Converting a paper proforma template to a user friendly electronic database to collect traumatic brain injury data

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Abstract: A structured reporting system which is based on a uniform template will permit uniform data collection and future statistics and will facilitate and validate independent or comparative audit of performance and quality of care. The successful establishment of a multi-center registry depends on the development of a concise data entry form, data entry system and data analysis to continuously maintain the registry. In the first phase we introduced the paper data collection form, in second phase this data form was converted to an electronic interface. In this second phase of the study the paper proforma which was developed in the first phase was converted into an electronic database by using the FileMaker Pro 13 Advanced®. The FileMaker Pro 13 Advanced® is capable to store the data, provides user friendly interface to enter data and can be converted the standalone runtime program to install in any other computer system. The next step is to explore the possibility whether it would be feasible to use this as a multi-center traumatic brain injury registry.

Key words: registry, trauma, head injury, traumatic brain injury, FileMaker Pro 13 Advanced®.

Introduction

The successful establishment of a multi-center trauma registry depends on the development of a concise data entry form, data entry system and data analysis to continuously maintain the registry. (1) The use of the common trauma template has been shown feasible across international registries for the majority of the data variables. (2) Based on the recommendation we have selected different data variables and we are making continuous efforts to identify the core variables versus optional data which can easily be used across many centers without compromising the quality of data. (3-5) In present article we describe our ongoing experience to convert an
existing paper based data collection system into an electronic form based data collection interface.

**Material and methods**

The present study was conducted in the Departments of Hospital Administration, Neurosurgery and Department of Accident and Emergency Medicine of the Narayana Medical College and Hospital (NMCH) in Nellore, India. After approval from the institutional ethical committee, all patients with the diagnosis of traumatic brain injury (as per the criteria laid by International Classification of Disease injury codes ICD 10) presenting to the Departments of Neurosurgery and Emergency Medicine were included in the study. (6) It was the second phase of the ongoing project where core variables which were identified in the phase I were converted into an electronic database to maintain the uniformity and reproducibility. (7) In this second phase of the study the paper proforma which was developed in the first phase was converted into an electronic database by using the FileMaker Pro 13 Advanced®. The FileMaker Pro 13 Advanced® is capable to store the data, provides user friendly interface to enter data and can be converted the standalone runtime program to install in any other computer system. Variables were identified as per the international norms and the data points were selected which included demographic details, pre-hospital characteristics, clinical details in emergency room, injury details, course during hospital stay, treatment, diagnosis, disposition and follow up. (8-10) Glasgow Coma Scale score was used to classify severity of the traumatic brain injury (11) and acute injury severity scoring (AIS) was used to grade the severity of the injury. (12) Additional grading systems were used to classify the severity of diffuse axonal injury (13) and subarachnoid hemorrhage on CT scan. (14, 15) Glasgow Outcome Scale (GOS) will be used to assess the follow up and outcome. (16)

**Statistical analysis**

Data were presented as the mean and standard deviation for continuous variables and as a percentage for categorical variables. Statistics were calculated using PSPP Statistical Software. (17)

**Results**

Paper proforma (Annexure I) which was used for data collection able to collect the patient information, clinical details, injury details, details regarding pre-hospital care, emergency room data, investigation detail (including details of CT scan), management offered, immediate outcome and details of short as well as long term follow up. Electronic counterpart which was developed by using the FileMaker Pro 13 Advanced® replicated all these details and had all the variables which were included on the paper proforma. All the variables were stored in a single table in the background. This similarity provided an opportunity to uniformly display the contents and ease of data entry. To facilitate data entry, data were separated into sub groups by tabs which included patient demographics, injury details, emergency evaluation, treatment, in-hospital course, discharge details, diagnosis and follow up. The collected data can be exported into spreadsheet for further analysis by any statistical software program. Interim
analysis revealed that we were able to capture data for age, gender, education, brought by, date of admission, loss of consciousness, vomiting, nausea, ear bleed, nasal bleed, oral bleed, headache and seizures in all 100% instances (Table 1). The most useful features of the program were similarity between paper and electronic interface (means easy to capture data and easy to enter data feature) (Figure 1) and ability to export data in a format which can be easily utilized for data analysis.

Discussion

Many of the data registries are guided through the American College of Surgeons guidelines for selection of data points. (18, 19) The amount of information captured may vary from a "minimal dataset" collected in emergency departments to a "comprehensive dataset" with information encompassing from pre-hospital care, management, follow up to rehabilitation. (19-22) The paucity of data, incomplete understanding of the problem and non-availability of definitive guidelines is a challenge to answer many important clinical questions and questions related to the management of traumatic brain injuries. (23) Data collection particularly a registry database is considered indispensable (at the same time it must be as inexpensive as possible). (24) In our previous studies we have found that a well-designed Proforma based under supervision data collection in a relatively low volume trauma center and at regular intervals can be cost- effective which can be managed by personnel with basic training. (7, 25-29)

<table>
<thead>
<tr>
<th>TABLE I</th>
<th>Completeness of data details in the ongoing for the selected variables</th>
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<tbody>
<tr>
<td>Data variable</td>
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<td>Gender</td>
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<td>Education</td>
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<td>Brought by</td>
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<td>Date of Admission</td>
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<td>Loss of consciousness</td>
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<td>Oral bleed</td>
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<td>Headache</td>
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<td>Seizures</td>
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<td>Arrival Time In ED</td>
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<td>Left Time From ED</td>
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<td>Glasgow coma scale</td>
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<td>Best motor response</td>
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<td>Blood pressure diastolic</td>
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<td>Best eye response</td>
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<tr>
<td>Best verbal response</td>
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<tr>
<td>Pulse rate</td>
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<td>Temperature</td>
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<tr>
<td>Respiratory rate</td>
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<td>Hemoglobin</td>
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<td>Blood Sugar Random</td>
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<td>Date of Discharge</td>
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</tr>
<tr>
<td>Total leucocyte count</td>
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<tr>
<td>Time of Injury</td>
<td>67</td>
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<td>Date of Injury</td>
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</table>
Figure 1 - Screenshot demonstrate that the exactly similar appearance between paper proforma and screen appearance
### Common Data Elements in Traumatic brain Injury Pilot Study

#### Department of Neurosurgery

#### Narayana Medical College, Nellore

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Clinical Details</th>
<th>Injury Details</th>
<th>Pre-Hospital and ED Care</th>
<th>Investigations</th>
<th>Management</th>
<th>Outcome</th>
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<td><strong>Examination</strong></td>
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<td>Diabetes</td>
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<td>Hypertension</td>
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#### IP First Name
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<th>Investigations</th>
<th>Management</th>
<th>Outcome</th>
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<td>Seat belt</td>
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<td>GCS at scene</td>
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<td>GCS upon arrival in hospital</td>
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<td>Highest Level of Pre Hospital Care Provided</td>
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<tr>
<td>Type of Transportation</td>
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<td>Activation of the Trauma Team</td>
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<td>Arrival Time In ED</td>
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<td>Left Time From ED</td>
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</table>

### Common Data Elements in Traumatic brain Injury Pilot Study
Department of Neurosurgery
Narayana Medical College, Nellore

<table>
<thead>
<tr>
<th>Hemoglobin</th>
<th>Total leucocyte count</th>
<th>Blood Investigations</th>
<th>Blood Sugar Fasting</th>
<th>Blood Sugar Random</th>
<th>Blood Sugar PP</th>
<th>Blood Group</th>
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<tbody>
<tr>
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<td>Time/CT</td>
<td>Scheduled for operation</td>
<td>CT Brain</td>
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</table>

#### Blood Investigations
- Diffuse Injury I
- Diffuse Injury II
- Extravacated Mass Lesion
- Diffuse Injury III
- Intraventricular hemorrhage
- Depressed fracture
- Hydrocephalus
- Intracranial air
- Infratentorial hemorrhage
- Massive effect pressure
- Seizure
- Malignant
- Subarachnoid hemorrhage
- Subdural hemorrhage
- Intracranial shift
- Hydrocephalus
- Intracranial air
- Subdural hemorrhage
- Subarachnoid hemorrhage
- Infratentorial hemorrhage
- Massive effect pressure
- Seizure
- Malignant

#### CT Classification Category
- Diffuse Injury I
- Diffuse Injury II
- Extravacated Mass Lesion
- Diffuse Injury III
- Intraventricular hemorrhage
- Depressed fracture
- Hydrocephalus
- Intracranial air
- Infratentorial hemorrhage
- Massive effect pressure
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#### Time/CT

#### Scheduled for operation

#### Blood Sugar Fasting

#### Blood Sugar Random

#### Blood Sugar PP

#### Blood Group

#### CT Brain

#### Date/CT
### Common Data Elements in Traumatic Brain Injury Pilot Study
**Department of Neurosurgery, Narayana Medical College, Nellore**

#### Demographics
- Age
- Sex
- Race
- Ethnicity
- Education
- Occupation
- Marital Status
- Income
- Insurance

#### Clinical Details
- Medical History
- Family History
- Social History
- Past Medical History

#### Injury Details
- Date of Injury
- Time of Injury
- Location of Injury
- Mechanism of Injury
- Trauma Score

#### Pre-Hospital and ED Care
- Time to Transport
- Time to ED
- Time to Intervention
- Details of Trauma Care

#### Investigations
- Imaging Studies
- Laboratory Tests
- Other Tests

#### Management
- Revascularization
- Surgery
- Medication
- Rehabilitation

#### Outcome
- Recovery
- Disability
- Mortality

### Discharge Data
- Date of Discharge
- Discharge Details
- Discharge Diagnosis

#### Diagnosis Selection
- SEB1: Fracture of vault of skull
- SEB2: Fracture of base of skull
- SEB3: Fracture of orbital floor
- SEB4: Multiple fractures involving skull and facial bones
- SEB5: Fracture of other skull and facial bones
- SEB6: Fracture of skull and facial bones, part unspecified
- SEB6.6: Concussion
- SEB5.1: Traumatic cerebral oedema
- SEB5.2: Diffuse brain injury
- SEB5.3: Focal brain injury
- SEB5.4: Epidural haemorrhage
- SEB5.5: Subdural haemorrhage
- SEB5.6: Subarachnoid haemorrhage
- SEB5.7: Intracerebral injury with prolonged coma
- SEB5.8: Other intracranial injuries
- SEB5.9: Intracranial injury, unspecified
- SEB5.1: Crushing injury of skull

### Common Data Elements in Traumatic Brain Injury Pilot Study
**Department of Neurosurgery, Narayana Medical College, Nellore**

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- SEB5.7: Intracerebral injury with prolonged coma
- SEB5.8: Other intracranial injuries
- SEB5.9: Intracranial injury, unspecified
- SEB5.1: Crushing injury of skull
Data variables

Before establishing a multi-center national data registry it is advisable to develop a suitable and concise registry data entry form, database, secure electronic form, availability accessibility to a computer and Internet connection, funded data entry personnel and experienced personnel in trauma injuries in order to continuously maintain and analyze the registry. Many studies have recommended that before starting the data registry it will be useful to define the data set well in advance as it will ensure standardization of variables and will ensure outcome comparison in terms of patient and injury characteristic across many international studies. (2, 19, 24, 30-32) However, the datasets of existing trauma registries frequently lack compatible definitions of common data variables. (33-37) The fundamental principle to develop a data collection form is to avoid a cumbersome forms and the data collection forms should be of simple digital, analogue and 'tick box' design as where possible. (3) It is important to understand that too little data would behaving limited value, but too much data could be time-consuming and expensive to collect and administer. (38-42)

Database

Now a days relational databases are the becoming popular as these are simpler and reliable. 1 The database can be developed as a standalone system or as a web-based system which depend on the ultimate purpose of this database. 1 While converting a paper based data registry to computer based registry many technical considerations (include expert advice from information technologists) needs to be addressed which include selection of hardware, software, operating systems, memory support, and security. (30) It has been found that a simple standalone database is preferred to establish own data registry and a web-based model is preferred to establish a nationwide multi-center trauma registry then a web-based model is preferred. (1) In addition an attractive yet simple user interface will help to simplify the medical terminology and trauma score complexities. (1) To address the issue of an uninterrupted power supply (a condition unattainable in most developing countries) portable computer platforms can be the excellent solution. (43)

Data collection

Real-time data collection is the ideal but needs extensive funding, the continual presence of a dedicated data collector and almost unlikely to be practical in the pre-hospital phase (3) particularly in developing countries. A careful prospective planning for collecting data and full co-operation between pre-hospital and in-hospital personnel is mandatory to minimize the possibility of omission or duplication of data. (3) Further data collection can be optimized and simplified if the baseline data can be imported from the hospital electronic medical record system. (19, 30, 44-46) Data security can be ensured by providing username and password, encrypted data transfer which will give access to only authorized technicians and data managers. (1)

Challenges

The main factors leading to the successful establishment of a multi-center trauma registry are the development of a concise data entry form, development of a user-friendly
secure web-based database system, the availability of a computer and Internet connection in each data collection center, funded data entry personnel well trained in extracting medical data from the medical record and entering it into the computer, and experienced personnel in trauma injuries and data analysis to continuously maintain and analyze the registry. (1, 30) Data collection efforts can be hampered by several difficulties, particularly scarcity of funds and lack of adequately trained staff. (30) The cost can be a major determinant for the successful deployment of a data registry system; however as our previous experience has also revealed data trauma registries can be implemented in a cost-effective manner in developing countries. (7, 29, 30) Further as has been described in the literature our study was conducted in a single tertiary-care academic institution with an electronic record keeping system, full-fledged trauma team and round-the-clock availability of computed tomography (CT) and many other diagnostic modalities and these setting may not reflect the reality of many of the health care facilities in developing countries. (47)

**Recommendations**

Implementation of the paper trauma registry can be a useful adjunct before the planned implementation of the electronic data collection system. (9) It is evident that a structured reporting system which is based on a uniform template will permit uniform data collection and future statistics and will facilitate and validate independent or comparative audit of performance and quality of care. (48, 49) Although different personnel take part at different stages of trauma care with requirements for data collection, yet there is a potential for the development of a single unifying model which can include a glossary of terms used in the pre-hospital and early hospital phase, and definitions, time points, and intervals. (3) We agree with the recommendations made in 1996, during the 9th ITACCS Symposium in London, where the working group suggested an urgent need for a common terminology and reporting template to facilitate the acquisition, processing, audit and analysis of data which will not only be compatible but comparable also. (3)

**Conclusion**

We believe that the present data entry system has the potential to provide a clearer and user friendly descriptive data collection platform based on that a multicenter data entry template can be developed. In the first phase we introduced the paper data collection form, in second phase this data form was converted to an electronic interface. The data collection is continued in the paper form which is now entered into the electronic database for future reference. The next step is to explore the possibility whether it would be feasible to use this as a multi-center traumatic brain injury registry.

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References