## The ABIC Database System

This system is intended to support the activities of the American Brain Injury Consortium by serving as a repository of data on patients admitted to hospitals with documented head injuries.

*Assumptions:*

- All patients admitted to the Neurosurgical Intensive Care Unit (NICU) with a head injury will be entered into the system.
- Assume that a patient is admitted for one and only one head injury at a time. However, it is possible that a single patient may be admitted numerous times for separate head injuries.
- The entire patient stay in the NICU will be documented using this system, with entries made on admission, after 24, 48, 72, and 96 hours, and after 7, 14, and 21 days. Entries will cease on day 21 for all patients. Repeated measures include the clinical examinations and GCS score data, and patients may receive multiple radiologic studies on each admission. The required data elements are described below.

*Functionality:*

- The system will be used by research nurses on a notebook computer, to abstract medical records in the NICU.
- The system should allow the nurse to look up patients, and add head injury admissions as they occur.
- The system is intended to register patients for inclusion in research studies of the American Brain Injury Consortium (ABIC). Not all head injury patients qualify for these studies, and inclusion/exclusion criteria are given below. However, it is important that all patients admitted with head injury are included in the database. The system should tell the nurse whether or not the patient qualifies for an ABIC study at the time of entry, based on her responses to the inclusion/exclusion criteria. At a given admission, a subject can be enrolled in one or more ABIC studies. Patients admitted multiple times for head injuries must not be enrolled in the same ABIC study more than once!
- ABIC inclusion criteria: Subject is 25-70 years of age on admission; Subject is male, or post-menopausal or non-pregnant female; Subject has sustained a closed head injury with a Glasgow Coma Score (GCS) less than 10 following resuscitation, and prior to administration of paralytic agents; OR, subject will be enrolled in the study and receive study drug within 24 hours of the time of injury.
- ABIC exclusion criteria: Subject's time of injury not documented; Subject has received an investigational drug within 30 days prior to this admission; Subject has evidence of severe anoxic intracerebral damage prior to study entry, or will not be treated aggressively for his/her head injury; Subject has other significant injuries and is not stable at time of enrollment; there is doubt that the subject's neurological status is a result of head trauma; OR, the subject has a severe complicating illness.
- Whenever the nurse enters a value that is out of range, she should be told of the error and why.
- The interface must adhere to the best principles of user interface design, incorporating objects, fonts, color, object grouping, and other methods as appropriate.

*Data elements:*

- Demographics: Patient name, Medical record number, Date of birth, Race (Asian/black/white/other, other specify) ABIC study number (only if patient is eligible, blank otherwise, including the following elements: Center (1-99), Therapy trial (1-99), Patient ID (1-9999).

- Admission information: Date and time of admission; Date and time of injury; Glasgow Coma Score (1-15); Injury severity (minor/severe); Did patient talk on admission (yes/no); If patient had GCS>8: Loss of consciousness (yes/no), if yes, how long (1-99 minutes), if no, was there amnesia for impact? (yes/no); Date and time initial therapy begun; Gunshot wound (yes/no); Automobile accident (yes/no); Bicycle accident (yes/no); Motorcycle accident (yes/no); Spinal cord injury (yes/no)

- ABIC study: Study name; Date enrolled; Time enrolled; Type of consent (informed/refused/waived)

- GCS data: GCS(1-15); Eye opening (none/to pain/to sound/Spontaneous); Verbal response (none/unintelligible sounds/inappropriate words/confused/oriented/intubated/oral or facial injury); Motor response (none/extensor/abnormal flexion/withdrawal/localizes/obeys commands/immobilized); Right pupil response (response/no response); Left pupil response (response/no response)

- Clinical examination: Highest heart rate; Highest systolic and diastolic blood pressure; Highest respiratory rate

- Radiologic data: Study type (CT/MRI); Date performed; T2 (yes/no); MRI/T1 (yes/no); MRI/Gradient echo (yes/no); MRI/Spin echo (yes/no); MRI/Fast spin echo (yes/no); MRI/Grass (yes/no); MRI/Spoiled Grass (yes/no); MRI/DWI (yes/no); MRI/Proton density-weighted image (yes/no); Normal result (yes/no)- [if no: Midline shift in millimeters (1-15); Small/slit ventricles (yes/no); Herniation (yes/no)- [if Herniation: Tentorial left (yes/no); Tentorial right (yes/no); Subfalcine left (yes/no); Subfalcine right (yes/no); Central (yes/no); Tonsillar (yes/no); Upward (yes/no)]]

    - Localization data (for each lesion seen on each radiologic image- there may be more than one!): Lesion type (intraventricular hemorrhage/cerebral edema/pneumocephalus/diffuse axonal injury/infarction/other); Areas (enter 0-20)- Extracerebral; Frontal cortex; Central cortex; Parietal cortex; Temporal cortex; Occipital cortex; Insular cortex; Frontal subcortical; Parietal subcortical; Temporal subcortical; Occipital subcortical; Insular subcortical; Internal capsule; Basal ganglia; Thalamus/Hypothalamus