

Management of Perceived Devastating Brain Injury after Hospital Admission

A Consensus Statement from Stakeholder Professional Organisations

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## Abstract

Patients with the most severe grades of life threatening brain injury are commonly characterised as having Devastating Brain Injury (DBI). For the purpose of this manuscript DBI is defined as "any neurological condition that is assessed at the time of hospital admission as an immediate threat to life or incompatible with good functional recovery AND where early limitation or withdrawal of therapy is being considered"

The outcome in DBI patients is often death or survival with severe disability, with the consequence, that rapid withdrawal of life sustaining therapies (WLST) is commonly contemplated or undertaken. However, accurate prognostication in life threatening brain injury is difficult, particularly at an early stage. Controlled studies to provide evidence to guide decision making are limited, and there is a clear risk of a "self-fulfilling prophecy", where early prognostication leading to early WLST and death.

There is a need to develop clear professional guidance in this area. The Joint Professional Standards committee of the Faculty of Intensive Care Medicine and the Intensive Care Society convened a consensus group with representation from stakeholder professional organisations to produce this guidance. It recognised that the weak evidence base makes GRADE guidelines difficult to justify. We have made twelve practical, pragmatic recommendations we hope will help clinicians deliver safe, effective, equitable and justifiable care within a resource constrained NHS.

In the situation where patient centred outcomes are recognised to be unacceptable, *regardless of the extent of neurological improvement*, then early transition to palliative care without admission to ICU would be appropriate. This consensus statement is intended to apply where the primary pathology is DBI, rather than to the situation where DBI has compounded a progressive and irreversible deterioration in other life threatening co-morbidities.

## 1. Introduction

It is recognised that accurate prognostication in life threatening brain injury is difficult, particularly at an early stage. The eventual outcome for such patients is often death or survival with severe disability. Many consider that admitting such patients to the Critical Care Unit<sup>i</sup> has little to offer in the absence of a therapeutic option, or that admission is inappropriate because it prolongs the dying process and is wasteful of precious resources. Therefore in these circumstances withdrawal of life sustaining treatments (WLST) is common practice and considered justifiable.

A UK neurosciences ICU which sought to change current practice by admitting this patient cohort for observation, primarily to aid prognostication, has recently published their experience<sup>1ii</sup>. This has confirmed in a UK context what many intensivists, neurologists and neurosurgeons already accept; that occasionally patients go on to make a good recovery despite very poor early prognostic signs<sup>2</sup>.

Without controlled studies the evidence to guide decision making will be weak when compared with other interventions in critical care. Such studies are unlikely and the risk of a "self-fulfilling prophecy", with early prognostication leading to early WLST and death, continues to exist. Case series and the development of appropriate registries can be helpful in increasing the evidence base. Evidence based guidelines as constructed by agreed GRADE criteria in such circumstances will often lead to weak recommendations. Nonetheless the Neurocritical Care Society in the United States has recently undertaken a systematic review and made several recommendations<sup>3</sup> that have helped inform this consensus statement. The Joint Professional Standards Committee of Faculty of Intensive Care Medicine and the Intensive Care Society recognises that the weak evidence base makes the development of guidelines and protocols difficult to justify, but believes that guidance in this area would help practicing clinicians deliver safe, effective, equitable and justifiable care within a resource constrained NHS. The Joint Professional Standards committee therefore convened a consensus group with representation from stakeholder professional organisations to produce this guidance.

This statement is intended to help consultants when making decisions on the management of patients admitted with a perceived devastating brain injury (DBI), and should not replace their clinical judgment.

<sup>&</sup>lt;sup>i</sup> CCU or ICU throughout this document

<sup>&</sup>lt;sup>ii</sup> also available open access at <u>http://journals.sagepub.com/</u>doi/full/10.1177/1751143716670410

## 2. Definition of Devastating Brain Injury (DBI)

For the purpose of this statement DBI is defined as:

## "Any neurological condition that is assessed at the time of hospital admission as an immediate threat to life or incompatible with good functional recovery AND where early limitation or withdrawal of therapy is being considered"

This definition emphasises both the importance of an early clinical assessment of the mortality risk and the likely functional outcomes, as well as the proposed clinical course of action. It is derived from the recommendations of the Neurocritical Care Society<sup>3</sup> and from UK experience in admitting such patients from the Emergency Department (ED) to the ICU<sup>1,4</sup>. Many patients admitted with neurological conditions that are an immediate threat to life or considered as incompatible with a good functional recovery are still treated actively and aggressively. The definition is only met when a treatment limitation or withdrawal decision is also being considered at this early stage. This definition of DBI is not dependent on the underlying diagnosis. It can be used in patients with any primarily neurological diagnosis, most commonly traumatic brain injury, subarachnoid haemorrhage, intra-cerebral haemorrhage, stroke and hypoxic brain injury from a range of causes. The early limitation or WLST is usually considered in DBI because the presenting neurological insult is not thought to be compatible with survival and not amenable to active intervention. In practice this usually means that a short period of organ and airway support is provided in the emergency department followed quickly by a transition to palliative care and terminal extubation.

Although many patients with hypoxic brain injury following the return of spontaneous circulation after a cardiac arrest may have met the criteria for DBI in the past, currently only a minority of these patients have an early treatment limitation decision applied since current international post resuscitation guidelines <sup>5</sup> recommend the admission of such patients to ICU and delayed prognostication.

In the situation where patient centred outcomes are recognised to be unacceptable, *regardless of the extent of neurological improvement*, then early transition to palliative care without admission to ICU would be appropriate. **This consensus statement is intended to apply where the primary pathology is DBI**, rather than to the situation where DBI has compounded a progressive and irreversible deterioration in other life threatening co-morbidities.

### 3. Recommendations

- 1. Patients who present with severe brain injury often require time sensitive interventions. Where these are potentially meaningful in the overall clinical context, such interventions should be undertaken without delay.
- 2. There are patients in whom severe brain injury is perceived to be devastating and active intervention not thought to be appropriate. However, prognostication at this stage can be inaccurate, and a period of physiological stabilisation and observation is recommended to improve the quality of decision making.
- 3. Patients who are intubated will require admission to critical care for this period of observation, unless the extent of co-morbidity makes continued organ support of no overall benefit regardless of the extent of potential neurological recovery. Patients not requiring stabilisation with airway, ventilatory or circulatory support can be observed on a medical ward.
- 4. During the period of observation the therapeutic aim is to provide cardiorespiratory stability in order to facilitate accurate neurological prognostication. If the patient's neurological function continues to deteriorate despite cardiorespiratory stability the multi-disciplinary team (MDT) may consider this to be an appropriate trigger for a decision to WLST. If the patient shows signs of improvement the MDT should reconsider the treatment limitation decision.
- 5. Communication of the aims and goals of treatment should be consistent and made clear to the family and members of the MDT from the outset. Admission to ICU may raise unrealistic expectations. The patient's family should be informed of the expectation of continued deterioration with death the most likely outcome, but that additional time will increase the certainty of this prognosis.
- 6. The duration of the period of observation should be determined by a combination of clinical judgement, changes in neurological function, the degree of support required to maintain physiological stability, and communication with patient's family to determine patient preferences.
- 7. The diagnosis of brain stem death often aids communication and decision making at the end of life. Continuation of intensive care in order to support the diagnosis of BSD is appropriate in such circumstances.
- 8. Organ donation should be a routine consideration in end of life care planning.
- 9. An approach for consent to organ donation should only occur after the family understand and accept the diagnosis of brain death or the reasons for WLST, and then undertaken in collaboration with a specialist nurse for organ donation.
- **10.** The Joint Standards Committee of the FICM / ICS should engage with other stakeholder organisations to remove barriers to the adoption of these

recommendations. Stakeholder organisations should work with ICNARC and the Society of British Neurological Surgeons to ensure data are captured on this cohort within critical care, the emergency department and the wider hospital environment.

- 11. Mortality is an inappropriate performance metric in this patient cohort. Detailed analysis is required to assess the effect of implementation of these recommendations on both individual consultant and unit mortality statistics, and to explain possible outliers that may result.
- 12. Audit and analysis of outcome data for these patients should be routinely collected nationally to ensure good governance.

### 4. Prognostication

The prognostication of outcome from neurological disease has received much attention. Some variables have prognostic significance across several diagnostic categories. These include age, conscious level at presentation, physiological status, extent of brain injury identified by imaging, and the presence and severity of comorbidities<sup>6,7.</sup> These have been integrated to varying extents in disease-specific prognostic schemes for traumatic brain injury (TBI) <sup>8</sup> <sup>9</sup>, aneurysmal subarachnoid haemorrhage <sup>10-12</sup>, intracerebral haemorrhage<sup>13</sup>, ischaemic stroke<sup>14</sup>, and cardiac arrest<sup>15,16</sup>. These schemes are based on probabilistic models that relate clinical features and investigations at presentation to outcome, and display varying degrees of accuracy and precision. While the performance of many of these schemes has been subject to validation in populations of patients, they all suffer from problems that make their application to individual patients unsatisfactory.

First, though their performance in groups of patients may be acceptable, the precision of prediction is either not routinely provided, or tends to be inadequate for decision-making in individual patients. For example, the CRASH prognostic model<sup>9</sup> often shows confidence intervals of up to  $\pm$  5% when predicting mortality in TBI. Consequently, a predicted mortality close to 100% may have a lower CI of ~95%, suggesting survival of one in 20 patients. Such imprecision may be particularly relevant when prognostic schemes that have been developed in one context are applied to a different clinical environment, where they may need recalibration to restore even baseline levels of precision<sup>17</sup>.

Second, many prognostic schemes tend to provide prediction of mortality, rather than functional outcome, a substantial failing when the quality of survival is seen as important by patients and their families. Where functional outcomes are provided, precision tends to be either unreported, or imperfect, as for mortality.

Third, even recently published prognostic schemes are reliant on large retrospective datasets, and consequently do not reflect current therapeutic possibilities. Accumulating data, and/or emerging advances and changed management in several conditions may invalidate prognostic expectations (as for the prognostic import of

motor responses and myoclonus following cardiac arrest<sup>16</sup>), or a prognostic feature may undergo refinement in a way that was not appreciated when the original prognostic scheme was devised (as for myoclonus<sup>18</sup>). The sensitivity of prognostic features may be altered by changes in therapy (for example, the common use of prehospital sedation has diminished the prognostic power of the GCS<sup>19</sup>, and the significance of motor responses following cardiac arrest has been altered by the use of therapeutic hypothermia<sup>20</sup>). Further, newer therapies and more aggressive management may mean that current outcomes are often better than established prognostic schemes and past experience might suggest, even for conditions that might be perceived to be devastating<sup>21,22</sup>.

Fourth, the validation of existing prognostic schemes is heavily confounded by the likelihood that patients with the worst expected prognosis often have less aggressive therapy or have therapy withdrawn <sup>23</sup>, making prediction of mortality a self-fulfilling prophecy<sup>24</sup> <sup>25</sup>. This phenomenon can result in erroneous reinforcement of prognostic schemes. Even where patients do not die, their functional outcomes may not be as favourable as might have been achieved by continued aggressive therapy. Also there is an emerging realisation that severe brain injury takes a long time to achieve maximal outcome, and the typical assessment of outcome at hospital discharge, or even at six months may underestimate the quality of survival, particularly in patients who have undergone extremely aggressive management <sup>26</sup>.

Finally, societal expectations of what is accepted as a "life worth living" are constantly being recalibrated, and many patients who are severely disabled express satisfaction with quality of life<sup>27-29</sup>. Understanding these changing trends is important if clinicians and clinical services are to reflect the expectations of the populations we treat.

However, notwithstanding these imperfections in prediction of outcome in individual patients, clinical care of patients with severe brain injury demands that clinicians make judgments regarding the advisability of continued active therapy in the face of a high risk of undesirable functional outcome<sup>7</sup>. Consequently, we need to find ways to provide greater assurance of prediction of such undesirable outcome. The change in status with physiological stabilisation, and the initial response to active therapy provides one route to such greater assurance. Most prognostic schemes are populated by variables that are recorded at a single time point typically at admission. Assessment of response to stabilisation and active therapy not only refines the precision of such prognostication, but also ensures that potentially retrievable patients are not mistakenly abandoned, and that the potential of clinical outcome in survivors is maximised<sup>7.</sup> Indeed, it is precisely this group of patients with the worst expected prognosis, who might have their outcome substantially benefitted by aggressive management and specialist care <sup>23,30,31</sup>. The period of such stabilisation and interval to reassessment will depend on the individual patient, but may lie between 24 and 72 hours.

## 5. Observation & Limitations of therapy

The purpose of an admission to ICU in the context of DBI is to provide physiological support whilst allowing further time for observation and monitoring, rather than the prolongation of an inevitable death. Observations and further investigations are aimed at confirming the initial prognostication and the exclusion of potential confounders. Treatment limitations should be agreed and communicated with patient's family and ICU team at the outset. This may include limitation of additional organ support and interventions, for example renal replacement therapy, neurosurgical interventions, ICP monitoring and the application of a DNACPR decision.

The key observation is simple repeated clinical monitoring of conscious level (Glasgow Coma Score) and pupillary reactions after physiological stability has been achieved and any confounders<sup>iii</sup> recognised and treated. This management can be provided in the patient's local ICU. The development of physiological instability and organ dysfunction during the period of observation is common. Mechanical ventilation and inotropic support are usually required and are appropriate. When a rapid and significant escalation in therapy is required to maintain physiological stability, the responsible consultant should review the relative harms and burdens of continued intensive care regularly.

In patients who show an improvement in their neurology, further discussion with a regional neurosciences centre is recommended; repeat imaging, neurophysiological studies and / or patient transfer may be required.

The use of sedative medication early in the presentation of patients with DBI is recommended as a part of emergency resuscitation to prevent secondary brain injury, for example during intubation<sup>32</sup>. After that sedatives should only be used if required to control seizures, allow tolerance of mechanical ventilation, and to manage any concerns about pain or distress. Concerns of this kind often suggest neurological recovery and consideration should be given to transitioning to active therapy. The doses used should be kept minimal to allow continued observation of the pupils and motor responses, and sedation holds practiced as usual.

A proportion of patients with DBI will develop raised intracranial pressure with subsequent brainstem compression and secondary hypertension during the period of observation. This is the expected progression of many conditions presenting as DBI. Short acting sedative agents may be used to manage the hypertension but there are advantages to the use of short acting Beta-blocking agents (e.g. esmolol) in this context. It may be considered appropriate to continue and indeed escalate support to allow a diagnosis of brain stem death when this is a possibility. The diagnostic certainty of death confirms prognostication and futility, and can aid communication with families.

<sup>&</sup>lt;sup>iii</sup> See Appendix 1.

## **Co-Morbidity**

Age is recognised to significantly worsen the outcome of patients with critical illness and brain injury<sup>9</sup>, a relevant factor may be the incidence of comorbidity. The influence of comorbidity on the decision to admit a patient to ICU should be the same for a patient with DBI as for patients with other diagnoses. Even in the minority of cases that may have good neurological outcomes, there will usually be functional deficits. Recovery will be prolonged and may require aggressive interventions. If these aspects are unacceptable or inappropriate for a patient, then the additional prognostic certainty as to the exact neurological deficit resulting from DBI is not helpful in decision-making. In the situation where patient centred outcomes are recognised to be unacceptable, *regardless of the extent of neurological improvement*, then early transition to palliative care without admission to intensive care would be appropriate. This consensus statement is intended to apply where the primary pathology is DBI, rather than to the frequent situation where DBI has compounded progressive and irreversible acute or chronic deterioration in other organ function.

## Communication

An admission to intensive care is usually for therapeutic purposes, which can improve the patient's chances of achieving an outcome acceptable to them. Intensive care admission usually leads to hope and expectations amongst patients, families and the wider MDT (including their treating intensive care team). In the situation of admission of DBI for the purposes of prognostication such hopes and expectations need to be managed by honest and realistic discussions of the most likely outcome. Multi speciality communication is important in ensuring consistency.

It is important that all parties understand the reasons for ICU admission, any limitations in applied therapies, and the likely trajectory of deterioration and subsequent death. Difficult conversations may need to occur in stages, and communication should be tailored to the needs of patients and families. Establishing the patient's values and preferences is useful in planning end of life care. Intensive care teams are experienced in the transition from active therapy to palliative care, and it may be that the emotional impact of this experience is reduced with intensive care admission.

## 6. Transition to active therapy

Improvements in neurological status should prompt rapid clinical re-evaluation and consideration of escalation in therapy to continue to support recovery and other specific measures to protect the brain. The patient should be discussed once again with regional neurosciences centre, as a change of focus to active management of intracranial pathology may necessitate further investigation and / or transfer to a tertiary neurocritical care facility.

It is important that the treating MDT remains clear about the aims and goals of treatment at all times. If there is improvement and the patient is transitioned to

active therapy this should be clearly documented, along with any limitations that remain in force, and the new treatment goals communicated to patient's family and the MDT. It is essential to ensure that the family's expectations remain realistic, explaining that any initial improvement may be transitory and is a trigger for continued observation and support, and not necessarily an indication of an improved prognosis.

A clear understanding of patient wishes and preferences will influence decision making in such circumstances, as discussed in the next section.

## 7. Transition of End of Life Care & Organ Donation

A crucial intervention in the DBI pathway is delaying the decision to WLST and achieving physiological stability <sup>3</sup>. The primary objective is to stabilise the patient and allow more time to observe the patient ensuring accurate prognostication. A minority of patients will show signs of neurological improvement and their treatment plan should be revised accordingly. The majority will however deteriorate further or even progress to neurological death. The increased time afforded by delaying the WLST will also allow secondary objectives to be met i.e. better communication, planning and delivering individualised end of life care and the consideration of organ donation when appropriate<sup>1,4</sup>.

End of life care planning should begin at the time of admission to the ED or ICU rather than at the time of making a decision to WLST. This begins with a frank and open discussion with the relatives including the high likelihood of death and the possibility of survival with disability. The interview with the relatives should also explore the patient's values and preferences and incorporate these into a bespoke end of life care plan<sup>33</sup>. A shared decision making approach between the clinical staff and the family should be adopted as recommended by many international critical care societies<sup>34</sup> and required by the Mental Capacity Act (Adults with Incapacity Act in Scotland). This avoids both a paternalistic approach to decision making or an informed approach where relatives have to make difficult decisions at a stressful time<sup>33</sup>. All treatment plans must identify clear objectives and outcomes within a specific time frame and these should be agreed with the patient's relatives <sup>35</sup>. The value of incorporating palliative care as part of the end-of-life care in ICU is increasingly accepted as a means of improving the quality of care<sup>36</sup>. It aims to prevent and relieve suffering by means of early identification, assessment and treatment of pain and other physical, psychosocial and spiritual problems<sup>37 38</sup>.

Consideration of organ donation should begin when a patient continues to deteriorate and WLST is being considered, or alternatively when it appears likely that a patient will meet the criteria for confirming death using neurological criteria. Both scenarios should lead to an early notification and discussion with a specialist nurse in organ donation (SN-OD) as recommended by the National Institute for Health and Clinical Excellence<sup>39</sup> and best practice guidelines<sup>40</sup>. The relatives should not be approached to request organ donation until they have accepted the futility of continued organ support and the reasons for the WLST and the consequent inevitability of death, or after the confirmation of death using neurological criteria. It is good practice to decouple the conversation about neurological testing or the WLST

from the family approach regarding organ donation<sup>41</sup>. A planned and collaborative approach between the ICU team and the SN-OD team should be routine practice<sup>35</sup>. This not only improves the quality of the information and support provided to the family, but also improves consent rates<sup>42</sup>.

## 8. Governance

- a. There should be an identified lead clinician for the management of DBI patients within each trust. This could be incorporated within existing clinical management roles, for example within the Emergency Department, Intensive Care or Neurology / Neurosurgical Services.
- b. Prospective audit of patients admitted with DBI should be undertaken locally and nationally.
- c. Cases from this patient cohort should be regularly reviewed in a multidisciplinary meeting, for example morbidity and mortality meetings.
- d. In clinical environments where the transfer of DBI patients is sometimes necessary, joint case review with regional centres would be ideal.

## 9. Existing Relevant Guidance

- Good Medical Practice. General Medical Council. 2013.
- Treatment and care towards the end of life. Good practice in decisionmaking. General Medical Council. 2010.
- Mental Capacity Act 2005, HM Government & Adults with Incapacity (Scotland) Act 2000.
- Guidelines for the Provision of Intensive Care. Faculty of Intensive Care Medicine and The Intensive Care Society. 2015.
- Organ donation for transplantation: early identification of potential organ donors. National Institute of Health and Care Excellence. 2016.
- Timely identification and referral of potential organ donors. National Health Service Blood and Transplant. 2012.
- Approaching the families of potential organ donors. National Health Service Blood and Transplant. 2013.
- A code of practice for the diagnosis and confirmation of death. Academy of the Royal Colleges. 2010.

### **10.** Barriers to implementation & Other Considerations.

#### **Resources**

### a. ICU Capacity

Even in countries with considerably higher ICU capacity than the UK the practical, moral and financial impacts of using increased ICU resources at the end of life are increasingly recognised<sup>43</sup>. The equitable and ethical management of scare ICU beds and resources is an everyday challenge for ICU consultants in the UK and a skill that is expected of this role. Relevant GMC guidance is useful, for example Good Medical Practice states "Decisions about what treatment options can be offered may be complicated by resource constraints – such as funding restrictions on certain treatments in the NHS, or lack of availability of intensive care beds. In such circumstances, you **must** provide as good a standard of care as you can for the patient, while balancing sometimes competing duties towards the wider population, funding bodies and employers".

b. ED Capacity.

It is envisaged that admission of patients with DBI to critical care units will have little impact on emergency department capacity. While there may be a delay while a critical care bed is obtained this is likely to be similar to, or less than, the time taken to manage treatment withdrawal with in the emergency department.

c. Equipment

Access to specialised investigations (MRI, EEG) or techniques (ICP monitoring) may hamper decisions on prognostication and optimal management of the DBI patient outside a regional centre. Early communication with the regional neuroscience centre is recommended.

d. Communication & Referral Pathways

The frequency with which some critical care staff will manage DBI patients will be low, particularly in smaller units. Confidence in decision making will be improved by good communication and referral pathways between regional neuroscience centres and secondary care hospitals.

#### **Quality Metrics**

e. ICNARC, Unit and Hospital Mortality

The available data on outcomes for patients with DBI is limited for the reasons outlined in the introduction. This lack of outcome data, and potentially the impact of high mortality, may hamper acceptance of the potential benefit of a prognostication window. Lack of demographic,

subgroup and length of stay information may prejudice appropriate resource allocation by both providers and commissioners.

f. Surgical Outcomes

There are good reasons to question the use of mortality statistics as a measure of the quality of surgical practice<sup>44</sup> and the abuse of such statistics serves as a potential barrier, and a disincentive, to decision making in the patient's best interest in the setting of DBI. We recommend that these patients are excluded from the neurosurgical / intensive care unit's quality metrics which make use of standardised mortality ratios as an outcome measure. It may be helpful if the admitting consultant were to be the duty intensivist.

## Education

g. Improved understanding of which patient subgroups may benefit from a prognostication window will require collection of quality data, and our recommendations include the capture of robust data. The existing evidence base and the results of future data analysis need to be understood by clinicians and this subject area would be an appropriate topic for local CPD sessions.

## **Staff Training**

h. Communication Skills

Managing the expectations of relatives and staff when a patient is admitted with limited prospect of recovery will require excellent communication skills. Advanced communication training can be a useful addition to intensive care unit educational programs<sup>45</sup>.

## **Psychological Issues**

i. The multi professional staff who look after patients with limited prospective of recovery may need psychological support. Existing unit resources may be supplemented by specific support mechanisms, e.g. Swartz rounds.

# Appendix 1 - Table of potential confounders of poor initial GCS in TBI

Drugs (prescription, administered, illicit) inc. alcohol

Seizure activity

Spinal cord injury

Direct cranial nerve injury

Physiological derangement (hypotension, hypoventilation, hypoxia and hypercapnia)

Ophthalmological injury / conditions

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