Original Article

A minimum data set for traumatic brain injuries in Iran

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\textbf{A B S T R A C T}

\textbf{Purpose:} Traumatic brain injury (TBI) is one of the major public health concerns worldwide. Developing a TBI registry could facilitate characterizing TBI, monitoring the quality of care, and quantifying the burden of TBI by collecting comparable and standardized epidemiological and clinical data. However, a national standard tool for data collection of the TBI registry has not been developed in Iran yet. This study aimed to develop a national minimum data set (MDS) for a hospital-based registry of patients suffering from TBI in Iran.

\textbf{Methods:} The MDS was designed in 2 phases, including a literature review and a Delphi study with content validation by an expert panel. After the literature review, a comprehensive list of administrative and clinical items was obtained. Through a two-round e-Delphi approach conducted by invited experts with clinical and research experience in the field of TBI, the final data elements were selected.

\textbf{Results:} A MDS of TBI was assigned to 2 parts: administrative part with 5 categories including 52 data elements, and clinical part with 9 categories including 130 data elements.

\textbf{Conclusion:} For the first time in Iran, we developed a MDS specified for TBI consisting of 182 data elements. The MDS would facilitate implementing a TBI's national level registry and providing essential, comparable and standardized information.

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Introduction

Traumatic brain injury (TBI) is one of the major public health concerns worldwide as it results in considerable mortalities and lifelong devastating physical, cognitive and emotional morbidities. This poses significant social and economic burdens on patients, families, and societies. The prevalence of TBI has been increasing since 1990. In 2016 the number of TBI victims was estimated to be 55.5 million individuals around the world.\textsuperscript{1, 2} Globally, organizations such as the International Initiative for Traumatic Brain Injury Research have launched international collaborative research since 2010 and developed a standardized data collection called Common Data Elements for TBI.\textsuperscript{3} However, in low- and middle-income countries (LMICs), due to TBI-related limited research funding and efforts, a high-quality data-specific registry at the national level is scarce. Meanwhile, the evidence carried out in high-income countries is not translatable and applicable for LMICs owing to far differences in their care strategies and resources.\textsuperscript{4} A TBI-specific registry in which comparable and standardized epidemiological and clinical data are collected is an advantageous mechanism to characterize TBI, quantify its true magnitude and economic and social burdens caused by this injury in LMICs. Besides, it could assist in monitoring and evaluating the quality of care and converting the research results into recommendations for more effective management of clinical conditions. As mentioned before, there is an unmet need for developing a national registry system and minimum data set (MDS) for TBI in LMICs. A MDS tool specifically concerning TBI could provide a set of standardized minimum data for each patient suffering from TBI and unifying definitions for terms and data elements. The data generated from studies implementing the MDS will be comparable and consistent at national and international levels. This would enable researchers and health care professionals to enhance basic and clinical research and practices. This study aimed to develop a national MDS for a hospital-based registry of TBI patients in Iran.

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Table 1
Administrative data elements related to traumatic brain injury inpatients.

| Administrative data elements | Agreement level (%) | Final decision |
|------------------------------|---------------------|----------------|
|                              | First round | Second round | Kept | No. of elements |
| Demographics                 |             |              |      |                |
| Name\textsuperscript{9,10}   | 100        |              | ✓    | 9              |
| Age\textsuperscript{9-11}    | 100        |              | ✓    |                |
| Sex\textsuperscript{9-11}    | 100        |              | ✓    |                |
| Marital status\textsuperscript{10,12} | 69 | 75 | ✓ |                |
| Ethnicity\textsuperscript{9-11} | 53.8 | 25 | |                |
| Race\textsuperscript{9-11}   | 69.2       | 25           | ✓    |                |
| Birth country name\textsuperscript{10,11} | 61.5 | 100 | ✓ |                |
| Current country of resident\textsuperscript{10,12} | 76.9 | | ✓ |                |
| Population size of place of residence\textsuperscript{10,12} | 100 | | ✓ |                |
| Primary language\textsuperscript{10,12} | 69.2 | 100 | ✓ |                |
| Fluent written/spoken languages\textsuperscript{12} | 69.2 | 25 | ✓ |                |
| Handedness\textsuperscript{9-11} | 64.2 | 75 | ✓ |                |
| Socioeconomic status         |             |              |      | 8              |
| Education                    |             |              |      |                |
| Level of education (highest degree)\textsuperscript{9-11} | 69.2 | 50 | |                |
| Education (number of years completed)\textsuperscript{10-12} | 69.2 | 100 | ✓ |                |
| Parent's years of education; if child\textsuperscript{10,12} | 69.2 | 100 | ✓ |                |
| Classified as a special student\textsuperscript{10,12} | 53.8 | 25 | |                |
| Ever expelled from school\textsuperscript{10,12} | 53.8 | 25 | |                |
| Ever failed to advance to the next grade\textsuperscript{10,12} | 69.2 | 25 | |                |
| Employment                   |             |              |      |                |
| Current primary occupational status\textsuperscript{10,12} | 100 | | ✓ |                |
| Job classification\textsuperscript{12} | 92.3 | | ✓ |                |
| Employment level\textsuperscript{9-11} | 38.5 | | |                |
| Working for paid/unpaid work\textsuperscript{10,12} | 38.5 | | |                |
| Number of months with job in last year\textsuperscript{10,12} | 53.8 | 25 | |                |
| Number of employers\textsuperscript{10,12} | 33.3 | | |                |
| Number of people supervised by patient in job\textsuperscript{10,12} | 38.5 | | |                |
| Cohabits                     |             |              |      |                |
| Living situation\textsuperscript{9,10} | 76.9 | | ✓ |                |
| Primary people living with\textsuperscript{9,11} | 69.2 | 50 | |                |
| Number of patient’s children\textsuperscript{12} | 69.2 | 50 | |                |
| Number of cohabits\textsuperscript{12} | 38.5 | | |                |
| Number of children living with\textsuperscript{12} | 53.8 | 25 | |                |
| Parents status (dead/alive)\textsuperscript{12} | 38.5 | | |                |
| Type of primary caregiver\textsuperscript{12} | 69.2 | 25 | |                |
| Income                       |             |              |      |                |
| Annual income of household\textsuperscript{12} | 53.8 | 50 | |                |
| Number of people supported by the income\textsuperscript{12} | 38.5 | | |                |
| Home-ownership\textsuperscript{12} | 46.2 | | |                |
| Insurance                    |             |              |      |                |
| Possession of health insurance\textsuperscript{10,12} | 92.3 | | ✓ |                |
| Type of health insurance\textsuperscript{10,12} | 92.3 | | ✓ |                |
| Deployment                   |             |              |      |                |
| Military status^11,12 | 46.2 |
|-----------------------|------|
| Military occupational status^11,12 | 38.5 |
| Branch of service in military^11,12 | 30.8 |
| Military rank^11,12 | 30.8 |
| Place of deployment^12 | 30.8 |

### Sport

| Participation in school sports^12 | 38.5 |
|----------------------------------|------|
| Type of school sport played primarily^12 | 38.5 |
| Number of years of school sport played^12 | 38.5 |
| Type of school sports played secondarily^12 | 30.8 |
| Participation in recreational sports^12 | 23.1 |
| Type of recreational sport^12 | 38.5 |
| Participation in professional sports^12 | 84.2 |
| Type of professional sport^12 | 69.2 |
| Number of years of professional sports played^12 | 46.2 |

### Past medical history

#### Behavioral history

| Current alcohol, tobacco or illicit drug usages^9,11 | 100 |
|-----------------------------------------------------|-----|
| Number of days per month with minimum one alcoholic drink^10,12 | 69.2 |
| Average number of alcoholic drinks per day^10,12 | 46.2 |
| Number of days in last month with 5 for men, 4 for women or more drinks^10,12 | 30.8 |
| Alcohol usage in more than 1 year ago^9,12 | 61.5 |
| Alcohol usage duration^10,12 | 46.2 |
| Type(s) of tobacco used^9,12 | 61.5 |
| Type(s) of illicit drug used^9,12 | 74.6 |
| Tobacco or illicit drug usage duration^9,12 | 74.6 |
| Marijuana usage in past^9 | 61.5 |
| Cigarette usage in past^9 | 69.2 |
| Being in trouble in society because of drug use^9 | 53.8 |

#### History of TBI

| Number of prior concussions^10,11 | 73.3 |
|----------------------------------|-----|
| Number of prior TBI^10,11 | 92.3 |
| Number of prior traumatic injury^10 | 73.3 |
| Number of blasts experienced^10,11 | 61.5 |
| LOC experienced in prior TBI(s)^10,11 | 61.5 |
| Longest duration of LOC in prior TBI(s)^10,11 | 61.5 |
| Youngest age at LOC in prior TBI(s)^10,11 | 69.2 |
| Confusion experienced in prior TBI(s)^10 | 76.9 |
| Longest duration of confusion in prior TBI^10 | 76.9 |

#### Medical history

| Medical problems/conditions^9,12 | 100 |
|-----------------------------------|-----|
| Medical problems time-points^10,12 | 69.2 |
| Ongoing medical condition/disease^10,12 | 84.6 |
| History of perinatal neurologic condition^10 | 61.5 |
| History of attention/learning deficit in developmental years^10,11 | 84.6 |
| History of psychiatric or emotional problems^9,11 | 100 |
| History of hospitalization for emotional or psychiatric problems^9 | 100 |
| Prior or concomitant medication (name, dosage, rout)^9,11 | 92.3 |
Methods

The MDS was designed in 2 phases, including a literature review and a Delphi study with content validation by an expert panel.

The literature search was performed using keywords in MEDLINE (via PubMed) and Google Scholar in January 2019. In PubMed, the Medical Subject Headings (MeSH) terms “Brain Injuries”, “Data Collection”, “Common Data Elements”, and “Registries” were used. In addition, the Google search engine was used to find the scientific association publications related to the registration of TBI patients. Inclusion criteria were currently ongoing registries and English language. Two researchers extracted all the data elements independently and determined a comprehensive list of administrative and clinical items.

Through a 2-round e-Delphi approach, the final data elements were chosen by 16 invited experts with clinical and research experience in the TBI field. They were informed about the study’s process. The experts should only consider the feasibility (or applicability) of elements whose main criteria, including validity, reliability, sensitivity, and specificity were already proven. To this end, they were asked to choose elements with respect to local capacity and limitations of registries, hospital settings, and health care resources in Iran. An online questionnaire was developed which contained dichotomous questions (agree/disagree answers) concerning the necessity of each data element. Each item with more than 75% agreement was included, and one with less than 50% agreement was excluded in the first round. In the second round, the items with 50%–75% agreement were surveyed again, and if there was 75% consensus over a subject, it was included.

Results

Three hundred data elements were compiled in the final list from 3 current large multi-center TBI-registries and a national institute of data standardization in the United States. The data elements were classified into 2 parts, including administrative and clinical data (Tables 1 and 2). Fourteen experts participated in the Delphi process, 79% of whom had more than 10 years of experience in trauma center hospitals. In the first round, 152 items were marked as definitive, 58 items were deleted, and 89 items were moved to the next round. In the second round, the experts removed 59 items and accepted 30 items. The resulting MDS had 2 parts, 14 categories, 22 subcategories, and 182 items (Tables 1 and 2, colored cells).

In the first round, items related to the “Injury” and “Post-Discharge Status” categories were approved more than other categories (n = 17, 94.4%; n = 35, 94.6%, respectively). At the end of the process, “Post-Discharge Status” and “Socioeconomic Status” classifications had the highest and lowest approval rating, respectively (n = 36, 97.3%; n = 8, 20%).

Table 3 shows 4 included data standards and the number of data elements. The present MDS was the most adapted according to the National Institute of Neurological Disorders and Stroke and the...
| Clinical data elements                                                                 | Agreement level (%) | Final decision | No. of elements |
|---------------------------------------------------------------------------------------|---------------------|----------------|-----------------|
| Pre-hospital presentation                                                             |                     |                | 8               |
| Type of initial medical services provided at scene\textsuperscript{10,11}              | 84.6                | ✔              |                 |
| Initial medical care provider at scene\textsuperscript{10,11}                        | 61.5                | 100            | ✔               |
| Time interval from injury scene to hospital\textsuperscript{10}                      | 73.3                | 50             |                 |
| Mode of transport from injury scene to hospital\textsuperscript{10,11}               | 84.6                |                |                 |
| Worst vital signs (systolic/diastolic blood pressure, pulse rate, respiratory rate, temperature, arterial oxygen saturation)\textsuperscript{10,12} | 100                 | ✔              |                 |
| Hypotensive episode\textsuperscript{10-12}                                            | 92.3                | ✔              |                 |
| Best GCS\textsuperscript{9,10,12}                                                     | 69.2                | 25             |                 |
| Worst GCS\textsuperscript{9,10,12}                                                   | 100                 | ✔              |                 |
| Seizure\textsuperscript{10,12}                                                       | 100                 | ✔              |                 |
| Duration of seizure\textsuperscript{10,12}                                            | 100                 | ✔              |                 |
| Emergency department                                                                 |                     |                | 13              |
| Name of primary or secondary referral hospital\textsuperscript{10,11}                | 92.3                | ✔              |                 |
| Hospital admission time-point\textsuperscript{10,11}                                 | 100                 | ✔              |                 |
| Primary hospital admission time-point\textsuperscript{10,11}                         | 73.3                | 50             |                 |
| Reason; if injury late presentation\textsuperscript{10,12}                           | 69.2                | 50             |                 |
| Professional referral; if injury late presentation\textsuperscript{10,12}            | 61.5                | 25             |                 |
| Arrival vital signs (systolic/diastolic blood pressure, pulse rate, respiratory rate, temperature, arterial oxygen saturation)\textsuperscript{9-11} | 100                 | ✔              |                 |
| Arrival mode of ventilation (assisted or spontaneous)\textsuperscript{10,11}         | 100                 | ✔              |                 |
| Type of respiratory support device\textsuperscript{10,11}                            | 91.7                | ✔              |                 |
| Partial pressure of oxygen and carbon dioxide\textsuperscript{10,11}                 | 66.7                | 100            | ✔               |
| Arrival GCS\textsuperscript{9,10}                                                    | 100                 | ✔              |                 |
| GCS confounders\textsuperscript{9,11}                                                | 91.7                | ✔              |                 |
| Arrival pupil reactivity\textsuperscript{10,11}                                      | 92.3                | ✔              |                 |
| Arrival pupil size\textsuperscript{10}                                                | 91.7                | ✔              |                 |
| Discharge vital signs (systolic/diastolic blood pressure, pulse rate, respiratory rate, temperature, arterial oxygen saturation)\textsuperscript{9,10} | 73.3                | 25             |                 |
| Discharge mode of ventilation (assisted or spontaneous)\textsuperscript{10}          | 73.3                | 25             |                 |
| Discharge GCS\textsuperscript{10}                                                    | 73.3                | 25             |                 |
| Discharge pupil reactivity\textsuperscript{10}                                       | 73.3                | 50             |                 |
| Discharge pupil size\textsuperscript{10}                                              | 73.3                |                |                 |
| Systemic second insults (hypoxia, hypotension, coagulopathy, aspiration, seizure, cardiopulmonary arrest)\textsuperscript{10,12} | 83.3                | ✔              |                 |
| Best motor response score\textsuperscript{11}                                         | 73.3                | 25             |                 |
| Sedated\textsuperscript{11}                                                         | 73.3                | 50             |                 |
| Fluid therapy\textsuperscript{9,10}                                                   | 91.7                | ✔              |                 |
| Emergency department discharge time since injury\textsuperscript{10}                 | 61.7                | 25             |                 |
| Discharge destination\textsuperscript{10,12}                                         | 92.3                | ✔              |                 |
| In-patient daily neurologic assessment | 5 |
|---------------------------------------|---|
| Type of GCS (adult/pediatric)\(^8,10,12\) | 84.6 | ✓ |
| GCS\(^9,12\) | 100 | ✓ |
| Worst GCS during the first 24-hour\(^10\) | 61.7 | 50 |
| GCS trend during the first 48-hour\(^10\) | 73.3 | 50 |
| GCS confounders\(^9,12\) | 83.3 | ✓ |
| Pupils size\(^11,12\) | 91.7 | ✓ |
| Pupils shape\(^12\) | 50  | 25 |
| Pupils reactivity\(^11,12\) | 100 | ✓ |

| In-patient physical assessment | 12 |
|--------------------------------|----|
| LOC\(^10,11\) | 100 | ✓ |
| Duration of LOC\(^10,11\) | 91.7 | ✓ |
| Source of verification of LOC\(^10,11\) | 69.2 | 25 |
| Lucid interval of LOC\(^10,11\) | 91.7 | ✓ |
| PTA\(^10,11\) | 100 | ✓ |
| Duration of PTA\(^10,11\) | 83.3 | ✓ |
| Source of verification of PTA\(^10,11\) | 69.2 | 25 |
| AOC\(^10,11\) | 91.7 | ✓ |
| Duration of AOC\(^10,11\) | 83.3 | ✓ |
| Source of verification of AOC\(^10,11\) | 69.2 | 25 |
| TBI symptom/sign category\(^10,12\) | 100 | ✓ |
| TBI symptoms/signs\(^10-12\) | 100 | ✓ |
| Worsens with cognitive activity\(^10-12\) | 83.3 | ✓ |
| Worsens with physical activity\(^10-12\) | 83.3 | ✓ |
| Self-assessment of symptoms severity\(^10,12\) | 83.3 | ✓ |
| Head circumference in each hospital unit\(^13\) | 33.3 |  |
| Weight in each hospital unit\(^11,12\) | 25 |  |
| Height in each hospital unit\(^11,12\) | 25 |  |
| Weight and height measurement type\(^11,12\) | 58.3 | 25 |

| Second insults/complication | 17 |
|-----------------------------|----|
| Complication\(^11,12\) | 100 | ✓ |
| Type of complication\(^10-12\) | 91.7 | ✓ |
| Wound\(^10,12\) | 91.7 | ✓ |
| Type of wound\(^10,12\) | 83.3 | ✓ |
| Laboratory abnormalities\(^9,12\) | 91.7 | ✓ |
| Hypotensive episode\(^10,12\) | 91.7 | ✓ |
| Hypertension\(^9,12\) | 83.3 | ✓ |
| Hypoxic episode\(^10,12\) | 91.7 | ✓ |
| Inadvertent hypocapnia\(^10-12\) | 61.5 | 75 | ✓ |
| Hyperventilation\(^12\) | 71.3 | 75 | ✓ |
| Cardiac arrest\(^10,12\) | 100 | ✓ |
| Seizure(s)\(^10-12\) | 100 | ✓ |
| Type of seizure\(^10-12\) | 83.3 | ✓ |
| Seizure duration\(^10,12\) | 83.3 | ✓ |
| Hypothermia\(^10,12\) | 66.7 | 100 | ✓ |
| Hyperthermia\(^12\) | 83.3 | ✓ |
| Electroencephalography monitoring type\(^12\) | 41.7 |  |
| Aspiration of foreign materials\(^12\) | 66.7 | 75 | ✓ |
| **Surgery** |  |
|---|---|
| Surgical procedure description<sup>10-12</sup> | 100 | ✓ |
| Surgery time-point<sup>10-12</sup> | 91.7 | ✓ |
| Duration of surgery<sup>10-12</sup> | 91.7 | ✓ |
| Surgery type (elective/emergent)<sup>10,12</sup> | 100 | ✓ |

| **Anesthesia** |  |
|---|---|
| Anesthesiologist visit<sup>10,12</sup> | 100 | ✓ |
| Standard American Society of Anesthesiologists monitors<sup>12</sup> | 66.7 | 25 |
| Temperature<sup>12</sup> | 45.5 |  |
| Partial pressure oxygen brain tissue measurement<sup>12</sup> | 53.8 | 25 |
| Inadvertent hypocapnia<sup>12</sup> | 69.2 | 25 |
| Hypotensive episode<sup>12</sup> | 53.8 | 25 |
| Hypoxia<sup>12</sup> | 73.3 | 25 |
| Intra-venous anesthesia drug<sup>12</sup> | 66.7 | 75 | ✓ |
| Arterial line<sup>12</sup> | 69.2 | 25 |
| Foley catheter<sup>12</sup> | 75 | ✓ |
| Transfusion<sup>12</sup> | 100 | ✓ |
| Transfusion type<sup>12</sup> | 92.3 | ✓ |
| Extubated at end<sup>12</sup> | 76.9 | ✓ |
| Microdialysis glutamate value<sup>12</sup> | 33.3 |  |
| Microdialysis lactate to pyruvate ratio<sup>12</sup> | 25 |  |
| Cerebral spinal fluid drainage<sup>12</sup> | 83.3 | ✓ |

| **Medications** |  |
|---|---|
| Name of medications<sup>10,11</sup> | 100 | ✓ |
| Dose of medication administered<sup>10,11</sup> | 100 | ✓ |
| Route of medication administered<sup>10,11</sup> | 100 | ✓ |
| Duration of medication administered<sup>10,11</sup> | 100 | ✓ |

| **Hospital units** |  |
|---|---|
| Units hospitalized in<sup>10,12</sup> | 69.2 | 75 | ✓ |
| Timeframe hospitalized in each unit<sup>10,12</sup> | 92.3 | ✓ |

| **Laboratory** | 11 |
|---|---|
| Sampling time-points<sup>11,12</sup> | 100 | ✓ |
| Type of lab specimen<sup>10,12</sup> | 62.3 | 25 |

| **Chemistry** |  |
|---|---|
| Glucose<sup>10-12</sup> | 83.3 | ✓ |
| Glycosylated hemoglobin<sup>12</sup> | 8.3 |  |
| Urea<sup>11,12</sup> | 50 | 100 | ✓ |
| Creatinine<sup>10,12</sup> | 66.7 | 75 | ✓ |
| Amylase<sup>11,12</sup> | 33.4 |  |
| Serum glutamic oxaloacetic transaminase<sup>11,12</sup> | 41.7 |  |
| Serum glutamic pyruvic transaminase<sup>11,12</sup> | 33.3 |  |
| Lactate dehydrogenase<sup>10-12</sup> | 41.7 |  |
| Alkaline phosphatase<sup>11,12</sup> | 16.7 |  |
| Gamma-glutamyl transferase<sup>12</sup> | 8.3 |  |
| Total bilirubin<sup>11,12</sup> | 33.3 |  |
| Sodium<sup>10,11</sup> | 66.7 | 75 | ✓ |
| Potassium<sup>10,11</sup> | 58.3 | 75 | ✓ |
| Calcium<sup>11</sup> | 50 | 25 |  |
| Chloride<sup>10</sup> | 25 |  |
| Magnesium<sup>11</sup> | 66.7 | 75 | ✓ |
| Cholesterol<sup>12</sup> | 16.7 |  |
| Parameter                                      | Value |
|-----------------------------------------------|-------|
| Triglyceride                                  | 16.7  |
| Low-density lipoprotein                       | 16.7  |
| High-density lipoprotein                      | 16.7  |
| Very low density lipoprotein                  | 8.3   |
| Apolipoprotein B                              | 8.3   |
| Apolipoprotein E                              | 8.3   |
| Apolipoprotein A                              | 8.3   |
| Atrial natriuretic peptide                    | 16.7  |
| Brain natriuretic peptide                     | 16.7  |
| Insulin                                       | 16.7  |
| Cortisol                                      | 25    |
| Ferritin                                      | 8.3   |
| Total iron binding capacity                   | 8.3   |
| Cobalamin                                     | 16.7  |
| C-reactive protein                            | 25    |
| Creatine kinase-MB                            | 25    |

### Hematology

| Parameter                                                      | Value |
|---------------------------------------------------------------|-------|
| Complete blood count with differential                        | 83.3  |
| Prothrombin time/ International normalized ratio              | 75    |
| Partial thromboplastin time                                   | 75    |

### Other tests

| Test                                           | Value |
|------------------------------------------------|-------|
| Alcohol blood test                              | 50    |
| Toxic drug test                                 | 66.7  |
| Pregnancy test                                 | 33.3  |
| Arterial blood gas                              | 66.7  |

### Discharge status

| Event                                                   | Value |
|---------------------------------------------------------|-------|
| Vital status on discharge (alive/died)                 | 84.6  |
| Discharge time-point                                   | 100   |
| Discharge time since injury                            | 66.7  |
| Destination upon discharge from hospital               | 91.7  |

**If Alive:**

| Parameter                                      | Value |
|-----------------------------------------------|-------|
| GCS                                           | 100   |
| GCS confounders                               | 91.7  |
| Pupil size                                    | 92.3  |
| Pupil reactivity                              | 91.7  |
| Pupil shape                                   | 33.3  |

**If Died:**

| Parameter                                      | Value |
|-----------------------------------------------|-------|
| Death time-point                              | 100   |
| Place of death                                | 84.6  |
| Principle cause of death                      | 84.6  |
| Death cause reliability                       | 84.6  |

### Post-discharge status

| Event                                     | Value |
|-------------------------------------------|-------|
| Follow-up time since injury               | 100   |

### Socioeconomic

| Parameter                                      | Value |
|-----------------------------------------------|-------|
| Living situation                              | 92.3  |
| Reasons for changes in living situation       | 83.3  |
| Education status                              | 84.6  |
| Status of school attendance                   | 83.3  |
| Returned to work/school after discharge       | 91.7  |
| Employment status                             | 91.7  |
Transforming Research and Clinical Knowledge in Traumatic Brain Injury (73.6% and 72.5%, respectively).

The inclusion criteria were considered as patients with TBI who would present at the hospital within 24 h of injury and require an emergency brain CT scan per the Canadian CT Head Rule.13

**Discussion**

For the first time in Iran, we established a TBI-specific MDS comprising 181 data elements. It would facilitate implementing a national-level TBI registry. To date, a handful of studies regarding

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### Table 3

| Included data standards | Number of elements | All Extracted for 1st round, n = 300 | Kept after 2nd round, n = 182 | Specific for present MDS |
|-------------------------|--------------------|--------------------------------------|-----------------------------|-------------------------|
| Collaborative European neuro-trauma effectiveness research in TBI | 56 29 | 22 | 0 |
| Transforming research and clinical knowledge in TBI | 417 182 | 132 | 12 |
| International mission for prognosis and analysis of clinical trials in TBI | 198 126 | 95 | 2 |
| National institute of neurological disorders and stroke | 526 188 | 134 | 36 |

MDS: minimum data set, TBI: traumatic brain injury

GCS: Glasgow Coma Scale, LOC: loss of consciousness, PTA: post-traumatic amnesia, AOC: alteration of consciousness
TBI have been conducted sporadically in Iran; however, the data were not recorded systematically and did not provide sufficient, comparable, and standardized basic information.\textsuperscript{14–17} Compiling data elements from current large studies collaborating in the International Initiative for Traumatic Brain Injury Research\textsuperscript{7} could be one of the strengths of the MDS. Benefit from the good updated resources could result in providing standard and consistent MDS at the international level.\textsuperscript{9–12} In addition, applying the Delphi technique would lead to developing the MDS based on the collective knowledge of experts in the field.

Among the reference studies, the approved data elements of our MDS were to a greater extent identical to the National Institute of Neurological Disorders and Stroke\textsuperscript{16} as a consistent structure of the Common Data Elements for TBI\textsuperscript{11} that could ensure compatibility of MDS.

Data element determination and the level of details should depend on the aim of the study.\textsuperscript{13} In designing the current MDS, the administrative and clinical data elements were collected according to the requirements of a hospital-based registry. Consideration of scopes, resources, and capacities could be critical to the success of a registry.\textsuperscript{18} Eventually, although we made our best effort to develop a reliable, high-valued MDS concerning TBI, this MDS should undertake pilot studies in Iran in the future to identify its limitations and deficiencies.

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**Ethical statement**

The study was reviewed and confirmed by the Ethics Committee of Sina Trauma and Surgery Research Center, Tehran University of Medical Sciences, Tehran, Iran.

**Declaration of competing interest**

The authors declare that they have no conflicts of interest.

**Author contributions**

Hamid Reza Khayat Kashani designed the original idea. Maryam Edalatfar and Mohsen Sadeghi-Naini carried out the study and collected data. Maryam Edalatfar and Mitra Movahed prepared the manuscript. Mahdi Sharif-Alhiseini supervised the study.

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