International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

INPLASY202680063

doi: 10.37766/inplasy2026.8.0063

Received: 16 August 2026

Published: 16 August 2026

Reporting and analysis in observational studies of traumatic intracranial haematoma evacuation and intracranial pressure monitoring: a systematic methodological review and framework-development protocol

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ADMINISTRATIVE INFORMATION

Support - Gov RTP Scholarship. No COI.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - The authors declare no conflicts of interest.

INPLASY registration number: INPLASY202680063

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 August 2026 and was last updated on 16 August 2026.

INTRODUCTION

Study aim The primary aim is to systematically assess how observational studies in two time-sensitive neurosurgical intervention streams—traumatic intracranial haematoma (TICH) evacuation and invasive intracranial pressure monitoring (ICPm)—define, collect, report and analyse the information needed to interpret intervention–outcome associations, and to use these findings to develop an evidence-informed, standardised data collection and analysis framework.

The objectives are to: (1) identify eligible reports from the two completed systematic reviews and updated searches; (2) map reporting of cohort entry, baseline patient and injury severity, transfer pathway, time zero, intervention eligibility and selection, treatment limitations, intervention timing and technical details, subsequent treatment delivery, mortality, functional outcomes, missing data and analytical adjustment; (3) quantify reporting completeness and variation in definitions; (4) map reported elements to the Australian Traumatic Brain Injury Initiative (AUS-TBI) single data dictionary and the NINDS Traumatic Brain Injury Common Data Elements version 3.0; and (5) develop a proposed common core with separate TICH- and ICPm-specific modules, specifying each element's definition, acceptable source, measurement time point and rationale.

Background Severe traumatic brain injury (TBI) often requires urgent treatment before prognosis is clear. Two important intervention streams are evacuation of traumatic intracranial haematoma (TICH) and invasive intracranial pressure monitoring (ICPm). Their effects are commonly evaluated using observational cohorts because randomising clinically necessary surgery or withholding usual monitoring may be infeasible or unethical. These studies are particularly vulnerable to confounding by indication and time-related bias: baseline severity, perceived salvageability, transfer pathway and survival to intervention can influence both whether and when treatment occurs and the eventual outcome.

Our completed TICH review included 17 heterogeneous studies; only a minority reported comparable time intervals or adequately described treatment-selection variables. Our completed ICPm review included 31 comparative studies and found substantial clinical and methodological heterogeneity, inconsistent functional-outcome reporting and variable adjustment for baseline prognosis. Across both streams, definitions of cohort entry, severe TBI, time zero, intervention exposure, mortality and functional outcome differ.

Existing resources, including the AUS-TBI single data dictionary and NINDS TBI Common Data Elements, provide a strong general foundation for harmonised TBI research. General reporting guidance such as STROBE and RECORD is also relevant. However, observational studies of time-sensitive neurosurgical interventions require intervention-specific information about eligibility, decision-making, delays, technical details, subsequent treatment and treatment limitation. A systematic methodological review is needed to identify recurrent reporting and analysis gaps and develop a practical framework for consistent data collection across these two study streams.

Rationale Meaningful comparison, risk adjustment and future data pooling require more than a common list of demographic variables. For TICH evacuation, studies must distinguish injury or first emergency-service contact, presentation, imaging, referral, treatment decision, theatre and evacuation times, while also describing lesion type, operative indication and direct admission or interhospital transfer. For ICPm, studies must record eligibility, reasons for providing or withholding monitoring, insertion time, device type, monitoring duration, intracranial hypertension, treatments triggered by monitoring and survival to monitor placement. Both streams require consistent baseline prognostic factors, treatment limitations, mortality time points and validated functional outcomes.

Developing a new framework without examining existing standards risks duplication; relying only on broad TBI dictionaries risks missing variables needed to interpret these particular interventions. This study will therefore combine report-level evidence mapping with explicit comparison against the AUS-TBI single data dictionary, NINDS TBI Common Data Elements and applicable reporting guidance. Established elements will be retained where suitable, and additional elements will be proposed only where the review identifies an intervention-specific need.

The output will be an evidence-informed common core with separate TICH and ICPm modules. It will not be described as a validated minimum dataset or international consensus standard. Formal stakeholder consensus, retrospective feasibility assessment and multicentre prospective testing are separate subsequent phases.

METHODS

Search strategy Three linked search streams will be used.

TICH evidence stream: the 17 reports included in the registered 2024 TICH timing review will be rescreened under the present criteria. PubMed, Ovid MEDLINE, CINAHL and Web of Science will be updated from 1 May 2023.

ICPm evidence stream: the 31 reports included in the completed registered ICPm review will be rescreened under the present criteria. MEDLINE/PubMed, Embase, the Cochrane Central Register of Controlled Trials and Web of Science will be updated from 2 August 2025. Google Scholar and citation searching will be supplementary sources.

Reporting/data-standards stream: MEDLINE/PubMed, Embase and Web of Science will be searched from inception for TBI common data elements, data dictionaries, minimum or core datasets, outcome frameworks and reporting standards. Official NINDS TBI Common Data Elements and AUS-TBI documents will be searched directly.

Controlled vocabulary and free-text terms will be adapted for each database. The core PubMed concepts are as follows and will be adapted to further databases.

TBI: ("Brain Injuries, Traumatic"[MeSH] OR "Craniocerebral Trauma"[MeSH] OR "traumatic brain injur*"[tiab] OR TBI[tiab] OR "head injur*"[tiab]);

TICH: ("Brain Hemorrhage, Traumatic"[MeSH] OR TICH[tiab] OR acute traumatic subdural, epidural/extradural, intracerebral or intraparenchymal haematoma/hematoma/haemorrhage) AND (craniotom* OR craniectom* OR evacuat* OR operative/surgical intervention) AND (time OR timing OR delay* OR interval* OR pathway* OR prehospital OR intrahospital);

ICPm: ("intracranial pressure monitor*" OR "monitoring of intracranial pressure" OR "ICP monitoring" OR ICPm);

standards: ("common data element*" OR "data dictionar*" OR "minimum data set" OR "core dataset" OR "common outcome measure*" OR "core outcome set*" OR "standardised reporting" OR "standardized reporting" OR "data harmonisation" OR "data harmonization" OR "standardised data collection" OR "standardized data collection" OR "Australian Traumatic Brain Injury Initiative").

No date, geographic or language restrictions will be applied except the stated update dates. Animal studies will be excluded. Backward and forward citation searching will be performed for included reports and key standards. Preliminary PubMed searches were run on 13 August 2026. Final searches will be rerun before screening is completed, with full database-specific strategies, dates and yields retained.

Eligibility criteria Two linked clinical evidence streams and one standards set will be included.

TICH stream: observational primary human reports of adults with acute, radiologically confirmed traumatic intracranial haematoma treated by urgent evacuation with craniotomy or craniectomy, reporting intervention timing or pathway and clinical outcomes. Eligible observational designs include prospective or retrospective cohorts, registry studies, case-control studies and case series. Chronic, subacute or acute-on-chronic collections, non-traumatic haemorrhage, penetrating injury, delayed surgery after initial conservative management and decompression performed solely for intracranial hypertension will be excluded.

ICPm stream: observational primary human studies of hospitalised TBI patients comparing invasive ICP-monitored and non-monitored groups and reporting mortality and/or functional outcome. Eligible designs include prospective or retrospective cohorts, registry-based cohorts and case-control studies. Mixed-age or paediatric cohorts may be retained, with age composition recorded, consistent with the completed source review.

Standards set: methodological reports, data dictionaries, common data elements, core or minimum datasets, common outcome sets and reporting or data-harmonisation frameworks applicable to acute human TBI research. Official AUS-TBI and NINDS TBI CDE documents are eligible.

The concept of interest is the definition and reporting of information required to interpret intervention selection, timing, delivery and outcome: cohort entry; demographics and premorbid state; clinical, physiological, biochemical, imaging and extracranial injury severity; transfer pathway; treatment eligibility and reasons for providing or withholding treatment; time anchors and intervals; intervention details; subsequent treatments; treatment limitations; mortality; functional outcome; missing data; and adjustment methods.

Eligible contexts include prehospital, emergency, trauma-system, neurosurgical, operating-theatre and intensive-care care in any country. There will be no restriction by publication year or language. Randomised trials, case reports, non-original reviews or editorials, preclinical studies, non-traumatic conditions, device-accuracy studies without a relevant clinical intervention cohort, retracted reports and reports without extractable methodological information will be excluded from the primary reporting-frequency synthesis. Reviews and excluded trials may be used for citation searching or contextual comparison. Overlapping publications will be linked. The primary unit of analysis will be the report, with sensitivity analysis at unique-cohort level where appropriate.

Data extraction Records will be deduplicated and screened against prespecified criteria independently by two reviewers; disagreement will be resolved by consensus or a third reviewer. A piloted extraction form will be completed by one reviewer and independently verified by a second.

For each clinical report, extraction will cover bibliographic details, country, setting, design, data source, recruitment period, sample size, eligibility, cohort entry and time zero; demographics and premorbid state; GCS and pupil assessment; hypotension, hypoxia and other physiology; CT phenotype; extracranial injury; transfer; treatment eligibility, selection and limitation; pathway and intervention timestamps; intervention details; subsequent treatments; mortality definition and time point; functional-outcome instrument, source and time point; missing-data handling; and analysis methods. Baseline variables merely reported will be distinguished from variables entered into adjusted models. TICH-specific items will include lesion and operative details. ICPm-specific items will include device type, insertion timing, monitoring duration, intracranial hypertension and treatments initiated in response to monitoring.

For standards documents, each candidate element, definition, permissible values, source and measurement time point will be extracted. Clinical-report items will be mapped to AUS-TBI and NINDS TBI CDE as exact, partial or absent matches, with mapping verified by a second reviewer. Because the outcome is reporting practice, no overall risk-of-bias score will be used to weight reporting frequencies.

Outcome definitions The primary outcome is the reporting frequency of each prespecified data element, expressed as the number and percentage of eligible reports in which the element is explicitly reported with enough information to code it without unsupported inference. Items that are genuinely not applicable will be excluded from that item's denominator and reported separately.

Co-primary methodological outcomes are: (1) consistency of definitions, time anchors and outcome windows across reports; and (2) coverage of candidate elements by the AUS-TBI single data dictionary and NINDS TBI CDE v3.0, classified as exact match, partial match or absent.

Secondary outcomes are reporting completeness within the domains of cohort definition, baseline prognosis, transfer, treatment eligibility and selection, timing, intervention details, subsequent treatment, treatment limitation, mortality, functional outcome, missing data and statistical adjustment; differences by intervention stream, design, publication era, setting and region; and the provenance and rationale for each proposed framework item.

The final methodological output will comprise a proposed common core plus separate TICH and ICPm modules. Mortality and functional outcomes are reporting domains; no pooled estimate of clinical treatment efficacy is planned.

Strategy of data synthesis / Statistical analysis Study selection will be reported using PRISMA 2020, with searches documented according to PRISMA-S principles. Study and report characteristics will be summarised descriptively. For each candidate element, reporting frequency will be presented as n/N and percentage, with 95% confidence intervals where informative. Definition variants, time anchors, reported baseline variables and variables used in adjusted models will be tabulated separately. Study-by-item heat maps will display reporting patterns. Domain-level completeness will be presented without treating an unvalidated aggregate score as a measure of study quality.

Results will be stratified by TICH versus ICPm, design, publication era, region and data source where numbers permit. Exploratory comparisons will use Fisher's exact or chi-squared tests; temporal trends may be examined using regression with publication year. Overlapping reports will be linked, and report-level findings will be checked in a sensitivity analysis using unique cohorts.

Candidate elements will be mapped to AUS-TBI and NINDS TBI CDE as exact, partial or absent matches. A proposed element will be retained when supported by an existing standard or when the methodological review demonstrates that it is needed to interpret eligibility, selection, timing, treatment or outcome. Definitions, source, time point, rationale and decision provenance will be recorded transparently. No clinical effect-size meta-analysis and no formal Delphi consensus are planned. The TICH and ICPm results will be synthesised separately before shared core elements are identified.

Country(ies) involved Australia.

Other relevant information This registration concerns the systematic methodological review and evidence-informed framework-development component of Study 5. It uses published information and does not require human research ethics review. The downstream retrospective feasibility assessment, patient-level adjusted analyses and any future multicentre validation are separate studies or phases governed by the relevant ethics and governance approvals; they are not covered by this registration.

A preliminary PubMed pilot on 13 August 2026 retrieved 355 TICH update records, 121 ICPm update records and 100 reporting/data-standards records. These are retrieval counts, not included-study counts; formal independent eligibility screening has not commenced. Protocol amendments will be dated, justified and reported. The final framework will be labelled proposed and evidence-informed, not a validated minimum dataset or consensus standard.

Keywords traumatic brain injury; intracranial pressure monitoring; traumatic intracranial haematoma; observational studies; common data elements; data dictionary; treatment timing; patient selection.

Dissemination plans Results will be submitted to a peer-reviewed journal and incorporated into a PhD thesis. Findings will also be presented at relevant trauma, neurosurgical and research-

methodology meetings. The proposed data dictionary, reporting framework, element definitions, evidence-mapping tables and complete reproducible search strategies will be provided as supplementary material where copyright and institutional requirements permit. Plain-language summaries will be shared with relevant TBI research networks. Formal stakeholder consultation, retrospective feasibility testing and multicentre prospective validation will be proposed as subsequent work rather than represented as completed within this review.

Contributions of each author

Author 1 - Michael Merakis - Conceptualisation; protocol development; search strategy; screening; data extraction; synthesis; framework development; manuscript drafting; project administration; guarantor.
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