# Core Outcomes and common Data Elements in Chronic Subdural Haematoma (CODE-CSDH): A systematic review of the literature focusing on baseline and peri-operative care data elements

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**Abstract**

Chronic subdural hematoma (CSDH) is an increasingly common subtype of head injury, especially in the elderly population. The optimisation of treatment strategies has been hampered by the collection of heterogeneous outcome measures and data elements, precluding cross-study comparisons. This study aimed to quantify the heterogeneity of data elements in the pre-operative, operative and post-operative phases of care and build the basis for the development of a set of common data elements (CDEs) for CSDH.

This systematic review adhered to the PRISMA statement and was registered with the PROSPERO register of systematic reviews (CRD42014007266). All full text English studies with >10 patients (prospective) or >100 patients (retrospective) published after 1990 examining clinical outcomes in CSDH were eligible for inclusion.

One hundred and two eligible studies were found. Only 40 studies (39.2%) reported the main presenting symptom/feature and 24 (23.5%) reported additional symptoms/features. Admitting neurological/functional status was classified by the Glasgow Coma Scale (GCS)(25 studies, 24.5%), the Markwalder Score (26, 25.5%) and the modified Rankin Scale (mRS)(3, 2.9%). Fifty-four studies (52.9%) made some mention of patient co-morbidities and 58 studies (56.9%) reported the proportion or excluded patients on anticoagulant medication. Eighteen (17.6%) studies reported baseline coagulation status. Sixty-four (62.7%) studies stratified or assessed severity based on radiological findings, although the methods used varied widely. There was variable reporting of surgical technique and post-operative care; 32 studies (31.4%) made no mention of whether the operations were performed under general or local anaesthetic.

This study, a part of the Core Outcomes and Common Data Elements in CSDH (CODE-CSDH) project, confirms and quantifies the heterogeneity of data elements collected and reported in CSDH studies to date. It establishes the basis for the consensus-based development of a set of common data elements, facilitating robust cross-study comparisons and resulting improvements in patient outcomes.

## Introduction

Chronic subdural hematoma (CSDH) has an incidence of about 10/100,000/year, making it one of the most common subtypes of head injury.[1, 2] It often occurs with very minor or no traceable trauma. Its incidence is expected to rise, primarily due to a continually aging population and the increasing use of anticoagulant/antiplatelet medication, both well-recognised risk factors.[1, 2] Despite the rising incidence, there remain many unanswered questions surrounding the management of these patients in terms of pre-operative, operative and post-operative care (Figure 1).[1, 3, 4]

Despite numerous studies investigating the management of CSDH patients, there are a number of barriers that prevent the development of rigorous evidence-based management strategies. One of the main barriers is the collection of heterogeneous data points, be that pre-operative patient data, details on operative intervention or clinical outcomes.[1, 3, 5, 6] Our recent systematic review identified the heterogeneity in outcome measures.[6] Harmonising these outcome measures, which can be achieved through the development of a core outcome set,[7, 8] is meaningless without standardising the collection of data in the pre-operative, intra-operative and post-operative phases of care. This facilitates standardised comparisons across studies, allowing for adjustment of differences in independent variables in the study populations.

One way of harmonising this data is through the development of a set of common data elements (CDEs), with the aim of "[standardizing] the collection of investigational data in order to facilitate comparison of results across studies and more effectively aggregate information into significant metadata results".[9] This has been pioneered by the National Institute of Neurological Disorders

and Stroke (NINDS) CDE Project, which has developed CDEs for a number of neurological conditions including stroke and TBI.[10-12]

CDE sets are developed through a consensus methodology, involving a number of different stakeholders including clinicians, academics, allied healthcare professionals and patients. They are designed to be constantly evolving data sets, based on feedback from users.[10] They have been shown to improve data quality and have become incorporated into NIH grant applications.[13]

The aims of this systematic review were to quantify the heterogeneity in data elements collected in CSDH studies and act as a basis for the development of a CDE set for CSDH that would standardize data collection across studies.

## Methods

This systematic review adhered to the PRISMA statement and has been registered with the PROSPERO prospective register of systematic reviews (CRD42014007266). The MEDLINE and EMBASE databases were searched for the terms “chronic AND subdural” on 10th January 2014. Titles and abstracts were screened for relevance. Full text articles were then assessed for eligibility according to the following inclusion criteria:

- English full text.
- Publication date post 1990.
- Examining clinical outcomes of adult patients with CSDH
- Prospective study with >10 patients or retrospective study with >100 patients

The reference lists of eligible studies and relevant review articles were scanned for further studies not identified by the search strategy. The search strategy is summarised in Figure 2. Full text manuscripts were requested from corresponding authors of studies that were not accessible.

Relevant data from included studies was collected independently by two authors (AC, KCH) via a piloted data collection tool. Any discrepancies were settled by consultation between the two authors with reference to the original article. Included studies were examined for pre-determined primary and secondary outcomes. All reported outcomes were examined for definitions and time points. Data was analysed using Microsoft Excel® (Microsoft Inc, Seattle, WA, USA).

## Results

*Study Details*

A total of 102 studies were eligible for inclusion, comprising 21,598 patients. Thirty-two (31.4%) were prospective studies, 66 (64.8%) were retrospective and 4 (3.9%) had a combination of prospective and retrospective data. There were 14 (13.7%) randomised controlled trials, one single arm trial (1.0%), 25 (24.5%) cohort comparison studies and 62 (60.8%) cohort studies. Further details about the studies are available in our previous study.[6] A risk of bias tool was not applied to the included studies as the inherent nature of the present study was to assess risk of bias based on study design and reporting. The complete list of included studies is provided in our previous study. [6]

*Study Methodology and Design*

Seventy nine (77.5%) studies had clear inclusion criteria and 56 (54.9%) had clear exclusion criteria. Only 32 (31.4%) had clearly defined primary outcomes whilst 7 (6.9%) had clearly defined primary and secondary outcomes. These figures increased only slightly when the cohort of prospective (n=32) and prospective randomised controlled trials (n=14) were considered separately (Table 1). Only 15 (46.9%) prospective studies and 5 (35.7%) randomised controlled trials reported having gained ethical approval for the study.

*Baseline data elements*

Almost all the studies presented descriptive statistics for the age (100, 98.0%) and sex (98, 96.1%) distributions of the included patients. Forty studies (39.2%) reported the main presenting symptom/feature, 24 (23.5%) of which mentioned additional symptoms/features; there was no established method of uniformly classifying these symptoms. Admitting neurological/functional status was classified by the Glasgow Coma Scale (GCS; 25 studies, 24.5%), the Markwalder Score (26, 25.5%) and the modified Rankin Scale (mRS)(3, 2.9%) (Figure 3). Only two (2.0%) had a baseline functional status, one of which was the Karnofsky Performance Score (KPS). Although a number of studies had “hemiplegia” or “hemiparesis” as part of the presenting feature(s), only 9 (8.8%) presented a systematic neurological examination. Only one study (1.0%) reported examining pupil status.

Sixty-four studies (62.7%) reported the proportion of patients able to trace a precipitating trauma event, with 23 (22.5%) identifying the time between trauma and presentation and 3 (2.9%) stratifying the severity of trauma.

Fifty-four studies (52.9%) made some mention of patient co-morbidities, although 21 (20.6%) were limited to the presence/absence of a very limited selection of co-morbidities such as a history of excess alcohol consumption (13, 12.7%) or presence of coagulopathy (3, 2.9%). In terms of medication, 58 studies (56.9%) reported the proportion of patients on anticoagulant medication (or specified excluding these patients), 45 (44.1%) reported the proportion of patients on antiplatelet medication (or specified excluding these patients). Only 30 studies (29.4%) distinguished between the two groups and only two (2.0%) reported the indication for such medication.

In terms of key investigations, 18 (17.6%) studies mentioned baseline coagulation status. All 102 (100%) used imaging (mostly CT) to confirm the presence of CSDH. Sixty-four (62.7%) studies stratified or assessed severity based on radiological findings, although the methods used varied widely (figure 4). Seventy-seven (75.5%) reported the laterality of haematomas (including bilateral) and 6 (5.9%) specifically excluded patients with bilateral collections.

*Pre-operative phase of care*

Eleven studies specified the use of adjuvant medications, such as steroids and/or antiepileptic agents; in the majority, this was the main focus of the study. Four (36.4%) did not specify the dose of drug used and four (36.4%) did not specify the duration of use.

*Operative phase of care*

There was highly varied documentation of surgical technique, which could broadly be split into the three commonly accepted groups of techniques; craniotomy, burr hole craniostomy and twist drill craniostomy. However, the terminology used was heterogeneous, with interchangeable words such as “trepanation” and “trephination” and there was seldom specification of the size of the burr hole/twist drill/craniotomy. Manuscripts where surgical technique was clearly described often specified whether or not subdural/subgaleal drains were used and whether they were placed on suction or drained with the effect of gravity. Whilst some manuscripts specified the use (or not) of irrigation, others did not.

Thirty two studies (31.4%) made no mention of whether the operations were performed under general or local anaesthetic.

*Post-operative phase of care*

Variations in post-operative care were poorly delineated. Unless this was the specific focus of the study, few studies reported whether patients were allowed to mobilise or prescribed bed rest post-operatively or if/when post-operative prophylactic anticoagulation was commenced. As is evident in the literature, these are important variables that may affect recurrence and functional outcomes.

## Discussion

This study indicates that there is significant heterogeneity in the data elements that are collected and reported as part of clinical studies examining outcomes for CSDH. This precludes adjustment for independent variables between studies and therefore prevents meaningful cross-study comparisons.

*Reporting of baseline data elements*

One of the most important findings of this study was the variability of reporting baseline features. Although age and sex were presented in almost all the studies, many studies did not report the presenting complaint(s), admission neurological examination or baseline functional status of the patient; the GCS, a ubiquitous tool for the assessment of consciousness level was only reported in 24.5% of studies. It is interesting to note that only one study reported pupil reactivity, perhaps an indication that the reactivity is not important in this setting, especially if the majority of patients present with a relatively high level of consciousness. In terms of investigations, baseline blood test results were not universally reported; although it may not be crucial to report all blood test results for CSDH, coagulation status is an important variable but was reported in only 17.6% of studies. Although all the studies used CT or MRI to diagnose the collections, there was little consensus on how to classify/stratify these scans (Figure 4). These clinical and radiological factors form the basis of the initial assessment and subsequent management of the patient. The consensus process will be crucial in defining a way in which to report these baseline assessments in a comprehensive, yet easily reproducible fashion.

*Reporting of pre-operative, operative and post-operative phases of care*

Studies must also make a concerted effort to present the management strategy of the patient in a systematic, reproducible fashion. The reasons for this are two-fold. Firstly, it allows for the evaluation of co-intervention biases, which may arise from differences in the management strategy that are not specifically being evaluated by the study.[14] Secondly, it facilitates reproduction of the management strategy by clinicians in their everyday practice.

This involves clearly outlining practices in the pre- and post-operative phases of care such as method of correction of anticoagulation (for those patients who have a coagulopathy), use of adjunctive medications (eg antiepileptics or steroids), limitation of post-operative mobility, and use of post-operative prophylactic anticoagulation to prevent venous thromboembolic events. In addition, the consensus process must consider a standardised system for reporting operative technique; this study identified heterogeneous terms used for similar operative procedures (eg. “trephination”, “trepanation”, “burr holes”, “burr hole craniotomy”, “craniotomy”, “mini-craniotomy”) without standardised definitions. Studies must also report intra-operative variables such as the use of irrigation, use and location of post-operative drains and method of anaesthesia as these may vary between studies and may have an effect on post-operative outcomes.

*Study Limitations*

The limitations of the current study relate to the search criteria. Selecting only English full-text studies was driven by the observation that detailed reporting of data elements are often omitted in abstracts/short reports and would be difficult to elicit from non-English language studies. In addition, the date limitation was set to ensure a contemporary cohort of studies. Despite these limitations, we feel we have successfully satisfied the aims of the study in establishing the

heterogeneity in data elements and providing a basis for the consensus process to develop a set of common data elements.

*Future Directions*

This systematic review represents the first step in the process of developing a set of common data elements for CSDH. We aim to derive the set of common data elements for CSDH via a multi-agency consensus process, an established method for developing a common data element set. [10]

In addition to the development of a set of common data elements, the Core Outcomes and common Data Elements in Chronic Subdural Haematoma (CODE-CSDH) project (figure 5) also aims to develop a set of core outcomes for CSDH.[6] By standardising a minimum set of data elements and outcome measures to be collected by all future CSDH studies, future reports on aspects of CSDH treatment can serve as a more robust basis for our understanding of this common condition and will allow meaningful cross-study comparison of established and novel therapeutic interventions.

## Conclusions

This systematic review of data elements presented in CSDH studies identifies heterogeneity in the reporting of baseline data elements and details of pre-operative, operative and post-operative phases of care. It successfully establishes the basis for the development of a consensus-based set of common data elements, including standardised terminology for operative technique, as part of

the Core Outcomes and common Data Elements in Chronic Subdural Haematoma (CODE-CSDH) project.[6]

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