otherwise, specify the thickness of the ASDH. As per EDH above, the thickness of an ASDH should be measured from the inner table of the skull to the point where the haematoma extends maximally into the intracranial space (see figure 2).



1 A preoperative CT brain of a right-handed 63-year-old 1

Figure 2 – ‘A’ represents the thickness of the subdural haematoma, measured from the inner table of the skull to the maximum depth of the haematoma. ‘B’ represents the midline shift (see above). Image taken from <https://www.semanticscholar.org/paper/Prognostic-significance-of-hematoma-thickness-to-in-Moussa-Khedr/4bfeca4714a5593e2344b53f6d6749d446e133ec>.

Supratentorial traumatic parenchymal lesion: Also known as a traumatic intracerebral haemorrhage (ICH), traumatic intraparenchymal haemorrhage or contusion. Answer ‘Large’ if the volume of the traumatic parenchymal lesion is greater than 30cm³. We advise using the ABC/2 method to estimate volume of a traumatic parenchymal lesion – (diameter in the saggital plane (in mm) x diameter in the axial plane (in mm) x diameter in the coronal plane (in mm)) / 2 – which has been validated for this purpose also (46, 47). If there are multiple traumatic parenchymal lesions, answer this question based on the largest lesion visible. Petechial haemorrhages (suggestive of diffuse axonal injury) are NOT considered traumatic parenchymal lesions for the purposes of this question.

Is there a traumatic posterior fossa haemorrhage?: Answer ‘yes’ if there is any evidence of a traumatic posterior fossa haemorrhage, regardless of whether it is extradural, subdural or traumatic parenchymal haemorrhage.

- **If yes, is there evidence of distortion, dislocation or obliteration of the fourth ventricle?:** Due to its location, a traumatic haematoma in the posterior fossa can cause distortion, dislocation or obliteration of the fourth ventricle. For some examples of compression of the fourth ventricle, see figure 3. If any compression of the 4th ventricle is observed, answer ‘Yes’ to this question.

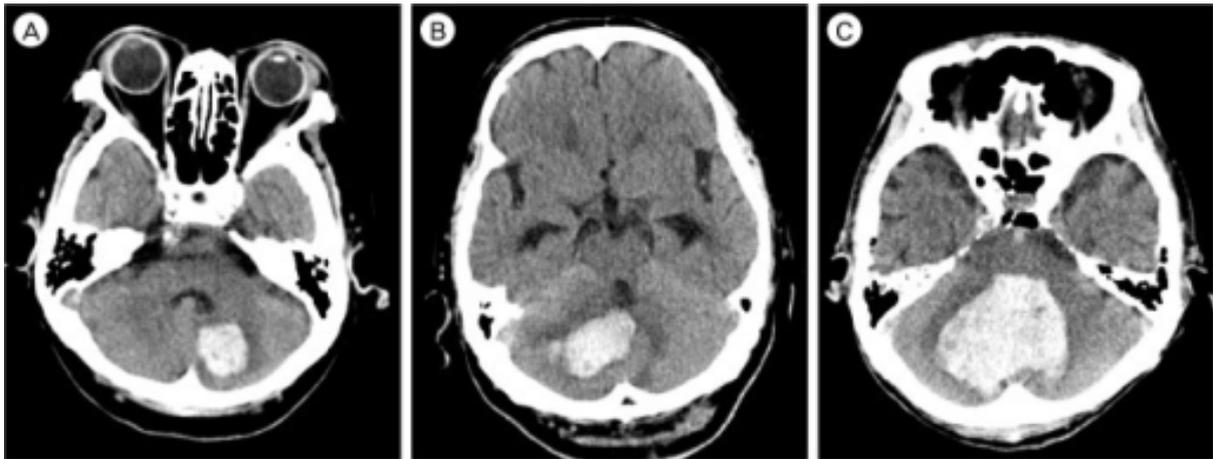


Figure 3 – The above images demonstrate different degrees of compression of the fourth ventricle. In these images, the compression is due to haemorrhagic stroke instead of traumatic posterior fossa haemorrhage, however the appearances of compression are similar in trauma. Image A demonstrates a 4th ventricle of normal size and location. In image B, the 4th ventricle is partially compressed and shifted. In image C, there is complete obliteration of the 4th ventricle. Image taken from https://openi.nlm.nih.gov/detailedresult.php?img=PMC4626341_jcen-17-185-g001&req=4.

- **If yes, is there evidence of obstructive hydrocephalus?:** Clinicians experienced in the management of neurotrauma will be able to identify obstructive hydrocephalus on a CT scan with confidence. For further information regarding obstructive hydrocephalus, see here: <https://radiopaedia.org/articles/obstructive-hydrocephalus>.

16.2 Operative data

Grade of most senior surgeon present in the operating theatre: Note that this question is asking who the most senior surgeon present in the operating theatre was. This individual may not be the primary surgeon actually performing the procedure – for example, a fully qualified neurosurgeon may be present unscrubbed in the operating theatre but the surgeon scrubbed and performing the procedure could be a neurosurgeon-in-training; in this situation, the correct answer to this question would be ‘Fully-qualified neurosurgeon’.

1. ‘Fully qualified neurosurgeon’ refers to an individual who has completed a neurosurgical training programme. They are often referred to as ‘Consultants’ or ‘Attendings’.
2. ‘Neurosurgeon-in-training’ refers to an individual who is currently completing a neurosurgical training programme (known in many countries as a ‘residency’). It also includes neurosurgeons who are undertaking fellowship training.
3. ‘Other fully qualified surgeon’ refers to an individual who has completed a surgical training programme in a surgical specialty other than neurosurgery. In some parts of the world, general surgeons or trauma surgeons will perform emergency surgery for TBI.

4. 'Other surgeon in training' refers to an individual who is currently completing a surgical training programme in a surgical specialty other than neurosurgery. See 'Other fully qualified surgeon' above.
5. 'Medically qualified but not in a surgical training programme' refers to an individual who has a medical degree but is not a fully qualified surgeon or in a surgical training programme. An example would be a general practitioner/general medical doctor in a rural practise.
6. 'Not medically qualified surgical provider' refers to an individual who does not have a medical degree but is performing neurosurgical procedures. In some settings, 'Clinical Officers' or 'Non-physician Clinicians' are given this role.

Grade of most senior anaesthesia provider present in the operating theatre:

1. Similar to the above categories.

Type of anaesthesia: For the majority of emergency surgery for TBI, we anticipate that patients will receive general anaesthesia. However, in certain situations, local anaesthesia may be deemed more appropriate or even be the only resource available. In certain low-resource settings, it is possible no anaesthesia is available.

Date/time operation started and finished: The time the operation starts can be defined as the time the first incision is made, not when the patient arrives in the operating theatre.

Were pre-incision prophylactic antibiotics given?: The World Health Organisation Surgical Safety checklist recommends patients receive prophylactic antibiotics in the 60 minutes prior to the skin incision for all procedures to reduce the risk of surgical site infection.

Location of surgery:

- The majority of procedures are likely to fall simply into either the 'Left' or 'Right' categories.
- Certain procedures might be more appropriate to designate as 'Bilateral', such as a bifrontal decompressive craniectomy for raised intracranial pressure.
- 'Midline' refers to procedures predominantly involving the midline – for example, a depressed skull fracture or penetrating brain injury in the midline.
- Patients may have multiple intracranial injuries which require complex procedures to treat them. In these cases, enter the location of the procedure which dealt with the most clinically significant injury.
 - As an example, a patient may present with a right acute subdural haematoma and a left acute extradural haematoma and the surgeon performs a separate craniotomy on both sides. Even if the procedure does not involve re-draping the patient in between craniotomies and even if the same incision is used to perform both craniotomies, you should only enter the procedure that is dealing with the more clinically significant injury – for example, if the right-sided acute subdural haematoma appears to be

exerting more mass effect on the brain than, for this case, you should enter the procedure took place on the 'Right'.

- a. Situations in which a bifrontal decompressive craniectomy is performed may be confusing. If the procedure is performed predominantly to control raised intracranial pressure, it would be appropriate to select 'Bilateral' here and 'Decompressive craniectomy to control raised intracranial pressure (no significant haematoma evacuated)' below. Similarly, if the procedure is performed to evacuate similarly sized traumatic supratentorial haematomas on both sides, then it would be appropriate to select 'Bilateral' here and 'Supratentorial craniotomy/craniectomy for traumatic mass lesion' below. Conversely, if there is, for example, a large haematoma on right side which is thought to be predominantly responsible for the patient's symptoms and signs and a smaller haematoma on the left side, if a bifrontal decompressive craniectomy is performed mainly to evacuate the larger haematoma then it would be more appropriate to select 'Right' here and 'Supratentorial craniotomy/craniectomy for traumatic mass lesion' below.

Type of surgical wound: The Center for Disease Control (CDC) advises classifying surgical wounds into 4 categories, depending on the degree of contamination of the surgical wound at the time of the operation (48). These are:

- **Clean:** *"An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria".* An example of an emergency operation for TBI that fits in this category would be a trauma craniotomy for evacuation of extradural or acute subdural haematoma.
- **Clean-Contaminated:** *"Operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered."*
 - No neurosurgical operations fit into this category.
- **Contaminated:** *"Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (for example, open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered, including necrotic tissue without evidence of purulent drainage (for example, dry gangrene), are included in this category".*
 - Examples
 - Surgical debridement of a penetrating injury that occurs soon after the trauma occurred

- Elevation of compound depressed skull fracture that occurs soon after the trauma
- Trauma craniotomy for evacuation of extradural or acute subdural haematoma in which the incision used extends/incorporates an existing laceration sustained at the time of the trauma
- **Dirty or Infected:** *“Includes old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation”.* An example of an emergency operation for TBI that fits in this category is the surgical debridement of a penetrating injury that occurs a significant amount of time after the trauma occurred, particularly if there is evidence of infection.

What was the main procedure undertaken?: In order to keep the data entry form as simple as possible, we have minimised the number of categories that you can choose to describe the procedure that was performed. We acknowledge that there will be a proportion of patients who have multiple intracranial injuries who may fit into multiple categories. In these situations, similar to the ‘Location of injury’ question above, we advise selecting the procedure that treated the most significant intracranial injury. There is a comments section after this question where you can add further information about the procedure if you feel it is appropriate.

1. Exploratory burr holes

- b. In some rural and/or low resource settings, it may be the case that a patient has signs of a traumatic intracranial haematoma (history of trauma, decreased conscious level, dilated pupil) and a CT scan is not available in a timely fashion to confirm the diagnosis. In such situations, the treating team may decide to proceed to perform ‘Exploratory burr holes’.
 - i. If you select ‘Exploratory burr holes’, you will be prompted with a further question as to what your intraoperative findings are. You can select extradural, acute subdural and intracerebral haematoma as options – you can also select ‘no findings’ if no haematoma was found in any of the burr holes performed.
 - ii. If you select ‘Exploratory burr holes’, you will also be prompted with a further question as to how you proceeded intra-operatively.
- c. If you are performing burr holes to evacuate a CT-confirmed chronic subdural haematoma then that is a different procedure to exploratory burr holes performed in the context of an acute history of trauma and that patient is NOT eligible for inclusion in this study. However, if you perform emergency exploratory burr holes (no pre-operative CT) and find a CSDH then that patient can be included.

2. Supratentorial craniotomy/craniectomy for traumatic mass lesion

- a. If you select this option, you will be asked to specify whether the operation was performed for evacuation of an extradural haematoma (EDH), acute subdural

haematoma (ASDH) or traumatic parenchymal haemorrhage (also known as intracerebral haemorrhage – ICH – or contusion). If the patient has multiple types of bleed on a single side, select the operation performed which dealt with the most significant intracranial pathology. For example, if a patient is found to have a large extradural haematoma intra-operatively with a smaller subdural haematoma also encountered, then you should select ‘Evacuation of supratentorial EDH’ as the procedure.

i. If you select any of the procedures under ‘Supratentorial craniotomy craniectomy for traumatic mass lesion’, you will then be presented with a further question as to what you did with the bone flap after the procedure.

1. ‘Replaced and fixed’ – the bone is replaced and fixed with cranioplates, craniofix or sutures.
2. ‘Replaced and left floating/hinged’ – the bone is replaced, but is either not secured anywhere (‘floating’) or is secured on one side only (‘hinged’)
3. ‘Removed and placed in abdomen’ – placed in the abdomen for replacement at a later date.
4. ‘Removed and stored’ – stored in a fridge for replacement at a later date.
5. ‘Removed and discarded’ – self-explanatory.

b. If you performed one or more exploratory burr holes first and, on the basis of your intraoperative findings, proceeded to perform a supratentorial craniotomy or craniectomy then you should initially select ‘Exploratory burr holes’ instead of ‘Supratentorial craniotomy/craniectomy for traumatic mass lesion’ – as above, you will then be presented with options asking you as to what the intraoperative findings were and how you proceeded intra-operatively (e.g. connection of the holes to create a craniotomy).

c. If you performed a decompressive craniectomy (either unilateral or bilateral) and the main indication for the procedure was control of raised intracranial pressure rather than evacuation of a haematoma, please instead select ‘Decompressive craniectomy to control raised intracranial pressure (no significant haematoma evacuated)’.

3. Infratentorial craniotomy/craniectomy for traumatic mass lesion

a. If you select this option, you will then be asked to specify whether the operation was performed for evacuation of an extradural haematoma (EDH), acute subdural haematoma (ASDH) or traumatic parenchymal haemorrhage (also known as intracerebral haemorrhage – ICH – or contusion).

b. If a posterior fossa decompression was performed but no significant haematoma was evacuated, then do not select this option but select ‘Posterior fossa decompression (no significant haematoma evacuated)’ (see below) instead.

4. Operations to decrease intracranial pressure

- a. **Decompressive craniectomy to control raised intracranial pressure (no significant haematoma evacuated)**
 - i. Self-explanatory.
 - b. **Posterior fossa decompression (no significant haematoma evacuated)**
 - i. Self-explanatory.
 - c. **Cisternostomy**
 - i. Certain units throughout the world have adopted the practise of performing a cisternostomy in certain situations following TBI. While this technique is relatively new and remains controversial in the neurosurgical community, we have included it here in the interests of being all-inclusive.
 - ii. You should only select this option if this was the main procedure performed – if another procedure was performed (e.g. evacuation of a subdural haematoma) and this was done as an adjunct, select the other procedure.
5. **Other operation for cranial trauma**
- a. **Elevation of depressed skull fracture/other operation for depressed skull fracture**
 - i. If the patient has a depressed skull fracture and an underlying intracranial haematoma, whether to place the procedure in this category or in the ‘Supratentorial craniotomy/craniectomy for traumatic mass lesion’ category depends on the main reason for performing the procedure. If the procedure was predominantly performed to elevate the depressed skull fracture and there was only a small underlying haematoma, it should be listed as ‘Elevation of depressed skull fracture/other operation for depressed skull fracture’. If the procedure was performed predominantly because there was a large intracranial haematoma associated with a depressed skull fracture, it should be listed as ‘Supratentorial craniotomy/craniectomy for traumatic mass lesion’.
 - b. **Surgical debridement for penetrating brain injury**
 - i. This category includes all procedures performed due to penetrating brain injury (PBI), including those in which a foreign body is removed.
 - ii. Operations to repair dural venous sinus injuries secondary to PBIs should be included in this category.
 - iii. Penetrating brain injuries are often associated with a depressed skull fracture – it is up to your discretion which category to include such operations in, based on what the main reason for performing the procedure was.

Comments: Where it is felt to be needed, it is possible to enter further details regarding the operation performed in a free text section here.

Was a duraplasty performed?: This question asks whether or not any procedure was performed to repair the dura. See below for explanations of some of the terms used:

- ‘Autologous graft’ means tissue transplanted from one part of a patient’s body to another. Examples of autologous grafts for duraplasty include pericranium or fascia lata.
- ‘Non-autologous graft’ refers to any other material used for dural repair other than an autologous graft. These include allografts (tissue transplanted from another human – e.g. AlloDerm or Tutoplasty [human]); xenografts (tissue transplanted from another species – e.g. Duraguard, Durepair, Duragen, Tutoplast [bovine] and Tissudura) and synthetic grafts (Synthecel and GORE)

Brain lobectomy: Self-explanatory.

Did the patient have an episode of hypotension (systolic BP <90mmHg*) at any point during their surgery?: Intraoperative hypotension (IHT) can occur during a trauma craniotomy, often after dural opening, and its development is associated with a less favourable outcome (49-53). If there is no documentation whatsoever of intraoperative systolic blood pressure then select ‘Not measured during surgery’.

* The lowest limit of systolic BP for children (< or = 18 years) with severe TBI (as recommended by the Guidelines for the Acute Medical Management of Severe Traumatic Brain Injury in Infants, Children and Adolescents) varies with age according to the following formula – $90 + (2 \times \text{age in years})$.

Did the patient have an intracranial pressure (ICP) monitor in place at the end of the procedure?: Self-explanatory.

Intraoperative death: Self-explanatory.

16.3 Outcomes

Was the patient admitted to the intensive care unit after the operation at any point during the 14-day follow up period?: If you answer ‘yes’ to this question then you will be prompted with further questions as to the date of admission (if the patient was admitted directly from the operating theatre, then put the date of the operation) and date of discharge from intensive care.

Did the patient return to the operating theatre for cranial surgery during the follow up period? Self-explanatory. If the patient returns to the operating theatre during the 14-day period, answer ‘yes’ to this question and you will be prompted to specify exactly what the reason for return to theatre is. Most of the options pertain to complications following the initial procedure that require surgical intervention – specifically, re-evacuation of haematoma, operations to manage postoperative infection or, if the bone flap was replaced at the end of the first procedure, the patient may require a subsequent decompressive craniectomy for postoperative swelling. Some units may also perform a cranioplasty during the 14-day follow up period and this is an option in this section. In addition, expansion of a smaller contralateral haematoma to the originally evacuated haematoma is a recognised complication of trauma craniotomies and, as such, has been included as an option.

Finally, if the patient had another neurosurgical procedure unrelated to their original procedure in the 14-day follow up period (for example, the patient's original procedure was craniotomy and evacuation of a right-sided subdural haematoma and the patient subsequently had expansion of a contralateral subdural haematoma which required a craniotomy and evacuation), then the option 'Other neurosurgical procedure unrelated to the first procedure'. If the patient returned to the operating theatre multiple times in the 14-day follow up period, then you should only enter the reason for return to theatre for the first re-operation the patient had.

Did the patient survive to the end of the follow up period (14 days post-operatively or until they were discharged from hospital, whichever came first)?: Self-explanatory. Depending on your responses to this question, the questions in figure 4 will be presented to the user.

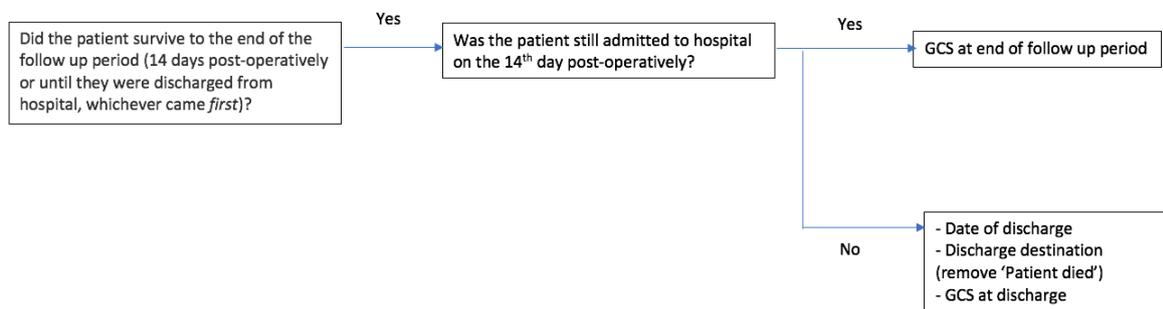


Figure 4 – Follow up questions

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