

***Brain-IT Core Dataset***  
**Manual of Operations**  
**Data Element Definitions**



***NOTE: ITEMS HIGHLIGHTED IN RED ARE SUGGESTED MODS TO  
LAST RATIFIED SCHEMA...***

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This manual of operations describes the data definitions for four categories of data being collected as the *Brain-IT* Core dataset. Note this dataset is based upon a core dataset standard defined at the *Brain-IT* Group meeting held in Glasgow – December 1<sup>st</sup>-2<sup>nd</sup> 2000

(see: [http://www.brainit.org/brainit/brainit\\_glasgow\\_meeting.htm](http://www.brainit.org/brainit/brainit_glasgow_meeting.htm))

This document defines the minimum compulsory data for collection from all centers. Note that many centers can and regularly do collect other data elements too *as part of routine clinical management* – these optional data elements will also be collected at the discretion of the individual center.

### ***Data Categories***

1. ONCE ONLY - Demographic and Clinical Information (Data collected just once per patient)
2. PERIODIC TIME-SERIES Physiological Monitoring (Data collected at regular intervals – e.g.: 1 /minute or 1/20 minutes...)
3. EPISODIC TIME-SERIES Intensive Care Management (Data collected more than once but at unpredictable times: e.g.: blood gases, GCS scores, nursing comments...)
4. EPISODIC TIME-SERIES Secondary Insult Management (Data collected more than once but at unpredictable times: e.g.: drug infusions, drug bolus's, changes in ventilation settings...)

## **GENERAL DEFINITIONS OF SPECIAL CONDITIONS AND HOW THEY ARE (CODED)**

### **Not Entered Data (*Not Set*)**

As a standard for BrainIT data collection instruments – all drop-down boxes should default to a “NOT SET” option so that users must select another option from the list to indicate they have just not missed the item...

### **Missing Values (*Unknown*)**

Missing values should be indicated as: unknown this will include cases where a test or evaluation is know to have been performed but it's result is not obtainable or just plain lost

### **Not Applicable Indicators (*Not Applicable*).**

In some cases a test which is applicable in one situation may not be applicable in another, for example – an adults psychological test battery response is “**Not Applicable**” to a child.

**Not Testable Indicators. (Not Testable)**

In many cases, a test or evaluation will be called for which cannot be performed. For example – an MRI test is “not testable” to a patient with known indwelling metal prostheses, or a patient’s verbal component of the GCS can not be determined because the patient is intubated. In these cases, this condition should be indicated as: **Not Testable**

**Invalid Numeric Data Indicators.**

In the case of numeric data in particular, data values may fall outside the expected physiological range for that variable due to technical reasons (transducer calibration, blood gas sample taken so pressure transducer is switched off...) In these cases, the data value **MUST NOT BE CHANGED** but highlighted by some means to indicate it falls outside accepted physiological range. BrainIT standardize on colour coding with BLUE to indicate under-range and RED to indicate over range

**Binary Fields (Yes/No)**

Data elements that have only two conditions (eg: intubated upon arrival?) will be coded as either **Yes** or **No**.

**Dates/Times**

ASCII data should use the following format:

YYYY-MM-DD HH:MM:SS. Eg: 2001/12/23 23:59:09

Record time of injury in the 24 hour military format. Eg. 8:00 AM = 0800, 12:30 PM=1230, 7:24 PM = 1924 [1200+724]).

XML data will use the default XML time string format:

YYYY-MM-DDTHH:MM:SS.xxxxx(z)+hh:mm

Where “T” separates the date from the time field

xxxxx = sub-second precision (as many digits as required ie: 2 for ms or 4 for microseconds...)

(z) optional – if present states time string already in UTC

+hh:mm = difference between time (due to time zone change) and UTC

*XML time stamp precision can be restricted on a field by field basis.*

If exact date is unknown, approximate the closest day. If exact time is unknown, attempt to approximate closest time. In the event that a time approximation is impossible, enter 12:00 (use 24 hour clock).



## **ONCE-ONLY DEMOGRAPHICS AND CLINICAL INFORMATION (Data Collected Only Once per Patient)**

### **Demographic Variables**

#### **Center Contributing Data.**

This is chosen from a drop down list (eg: Glasgow, Uppsala, Monza...). Where there is more than one centre per city contributing data than the City is appended by a number. Eg: Glasgow1, Glasgow2. These names are assigned to each centre when they join a *Brain-IT* project and are *contributing data* to that project. This information is used only by the *Brain-IT* data co-ordinating centre for data validation purposes and is not available for multi-centre analyses. The joint multi-centre database *will* contain a “centre” code but it will be anonymised (eg: Centre1, Centre2, Centre3...) these codes will be mapped to the originating centre codes (eg: Glasgow1, Glasgow2, Glasgow3...) only in a file contained at the *Brain-IT* data coordinating centre and will be used only for data validation purposes.

Centre codes:

Currently: 0-30

#### **Local Center Patient ID Number.**

This is the number assigned by each local Center to uniquely identify the patient within that center. It will NOT be transferred over the internet nor stored anywhere other than in a secure record-linking database held in the local centre. This database will map local Centre ID's to Brain-IT numbers (see below). It will be the responsibility of the local principal investigator to maintain this database with the help (funding dependant) of one of the centrally funded, region specific data validation staff.

No information which could uniquely identify a patient (name, address, date of birth or local centre ID...) will be transferred over the internet or stored in the *Brain-IT* database.

#### **Brain-IT Patient ID Number.**

This is the number assigned by the Brain-IT Coordinating Center to uniquely identify the patient within the Brain-IT database. It will be the responsibility of the local principal investigator or one of the centrally funded, region specific, data validation staff to obtain this number by using the internet to access the Brain-IT patient ID web page which automatically generates the BrainIT patient ID. *This field is an 8-digit numeric item eg: “12345678”.*

**NOTE: THIS NUMBER MUST BE UNIQUE SO MAKE SURE ANY NEW PROJECT NUMBERS DO NOT MATCH NUMBERS ALREADY ALLOCATED IN THE CURRENT DATABASE LIST: SEE NUMBERS THAT HAVE ALREADY BEEN ALLOCATED:**

**Sex**

Record the patient's gender as *Male or Female*.

**Age.**

Calculated value in years (difference between date of trauma and the patients' DOB)



## **Description of Injury Variables**

### **Date of Trauma:**

Record the date on which the patient was injured. (If not known exactly, approximate to nearest appropriate day).

### **Time of Trauma**

Record the time of the patient's injury. (If not know, approximate to 12:00 - using 24 Hour clock).

### **Type of trauma**

Select between:

**Pedestrian.** If patient was not in a vehicle, but was hit by a vehicle.

**Road traffic accident.** If patient was driving or operating the vehicle in which he/she was injured (include bicycle operators here) or if patient was in or on vehicle.

**Fall.** If the principal cause of the patient's injury was a fall – whether at work or at home

**Work.** If patient was injured during working activities – not-including a fall at work.

**Assault.** If patient was injured during a fight, brawl, assault, or mugging

**Sport.** If the patient was involved as a participant in organized sports, whether professional, amateur, or associated with academic institutions, even in elementary schools

**Unknown**

## **Medical History**

### **History of previous neurological dysfunction.**

Record if the patient has had any neurological dysfunction prior to this injury. Probe for the occurrence of previous head injury, stroke or seizures. Also, probe for the presence of retardation, psychosis or dementia. Record as:

- \* None
- \* Head Trauma
- \* Mental dysfunction

### **Influence of Alcohol/Drugs at Time of Injury.**

Record as either **None**, **Suspected** or **Confirmed** (+ve screen test) if the patient is suspected or confirmed to be under the influence of either alcohol or drugs at the time of injury. For example: a long term alcohol abuser who may not have a significant blood alcohol level but who had a fall while having delirium tremors would be categorised as *suspected*. A patient admitted with a tested blood alcohol level over the local countries driving limit would be classed as *confirmed*. Otherwise, record as **Unknown**.

### **Associated injuries**

Record if the patient has reported any major lesion injury during trauma. (**No**, **Yes**) A major lesion is a lesion that by itself requires hospitalization. (At least an overnight stay)

Record if there are associated injuries:

**Haemorrhage, Chest, Limb, Spinal, Facial, Abdominal, Pelvic**

### **Pre-neurosurgical hospital information (PNSH)**

These data should be drawn from the information collected by the Center that reflects the patient's pre-hospital evaluation and treatment. The sources of data include the Emergency Medical Services and the Emergency/Casualty Center admission data. Ideally, these data are completed as soon as possible after admission. Data from the scene of the accident is often communicated to a variety of health professionals. **If data is available from more than one source for the pre-hospital care, the data most indicative of the patient's post-resuscitation/pre-intubation condition should be chosen.**

### **Place of Evaluation (FOR EACH OF THE ELEMENTS BELOW – A PLACE OF EVALUATION MUST BE SEPERATELY SPECIFIED AS SHOWN BELOW)**

Record the setting from which the data are drawn. The findings and lab values refer to measures and observations made at the location specified.

- \* **Place of injury**
- \* **In Transit to First Hospital**
- \* **At First Hospital**
- \* **In Transit to Neurosurgical Center hospital**

### **PNSH Date of arrival**

Record the date of arrival at the first hospital at which the patient was treated. If the patient was brought directly to the Neurosurgical Center hospital, record this value as a Not Applicable code.

**PNSH Time of arrival**

Record the time of arrival at the first hospital at which the patient was treated. If the patient was brought directly to the Neurosurgical Center hospital, record this value as a Not Applicable code.

**PNSH Cardiac arrest.**

Indicate if the patient had a cardiac arrest before neurosurgical hospital admission. (*No Yes*)

**PNSH Initial BP Systolic and diastolic**

Initial blood pressure is the first blood pressure taken or recorded at the accident scene or at the time-point in closest proximity to the accident scene. Record as *0-300 systolic/diastolic*. Use a missing value code if unknown.

**PNSH Initial Oxygen saturation**

Record the oxygen saturation noted at the scene or at the time-point in closest proximity to the accident scene as *0-100*. Use a missing value code for unknown respiratory rates.

**PNSH Evidence of hypoxia**

Hypoxia is defined as PO<sub>2</sub> of less than 60mm Hg.

- \* Record as *Definite* episode if measured PO<sub>2</sub> is less than 60mm Hg or if SpO<sub>2</sub> < 90%
- \* Record as *Clinical* if the patient was observed to be cyanotic or apneic or had a pH of <7.25.
- \* Record as *No* if none of the above.
- \* If *Unknown*, use a unknown code

**PNSH Evidence of hypotension (+ PLACE OF EVALUATION)**

Hypotension is defined as systolic arterial pressure of less than 90mm Hg.

- \* Record as *Definite* if documented SBP <90, or in a child if the SBP is < 85 mmHg.
- \* Record as *Clinical* if patient reported to be in shock without a documented SBP <90.
- \* Record as *No* if none of the above
- \* If *Unknown*, use unknown code

**PNSH Patient intubated in field?**

- \* Record as *Yes* if any of the following were used on the patient in the field: oral pharyngeal, nasopharyngeal, esophageal obturator, endotracheal, tracheostomy.
- \* Record as *No* if no intubation was performed.

### **PNSH GCS-best eye**

Use an "untestable" answer for eyes which are patched, injured, swollen, or for patients who have had tarsorrhaphy or treatment with barbiturates, narcotics, or paralytic agents.

Note – it is important to add the text for GCS scores exactly as shown in drop down boxes including “=1,2...” this is because some centres only know the GCS components as “numbers eg: GCS = 3,4,2” for eyes opening to sound, motor response = flexing, and verbal response = “no intelligible sounds”. Other centres only know it via the word codes: None, To Pain... However only the numbers should be entered into the database as these must be numeric as often need to sum the components (eye+Motor+verbal = 15)...

- \* None=1
- \* To pain = 2
- \* To sound = 3
- \* Spontaneous = 4
- \* Patched, Tarsorrhaphy, Injured, Swollen, Barbiturates, Narcotics, or Paralytic Agents = *Not Testable*
- \* Unknown

### **PNSH GCS-best motor**

The motor response to be coded is that which is the best obtained from each of the upper limbs. Therefore, each limb should be tested, and the best response recorded. Use an "untestable" answer for motor response for patients with limb injuries and/or immobilization, spinal cord injuries, or who have been treated with barbiturates, narcotics, or paralytic agents.

- \* None = 1
- \* Extensor = 2
- \* Abnormal Flexion = 3
- \* Withdrawal = 4
- \* Localizes = 5
- \* Obeys commands = 6
- \* Limb injuries and/or immobilization, spinal cord injuries, barbiturates, narcotics, or paralytic agents = *Not Testable*
- \* Unknown

### **PNSH GCS-best verbal**

*BrainIT Core Dataset Definition - 22/09/2010*

For all patients who are intubated, trached, or who have oral/facial injuries, aphasia, dysarthria, or who have been treated with barbiturates, narcotics, or paralytic agents enter the score of *not testable*.

- \* None = 1
- \* Unintelligible sounds = 2
- \* Inappropriate words = 3
- \* Confused = 4
- \* Oriented = 5
- \* Intubated, tracheostomy, oral/facial injuries, aphasia, dysarthria, or barbiturates, narcotics, or paralytic agents treatment = *Not Testable*
- \* Unknown

**PNSH Pupils** indicate the pupils reactivity and the pupils size. The combination of these two pieces of information will allow us to describe all the possible conditions. **If data is available from more than one source for the pre-hospital care, the data most indicative of the patient's post-resuscitation/pre-intubation condition should be chosen.**

Record Left and Right Eye Separately thus:

LEFT/RIGHT

*Reactivity*

Reacting

Not Reacting

Not Testable (as for GCS-eyes conditions)

Unknown

*Size*

Small

Normal

Dilated

Not Testable (as for GCS-eyes conditions)

Unknown

### **Neurosurgical hospital information (NSH)**

#### **NSH Date of arrival**

Record the date of arrival at the Neurosurgical hospital.

#### **NSH Time of arrival**

Record the time of arrival at the Neurosurgical hospital.

#### **NSH Initial BP Systolic and Diastolic**

Initial blood pressure is the first blood pressure taken or recorded in the Neurosurgical Hospital.

Record as 0-300 systolic/diastolic.

#### **NSH arterial Blood gases:**

Record the initial pH, PO<sub>2</sub>, PCO<sub>2</sub> of the first arterial blood gas drawn in the Neurosurgical Hospital

##### **Initial pH:**

Record as 6.00-7.9

##### **Initial paCO<sub>2</sub>**

Record as 15-70 mmHg

##### **Initial paO<sub>2</sub>**

Record as 40-700 mmHg

##### **Initial hematocrit:**

Record 5.0-60.0%

**Initial Glucose:**

Record 20-1000 mEq/Litre

Note – it is important to add the text for GCS scores exactly as shown in drop down boxes including “=1,2...” this is because some centres only know the GCS components as “numbers eg: GCS = 3,4,2” for eyes opening to sound, motor response = flexing, and verbal response = “no intelligible sounds”. Other centres only know it via the word codes: None, To Pain... However only the numbers should be entered into the database as these must be numeric as often need to sum the components (eye+Motor+verbal = 15)...

**NSH GCS-best eye**

Use an "Not Testable" answer for eyes which are patched, injured, swollen, or for patients who have had tarsorrhaphy or treatment with barbiturates, narcotics, or paralytic agents.

- \* None=1
- \* To pain = 2
- \* To sound = 3
- \* Spontaneous = 4
- \* Patched, Tarsorrhaphy, Injured, Swollen, Barbiturates, Narcotics, or Paralytic Agents = *Not Testable*
- \* Unknown

**NSH GCS-best motor**

The motor response to be coded is that which is the best obtained from each of the upper limbs. Therefore, each limb should be tested, and the best response recorded. Use an "untestable" answer for motor response for patients with limb injuries and/or immobilization, spinal cord injuries, or who have been treated with barbiturates, narcotics, or paralytic agents.

- \* None = 1
- \* Extensor = 2
- \* Abnormal Flexion = 3
- \* Withdrawal = 4
- \* Localizes = 5
- \* Obeys commands = 6
- \* Limb injuries and/or immobilization, spinal cord injuries, barbiturates, narcotics, or paralytic agents = *Not Testable*
- \* Unknown

## NSH GCS-best verbal

For all patients who are intubated, trached, or who have oral/facial injuries, aphasia, dysarthria, or who have been treated with barbiturates, narcotics, or paralytic agents.

- \* None = 1
- \* Unintelligible sounds = 2
- \* Inappropriate words = 3
- \* Confused = 4
- \* Oriented = 5
- \* Intubated, tracheostomy, oral/facial injuries, aphasia, dysarthria, or barbiturates, narcotics, or paralytic agents treatment = *Not Testable*
- \* Unknown

## NSH Pupils

**If data is available from more than one source for the NSH admission care, choose the pupil scores taken at the same time as the “Best” GCS scores recorded for NSH admission.**

Indicate the pupils reactivity and the pupils size. The combination of these two pieces of information will allow us to describe all the possible conditions. Insert any change of the pupillary status.

Similar to GCS eyes measurement, use an "untestable" (NT) answer for eyes which are patched, injured, swollen, or for patients who have had tarsorrhaphy or treatment with barbiturates, narcotics, or paralytic agents.

Record Left and Right Eye Separately thus:

LEFT/RIGHT

*Reactivity*

Reacting

Not Reacting

Unknown

*Not Testable*

*Size*

Small

Normal

Dilated

Unknown

*Not Testable*

*Not Testable*



### **NSH Airway Status**

Was the patient intubated AND ventilated at the moment of arrival in the Neurosurgery Hospital?

Record as **Yes** if the patient was intubated AND ventilated before arrival to the Neurosurgery Hospital.

Record as **No** if the patient was not intubated AND ventilated at the arrival at the Neurosurgery Hospital.

Record as "**AT NSH**" if the patient was intubated AND ventilated AT the Neurosurgery Hospital.

Record as **Unknown** if missing or unknown

### **NSH Medication Info on arrival at the NSH:**

Record as **Yes** if the patient was under sedation, analgesia, paralysis or received oxygen at arrival to the NSH. Record as **No** if the patient was not under sedation, analgesia, paralysis or received oxygen upon arrival at the Neurosurgery Hospital. Record as **Unknown** if missing or unknown

### **NSH Monitoring Info on arrival at the NSH:**

Record all the monitoring in use (**Yes**) at NSH (e.g. oxygen saturation, non invasive BP, invasive BP, core temperature, ICP record as (**No**) if not in use. Record as **Unknown** if missing or unknown

### **NSH CT Scan Information**

Computerized tomography (CT) scans will provide data on degree of midline shift, presence or absence of intracranial pathology and/or surgical lesions, ventricular brain ratio, measurable lesions, and cerebral infarcts. In addition to identifying the particular characteristics of that scan, the data collected will allow classification of the injury into the TCDB criteria, which are described below.

**Record only the information from the initial CT scan** (the first CT Scan closest to the time of trauma , **even if performed before NSH Admission**) **AND on the worst CT, the worst CT is defined as the CT that better describes the clinical course of the patient.**

## TCDB Diagnostic Criteria

### NSH Date of CT:

Record the date on which the CT scan was performed.

### NSH Time of CT:

Record the time at which the CT scan was performed.

**Main lesion:** select between

None

Subdural

Extradural

Intraparenchymal

### Indicate the estimated volume (in ml) of the largest hyperintense lesion on first Ct scan

For volume calculation methods, please refer to Brain Trauma Foundation “Surgical Management of Traumatic Brain Injury”, Appendix I: Post-traumatic mass volume measurements in TBI patients p. 120 (downloadable at [www.braintrauma.org](http://www.braintrauma.org))

Using the appropriate technology, estimate the volume in ml.

Enter as <25ml or >25ml. Use (None) if there is no lesion.

Use a not known indicator (Unknown) if unknown.

### TCDB (Modified) classification:

*When choosing a category – consider the “Worst” abnormality seen on the CT Scan.*

- \* Diffuse Injury, no visible intracranial pathology on CT scan. (Diffuse 1)
- \* Diffuse Injury, cisterns present with shift 0-5mm and/or lesion densities present, but no high or mixed density lesion >25cc. May include bone fragments and foreign bodies. (Diffuse 2)
- \* Diffuse Injury with swelling, cisterns compressed or absent, shift 0-5mm, no high or mixed density lesion >25cc (Diffuse 3).
- \* Diffuse Injury with shift >5mm, no high or mixed density lesion >25cc. (Diffuse 4)
- \* Mass Lesion, high or mixed density lesion >25cc. (Mass Lesion)
- \* Unknown

## Other CT Findings

### Subarachnoid hemorrhage.

Record as **Yes** if subarachnoid hemorrhage is visible on the scan.

Record as **No** if not visible on the scan.

Record as **Unknown** if not known

### Pneumoencephalus

Record as **Yes** if this is visible on the scan.

Record as **No** if not visible on the scan.

Record as **Unknown** if not known

### Intraventricular hemorrhage.

Record as **Yes** if this is visible on the scan.

Record as **No** if not visible on the scan.

Record as **Unknown** if not known

### Hydrocephalus

Record as **Yes** if this is visible on the scan.

Record as **No** if not visible on the scan.

Record as **Unknown** if not known

### Ischaemic Areas

Record as **Yes** if this is visible on the scan.

Record as **No** if not visible on the scan.

Record as **Unknown** if not known

## Other (Specify)

### NSH Surgeries

#### NSH Date of surgery:

Record the date on which the surgery was begun using BrainIT Date Format

#### NSH Time surgery begun

Record time at which surgery was begun (closest estimate of when first skin incision was made) in the 24 hour military format. Eg. 8:00 AM = 08.00, 12:30 PM=12.30, 7:24 PM = 19:24

If exact time is unknown, attempt to approximate closest time. In the event that a time approximation is impossible, enter 12:00 (use 24 hour clock).

#### Type of surgery performed. Select all that applies (also more than one):

**THIS SECTION MAY CHANGE – NEEDS SOME WAY OF SPECIFYING ORDER OF IMPORTANCE...**

ICP placement  
Evacuation of Mass Lesion  
Elevation of depressed skull #  
Removal of foreign body from skull  
Anterior Fossa repair for CSF Leak  
Placement of Extra Ventricular Drain  
Active external decompression (with bone removal and duroplastia)  
Other  
Unknown

### **Discharge Status**

#### **Date of discharge from the NSH:**

Record the date the patient was discharged from the NSH.

#### **Type of facility to which the patient was discharged:**

Record the type of facility the patient entered on discharge from the hospital.

- \* Home
- \* Other Hospital Ward
- \* Other Acute Care Hospital
- \* Rehabilitation Facility
- \* Nursing Home
- \* Other Non-Hospital Place
- \* Discharge Against Medical Advice
- \* Died
- \* Unknown

#### **Cause of death (if applicable)**

Record the patient's cause of death, if the patient died.

Use the Not Applicable code (*NA*) if the patient is still alive.

Not Ascertained

Initial Head Injury

Secondary Brain Injury

Systemic Trauma

Medical Complication (Specify)

Other (Specify)

Not Applicable

## **Extended GOS at 6 Months Post Trauma**

Record the patient's GOSe (extended GOS) at 6 months  $\pm$  15 days from Trauma. The extended GOS can be obtained either by:

- a. Direct (face to face) or telephone interview with patient or with relative or with family doctor or
- b. By postal questionnaire to patient/relative

Use the structured questionnaire shown downloadable from the Web site:

<http://www.brainit.org/brainit/downloads/GOS/Gose.pdf>

Use this paper for guidance on how to complete the structured questionnaire which is downloadable from the Web site:

<http://www.brainit.org/brainit/downloads/GOS/Goseguide.pdf>

Show the options as below but just record the numbers in the database field (ie: 1-8 or Unknown):

- 1 DEAD
- 2 VEGETATIVE STATE (VS)
- 3 LOWER SEVERE DISABILITY (LOWER SD)
- 4 UPPER SEVERE DISABILITY (UPPER SD)
- 5 LOWER MODERATE DISABILITY (LOWER MD)
- 6 UPPER MODERATE DISABILITY (UPPER MD)
- 7 LOWER GOOD RECOVERY (LOWER GR)
- 8 UPPER GOOD RECOVERY (UPPER GR)

Interview method of obtaining data in order of preference:

- INTERVIEW WITH PATIENT.
- INTERVIEW WITH RELATIVE OR CARER
- QUESTIONNAIRE

**Apart from the GOSe coding** – also include information on:

Who was the “*respondent*” to the interview:

PATIENT  
RELATIVE OR CARER  
PATIENT + CARER  
GP

Indicate the “*most important factor in patients outcome is due to*”:

HEAD INJURY  
BOTH HEAD INJURY OR SYSTEMIC  
OTHER PART OF BODY

Also indicate whether the patient had any pre-existing disability prior to their injury. This information (gathered via the structured questionnaire) will allow special coding (\* coding) if required of the a patients disability status.

## **PERIODIC TIME-SERIES PHYSIOLOGICAL MONITORING**

*(Data which occurs more than once at regular intervals)*

Data here will be collected by PC link to bedside monitoring (or to a network Server) and will be continuous data sampled at a frequency of *at least one data value acquired per minute*. Typically data values are average values from over the preceding minute depending upon monitoring equipment (e.g.: mean/median of 12 x 5 second samples). *Sampling rate should be documented*.

With each monitored variable, software tools can allow the optional (NOT Core Dataset Items) collection of “location” (e.g.: femoral, radial, frontal, parietal...) and “source” (e.g.: Paratrend PbrO2 device, Licox PbrO2 device...).

### **Core Monitored Variables**

*This is the minimum monitoring data required for inclusion in the Brain-IT Database*

#### **Heart Rate**

Record heart rate based upon the ECG and not from pulse oxymetry. Record if an internal or external pacer is in place (Y/N).

#### **Respiration Rate**

Source of respiration rate should be described – i.e.: from the patient monitor (based upon impedance plethymography) or sampled directly from a signal taken from the patient ventilator.

#### **Bp mean**

If fluid-coupled transducers are used – describe whether the transducer is “zeroed” at the level of the right atrium or at the external auditory meatus.

Blood pressure transducers should be recalibrated once every 8 hours. Changes in Transducer Calibration should be noted (See Intensive Care Management Section)

#### **ICP mean**

Type of monitor should be specified. Choices:

- EVD (extra ventricular drain),
- fluid filled SDC (sub-dural catheter),
- fluid filled IVC (intraventricular catheter),

- Fiber optic or solid transducers (Camino, Spiegelberg, Codman, Rehau, Other).

Site of Measurement should be specified:

- ED (extradural),
- SD (subdural),
- IP (intraparenchymal),
- IV (intraventricular).

Side of Measurement should be specified ( Choices: Left, Right)

If fluid-coupled transducers are used – the transducer should be “zeroed” at the level of the external auditory meatus.

Changes in head elevation should be noted (see Intensive Care Management Section)

Changes in Transducer Calibration should be noted (See Intensive Care Management Section)

### **CPP mean**

It should be specified whether the mean CPP is taken directly from the bedside monitor or calculated by bedside PC as:  $CPP = Bp_{mean} - ICP_{mean}$ .



## **SaO<sub>2</sub>**

Type of probe (finger, ear clip) (*See Intensive Care Management Section*)

## **Temperature**

Core preferred if available – specify type in use: rectal/ oesophageal/ skin/ bladder

## Optional Monitored Variables

*These are optional monitored variables which should be transferred **with** the core data if it is being monitored in the patient. Examples are:*

**Bpsystolic** (*If available*)

**Bpdiastolic** (*If available*)

## **CVPmean**

CVP should be obtained from fluid coupled transducers and not by water manometer. If fluid coupled transducers are used, transducers must be “zeroed” relative to the superior vena cava and transducers recalibrated once every 8 hours.

*Changes in Transducer Calibration should be noted (See Intensive Care Management Section)*

## **EtCO<sub>2</sub>**

if available – but in addition to compulsory 3 blood gases / day. Recalibration of ETCO<sub>2</sub> monitor should be done at least once every 24 hours.

## **SjO<sub>2</sub>**

System type (Abbott, Baxter...) and the side of catheter placement should be specified. In-Vivo calibration against an external co-oximeter should be done once every 8 hours.

## **PbrO<sub>2</sub>**

System type (Licox, Neurotrends...) and the probe location should be specified. Also record whether probe placed in proximity to cerebral contusions or other relevant neuropathology.

## **Brain-Temperature**

System type (Licox, Neurotrend...) and the probe location (epidural, subdural, intraparenchymal) should be specified. Also record whether probe placed in proximity to cerebral contusions or other relevant neuropathology.

**Brain Microdialysis**

System type (CMA, Other...) and the probe location should be specified. Also record whether probe placed in proximity to cerebral contusions or other relevant neuropathology.

**Brain LDF**

System type (NeuroLabs...) and the probe location and depth of insertion should be specified. Also record whether probe placed in proximity to cerebral contusions or other relevant neuropathology.

**TCD MCA flow Velocity**

System type (Nicolet, Scimed, DWL) and the probe location (Left Temporal Window) and Vessel insonated (MCA, PCA...)

## **EPISODIC TIME-SERIES - INTENSIVE CARE MANAGEMENT INFORMATION**

*(Data Collected more than once At Unpredictable times)*

Data here will typically be collected by either text entry/menu driven PC software or in some cases by direct links to hardware (eg: infusion pump links). *Start times and end times must be given of any change in condition*

**GCS** (*minimum 3/day – maximum as clinically indicated*).

### **GCS-best eye**

Use an "untestable" answer for eyes which are patched, injured, swollen, or for patients who have had tarsorrhaphy or treatment with barbiturates, narcotics, or paralytic agents.

- \* None=1
- \* To pain = 2
- \* To sound = 3
- \* Spontaneous = 4
- \* Patched, Tarsorrhaphy, Injured, Swollen, Barbiturates, Narcotics, or Paralytic Agents = **Not Testable**
- \* Unknown
- \*

### **GCS-best motor**

The motor response to be coded is that which is the best obtained from each of the upper limbs. Therefore, each limb should be tested, and the best response recorded. Use an "untestable" answer for motor response for patients with limb injuries and/or immobilization, spinal cord injuries, or who have been treated with barbiturates, narcotics, or paralytic agents.

- \* None = 1
- \* Extensor = 2
- \* Abnormal Flexion = 3
- \* Withdrawal = 4
- \* Localizes = 5
- \* Obeys commands = 6
- \* Limb injuries and/or immobilization, spinal cord injuries, barbiturates, narcotics, or paralytic agents = **Not Testable**
- \* Unknown

### GCS-best verbal

For all patients who are intubated, trached, or who have oral/facial injuries, aphasia, dysarthria, or who have been treated with barbiturates, narcotics, or paralytic agents enter the score of 6.

- \* None = 1
- \* Unintelligible sounds = 2
- \* Inappropriate words = 3
- \* Confused = 4
- \* Oriented = 5
- \* Intubated, tracheostomy, oral/facial injuries, aphasia, dysarthria, or barbiturates, narcotics, or paralytic agents treatment = **Not Testable**
- \* Unknown

**Pupils** indicate the pupils reactivity and the pupils size. The combination of these two pieces of information will allow us to describe all the possible conditions. Insert any change of the pupillary status.

Record Left and Right Eye Separately thus:

LEFT/RIGHT

#### *Reactivity*

Reacting

Unreacting

**Not Testable (as for GCS-eyes conditions)**

#### *Size*

Small

Normal

Dilated

**Not Testable (as for GCS-eyes conditions)**

### Airway Status

*Intubated/Tracheostomy/None*. Select if the patient is not intubated (**none**) or if is **intubated** (either Oral or Naso). Indicate the presence of a **tracheostomy**. Insert any change of the airways protection status (example: from none to intubated to tracheostomy)

### Ventilation Status

*Yes(1)/No(0) with or without CPAP(3,4)* Indicate if the patient is ventilated (any form of support, e.g. CPPV, IMV, PS, ASB, SIMV, BIPAP,...) or not ventilated. Indicate separately if the patient is connected to a CPAP system and is breathing spontaneously: Insert any change of ventilatory support.

**Not Ventilated**

Not Ventilated + CPAP

Ventilated

### Daily Observations

**Sedation** - Indicate if the patient is sedated or not. Indicate continuous sedation if drugs are delivered by a continuous **Infusion** pump or indicate **Boluses** if sedation is delivered not continuously. If both infusion and bolus's given, indicate **Both**. Indicate if not sedated over the last 24 hours with "**None**". Indicate this only once every 24 hours, usually each morning or when ever it is normally performed.

**Analgesia** - Indicate if the patient receives analgesia or not. Indicate continuous analgesia if drugs are delivered by a continuous **Infusion** pump or indicate **Boluses** if it is delivered not continuously. If both infusion and bolus's given, indicate **Both**. Indicate if not analgesed over the last 24 hours with "**None**". Indicate this only once every 24 hours each morning.

**Paralysis** - Indicate if the patient is paralyzed or not. Indicate continuous if drugs are delivered by a continuous **Infusion** pump or indicate **Boluses** if paralysis is delivered not continuously. If **Both** infusion and bolus's given, indicate **Both**. Indicate if not paralysed over the last 24 hours with "**None**". Indicate this only once every 24 hours each morning.

**Fluid Input 24 Hour Total.** Sum all the liquid infused e.g., using a NGT. Indicate this only once every 24 hours each morning. (Include plasma/whole blood in "ml" and NOT "Units", other blood products.)

**Fluid Output 24 Hour Total.** Indicate the 24 Hour fluid Output Indicate this only once every 24 hours each morning. (typically Urine output but include CSF drainage if performed).

**Vasopressors – 0/1/>1.** Indicate if the patient receives vasopressors (0= none, 1= only one, >1 = two ore more vasoactive drugs (coded 2)). Indicate continuous infusion if drugs are delivered by a continuous infusion pump or indicate boluses if it is delivered not continuously. If both infusion and bolus's given, indicate BOTH. Indicate this only once every 24 hours each morning.

**none**

**Bolus (1)**

**Infusion (1)**

**Both (1)**

**Bolus (>1)**

**Infusion (>1)**

**Both (> 1)**

**Antibiotics** - Indicate if the patient receives antibiotics (**None, Bolus, Infusion, Both**). Indicate boluses or when drugs are infused. If both infusion and bolus's given, indicate BOTH. Indicate if not given antibiotics over the last 24 hours with "**None**". Indicate this only once every 24 hours each morning.

**Nutrition** – **None/Enteral/Parenteral**. Select if the patient do not receive nutrition or if receive nutrition select enteral or parenteral. Indicate this only once every 24 hours each morning.

**Notes (Nursing/Medical) - Fields.** Indicate any nursing procedure, medical procedure or other event that could interfere with the recorded parameters and record a starting time. For those longer duration events (eg physiotherapy, xray, line insertion... ) record both a starting and ending time (ALL – JUST **Yes/No**)

**suctioning**

**turning**

**hygiene**

**Syringe pump change-over (new)**

**pressure\_area\_care**

**xducer\_calibration**

**icp\_insertion**

**central\_line\_insertion**

**jugular\_line\_insertion**

**art\_line\_insertion**

**ven\_line\_insertion**

**blood\_sample**

**x-ray**

**physio**

**hand\_bagging**

**visitors\_enter**

**visitors\_leave**

**to\_ct**

**from\_ct**

**to\_theatre**

**from\_theatre**

**probe or line removed/dislodged**

**Doppler**

## **Labs**

***Blood Gases***\_(arterial + jugular venous if present at least 3 / day)

**FiO2 indicate the FiO2 at witch the ABG was drawn**

**arterial and venous pH:**

Record as between 6.0-7.9

**arterial and venous pO<sub>2</sub>**

Record as between 40 and 700 mmHg

**arterial and venous pCO<sub>2</sub>**

Record as between 15 and 70 mmHg

***Haematology***\_(at least 1 / day)

**Haemoglobin** Record as 1.0 - 20.0 g/dl

**White Cell Count** Record as 10 – 50,000 / mm<sup>3</sup>

**Hematocrit** Record as between 5 and 60%

**Packed Cell Volume (if no Hematocrit)**

Record as between 50 and 10000 ml

**Biochemistry** (at least 1 / day)

<b>Sodium</b>	Record as between 100 and 170 mEq/Litre
<b>Glucose</b>	Record as between 20 and 1000 mEq/Litre
<b>Potassium</b>	Record as between 2 and 8 mEq/Litre



## **EPISODIC TIME-SERIES - SECONDARY INSULT MANAGEMENT**

*(Data Collected more than once At Unpredictable times)*

Data here is to be limited to non-surgical management. *Start and end times must be given*

Each Therapy *must* be assigned a “Target” chosen from a drop down list of common Words:

### **Therapy Targets**

1. ICP
2. CPP
3. Neurological Deterioration (eg: loss  $\geq$  2 GCS points. Please, refer to Morris “Neurological Deterioration as a Potential Alternative Endpoint in Human Clinical Trials of Experimental Pharmacological Agents for Treatment of Severe Traumatic Brain Injuries Clinical Study”. Neurosurgery, December 1998, Volume 43, Number 6 1369)
4. Fever
5. Hyponatraemia
6. Hypoxia
7. Hypercapnia
8. Hypotension
9. SJO<sub>2</sub> or Brain tissue O<sub>2</sub> desaturation
10. Hyperglycemia
11. Seizures
12. Other (Specify)

## **Therapies**

### **Ventilation Change:**

Mild Hyperventilation (4-4.5kPa)  
Severe Hyperventilation (< 4.0 kPa)  
Other (Specify)

### **Sedation/Analgesia/Paralysis**

Specify: YES (1)/No (0)

### **Volume Expansion**

Crystalloids  
Colloids (including Plasma)  
Hypertonic Saline  
Erythrocytes  
Other (Specify)

### **Inotropes**

Catecholamines  
Other (Specify)

### **Anti-Hypertensive Therapy**

B-Blockers  
Alpha2 Agonists  
Other (Specify)

### **Anti-Pyretic Therapy**

eg: Paracetamol  
Cooling  
Other (Specify)

### **Cerebral Vasoconstriction**

Dihydroergotamine  
Indomethacin  
Other (Specify)

***Osmotic Therapy***

Mannitol  
Glycerol  
Other (Specify)

**Barbiturates**

Dose/day

**CSF Drainage**

Closed  
Intermittent Drainage  
Open Drainage

**Steroids**

Y/N

**Hypothermia**

Y/N

**Changed Head Elevation**

Increase/Decrease

**Other Treatments**

Insulin  
Other (Specify)