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 I

Completeness of data details in the ongoing for the selected variables

Data variable	Total	Percent
Age	311	100%
Gender	311	100%
Education	311	100%
Brought by	311	100%
Date of Admission	311	100%
Loss of consciousness	311	100%
Vomiting	311	100%
Nausea	311	100%
Ear bleed	311	100%
Nasal bleed	311	100%
Oral bleed	311	100%
Headache	311	100%
Seizures	311	100%
Arrival Time In ED	288	92.6%
Left Time From ED	285	91.6%
Time of Admission	283	91.0%
Glasgow coma scale	270	86.8%
Best motor response	270	86.8%
Blood pressure systolic	267	85.9%
Blood pressure diastolic	266	85.5%
Best eye response	262	84.2%
Best verbal response	262	84.2%
Pulse rate	260	83.6%
Temperature	206	66.2%
Respiratory rate	196	63.0%
Hemoglobin	91	29.3%
Blood Sugar Random	78	25.1%
Date of Discharge	70	22.5%
Total leucocyte count	68	21.9%
Time of Injury	67	21.5%
Date of Injury	58	18.6%

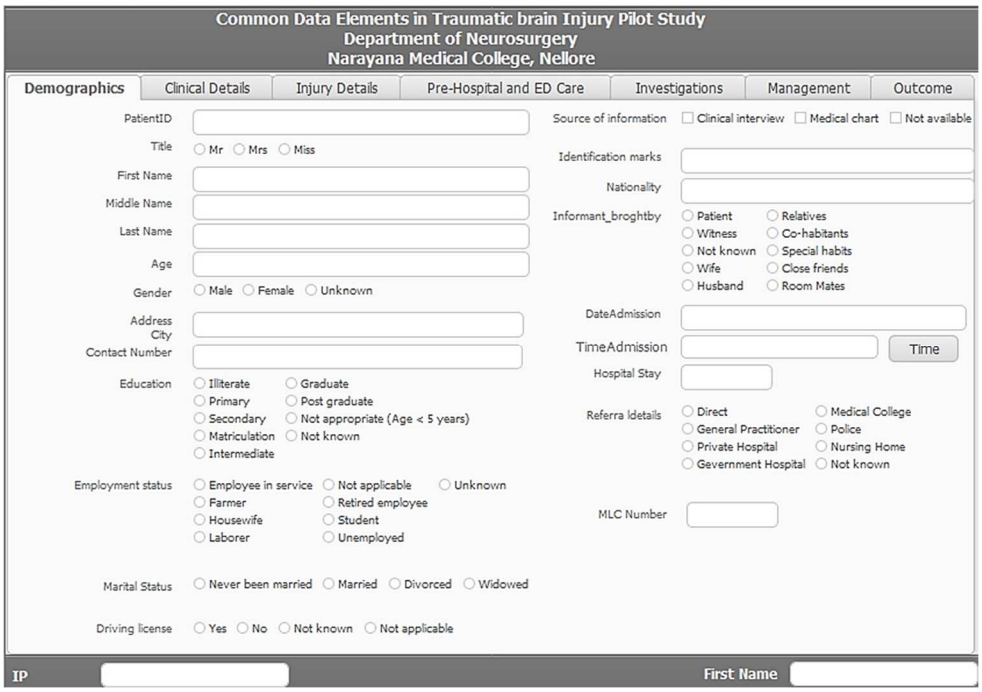
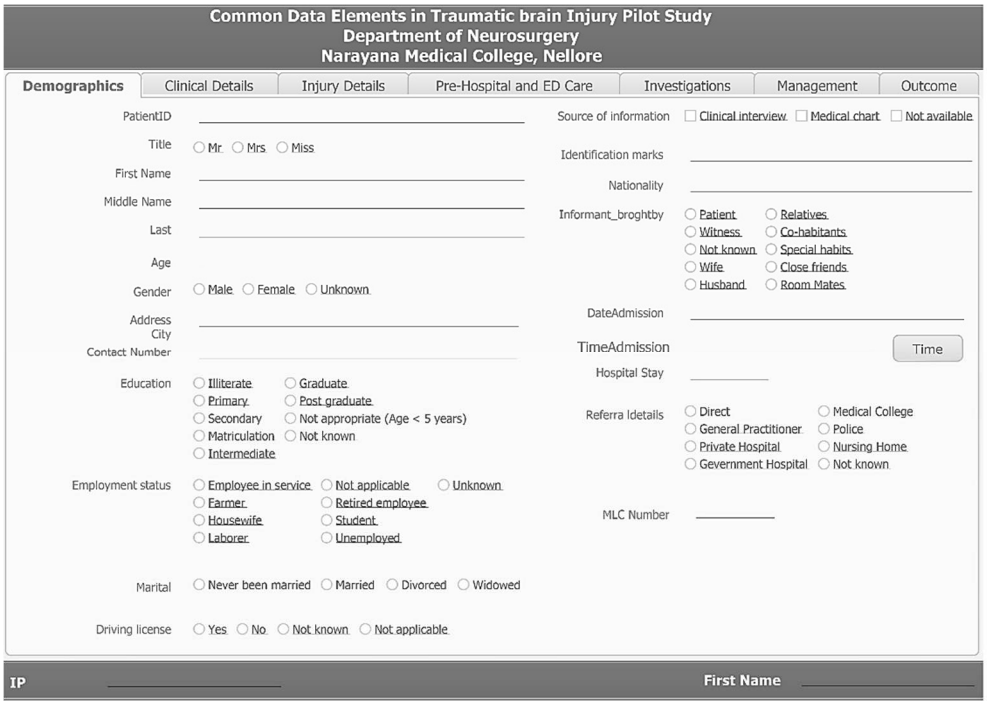
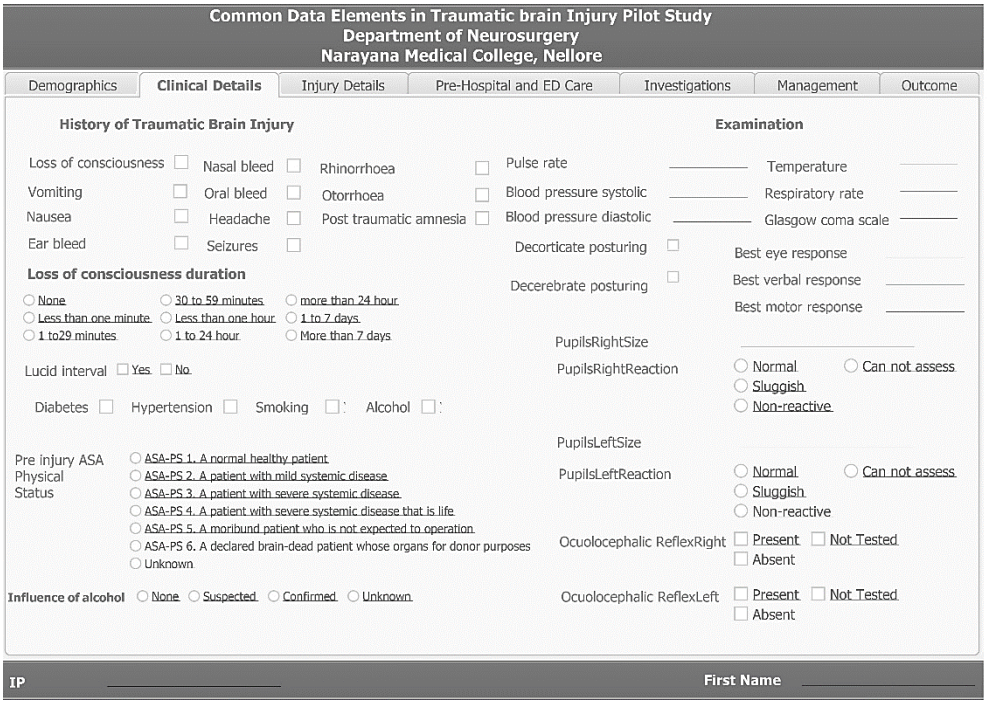


Figure 1 - Screenshot demonstrate that the exactly similar appearance between paper proforma and screen appearance





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

Demographics | **Clinical Details** | Injury Details | Pre-Hospital and ED Care | Investigations | Management | Outcome

History of Traumatic Brain Injury

Loss of consciousness ☐ Nasal bleed ☐ Rhinorrhoea ☐
Vomiting ☐ Oral bleed ☐ Otorrhoea ☐
Nausea ☐ Headache ☐ Post traumatic amnesia ☐
Ear bleed ☐ Seizures ☐

Loss of consciousness duration

○ None ○ 30 to 59 minutes ○ more than 24 hour
○ Less than one minute ○ Less than one hour ○ 1 to 7 days
○ 1 to29 minutes ○ 1 to 24 hour ○ More than 7 days

Lucid interval ☐ Yes ☐ No

Diabetes ☐ Hypertension ☐ Smoking ☐ Alcohol ☐

Pre injury ASA Physical Status
○ ASA-PS 1. A normal healthy patient
○ ASA-PS 2. A patient with mild systemic disease
○ ASA-PS 3. A patient with severe systemic disease
○ ASA-PS 4. A patient with severe systemic disease that is life
○ ASA-PS 5. A moribund patient who is not expected to operation
○ ASA-PS 6. A declared brain-dead patient whose organs for donor purposes
○ Unknown

Influence of alcohol ○ None ○ Suspected ○ Confirmed ○ Unknown

Examination

Pulse rate _____ Temperature _____
Blood pressure systolic _____ Respiratory rate _____
Blood pressure diastolic _____ Glasgow coma scale _____

Decorticate posturing ☐
Decerebrate posturing ☐

Best eye response
Best verbal response _____
Best motor response _____

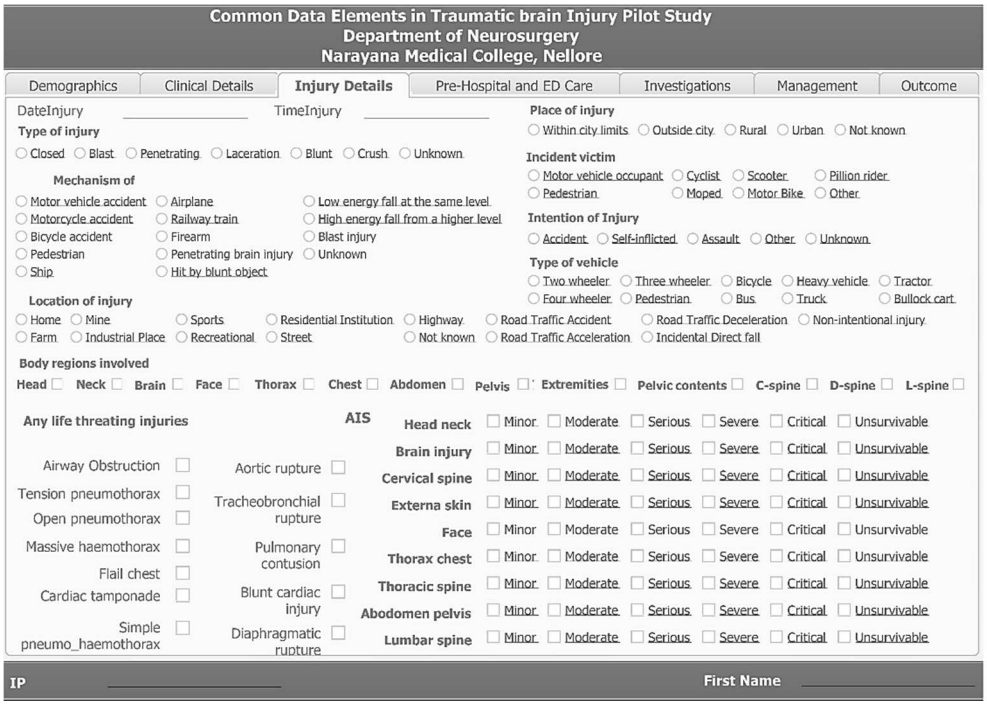
PupilsRightSize
PupilsRightReaction ○ Normal ○ Can not assess ○ Sluggish ○ Non-reactive

PupilsLeftSize
PupilsLeftReaction ○ Normal ○ Can not assess ○ Sluggish ○ Non-reactive

Ocuolocephalic ReflexRight ☐ Present ☐ Not Tested ☐ Absent

Ocuolocephalic ReflexLeft ☐ Present ☐ Not Tested ☐ Absent

IP _____ **First Name** _____



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Demographics | Clinical Details | **Injury Details** | Pre-Hospital and ED Care | Investigations | Management | Outcome

DateInjury _____ TimeInjury _____

Type of injury
○ Closed ○ Blast ○ Penetrating ○ Laceration ○ Blunt ○ Crush ○ Unknown

Mechanism of
○ Motor vehicle accident ○ Airplane ○ Low energy fall at the same level
○ Motorcycle accident ○ Railway train ○ High energy fall from a higher level
○ Bicycle accident ○ Firearm ○ Blast injury
○ Pedestrian ○ Penetrating brain injury ○ Unknown
○ Ship ○ Hit by blunt object

Location of injury
○ Home ○ Mine ○ Sports ○ Residential Institution ○ Highway ○ Road Traffic Accident ○ Road Traffic Deceleration ○ Non-intentional injury
○ Farm ○ Industrial Place ○ Recreational ○ Street ○ Not known ○ Road Traffic Acceleration ○ Incidental Direct fall

Place of injury
○ Within city limits ○ Outside city ○ Rural ○ Urban ○ Not known

Incident victim
○ Motor vehicle occupant ○ Cyclist ○ Scooter ○ Pillion rider
○ Pedestrian ○ Moped ○ Motor Bike ○ Other

Intention of Injury
○ Accident ○ Self-inflicted ○ Assault ○ Other ○ Unknown

Type of vehicle
○ Two wheeler ○ Three wheeler ○ Bicycle ○ Heavy vehicle ○ Tractor
○ Four wheeler ○ Pedestrian ○ Bus ○ Truck ○ Bullock cart

Body regions involved
Head ☐ **Neck** ☐ **Brain** ☐ **Face** ☐ **Thorax** ☐ **Chest** ☐ **Abdomen** ☐ **Pelvis** ☐ **Extremities** ☐ **Pelvic contents** ☐ **C-spine** ☐ **D-spine** ☐ **L-spine** ☐

Any life threating injuries

Airway Obstruction ☐
Tension pneumothorax ☐
Open pneumothorax ☐
Massive haemothorax ☐
Flail chest ☐
Cardiac tamponade ☐
Simple pneumo_haemothorax ☐
Aortic rupture ☐
Tracheobronchial rupture ☐
Pulmonary contusion ☐
Blunt cardiac injury ☐
Diaphragmatic rupture ☐

AIS

Head neck	☐ Minor	☐ Moderate	☐ Serious	☐ Severe	☐ Critical	☐ Unsurvivable
Brain injury	☐ Minor	☐ Moderate	☐ Serious	☐ Severe	☐ Critical	☐ Unsurvivable
Cervical spine	☐ Minor	☐ Moderate	☐ Serious	☐ Severe	☐ Critical	☐ Unsurvivable
Externa skin	☐ Minor	☐ Moderate	☐ Serious	☐ Severe	☐ Critical	☐ Unsurvivable
Face	☐ Minor	☐ Moderate	☐ Serious	☐ Severe	☐ Critical	☐ Unsurvivable
Thorax chest	☐ Minor	☐ Moderate	☐ Serious	☐ Severe	☐ Critical	☐ Unsurvivable
Thoracic spine	☐ Minor	☐ Moderate	☐ Serious	☐ Severe	☐ Critical	☐ Unsurvivable
Abodomen pelvis	☐ Minor	☐ Moderate	☐ Serious	☐ Severe	☐ Critical	☐ Unsurvivable
Lumbar spine	☐ Minor	☐ Moderate	☐ Serious	☐ Severe	☐ Critical	☐ Unsurvivable

IP _____ **First Name** _____

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Demographics | Clinical Details | Injury Details | **Pre-Hospital and ED Care** | Investigations | Management | Outcome

First aid: ○ Yes ○ No ○ Not known ○ Not applicable

Helemt: ○ Yes ○ No ○ Not known ○ Not applicable

Seat belt: ○ Yes ○ No ○ Not known ○ Not applicable

Pre hospital Cardiac Arrest: ○ Yes ○ No ○ Not known ○ Not applicable

GCS at scene: _____

GCS motor component at scene: _____

GCS upon arrival in hospital: _____

GCS Motor Component upon arrival in hospital: _____

Highest Level of Pre Hospital Care Provided: _____

Pre Hospital Airway Management: ○ Yes ○ No ○ Not known ○ Not applicable

Type of Transportation: ○ Ground ambulance ○ Walk-in ○ Helicopter ambulance ○ Police ○ Fixed-wing ambulance ○ Other ○ Private/public vehicle ○ Unknown

Activation of the Trauma Team: ○ Yes ○ No ○ The hospital has no formal trauma team activation ○ Unknown

Arrival Time In ED: _____

Left Time From ED: _____

Airway: ○ Clear ○ Adjunctive airway ○ Unknown ○ Obstructed ○ Intubated

Breathing: ○ Unknown ○ Spontaneous, adequate ○ Spontaneous, insufficient ○ Manual support with bag, valve, mask ○ Mechanical ventilation

Circulation: ○ No specific treatment ○ Vasopressors ○ IV fluids ○ CPR ○ Crystalloids ○ Unknown ○ Hypertonic saline - Colloids - Blood

Airway management: ○ No specific treatment ○ Supplemental oxygen via nasal tube or mask ○ Adjunctive airway ○ Temporary support with bag, valve, mask (for exampl ○ Intubation ○ Mechanical ventilation ○ Unknown

Discharge destination from ER: ○ Discharge home ○ Discharge other facility ○ Admission to hospital – ward ○ Admission to hospital – intermediate/high care unit ○ Admission to hospital – ICU ○ Admission to hospital – OT ○ Admission to hospital – other (e.g. observation unit) ○ Admission to hospital – Rehabilitation ○ Unknown ○ Death

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Demographics | Clinical Details | Injury Details | Pre-Hospital and ED Care | **Investigations** | Management | Outcome

Blood Investigations

Hemoglobin _____ Blood Sugar Fasting _____ Blood Sugar PP _____

Total leucocyte count _____ Blood Sugar Random _____ Blood Group _____

CT Brain

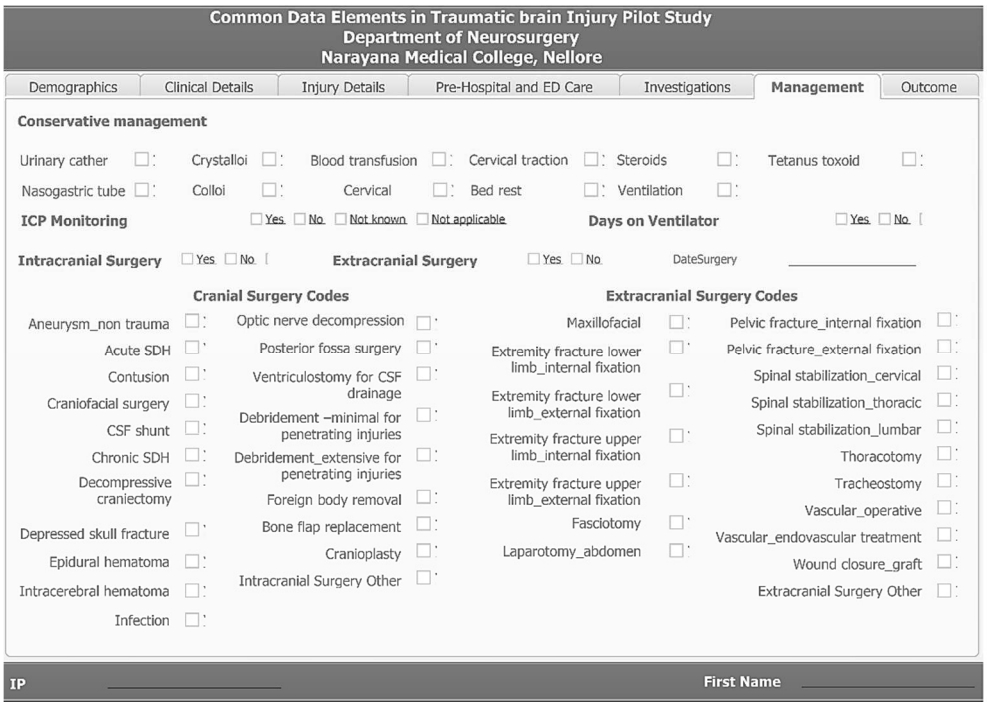
DateCT _____ TimeCT _____ Scheduled for operation _____

CTClassificationCategory: ☐ Diffuse Injury-I ☐ Diffuse Injury-III ☐ Evacuated Mass Lesion ☐ Diffuse Injury -II ☐ Diffuse Injury-IV ☐ Nonevacuated Mass Lesion

Extradural hemorrhage ○ Intraventricular hemorrhage ○ Depressed fracture ○ Acute subdural hemorrhage ○
Cerebral contusion ○ Mass effect pressure ○ Hydrocephalus ○ Chronic subdural hemorrhage ○
Subarachmoid hemorrhage ○ Midline shift ○ Intracranial air ○ Intracerebral hemorrhage ○

Fischers grade:
○ 1 No hemorrhage evident
○ 2 Subarachnoid hemorrhage less than 1 mm thick
○ 3 Subarachnoid hemorrhage more than 1 mm thick
○ 4 Subarachnoid hemorrhage of any thickness with intra-ventricular hemorrhage (IVH) or parenchymal extension

IP _____ **First Name** _____



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Demographics | Clinical Details | Injury Details | Pre-Hospital and ED Care | Investigations | **Management** | Outcome

Conservative management

Urinary cather ☐ | Crystalloi ☐ | Blood transfusion ☐ | Cervical traction ☐ | Steroids ☐ | Tetanus toxoid ☐
Nasogastric tube ☐ | Colloi ☐ | Cervical ☐ | Bed rest ☐ | Ventilation ☐

ICP Monitoring ☐ Yes ☐ No ☐ Not known ☐ Not applicable **Days on Ventilator** ☐ Yes ☐ No

Intracranial Surgery ☐ Yes ☐ No **Extracranial Surgery** ☐ Yes ☐ No DateSurgery _____

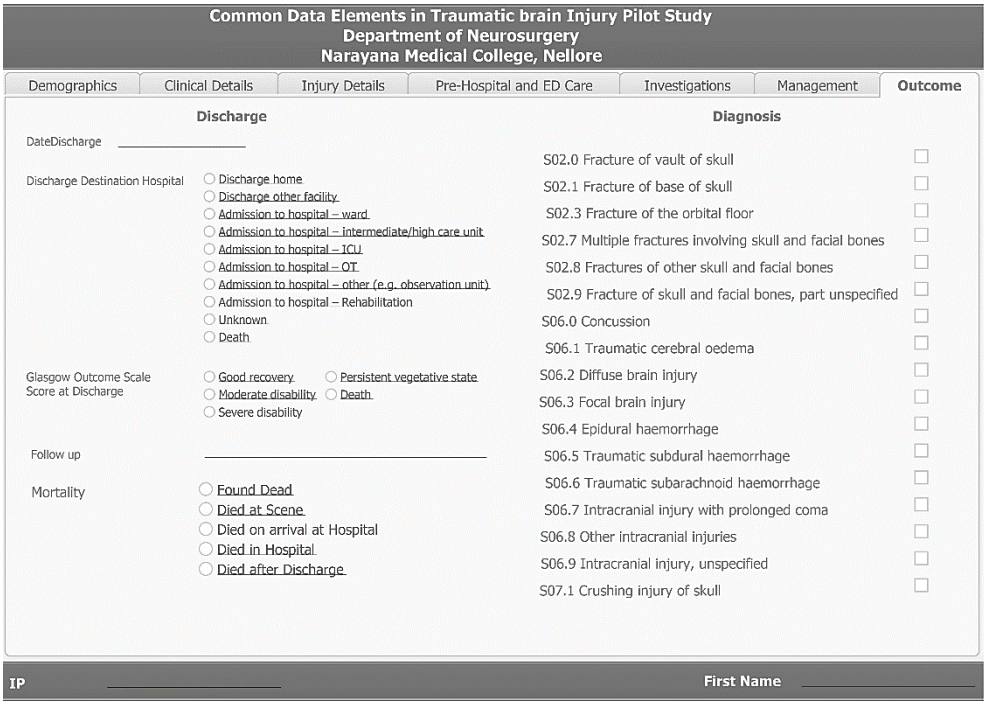
Cranial Surgery Codes

Aneurysm_non trauma ☐ | Optic nerve decompression ☐
Acute SDH ☐ | Posterior fossa surgery ☐
Contusion ☐ | Ventriculostomy for CSF drainage ☐
Craniofacial surgery ☐ | Debridement –minimal for penetrating injuries ☐
CSF shunt ☐ | Debridement_extensive for penetrating injuries ☐
Chronic SDH ☐ | Foreign body removal ☐
Decompressive craniectomy ☐ | Bone flap replacement ☐
Depressed skull fracture ☐ | Cranioplasty ☐
Epidural hematoma ☐ | Intracranial Surgery Other ☐
Intracerebral hematoma ☐
Infection ☐

Extracranial Surgery Codes

Maxillofacial ☐ | Pelvic fracture_internal fixation ☐
Extremity fracture lower limb_internal fixation ☐ | Pelvic fracture_external fixation ☐
Extremity fracture lower limb_external fixation ☐ | Spinal stabilization_cervical ☐
Extremity fracture upper limb_internal fixation ☐ | Spinal stabilization_thoracic ☐
Extremity fracture upper limb_external fixation ☐ | Spinal stabilization_lumbar ☐
Fasciotomy ☐ | Thoracotomy ☐
Laparotomy_abdomen ☐ | Tracheostomy ☐
Vascular_operative ☐
Vascular_endovascular treatment ☐
Wound closure_graft ☐
Extracranial Surgery Other ☐

IP _____ **First Name** _____



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Demographics | Clinical Details | Injury Details | Pre-Hospital and ED Care | Investigations | Management | **Outcome**

Discharge

DateDischarge _____

Discharge Destination Hospital
- ○ Discharge home
- ○ Discharge other facility
- ○ Admission to hospital – ward
- ○ Admission to hospital – intermediate/high care unit
- ○ Admission to hospital – ICU
- ○ Admission to hospital – OT
- ○ Admission to hospital – other (e.g. observation unit)
- ○ Admission to hospital – Rehabilitation
- ○ Unknown
- ○ Death

Glasgow Outcome Scale Score at Discharge
- ○ Good recovery ○ Persistent vegetative state
- ○ Moderate disability ○ Death
- ○ Severe disability

Follow up _____

Mortality
- ○ Found Dead
- ○ Died at Scene
- ○ Died on arrival at Hospital
- ○ Died in Hospital
- ○ Died after Discharge

Diagnosis

S02.0 Fracture of vault of skull ☐
S02.1 Fracture of base of skull ☐
S02.3 Fracture of the orbital floor ☐
S02.7 Multiple fractures involving skull and facial bones ☐
S02.8 Fractures of other skull and facial bones ☐
S02.9 Fracture of skull and facial bones, part unspecified ☐
S06.0 Concussion ☐
S06.1 Traumatic cerebral oedema ☐
S06.2 Diffuse brain injury ☐
S06.3 Focal brain injury ☐
S06.4 Epidural haemorrhage ☐
S06.5 Traumatic subdural haemorrhage ☐
S06.6 Traumatic subarachnoid haemorrhage ☐
S06.7 Intracranial injury with prolonged coma ☐
S06.8 Other intracranial injuries ☐
S06.9 Intracranial injury, unspecified ☐
S07.1 Crushing injury of skull ☐

IP _____ **First Name** _____

Data variables

Before establishing a multi-center national data registry it is advisable to development 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. (1) 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 import to understand that too little data would be having 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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