THE UNIVERSITY OF HULL

A STUDY OF OUTCOMES FOLLOWING HEAD INJURY AMONG CHILDREN AND YOUNG ADULTS IN FULL-TIME EDUCATION

Being a thesis submitted for the degree of Doctor of Medicine in the University of Hull

By

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August 2007

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Acknowledgements

Without whom this would not have been possible. Thank you to:

The medical and nursing staff and patients of Hull Royal Infirmary Emergency Department

Dr Ian Hanning, Clinical Biochemist, Clinical Chemistry Department at Hull Royal Infirmary

Dr William Townend, supervisor, for his tireless support and constructive criticism throughout

Trish and Emyr Jones, for their readiness to baby-sit and general support

Julie Cooper, for those extra days work

Dedication

To Anne-Mair, Alex and George

Introduction

1.1 Epidemiology of Head Injury

Head injuries are often claimed to account for more than one million attendances to emergency departments, across the United Kingdom, per year. A review of head injury epidemiology in the 1970's estimated the number of attendances to emergency departments to be between 1600 and 1700 per 100,000 of the population [1]. With the current UK population quoted as just over 60 million, this would estimate the attendance rate, following head injury, at between 960,000 and 1,020,000 per year.

In the introduction to the National Institute of Clinical Excellence's publication on head injuries [2], an estimate of the annual attendance rate of head injured patients to emergency departments in England and Wales was around 700,000, with an admission rate estimate of under 20%, based on data from the Hospital Episode Statistics data for 2000/01. The authors comment that 'there are no reliable up to date figures for the total denominator of attendees with a head injury at Accident & Emergency departments.' Estimated incidence of death from head injury was as low as 0.2% of all patients attending A&E with a head injury, with around 90% of attendees suffering what is considered a 'mild' injury.

A formalised review of the literature in 2004 by the WHO collaborating centre task force on mild traumatic brain injury (mTBI) [3] estimated a worldwide incidence for mTBI of 600/100,000. The authors concluded that the heterogonous nature of the studies made accurate estimates of incidence difficult, but did comment that men have twice the risk of injury than women, with the greatest risk in teenagers and young adults.

1.2 Classification of Head Injury Severity

A specific definition of what a head injury involves is required for the purposes of research and one that has been adopted previously is that proposed by the Oxford Head Injury Service of "any blow to the head causing a diagnosis of head injury to be made" [4]. This definition in itself does not suppose any underlying injury to the brain, and as such encompasses a wider group of patients than limited studies in only traumatic brain injury groups.

The World Health Organisation defines Traumatic Brain Injury as:

> An occurrence of injury to the head (arising from blunt or penetrating trauma or from acceleration-deceleration forces) with at least one of the following:
>
> > Observed or self-reported alteration of consciousness or amnesia due to head trauma,
> >
> > Neurologic or neuropsychological or diagnoses of skull fracture or intracranial lesions that can be attributed to the head trauma [5].

Further sub-group definitions of traumatic brain injured patients have been described widely in the literature. The main factors used for classification are the Glasgow Coma Score (GCS) [6], period of loss of consciousness, period of amnesia, with the GCS being the main differentiating factor.

(See Appendix I for Glasgow Coma Score)

The use of the Glasgow Coma Score is generalised and a common categorisation of head injury severity using the score is described in the Advanced Trauma Life Support® Course Manual.

Mild	GCS 13-15
Moderate	GCS 9-12
Severe	GCS ≤8

A committee of the American Congress of Rehabilitation Medicine has formally defined mild Traumatic Brain Injury [7], and this definition has been widely used in the published literature:

At least one of the following must apply:

- Any period of loss of consciousness;
- Any loss of memory for events immediately before or after the accident;
- Any alteration in mental state at the time of accident (e.g. feeling dazed, disorientated or confused); and
- Focal neurological deficit(s) that may or may not be transient;

But where the severity of the injury does not exceed the following:

- Loss of consciousness of approximately 30 minutes or less;
- After 30 minutes, an initial GCS of 13-15;
- Posttraumatic amnesia of not greater than 24 hours

1.3 Mortality and Morbidity from Head Injury

Death from head injury is thought to be low and quoted, in the UK, as between 6-10/100,000 of the population per year [2]. Although this figure appears small, it represents a leading cause of death in children, one study from 1990 demonstrating a mortality rate attributable to head injury of 15% in 1-15 year olds and 25% in 5-15 year olds [8].

An estimate of the number of neurosurgical procedures following head injury is in the region of 4,000 per year across the UK [2]. Two large-scale North American studies looking at the role of Computed Tomography (CT) in the mild head injury population quoted neurosurgical intervention rates of 1% [9] and 0.4% [10]. These same studies identified 6-8% of cases with intra-cranial abnormalities on CT scan.

Further morbidity following head injury has been investigated for many years, mostly amongst those patients admitted to hospital for their injuries. A large-scale UK study based in Glasgow [11] described the high incidence of post-injury disability amongst the admitted population. The data showed that the proportion of patients with a poor outcome was consistent regardless of the severity of initial injury. The figures quoted for this group were of 47%, with disability after one year, following an initially mild injury, 45% from the moderate group and 48% from the severe group. These groups were differentiated by the GCS on attendance as described earlier in this chapter.

1.3a Childhood Head Injury

Head injury rates are higher in childhood with attendance rates to emergency departments for 0-14 year olds being higher than other age groups [1]. Two peak periods of incidence are described for traumatic brain injury in the US, early childhood (0-5 years) and mid to late adolescence [12] and this has been borne out by a recent epidemiological study of emergency department attendances in the UK, which identified the highest rate of moderate to severe injury amongst the 15-19 age range [13]. Further studies suggest that severe injury during the first five years of life can have a significant effect on long-term outcome, with delay in reaching developmental milestones [14], and admission to hospital following injury in this age group has been linked with psychosocial defects appearing between the age of ten and thirteen. One theory behind this being that the injury affects the child's ability to adapt to the increasing demands of development [15].

A longitudinal study in Denmark followed a birth cohort of young men to look at the effect of age at injury, and severity of injury, on a draft board's compulsory cognitive functioning test, taken at the age of eighteen years [16]. The results suggested that a single head injury after eleven years of age, not requiring admission to hospital for more than one day, was linked with higher failure rate in the cognitive test when compared to the non-injured cohort.

1.3b Effect of injury on schoolwork

Cognitive functioning is just one area of impairment routinely described following head injury. Behavioural problems have been reported after paediatric head injury and Hawley linked these problems with a decline in academic performance and an increased risk of exclusion [17]. The author recommended that children should be screened for behavioural problems prior to return to school following injury and schoolteachers be made aware of the injury. In Hawley's study ethical approval for consent to be given by those aged thirteen and over was granted, a cut-off that was thought to be appropriate for the current project.

With regular examinations and ongoing assessments for coursework currently an accepted part of school life in the UK, the effect of a period of poor cognitive functioning and behavioural problems on future prospects may be more significant than previously identified. This study was not designed to verify the decline in future prospects but give an insight as to the potential scale of the problem. By identifying patients, from an at risk group, that could respond for themselves at interview, the objective was to highlight the rate of post-injury problems encountered and potentially isolate factors at presentation that could predict such problems.

1.4 Studies of discharged patients

With an estimated admission rate of 20% for head injured patients, approximately 80% of these patients attending the emergency department are discharged directly. If, as suggested by the Glasgow data, the initial severity of injury does not alter the proportion of patients with disability after one year, then any study in to the outcomes following head injury should logically include those discharged directly from the emergency department.

Four studies in adults were identified that have attempted to describe this group. The only one from the UK was by the Oxford Head Injury Service [18], who attempted to follow-up all patients attending the emergency department with a head injury – as defined previously. This study was looking to compare early intervention against standard management and the effect on post-injury symptoms at follow-up. The authors concluded that there may be some benefit in intervention for those with moderate to severe injury and admitted to hospital; however, 59% of those originally identified were lost to follow-up, making any conclusions difficult to draw.

Two other studies in adults from North America [19] and Europe [20] both excluded patients under the influence of drugs and alcohol in their attempt to identify prognostic factors that could indicate an increased risk of post-concussive symptoms. Dikmen and Levin commented that studies in to head injury should include those under the influence of intoxicants as they may have a confounding influence on the recruitment and outcome results [21].

The fourth study was from Melbourne, Australia and looked at the effect of an information leaflet and early interview on outcome at three months. The authors achieved an improved follow-up rate (62%) compared to the Oxford study and agreed that the intervention group had an improved outcome compared to the controls. However, they did not give any estimate of the incidence for post-concussive symptoms. A second study by the same authors in children not yet sixteen, did quote a PCS rate of 17% [22].

As such, no current accurate estimate for the incidence of post-concussive symptoms exists for all head injuries attending an emergency department in the United Kingdom. Using the incidences quoted for post-concussive symptoms after six months in three of the aforementioned studies results in a mean value of 23% of patients developing PCS.

1.5 The need for outcome prediction

Why should the cohort of patients who develop post concussive symptoms be identified at an early stage? Is it possible to reduce the impact of head injury and improve outcome by intervention?

In 1997, Wade and the Oxford Head Injury Service assessed the benefit of following up all head injured patients presenting to the emergency department at 7-10 days after the injury [18]. As a result of the high attrition rate for this study, the authors suggested that routine follow-up of all patients was not of any benefit. They did suggest that those with more severe injuries, that is either admitted or with post-traumatic amnesia of more than one hour, did show some benefit from the initial intervention when compared to a cohort of control patients without intervention. The assessment of intervention was performed after six months but the overall follow-up rate was poor at only 41% (478/1156).

A further study by the same authors, with a higher follow-up rate of 69%, looked at the benefits from early intervention in those admitted following their injury [4]. These interventions included information and advice about the likely problems faced and estimated recovery times, strategies to cope with the effects of cognitive and emotional stress and a graduated return to normal activities. These were provided by face-to-face or telephone consultation, with supplementary information leaflets also provided. This demonstrated significantly reduced levels of post-concussion symptoms and less social disability when compared with the control group.

A research group in Melbourne, Australia, led by Ponsford, performed similar studies in both adults [23] and children [22] attending the emergency department following head injury. Final outcomes were measured at three, rather than six, months and the intervention was within one week involving a formal outpatient interview with an information booklet being provided - which contained information on expected symptoms and suggested coping strategies.

Both of these studies demonstrated benefits in the intervention group, reducing the rate of symptoms reported at the outcome assessment and reduced behavioural and anxiety levels after three months, when compared with the non-intervention group.

Evidence, therefore, exists that simple intervention can reduce the impact of head injury in both mild and more severely injured cohorts, amongst both adults and children. The next step in the process is to focus this intervention at those most in need by identifying presentation factors that can predict a poor outcome, that is identify those most likely to benefit from intervention.

2.1 Acute Management of Head Injury

The acute management and investigation of head injured patients has received a high profile in recent times after the publication of the Canadian CT Head Rules [9] and the UK National Institute of Clinical Excellence (NICE) guidelines [2]. These two publications have led to the development of care pathways designed to identify and treat the early and life threatening complications of head injury.

The objective of care within the emergency department is to identify those patients presenting following head injury who have underlying intra-cranial or brain injury. A number of variables have been identified that aid the health-care practitioner in their task of identifying those with abnormal CT scans. These are discussed in the following section.

2.2 Initial presentation

2.2a History of Injury

Data collected at the time of presentation is generally focused on the detection of significant intra-cranial injury. Factors that can predict significant intra-cranial injury were identified by a meta-analysis review in 2004 [24], and included loss of consciousness. Also previously identified variables are vomiting on more than two occasions, high-risk mechanism of injury*, age over 65 and any coagulopathy [9]. These have been incorporated in to the current National Institute for Clinical Excellence guidelines on the management of head injuries [2].

* Includes pedestrian struck by car, occupant ejected from car, fall of greater than one metre or five steps.

2.2b Clinical Examination

Head injured patients should be subjected to a full neurological examination before they are considered safe for discharge. Examination variables that have been identified as predictive of significant intracranial injury include a reduction in Glasgow Coma Score (GCS) of less than fifteen [24, 25], focal neurology [24] and pupil reactivity (predictive of survival) [25].

The current documentation should include information on all of these factors as a minimum and the NICE guidelines suggest the completion of a proforma for all head injured patients as standard practice [2].

2.3 Imaging

2.3a Skull Radiographs

Skull radiographs have been utilised in the management of head injured patients for many years. The underlying premise was that a skull fracture is representative of increased forces involved in the injury and hence an increased likelihood of intracranial injury [26]. The NICE guidelines for management of head injuries [2] advocate a reduced role for skull radiographs in the identification of intracranial pathology. Two studies have shown good evidence of the poor sensitivity of skull fracture on radiography for the presence of ICH, the second of which is a meta-analysis of relevant studies [27, 28]. Lloyd and colleagues publishing their findings in the Lancet in 1997, suggested a 65% sensitivity for the presence of ICH with skull fracture on radiography, highlighting the fact that significant brain injury can occur without skull vault fracture [27]. Hofman's meta-analysis proposed an even lower sensitivity of 38%, based on studies where at least 50% of patients had CT scan to confirm ICH [28].

The increasing evidence against skull radiography then brought in to question current management strategies for patients following mild head injury. Computed Tomography – as recommended by the NICE guidelines – compared to skull radiography and observation or observation alone. Questions raised about the applicability of the NICE guidelines included the availability of 24 hour cover for CT and the reporting required, financial implications of CT against admission to a hospital bed and radiation exposure with its potential long-term effects – in particular on children.

These were sequentially addressed in a series of papers published following the introduction of the 2003 guidelines. The CHALICE study retrospectively analysed data from over 10,000 patients in the northwest of England [29]. The researchers looked at rates of skull radiograph, CT and admission in head injured patients under the age of sixteen. The actual rate was established and then models for strict adherence to RCS guidelines and NICE guidelines were extrapolated from the data. Current practice was shown to not follow RCS guidelines. The extrapolated data for the NICE guidelines were shown to produce a higher number of CT requests but a considerably lower skull x-ray and admission rate, and as such, the authors concluded, emphasis for these patients would shift from observation to early imaging.

A subsequent study looked at actual practice – not a theoretical model – within their emergency department, having abolished the use of skull radiographs for head injuries, in children. The authors analysed data collected about CT utilisation, radiation dose per head injury, detection of intracranial injury and admission rate both before and after the abolition of skull x-rays [30].

Whilst the percentage of patients undergoing CT doubled, the detection rate of intracranial injury remained the same (25% positive pick-up rate of those scanned). Radiation dose per head injury actually decreased slightly (with the caveat of a much larger number of patients received no radiation exposure at all). However, the admission rate did not differ significantly between the groups suggesting that a change in imaging policy would not affect the admission policy. The evidence does, however, support the notion that skull radiographs can be abolished in the search for intracranial injury.

2.3b Computed Tomography

CT is considered the gold standard of management for the early identification of intra-cranial injury following trauma. High quality published evidence for the detection of intra-cranial pathology has been widely accepted and developed into decision rules or guidelines across the developed world [2, 9, 31]. This evidence suggests a positive result, that is significant brain injury visible on CT scan, is obtained in approximately 8-10% of scans performed with only 1% requiring neurosurgical intervention [9, 32].

Evidence from the OCTOPUS study group in Sweden looked at both the overall costs and three month outcome data from a 'CT and discharge' plan as opposed to an 'admit and observe' plan [33, 34]. This group surmised that the CT strategy was not inferior to admission and observation with regard to outcome, complications and mortality. Financially, the 'CT and discharge' strategy was shown to be consistently cheaper, or more cost effective, in comparison to admission when considering both direct and indirect costs. Direct costs were calculated for room and board (including staff salaries, housing and drug costs). Indirect costs in the follow-up period were defined as the estimated loss in production caused by days off work (including parents of injured children). The authors did comment that they had no 'false-negative' scans on the CT strategy pathway, i.e. no patients returned with complications after a normal scan.

Concern over a false-negative rate for CT scans remains, but evidence suggests that this is minimal with a reported negative predictive value of 99.7% in one large study [35]. A systematic literature review for case reports on adverse outcomes following normal CT and discharge if GCS 15, revealed three confirmed case reports of deterioration within 48 hours of injury.

Eight other cases were described but all with poor data about initial management and clinical findings in the write-up, resulting in questionable significance [36]. These were the only reports from over 65,000 patients from a variety of sources.

Concordance between groups of radiologists reporting intra-cranial abnormalities has also been studied with an approximate discordance rate of 2-8% between on-call radiologists and neuro-radiologists [32, 35]. More often than not, these were false-negative reports but did not relate to potentially significant omissions.

The argument against the ‘CT and discharge’ strategy is further undermined by the fact that previous research has demonstrated that admission and observation is no guarantee for the detection of serious intra-cranial complications [37].

To date the evidence supports the use of head CT as the first-line investigation for the detection of clinically significant intra-cranial injury.

2.3c Radiation risk with CT scans

A large, well-constructed Swedish population based cohort study published in January 2004, looked at the effects of low-dose ionising radiation, for the treatment of cutaneous haemangiomas, on subsequent cognitive functioning [38]. The authors identified a negative dose-response relationship between the level of radiation exposure and cognitive function aged eighteen. In particular they highlighted the significant radiation dose at which these effects were identifiable, >100 mGy, and commented that this was about the same dose as delivered to a child undergoing head CT scan.

An American study in to the lifetime mortality risk from cancer associated with CT in childhood identified a significant increase for both abdominal and head CT scans [39]. The authors quoted an approximate rate of one in 1500 children undergoing a head CT subsequently developing cancer as a direct result of that scan.

A review of the problems identified was published in 2003, suggesting careful consideration of the need for radiation exposure, in particular CT scanning, in children and the incorporation of the 'As Low As Reasonably Achievable' (ALARA) approach to doses in those scans deemed essential [40].

Despite CT being considered as the gold standard for investigation of head injuries in the emergency department, the incidence of 8-10% of intra-cranial injury identified on CT does not correlate with current estimates for the incidence of post-concussive symptoms, in one UK sample as high as 47%.

2.4 Rehabilitation of head injured patients

It has been established that early intervention in patients with moderate or severe head injury by coordinated rehabilitation programs has the effect of reducing the impact of the injury on social interaction, concentration and ability to return to work. Specialist rehabilitation was recommended for this group of patients in the Galasko report in 1999 [41]. However, these rehabilitation services are limited and time consuming so the ability to identify those patients most at risk and refer them on early in the disease process becomes an important consideration.

The difficulty lies in the mild head injury group as once they are discharged they often have no formal follow-up, despite recommendations that all head injured patients should be followed up by their family doctors [41]. A large proportion of those who do suffer fail to identify themselves to medical/health services and as such, formal data for this group are difficult to obtain.

The first area of study that it was felt should be looked at was the identification of those head injured patients who go on to suffer with post-concussion symptoms or struggle to re-integrate to their previous life.

A variety of methods for identifying this group might be required and could include:

- Self-presentation to health services;
- Monitored follow-up for a set period of time or
- Specific identifying factors at initial presentation.

Self-presentation is an unreliable method to quantify the problem and, by definition, patients will present after suffering a period of disability so early intervention is not possible.

Monitored follow-up is time consuming and imposing on patients without problems so potentially has a high non-compliance rate thus skewing any data retrieved. This has been born out by the first head injury follow-up study conducted by Wade and colleagues in Oxford [18].

This leaves specific factors identified or measured at initial presentation used prospectively in association with follow-up of all patients.

2.5 Laboratory based testing

There exist a number of different factors involved in the initial doctor-patient encounter following a head injury. History taking and examination are the main tools for assessment and further investigations are directed following this in order to confirm a diagnosis or, as previously alluded to, to rule out significant pathology. These include laboratory tests and imaging. The current method of identifying life-threatening pathology is with imaging but the need for imaging is based on the history taking and examination findings. This is the basis of the NICE CT head guidelines. There currently exists no laboratory-based measurement of brain injury severity in practice in the UK.

Research in to this area has already been carried out to identify diagnostic markers that have good links with poor medium to long-term outcome after traumatic brain injury (TBI). One such marker is protein S100B, a neuroglycopeptide that is released from glial cells (astrocytes) when they have been damaged. Early studies in adults revealed that this marker could be measured in serum, with high levels being related to poor outcome after carotid surgery [42] and TBI [43, 44]. Subsequent to this research, elevated serum S100B concentrations have been demonstrated in non-brain injured cohorts [45] bringing in to question the sensitivity of this marker for brain injury. Further research in to the relationship with CT abnormalities has led some authors to suggest a role in the exclusion of traumatic brain injury amongst those without elevated levels [46].

Could this marker be used in conjunction with presentation risk factors to develop a scoring system or even an investigation/treatment protocol for minor head injuries? Certainly the possibility is there and the field of medicine that would benefit the most is emergency care.

In fact, in Hungary they are using serum protein S100B in the management algorithm for mild head injuries and there are plans to expand this to two centres in Sweden and Norway for further validation.

(Appendix II for Modified Scandinavian decision pathway)

2.5a Urinary S100B

The S100B marker has not only been proven to be useful with adult patients. Neonatologists in Italy have used the marker as an early diagnostic tool, with good research evidence that it will identify neonates with intra-ventricular haemorrhage before cranial ultrasound does, even with small bleeds [47]. The problem in dealing with neonates is that serial measurement of blood markers can cause anaemia, owing to the low total circulating blood volume, thus potentially worsening the patient's condition. An alternative fluid needed to be established. Cerebrospinal fluid (CSF) was too high risk with the possibility of infection being potentially disastrous, so urine was used and found to be a sensitive tool for measuring this marker, identifying neonates with brain injury from peri-natal asphyxia and correlating the concentrations measured with neurological outcome up to one year following birth [48]. Thus urinary S100B was considered as a potential diagnostic tool in hospital practice, obviating the need for repeated serum sampling, a stressful event for both patient and parents.

Berger, in the US, also demonstrated that serum protein S100B concentrations are elevated following traumatic brain injury in children when compared with controls with isolated long bone fractures [49]. There was no quantitative correlation with severity of initial injury, however.

The two separate uses for this marker, and a review article on the role of S100B suggesting the need for increased research in to urinary concentrations [50], raised the question that is part of this study. Can urinary S100B be measured in older children and if so are the levels indicative of traumatic brain injury? If this is the case then there is a potential predictive marker, entirely objective in nature, for patients who could benefit from referral to rehabilitation programs.

In order to try and answer this question, it must first be established that protein S100B is measurable in the urine of children following traumatic brain injury, and that the protein is not demonstrable in the urine of non-brain injured control subjects.

2.6 Summary and Hypotheses to Test

Head injury, and underlying brain injury, is a leading cause of death and lifelong disability in the United Kingdom. Such disability following even mild injury is now commonly recognised but the early identification of those developing these difficulties has not yet been adequately accomplished. Emergency departments will see and treat the majority of head injured patients, with about 90% of injuries considered to be mild in nature, and as such are in prime position to investigate this group in order to identify those who develop some post injury problems.

Academic assessment on a national scale is at ages 16 and 18, via GCSE and A level examinations, with subsequent educational and vocational prospects dependent on success in these assessments. Work for these exams spans the age range of 14-19, which is also the age group with the highest incidence of moderate to severe head injury in the UK. Traumatic brain injury has been shown to adversely affect academic achievement by worsening behavioural problems and affecting cognitive functioning.

As yet the effect of mild head injury, not requiring hospital admission, on outcome and schoolwork has not been assessed in the UK. Patients admitted following head injury, by definition, have sustained a more concerning injury and, as such, are not representative of the majority of emergency department head injury patients. It would, therefore, be appropriate to follow-up all head injured patients – regardless of initial severity – in the high-risk group identified, in order to gain an insight to the scale of the potential problem.

2.6a Primary Hypothesis

There exists a group of emergency department patients, presenting following head injury, who persist with disabling symptoms regardless of the initial severity of injury when assessed by conventional parameters. This study will identify the incidence of these problems amongst a sub-group of patients in whom such symptoms may have an adverse effect on their future. Having identified the proportion of selected patients with post-concussive symptoms, regression analysis of presentation data can be used to identify risk factors for post injury problems and subsequently aid the direction of further management from the emergency department.

2.6b Secondary Hypothesis

Serum concentrations of protein S100B are elevated following release after head injury and can be predictive of underlying brain injury. Urinary S100B excretion is reflective of this release and the measurable concentrations differ from those following extra-cranial injury. If this is so there may be a role for urinary S100B measurement in the emergency department to aid in the assessment of head injured children and the identification of underlying brain injury, without the need for blood sampling or intimidating imaging techniques.

Methods

Definition of a Head Injury:

"...Any blow to the head causing a clinical diagnosis of head injury to be made, even if insufficient enough to cause definite loss of consciousness." [18]

MOHICAN –

Monitoring **O**f **H**ead **I**njuries in **C**hildren and **A**dolescents in full-time educatio**N**

3.1 Recruitment

Obtaining a representative sample of the overall population in question is crucial to the validity of any research project. The group of patients investigated were those who had the most to lose from a period of disability, even if that disability subsequently resolved without intervention. This group of patients was those whose futures could be affected i.e. those in education. The aim was not to prevent this from happening but to identify relevant factors from this group that could be extrapolated to the larger population and thus help to identify those going on to suffer following head injury and, in turn, enable provision of early, focused counselling and rehabilitation to minimise the effects of any potential disability on future prospects.

3.2 Patient Sample and Setting

Patients presenting to the Emergency department at Hull Royal Infirmary were considered for recruitment by nursing and medical staff if they fulfilled the following criteria:

- Aged 13 to 21 years (inclusive);
- Had sustained a head injury (as defined by Wade [18]) and;
- In full-time education at the time of their injury.

There were no specific exclusion criteria for this project in order that the findings may be applicable to the emergency department setting in general. This would enable reproduction of the study on a larger scale, if required, to verify and validate any important findings.

Major trauma patients required additional, in-depth documentation that our proforma did not encompass and so data was collected from the trauma forms used in these cases.

3.3 Confounding Factors

It is common that patients sustaining head injuries have consumed alcohol or drugs [2], and so exclusion of this group of patients would not provide a representative sample of those we wish to study, hence their inclusion.

Patients with pre-injury morbidity were also included in the study as the outcome was to assess any change resulting from the head injury, comparing post-injury abilities to pre-injury and not to a gold standard or 'normal'.

Research in to outcomes following head injury in children has suggested that previous head injury, pre-existing learning difficulties and pre-morbid stressors show a link to those going on to suffer persistent symptoms or problems three months after the injury [51]. For this reason a record of past medical history and previous head injuries was included on the data collection proforma.

The use of Wade's definition of head injury was to ensure the assessment of outcome for of all head injuries and not pre-determined groups. The classification of head and traumatic brain injury is mentioned in the introduction and the difficulty in assigning a specific category to a patient at the initial presentation is well documented [18].

4 DATA COLLECTION

4.1 The development of the proforma

As the aim of this study was to look prospectively at head injury patients from the emergency department setting, it was important that the initial data collected for each patient was comprehensive and relevant. The main data collection was to be by proforma, completed at the initial presentation, rather than retrospectively collected from the patient's notes.

4.2 Pilot study

A two-week pilot study was performed within the department to evaluate the proforma. This had two effects:

- To raise awareness of the project and encourage all staff within the emergency department to play an active part,
- To provide important feedback about the forms and suggestions for improvement, which were both forthcoming and beneficial with a number of changes being instigated after the two-week period was complete.

4.3 Background

National Institute for Clinical Excellence (NICE) guidelines recommend the development of a proforma for all patients suffering head injury [2]. These are nationally distributed guidelines that may have a role in the prediction of persistent post-concussive symptoms despite not being proposed for this purpose. Whilst a simple data collection form would have been possible for this study in isolation, it was felt that the inclusion of the NICE CT criteria were crucial for information within the department in order to inform clinical practice and avoid duplication of data recording. Ultimately it was planned that the study proforma would be introduced as a departmental clinical tool once the study was completed.

(See Appendix III for CT head decision algorithm)

In 1999 the European Federation of Neurological Sciences set up a task force to look at Mild Traumatic Brain Injury. Its aim was to propose a definition of MTBI and to develop a set of guidelines for the initial management, investigation and follow-up of such patients.

One of the proposals was a list of recognised risk factors that could suggest more severe traumatic brain injury on top of the widely accepted assessment tools:

Admission Glasgow Coma Score (GCS);

Period of loss of consciousness (LOC);

Duration of post-traumatic amnesia (PTA)

The comment made about this list was not only that they should be included for the assessment of immediate complications (as with the NICE guidelines), but also that they may enable assessment of the risk of long-term complaints. This list included:

Uncertain accident history;

Continued PTA;

Trauma above the clavicles including clinical signs of skull fracture;

Retrograde (pre-traumatic) amnesia of > 30 minutes;

Severe headache;

Vomiting;

Seizure;

Focal neurological deficit;

Coagulation disorders;

Intoxication with drugs / alcohol;

Mechanism of injury – using the ATLS criteria for high-energy vehicle collision *(See appendix IV for criteria)*;

Age < 2 or > 60 years (not applicable to this study).

These were incorporated in to the form used in this study and amalgamated with the NICE CT head decision rule.

4.4 Proforma information

The information on the data collection form was grouped in to three main categories:

A. History

When and how the incident occurred;

Specific, relevant details about the mechanism of injury (to determine the severity of injury and potential for significant pathology);

Relevant past medical history;

The mechanism of injury was recorded freehand and then categorised in to one of the four main groupings. It was possible to fall in to a separate fifth 'other' category.

The four main categories commonly reported in the literature as the leading causes of head injury in this demographic are:

Road traffic collision (subdivided in to vehicle type and protective methods);

Fall

Sporting injury and

Assault.

The other category included injuries such as an object falling on to the head and bumping head on a stationary object as miscellaneous mechanisms of head injury.

Further information for each grouping was included, such as the wearing of helmets and the approximate speed of accident, as these have been shown to affect the severity of injury sustained.

The NICE guidelines on head injury management give a definition of dangerous mechanism of injury:

A pedestrian struck by a motor vehicle;

An occupant ejected from a motor vehicle or;

Fall from a height of greater than one metre or five stairs.

These were incorporated in to the proforma with the facility to record any other relevant facts.

Other epidemiologically relevant factors that may contribute to poor outcome following head injury are a previous history of head injury, epilepsy and coagulation disorder.

B. Symptoms

Those specifically identified as high risk by the NICE head injury criteria (i.e. indicative of the need for CT scanning);

Those suggested as potential predictors of long-term problems from head injury.

The NICE guideline risk factors for significant brain injury and requirement for neurosurgical intervention are suspected skull fracture (open, depressed or basal), vomiting on more than one occasion, post-traumatic seizure, coagulopathy, focal neurological deficit and age over 65 years. All of these factors relevant to our study were included in the symptoms section of the data. The Glasgow Coma Score was also recorded but later in the examination section of data.

In addition to the aforementioned risk factors the approximate period of loss of consciousness and amnesia (both pre- and post-traumatic) was recorded as this was felt to be relevant to both the CT decision process and outcome prediction (as suggested by previous studies for categorisation of TBI severity).

Also recorded was the presence of current symptoms, specifically three of the recognised post-concussion symptoms commonly encountered. These three, headaches dizziness and nausea, have been proposed to be the independent predictors of persistent symptoms from the other 13 listed in the original 16 described for the Rivermead post-concussion symptoms list [52].

C. Examination

General physiological observations (that may act as independent predictors of poor outcome);

Specific injuries to the head;

General findings and other injuries

The presence of any focal neurological abnormality was included in the EFNS task force and NICE risk factor list and is important in the prediction of intra-cranial pathology.

An important part of the examination of head injured patients is the eye examination and for this reason an in depth record of findings, including fundoscopy, was included.

On top of these data also collected were the basic physiological data at presentation including any pre-hospital recorded drop in GCS. This would be important in the decision to perform a CT scan on arrival in the department.

For ease of use the proforma included diagrams of the head / face and whole body to allow a simple pictorial record of other injuries sustained. This information was more to ensure that the patient records were complete than for our data. It was expected that the health care professionals would categorise each head injured patient with regards to the need for CT – which was a part of our data analysis.

The final section of the proforma was part of the recruitment process.

Firstly, a reminder of the inclusion criteria followed by documentation of the reasons for patients not being included in the study, and then a brief and simple test of cognitive function.

Digit Span Forward Test

One cognitive function test that has been shown to offer some predictive value is the Digit Span Forward test. This was found to be associated with a higher incidence of post-concussion symptoms in the female population in one study in America [53]. The test is scored out of a possible total of twelve points. The patient is asked to repeat an increasing list of random, single digit, numbers in order, starting with three and increasing up to eight in a row. If correct then a single point is awarded or zero for an incorrect list. This is repeated twice to get a total of twelve points.

3 7 6	1	9 8 3	1
5 9 2 8	1	5 2 7 4	1
6 8 3 0 1	1	1 9 6 4 2	1
7 5 8 3 9 6	1	3 1 5 9 4 7	1
8 6 7 2 0 1 4	1	2 8 9 4 0 6 1	1
1 5 8 3 4 9 7 2	1	6 3 7 9 1 3 8 2	1
Total	6 +		6 = 12

The Bazarian study showed that with a score <8 the probability of developing PCS at three months was greater than not developing PCS but did comment that the positive predictive value of this was low. They also commented that there was no statistical link between the cognitive tests used and PCS at six months post injury.

Patients and parents were then asked for their contact details, specifically the best method of contacting them, in order that follow-up recruitment rates could be maximised. They were offered a list of potential contact methods and the details were checked at the time of interview.

Letter by post

Home telephone

Mobile telephone

Text message

Email

All efforts were made to encourage participation in the study and secondary contact methods were used if the requested method initially returned no response.

(See Appendix V for proforma)

5 Emergency department research

5.1 Maximising recruitment

Whilst the content of the proforma was crucial, the layout was to play an important role in data collection. These forms were to be completed by busy professionals who do not have extended patient contact time. The amount of administrative work that these forms imposed on those completing them needed to be minimal or else recruitment levels would drop owing to time constraints.

Current documentation for these patients involved hand written notes on a blank side of A4 sized paper. The idea was for the forms to act as a replacement for the hand written notes, thus reducing the additional time required to complete documentation of the patient assessment. This would hopefully improve the likelihood of the forms being completed. It would also ensure that relevant information was recorded in all cases of head injury and allow for easy auditing of patient management through the department. The use of a standard data collection sheet for head injured patients has been proposed by previous working party reports [2, 41].

5.2 Information for recruits *(Appendices VI & VII)*

The local ethics committee stipulated that information about the project be available to both patients and parents prior to recruitment and that informed consent be obtained in all cases. For those approached in the department at the time of injury, approved information sheets were included with the data collection proforma as well as the consent form.

5.3 Departmental Education

All health care professionals attending to patients were asked to consider their patients for the study and complete the proforma for data collection. The aim was to recruit as many as possible at their initial presentation, which would involve cooperation with all department staff.

Techniques used to maximise publicity to staff for the project included:

- Posters around the department advertising the start of the project;
- Including all staff in the development of the proforma to raise awareness;
- Flyers in all (medical and nursing staff) pigeonholes during the data collection period;
- High profile location for the data collection proforma in appropriate areas of department;
- Posters at triage areas to encourage use of proforma for all eligible patients;
- Prizes for the highest number of appropriately completed forms in each group of health care professionals (Specialist Registrars, Clinical fellows, SHO, Nurse practitioners);
- Education sessions during dedicated teaching for each group of practitioners involved in recruitment of subjects;
- Branding the study with an emblem and easily remembered name (MOHICAN).

Despite these efforts the primary recruitment rate remained at ~ 40%, and a potentially unrepresentative sample, so a secondary recruitment strategy was required.

Potential methods were:

- Including reception staff in the recruitment process to attach the proforma sheets to a predefined patient group upon registration;
- Advertising the project in the waiting area thus empowering patients to ask to be included;
- Or a retrospective notes review of all potential patients.

5.4 Secondary Recruitment

In considering the best secondary recruitment method some simple facts had to be taken in to account. The first was that the logistics of reception staff attaching a pro-forma to patient notes was wholly impractical within the Hull Royal Infirmary Emergency Department. This fact, in conjunction with the difficulties in predefining who should be included based on registration data, ruled out the first option of our secondary recruitment strategies.

Advertising the study within the department waiting area would only expose a proportion of potential recruits to the information. A significant proportion of patients presenting with head injury could have alcohol (or other drugs) in their system and would probably not appreciate the information. Any patients arriving by ambulance or with a reduced conscious level would not encounter the advertisement. This left the potential increase in recruitment level as minimal and so the second of our potential strategies was rejected.

Diagnostic Coding in the Emergency Department in which the study was performed is inefficient and often incorrect. To review only the notes of those coded with head injury would miss a large number of potential recruits, which would reduce the validity of any results. It was decided that a review, manually, of every set of department notes of those in the selected age group, regardless of diagnosis would be the best option.

Demographic data on each patient was collected as routine at the time of registering in the department, and standard for every patient presenting to the department. Included in these data are a current address, telephone contact number and current educational or work status.

Once potential recruits had been identified ethical approval was granted to contact them by post, informing them of the project and the desire to include them in our patient group. Subsequently they were contacted by telephone for the progress interview.

From these potential recruits there were a number that were unable to be contacted because the demographic data included no other means of contact than their address (and often these were incorrect or the patient did not reply to the letter sent out).

Attempts to contact potential recruits were ceased at three months post-injury.

This secondary recruitment strategy also identified a number of patients within the age range whom had suffered a head injury but were not in full-time education. The education status was often poorly recorded in the demographic data collected at the time of presentation and added considerably to the time required for the follow-up work.

Patients were advised that should any problems be highlighted at the time of the progress interview they would be either advised to contact their GP or referred on for further help. A request was also made that they be contacted again a total of six months after their injury for a second interview to assess progress and symptoms. This six-month interview was the outcome interview and those still suffering symptoms were advised to contact their GP for further help. They were also advised that it was common for a proportion of patients to continue to suffer symptoms from their injury even at this late stage. No reassurance or information beyond the standard departmental head injury leaflet was given to those discharged directly from the emergency department.

5.5 Ethical considerations in recruitment

All components of this project were subject to ethical committee approval through the local research ethics committee.

The main study looking at outcomes following head injury (or M.O.H.I.C.A.N.) involved contact with the patient or family out of the hospital environment and thus could be considered an invasion of privacy. All recruits were informed of the desire for follow-up up to six months depending on the problems they were suffering. At this stage the identification of persisting problems required further input and it was appropriate to advise them as such. A referral pathway was not established for such instances but each participant's General Practitioner had been informed of the injury, and the study, and they were advised to contact their GP (as is current practice) for further assistance.

The ethics committee suggested a formal involvement of the Occupational Therapy department in the study to provide assistance for those with ongoing problems – however the department were unable to provide that service due to already being overstretched with other work. The main consideration was appropriate support for those identified in the poor outcome group and these were treated, as is the usual practice for such cases at present, through primary care and support services.

For the urinary S100B pilot study (or T.I.S.W.A.S.) further consideration had to be made about the retention of bodily products after recent national changes to guidelines on the retention and storage of specimens. Concerns were specifically raised about the acquisition of urine samples from the head injured children being investigated and the subsequent use of such samples, including the length of time for which such samples could be stored. Consent for participation is discussed below and also in chapter 9.

5.5b Consent to participation

Special consideration was made for the recruitment of patients under the age of 16 in both studies regarding the issue of consent to participate. Recruits aged 16 and over were able to provide their own consent.

Parental consent was required for all participants in the T.I.S.W.A.S. study and written consent was taken after verbal and written information were provided about the study. As mentioned in chapter 9.2 – those patients presenting unaccompanied (by ambulance with parents following) had a urine sample taken at presentation which could only be utilised for analysis pending subsequent parental consent.

For the M.O.H.I.C.A.N. study the ethics committee agreed that children aged 13 and above were able to provide consent to participate in a telephone interview should they so wish. Parents were also invited to be involved in such decisions and parental consent was also acceptable for recruitment. This is in line with current legal precedent often referred to as 'Gillick competence'.

This identifies children aged under 16 who have the legal capacity to consent to medical examination and treatment, providing they can demonstrate sufficient maturity and intelligence to understand and appraise the nature and implications of the proposed treatment, including the risks and alternative courses of actions.

6 Outcome score

This study aimed to look at the incidence of problems arising in young adults and children following head injury. A method of evaluating outcome was therefore clearly required. Validated outcome assessment instruments were available and adapted for the purposes of this study.

6.1 Extended Glasgow Outcome Scale *(Appendix VIII)*

One of the main outcome scoring systems that has been used in adults following head injury is the Glasgow Outcome Scale and its extended version, the GOSE [54-56]. This was first described in the Lancet in 1975 and has been in constant use since then.

The Scale was developed initially to allocate people who have suffered traumatic brain injury in to broad yet discrete outcome categories. It reflects disability and handicap rather than impairment; that is it focuses on the effects of head injury on function in the major areas of life, not on particular deficits and symptoms suffered by individual patients.

The lowest category is that of death but this must be attributable to the head injury as opposed to any associated major injuries that could have led to both coma and death. These patients were not included in the analysis as there was more interest in the milder end of the injury scale, but being certain that the cause of death was uniquely the head injury was not possible without the coroner's report, something that was not pursued for this project.

The lower, or more severe, end of the scale encompasses those patients who remain dependent on others for daily support, whether for physical or mental disability. This includes those in a vegetative state and others who are conscious but disabled.

The next broad level of function is for those who remain disabled but have functional independence. Again the disability can be either physical or mental in nature but the level of independence is often more than the widely recognised and used ‘activities of daily living’

The highest, or least severe, category on the scale is a good recovery or recovery to a previous level of functioning. In order to assign patients to this group it is important to assess the outcome in different aspects of the patient’s life. For example, a patient may not have been employed prior to injury or have been a particularly socially outgoing character; therefore assigning them to a moderate recovery group because they have no job and don’t go out would be incorrect. Compare this with the workaholic, social animal who has no job and no longer feels like going out at the time of assessment and the difficulties in outcome assignation become more apparent.

The inclusion of pre-injury status on the outcome assessment is therefore essential. Other concerns about the original scale described by Jennet and Bond have been raised over the years [57, 58] and for this reason the following guidelines were highlighted to improve reliability and practicality in 1998 [54]. These guidelines were suggested in conjunction with the proposal that a standard format be used for the interview itself.

Disability due to head injury is identified in change from pre-injury status,

Only pre-injury and current status should be considered,

Disability must be a result of mental or physical impairment,

Use the best source of information available.

Assignation of outcome category is from the hierarchical scale of the structured interview with the overall rating based on the lowest outcome category indicated. Difficulties arise, as previously mentioned, when attempting to group those patients who have a significant disability or level of dependence prior to injury. Wilson [54] suggested a possible solution to this by assigning these patients to an outcome category as if no prior disability existed. Marking their outcome with an asterisk to highlight the existence of pre-injury morbidity would allow for the analysis of these results to be dealt with appropriately and, depending on the research required, for more detail on the nature of the pre-injury status to be obtained.

(See Appendix IX for structured interview)

The structured interview for GOSE and GOS was evaluated in comparison to a series of other tests following head injury in 2000. The interview and outcome category assigned was compared to initial assessment tools, such as post-traumatic amnesia and Glasgow Coma Score [6], and disability scales, such as the Barthel Index for Activities of Daily Living and the Disability Rating Scale. Wilson also looked at numerous neuropsychological tests as well as well-being scales and symptoms (neuro-behavioural functioning inventory).

All of the results showed significant correlation with the GOSE and GOS when this tool was used with the structured interview format and the authors concluded that the GOS could be used as an overall summary measure of outcome after head injury. They do, however, specifically mention that the scale was intended to describe outcome in groups of cases and not of value in the assessment for treatment of specific problems related to head injury.

6.2 King's Outcome Scale for Childhood Head Injury (KOSCHI)

First described in 2001 as a specific paediatric adaptation of the original Glasgow Outcome Scale, the aim was to provide an expanded outcome scale to increase sensitivity at the milder end of the disability range [59]. It also attempted to simplify categorisation of outcome following head injury so that the assessment and assignation of category could be performed retrospectively from paediatric outpatient records and, in order to improve reproducibility, examples for each outcome category were described in some detail. The authors acknowledged that research into outcomes following paediatric traumatic brain injury is often complicated by the ongoing development of the child in question and proposed this scale as a reliable, reproducible and practical solution that would enable clinicians and researchers to describe the rate and extent of recovery. It would also be suitable to evaluate the effects of service and research interventions.

A study from North Staffordshire Hospitals used this scale for assigning outcomes from postal responses in those children admitted to hospital following head injury [60]. The authors concluded that a postal questionnaire incorporating the scale in a structured format would be a useful tool in the follow-up assessment of children admitted after head injury. This would potentially allow an outcome category to be assigned, to those children who reply, and identify those most requiring further intervention to aid recovery.

The main categories are:

1 – Death	
2 – Vegetative	
3 – Severe Disability (a & b)	Dependent
4 – Moderate Disability (a & b)	Independent
5 – Good Recovery (a & b)	

(See Appendix X for category examples)

6.3 Rivermead Post-Concussion Symptoms Questionnaire

First proposed by Professor Wade and the Oxford Head Injury Service in 1995 [61], the post-concussion symptoms questionnaire lists the 16 most common symptoms that are experienced following head injury, having derived the list from previous published material describing commonly occurring problems. The World Health Organisation has classified the cluster of symptoms described as the Post-Concussion Syndrome (PCS) [5]. These symptoms may significantly affect the patient's psychosocial functioning and are important in assessing persistent problems following head injury in all age groups. They are used in the literature as factors for attributing outcome categories in the KOSCHI studies.

The original questionnaire lists the 16 symptoms and asks patients to give each symptom a score from 0 to 4.

0 = Not experienced at all

1 = No more of a problem

2 = A mild problem

3 = A moderate problem

4 = A severe problem

They have proven reliability when both self-administered by patients and clinician-administered and as such were proposed as a systematic approach to post head injury symptom documentation.

(See Appendix XI for symptom list)

6.4 Development of Outcome Interview

Having identified three appropriate and validated outcome assessment scales for head injury follow-up an interview format that incorporated these scales was developed. By breaking down both the GOSE and KOSCHI scales to areas of functioning, those that were included in both scales were taken for the interview format. These included:

Assessment of return to normal life;

Effect on home life and family (alteration in behaviour/personality);

Social interactions and leisure activities;

Independent functioning within and outside the home and

Return to previous education (or work) level (cognitive function).

These broad areas of disability were then amalgamated with the symptoms from the Rivermead scale that were appropriate to each area of functioning – thus asking about specific impairments on top of the underlying disabilities. Four main areas of the interview were identified:

Return to normal functioning;

School function;

Social function and

Home life.

These are discussed further in the next chapter.

As the structured interview format shown in Appendix IX demonstrates, the level of recovery can be discretely categorized dependent on specific areas of function, for example if the patient is independent or not. The examples given in Appendix X for the KOSCHI outcome categories are similar to those from the GOSE and the interview used for this study was constructed to specifically identify such areas that enable a discrete outcome result.

Of all the areas included in the outcome scales, effect on education and the return to previous levels of function were the deliberate focus of the interview for this study because of the specific relevance to the objectives – that is outcome in a sample still in full-time education.

An additional area of personal interest was in the group of patients injured whilst playing sports, as previous evidence suggests that poor outcomes in this group are less prevalent. For this reason an additional section about return to sport was included in the interview – as an assessment of retention of skills and the effect of physical activity on symptoms.

7 Outcome Interview

The outcome scale used in the study was an amalgamation of these three previously validated scoring systems. The interview process was taken from the GOSE structure but reversed so that if the telephone respondents declared that there were no residual problems, symptoms or concerns the interview was terminated and the subject assigned an outcome of Good Recovery.

The aim was to develop an interview process that was structured yet succinct. However, it was necessary to include all of the relevant components of the outcome scales in order to be able to assign an outcome category to each subject.

7.1 Interview process

The Interview was divided in to five sections.

The first was the summary section with basic interview data such as the dates of injury and interview, date of birth, gender of patient and who the respondent was (patient, carer / parent or both). A series of overview questions to briefly assess recovery status were then asked.

Did they feel they were completely back to normal?

Had they had any problems returning to their previous life style?

Were they back at school?

How long had they had off school following the injury?

Were they having any problems on returning to school?

Were they suffering any headaches, dizziness or nausea and to what degree?

These initial data were required of all subjects and if any concerns were raised, or any symptoms suffered, they were enquired about in more detail and the entire questionnaire was completed. If it became apparent from the brief interview that the subject had absolutely no concerns (or even had forgotten about the injury) then the interview was ceased at this stage. If this was the case then a complete recovery was the outcome – category 5b.

The questions were designed to be very broad ranging and open in order that the subjects, or their families, were able to expand on any concerns that they may have had. Specifically three symptoms were enquired about from the Post-concussion syndrome spectrum. These were chosen following review of a report by Professor Tennant suggesting that they could be used as a separate entity when looking at PCS following head injury [52]. This same review assessed the Rivermead PCS list and concluded that the results could be simplified from a scale of 0-4, for each symptom, to a three-outcome scale of no problems, mild/moderate or severe problems with each symptom. This was incorporated in to the interview format in an attempt to simplify the process as much as possible without compromising validity.

The second section asked more detailed questions about their return to school and ability to cope with the demands of the classroom including the need for extra help / time with work. All of which was in comparison to requirements prior to the injury. This section allowed for an internal validity exercise in that the results here could be compared to the documentation of ongoing symptoms and problems in other areas of their life. This section provided a reflection of cognitive functioning, which has been recognised as one of the areas affected following head injury.

The next two sections were taken from the GOSE. Social and home-life was examined with specific symptoms and problems commonly encountered following TBI inquired about. With the majority of our subject group at the mild end of the scale, the ability to pick up subtle differences since the injury was more of a priority than activities of daily living – as with the GOSE.

The final section was an additional area of interest but not specifically related to outcome. Subjects injured whilst participating in sports were questioned about their return to sport, in particular the difficulties, if any, on returning to the sport in which they were injured.

(See Appendix XII for Interview format)

7.2 Outcome Grouping

Whilst the KOSCHI and GOSE aim to allocate a specific category to each subject, the aim in this project was to ascertain the number of those studied who actually have problems that interfere with their recovery. For this reason the outcome result was dichotomised, that is patients had either completely recovered or not – regardless of the degree of disability. This was complicated slightly by the outcome of 5a on the KOSCHI - which is a good recovery but with residual symptoms not affecting their life. The authors of KOSCHI did raise concerns about the possibility of on-going symptoms becoming more problematic in the future as the child develops. Those in category 5a were then classed as suffering mild symptoms compared with moderate symptoms (category 4b or worse) and these groups have been analysed separately and then together in the results section.

Previous evidence suggests that those who have recovered completely from the injury and its sequelae do not subsequently start developing symptoms after a symptom free period. For this reason, those who were deemed to have completely recovered at the progress interview were not contacted for an outcome interview.

7.3 Source of information

The interview questions could be answered either by patient, parent or both together. Potentially this could produce inaccurate results in that parents are not aware of any symptoms or problems if their child has not confided to them. The converse argument could be that the parents are the only ones who have noticed any changes and the patient is oblivious to subtle personality and behavioural changes, which can be the case with frontal lobe lesions. The ideal scenario would be an honest and open conversation with the completely insightful patient and observant parent. The age group in question had been chosen in order that the patients could respond themselves at the follow-up interview. Potential difficulties arose to the point that it was not appropriate to insist on the interview being only with the patient, in view of the fact that some parents were reluctant to let their child talk to a stranger over the telephone. For this reason data were collected on who performed the interview to compare the outcome results for any gross discrepancies.

8.1 Data Collection & Statistics

All data collected were entered into the SPSS for Windows (v. 14.0) database and analysed with this software. This was stored in a password-protected file in a locked room, as stipulated by the ethics committee.

Background data were analysed to establish that the sample of recruits was approximated to previous sample groups from published reports on outcomes following head or traumatic brain injury.

The sample data were then analysed using binary logistic regression in SPSS for Windows (v.14.0). This analysis was with the Enter method of regression and included 95% confidence intervals in the results.

Primary analysis was performed on the outcome interview data, that is, those recruits still suffering symptoms after six months. In particular previously described clinical parameters were assessed as potential prognostic indicators for a poor outcome.

Secondary analysis was performed on the progress interview data. Firstly those in category 4b were identified who went on to require a follow-up interview. This was then expanded to include all those with some symptoms (category 5a and 4b) after one month again using previously described clinical parameters as potential prognostic markers.

8.2 Sample Size Calculation

Estimates of the incidence of Post-Concussion Syndrome six months following head injury vary in the literature. The mean value was calculated using an average proportion estimate from those relevant studies identified. This mean value was 23.3% taken from the three studies identified that looked at emergency department patients specifically.[19, 20, 22] (The Ponsford study was taken at a three-month post-injury assessment rather than six months.)

Other studies have identified higher rates of PCS but in a group of admitted patients who, by being admitted, would be expected to have suffered a more significant injury.

The estimated study proportion was less than in other studies, as most of the patients were discharged directly from the emergency department. A paper analysing recruitment bias in mild traumatic brain injury suggested that the estimate of poor outcome following injury (around 20%) might be overstated [62].

The estimated incidence of post-concussive symptoms, amongst the chosen sub-group of patients, was taken to be 10%, after taking in to account previous published research and comments.

The sample size required was calculated for a 95% confidence interval using the online calculator at http://staff.soc.surrey.ac.uk/psturgis/SOCM11/0506/secalc.xls. The estimated incidence was set at 10% and confidence limits at 5%, which would be possible with a sample size of 140 patients.

9. Urinary Protein S100B

TISWAS - **T**esting for **I**ncreased **S**100B in **W**ee **A**fter **S**ignificant head injury

9.1 Subjects

For the pilot study in to the potential for urinary protein S100B to act as a biochemical marker following head injury, patients presenting to the emergency department at Hull Royal Infirmary were considered for recruitment if they fulfilled the following criteria:

Isolated head injury within twelve hours of attendance to the department;

Not having reached their thirteenth birthday.

Control subjects were approached if they had suffered an isolated limb injury within twelve hours of attendance to the department and not having reached their thirteenth birthday.

Exclusion criteria were previous neurosurgery, previous head injury or previous neurological condition including epilepsy as these were felt to be potential confounding factors for S100B concentrations.

9.2 Recruitment

Recruitment was voluntary and health care practitioners in the paediatric area of the department identified and approached those eligible for the study. Three patients in the head injury group did not have prospective consent for collection of urine owing to the nature of their injuries and the immediate lack of parental presence. In these cases, in line with the ethical committee approval, retrospective consent was obtained for the use of the sample collected that had been isolated in storage. In all other cases the parents were informed of the desire to collect samples and given an information sheet to read prior to written consent being given.

9.3 Sample collection

The same practitioners as for the head injury group performed the identification of the age- and sex-matched controls. A principal list of the remaining required recruits was kept in the paediatric triage area and patients suitable for the study were approached for consent at the time of their presentation.

Samples were collected from the subjects at the time of attendance to the department, following written consent from the parents and / or patient. The initial sample was collected in a universal sterile container as per routine management in the department. In the younger patients a standard urine collection bag was applied upon arrival and the first urination collected and transferred to the universal sterile containers. Only one patient in the study required catheterisation as part of their routine care and the urine was collected from the first sample drained.

Collection packs:

1 x Universal sterile container – pre-labelled with Study title and sample number.

2 x Sarstedt (Leicester, UK) tubes with screw caps (known locally as ACE tubes).

1 x Standard biochemistry form – pre-completed with Study title, Sample number, Consultant name and instructions for sample handling upon arrival in laboratory.

The sample collection containers were all pre-labelled and packaged within standard biochemistry sample forms. Patient details were not disclosed on any of the samples or forms transferred to the laboratory, with data anonymised numerically as per ethics committee stipulations. Instructions for the handling of the samples on arrival in the laboratory were included on the form, at the request of the clinical chemistry consultant, such that the handling of samples would be standardized.

9.4 Sample Handling

Italian studies looking at the measurement of urinary S100B involved the centrifuging of samples prior to freezing for storage [47, 63, 64]. The studies used the same centrifuge regimes for their studies, 900g for 10 minutes. They then defrosted the spun down samples and ran them through the Lia-Mat® analyser as for serum samples and obtained statistically high readings using this method. Owing to the success of this group we did not predict any problems using the immunoluminometric assay with urine samples despite the analyser being designed for use with serum and CSF in the product literature.

On arrival in laboratory the urine was separated in to two aliquots and put in to the two ACE tubes that were included in the collection packet. From there they were placed in to the -70^{o}C freezer until batch analysis was performed.

A single study on the pre-analytical stability of these samples was performed which illustrated no degradation in the sample stability if left at room temperature for up to 72 hours from collection [65]. From this we can extrapolate that the transfer time from the emergency department to the laboratory was not a significant factor as all samples were transferred on the day of collection.

When batch analysis was performed the samples were refreshed and then centrifuged prior to analysis. Results were then obtained on a sample number basis only and these were then matched with the initial data collected in the emergency department.

9.5 Analysis

The Liaison® Sangtec® 100 analyser from DiaSorin was used for all of the samples, which were analysed in batches for the ease of the biochemistry laboratory staff. This analyser has not been used elsewhere for urinary S100B measurements although the previous studies on urinary S100B have been performed on a similar immunoluminometric analyser by Lia-Mat®. The analyser uses a "2-step immunoluminometric sandwich assay with directly coated magnetic microparticles", has a detection limit of 0.02µg/L with a range of 0.02-30µg/L, and requires a sample size of 100µL.

9.6 Data & Statistics

All data results were tabulated in to the SPSS database and results analysed using this software. All information was password protected and in a locked office for reasons of confidentiality, as stipulated by the local research ethics committee.

The null hypothesis for this study was of no difference in protein S100B concentrations between subjects and controls. The Mann-Whitney U test was used to compare subject and control groups with respect to basic physiological data such as weight, height, age and time to collection of sample.

Results

10. M.O.H.I.C.A.N.

(Monitoring **O**f **H**ead **I**njuries in **C**hildren and **A**dolescents in full-time education**)**

10.1 Patients

Patients between the age of 13 and 22 (inclusive) and in full-time education, at the time of their injury, were recruited in the Emergency Department of Hull Royal Infirmary from August 15th 2005 to February 23rd 2006.

In total, 9726 patients from age 13 to 21 attended the emergency department over this six-month period. Patients were primarily recruited at the time of their presentation, with data collected on a pro-forma in the department. In order to maximise recruitment, emergency department records for all patients between these ages were accessed and potential recruits identified by hand searching each record.

Patients were considered eligible if there was any description of the following in their presentation history:

- Assault with head or facial injury;

  Description of a blow above the clavicles;
- Documentation of the words 'head injury' in the notes;
- Patients suffering scalp/ facial lacerations following blunt trauma or

  Anything that might be construed as a diagnosis of head injury.

10.2 Missing case-notes

In total, 378 / 9726 (3.9%) records were not traceable.

10.3 Ineligible patients

From the remaining 9348 notes, 715 (7.6%) patients had suffered a head injury and 8633 patients had not.

Of the 715 head injury patients, 2 died of their injuries shortly after arrival at hospital. A total of 356 were not in full-time education (248 identified from the initial notes and 108 identified at the progress telephone interview). The remaining 357 were either definitely in full-time education or it was not apparent either way.

10.4 Lost to follow-up

Of these remaining 357 patients, who appeared to fulfil the inclusion criteria, we were unable to immediately contact 169. These were 13 to 22 year olds who had suffered a head injury with no record of work or education status.

One hundred and fourteen of these 169 either had incorrect phone numbers recorded in the department's demographic data or were not contacted within the three months immediately following their injury, and were thus excluded.

The remaining 55 of these 169 patients had letters sent to their address (no contact phone number was recorded at presentation) but of these we had only three replies, two of whom were working and the other did not wish to be involved in the study.

This left 166 potential recruits whom we were unable to contact. Their basic data were analysed and are shown in chapter 12.4.

10.5 Valid Recruits

A total of 188 patients, therefore, were followed up over the six-month period, aged from 13 to 22 and in full-time education having suffered a head injury leading to their attendance.

Of this group, 138 were male and 50 female, consistent with previous studies showing and increased incidence of head injury in the male population [3, 11, 66, 67].

Of the valid recruits, 72 were recruited at the time of presentation to the department, with a completed data collection form, and the remaining 116 by the secondary recruitment method of letter and subsequent telephone call

10.5a Recruitment Rate

If the figures of those eligible and ineligible for the study, with contact details, are extrapolated - then 65% (356/[188+356]= 0.654) of these **166** patients lost to follow-up (0.654x166 = **109**) could be expected to be ineligible for the study. This would leave an estimated loss of **57** eligible patients from the valid arm of the study. This gives an estimated recruitment rate of 77% [188/(188+57) = 0.767].

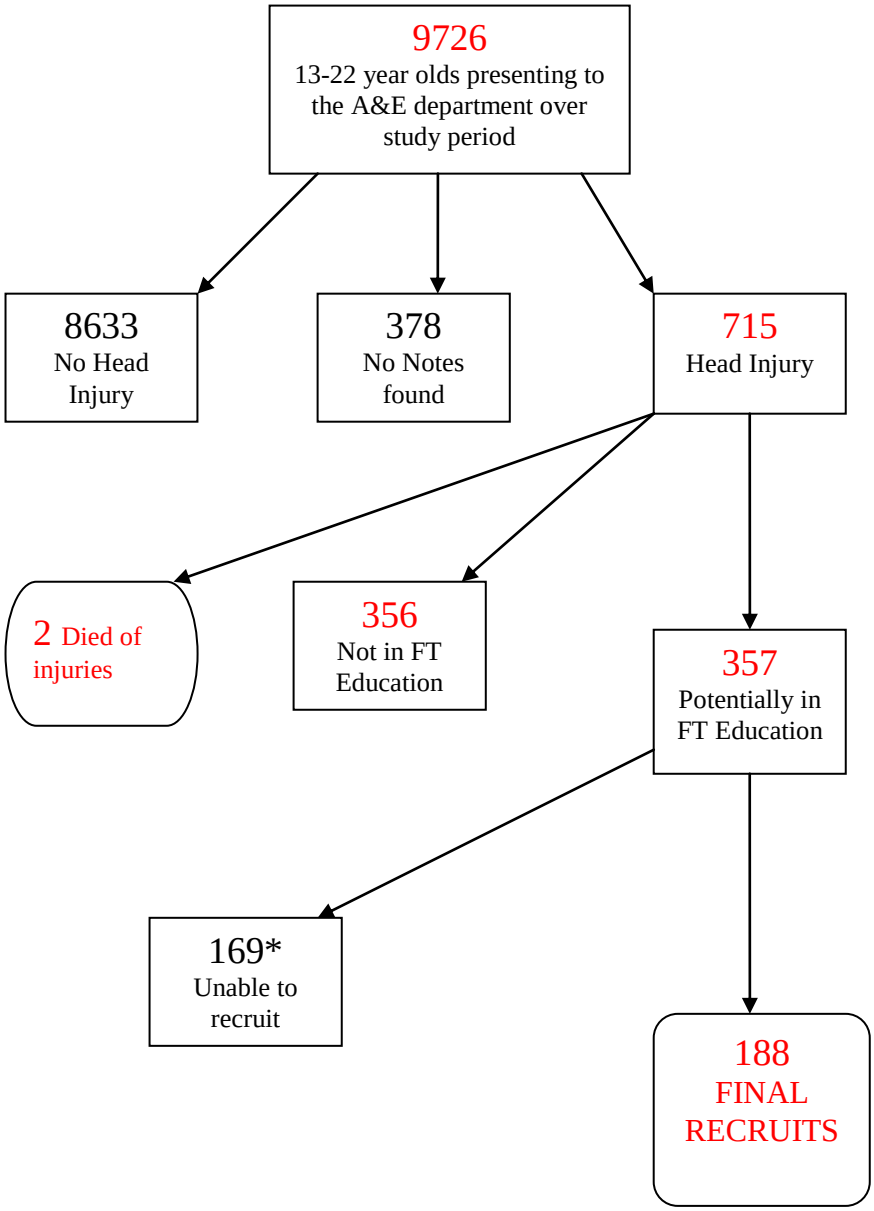
If all of those lost to follow-up were eligible then our recruitment rate would be considerably lower at approximately 53% [188/(188+166) = 0.531].

In Chapter 12.4 a better estimate of recruitment rate is calculated to be about 66% when the non-recruited patients' data are included.

Figure 10.1

Flow Chart for Recruits

* Three patients replied by post and proven ineligible



11. Baseline data

11.1 Age Groups

The majority of patients recruited were under the age of sixteen years with 121 (64.4%) of the total in this group.

University students were to be included in our data but only 14 of the 188 patients were over the age of 18 years (7.4%)

Figure 11.1

Figure 11.2

11.2 Time of Presentation

The time of injury was not recorded reliably. The time of presentation to the department was consistently recorded as standard demographic data and these are shown below. The graph and table demonstrate the breakdown of presentation time by age group.

The time frames selected represent what would be considered morning, evening and night shifts with the evening times being shorter than the other two. This corresponds to the shift patterns of medical staff within the department and demonstrates that nearly a fifth of these head injuries presenting to the department do so overnight. More than one in eight head injuries, in under-16 year olds, present to the department after 10 o'clock at night.

These figures are interesting from the perspective of provision of adequate cover for the management of head injuries "out of hours". In particular for CT scan provision and reporting, experienced healthcare professional presence and advice regarding potential problems.

Figure 11.3

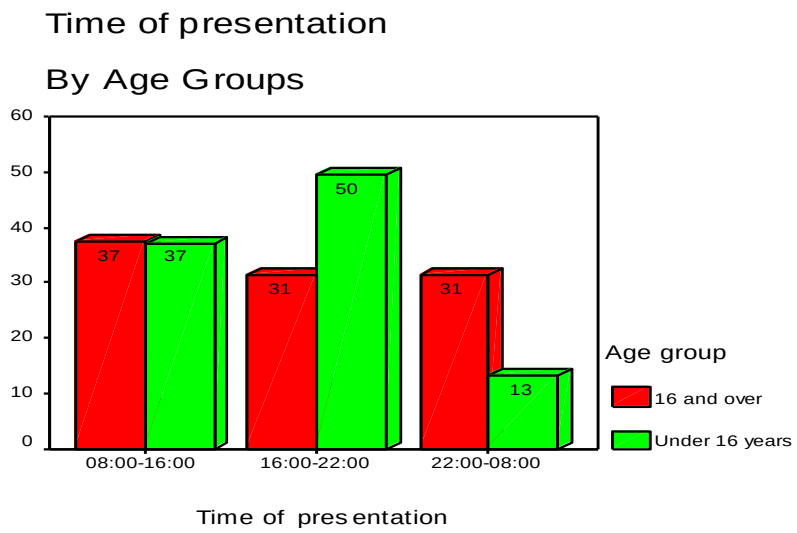


Table 11.1

Time of Presentation (by age group)

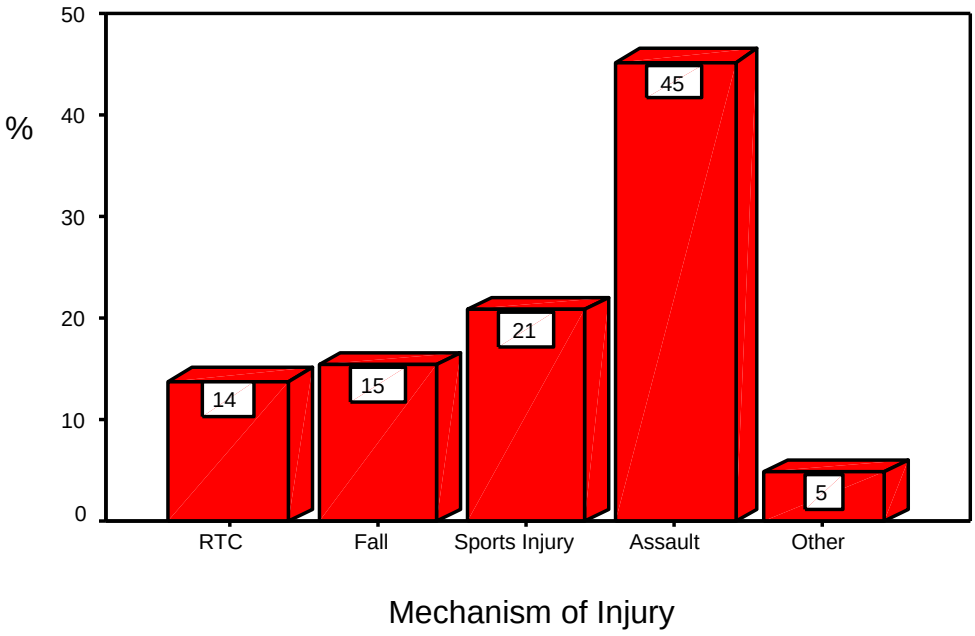
			Time of presentation			Total
			08:00-16:00	16:00-22:00	22:00-08:00	
Age group	**16 and over**	Count	**25**	**21**	**21**	**67**
		% Within Age group	37.3%	31.3%	31.3%	100.0%
	Under 16	Count	**45**	**60**	**16**	**121**
		% Within Age group	37.2%	49.6%	13.2%	100.0%
Total		Count	**70**	**81**	**37**	**188**
		% Within Age group	37.2%	43.1%	19.7%	100.0%

11.3 Mechanism of Injury

Five main mechanisms were identified prior to commencing the study. These were Road Traffic Collision (RTC), fall, Assault, Sports Injury and Other. The *Other* category included being hit by a falling object, hitting head on a stationary object or any other injury not encompassed by the main four categories.

The results for each category are as follows:

Figure 11.4



11.3a Road Traffic Collision

8/26 recruits were involved in either a car or lorry collision

2/26 recruits were involved in motorbike collisions with neither of them recorded as wearing a helmet.

The remaining 16 recruits were involved in a bicycle collision, nine of which were not wearing any protective headgear. The other seven have no record of headgear.

From the RTC data approximate speeds and degree of damage were recorded. In three cases no damage to the vehicle was noted, one case had minor damage and three further cases had major damage. The remainder had no records or did not know.

Approximate speeds can help in assessing the potential life-threatening effects of any road traffic collision [68] and a cut-off speed of 30mph was selected (the national speed limit for built-up areas). It is an important factor in the assessment of the mechanism of injury and could indicate the need for a CT scan so ideally should be reported in all trauma cases. Thirteen of the incidents were allegedly less than 30mph and two over the 30mph cut-off. The remainder had no record or did not know.

11.3b Falls

Of the 29 patients who fell, thirteen either tripped or slipped over. The results were then classified according to recommendations from National Guidelines [2]. Four fell less than one metre, six fell more than one metre and four fell down more than 5 steps. For two further cases no mechanism of fall was recorded.

11.3c Sports Injuries

Thirty-nine patients presented following a sports injury. Twenty-six of these were sustained during a contact sport of which only one person was wearing protective headgear, seventeen definitely were not wearing headgear and the other recruit had no record of it.

Thirteen patients sustained their head injury playing non-contact sport and twelve of the thirteen were not wearing any protective headgear, the other one has no record.

11.3d Assaults

Almost half of the subjects for this study sustained their injury from an alleged assault. Forty of the 85 were punched only, six were kicked only and nineteen were both punched and kicked. A further sixteen were assaulted with a weapon, which was deemed to be more significant than fists and feet together, so recorded as weapon only. Four of the assaulted victims had no recollection of their assault or the method by which they were beaten.

The majority of the scarring that scored subjects at a lower category for the progress interview was maxillo-facial scarring, deemed unsightly and affecting the subject.

11.4 Symptoms and Signs

Symptoms and signs that can signify the severity of a head injury were recorded. The most widely used measures are the Glasgow Coma Score [6], whether or not the patient was unconscious and the approximate period of post-traumatic amnesia.

Glasgow Coma Score (GCS)

Four of the 188 patients did not have a GCS recorded in the notes. 176 patients had a GCS of 15/15 at the time of assessment in the department. The remainder were as follows: six at GCS 14, one at GCS 13 and one at GCS 10. The latter two were admitted to HDU and ICU respectively.

Loss of Consciousness (LOC)

A history of loss of consciousness following head injury is considered to be an indicator of the initial severity of the injury as it can increase the risk of skull fracture and intracranial complications [69]. For this reason it is included in guidelines for the imaging of head injured patients [2, 9, 31].

133 of the 188 had no LOC reported. Twenty-five further cases were recorded as unknown. The remaining thirty were split as follows:

Eight uncertain about the amount of time,

Twenty less than 5 minutes and

Two between 5-15 minutes

No patients were reported to have been unconscious for longer than fifteen minutes.

Post-traumatic Amnesia (PTA)

Post-traumatic amnesia is defined as the period of time, following injury, when the patient loses the ability to form new memories or retain information given to them [31, 70]. This can be formally assessed with regular memory questions and the time interval to complete recovery being documented. It has been suggested that a PTA of less than 24 hours following head injury results in a good outcome for 100% of patients (using the Glasgow Outcome Score) [71].

In this study the period of amnesia was considered to be the time from injury until when the subject can start remembering events again, or an estimate of how much time they "have lost" (a much more loose definition). The EFNS (European Federation of Neurological Sciences) guideline on mild traumatic brain injury put forward the recommendation that "PTA shorter than 1 hour and/or retrograde amnesia shorter than 30 minutes are compatible with MTBI and are associated with a good outcome." [31]

One hundred and forty-seven of the 188 had no memory problems documented on assessment in the department. In eight cases no period of time could be obtained. From the remaining cases:

Fourteen were less than 10 minutes,

Eight between 10-30 minutes;

One between 30-60 minutes and

Ten were longer than 60 minutes.

No long-term measurement of amnesia was undertaken for those patients admitted or having PTA for longer than 60 minutes.

Using the definition for mild traumatic brain injury from the ACRM [7], ten of those included in this study would have been excluded as suffering a moderate brain injury based entirely on this duration of amnesia.

Vomiting

This symptom is included as a criterion for obtaining a CT scan of the brain following head injury. The NICE guidelines suggest that any patient vomiting on two or more separate occasions following their injury warrants an immediate head scan [2].

In this study only eight patients fulfilled this criteria (≥2 episodes of vomiting), with a further fifteen vomiting but on only one occasion.

12.1 Admissions and Outcomes

In total, 162 (86%) patients were discharged directly from the emergency department. Twenty-four (13%) were admitted to the ward for a period of observation with the remaining two (1%) patients admitted to critical care beds owing to the severity of their injuries.

Of those 162 discharged directly from the department, 124 (76.5%) made a good recovery and a further 25 (15.4%) suffered some minor symptoms (category 5a). Thirteen (8.1%) of those discharged directly from the department went on to have only made a moderate recovery at the time of their progress interview.

Of the 24 admitted to the ward for observation, 18 (75%) made a complete recovery and five were suffering some minor symptoms (20.8%). One (4.2%) of these patients had only made a moderate recovery at their progress interview.

The remaining two patients had only made a moderate recovery by the time they were interviewed.

Table 12.1

Outcomes by discharge status from department

Outcome [Percent] (95% CI)	Good Recovery (5b)	Good Recovery (5a)	Moderate Recovery (4b)	**TOTAL**
Discharged from ED¶	**124** [76.6%] (69-82)	**25** [15.4%] (11-22)	**13** [8.0%] (5-13)	**162**
Admitted to ward	**18** [75.0%] (55-88)	**5** [20.8%] (9-41)	**1** [4.2%] (1-22)	**24**
Admitted to HDU+	0	0	1	**1**
Admitted to ICU*	0	0	1	**1**
TOTAL [Percent] (95% CI)	**142 [75.6%] (69-81)**	**30 [16.0%] (11-22)**	**16 [8.5%] (5-13)**	**188**

(95% Confidence Intervals given to nearest whole number)

¶ ED = Emergency Department, + = High Dependency Unit, * = Intensive Care Unit

12.2 NICE CT guidelines and Outcomes

One hundred and eighty-seven recruits were allocated to one of the three NICE CT guideline categories, either:

Require a scan immediately (within one hour);

Require a scan within eight hours of injury or;

Do not require any further imaging.

(See Appendix III for NICE CT decision algorithm)

One hundred and seventy-one of these patients did not require any imaging following their injury, eleven required a CT scan within eight hours and five needed a scan within the hour.

Of the 171 not requiring any further imaging, 129 (75%) made a complete recovery, 29 (17%) were suffering from minor symptoms and 13 (8%) had only made a moderate recovery at their progress interview.

All eleven of the patients requiring a CT scan within eight hours had made a complete recovery at the time of being interviewed. However, five of these patients had not actually had a scan performed by the time they had been discharged. None of those who were scanned had any evidence of intracranial injury.

Of the five requiring immediate CT head scan on arrival to the emergency department, one had made a complete recovery, one was suffering minor symptoms and the remaining three were all suffering symptoms affecting their recovery.

12.2a Positive Scan Results

Four of the five scans performed immediately showed evidence of intracranial injury. In the table below are the four case summaries for the positive scan results.

Table 12.2

Data for patients with positive CT scans

Age	Mechanism of Injury	GCS¶	CT result	Admitted to…	1/12	6/12
16	RTC (motorbike)	13	1)Sub-arachnoid haemorrhage 2) Diffuse Axonal Injury 3) Basal skull #	ICU	4b	5a
14	RTC	15	Open skull #	Ward	4b	LTF*
15	Fall (>1m)	10	Contusion	Ward	5a	No f/u
14	Assault	14	1) Open skull # 2)Extra-dural haemorrhage 3) Contusion	HDU	4b	4b

¶ Glasgow Coma Score at presentation

* LTF = Lost to follow-up

All head injury patients presenting to Emergency Departments across the United Kingdom should be assessed for the need to perform a CT scan of the brain, specifically looking for potentially life threatening intra-cranial injuries. The reasons for and against scanning patients should be recorded for clinical governance purposes.

12.3 Common symptoms following head injury

Three of the most common problems that occur immediately following head injury are: headaches, dizziness and nausea / vomiting [61, 72].

These symptoms were specifically asked about at the time of assessment with a view to repeating the assessment at the progress and outcome interviews.

In total 76 (40.4%) patients were complaining of mild/moderate headache with seven having a severe headache in the emergency department. Eight cases had no records.

Thirty-six (19.1%) recruits had mild/moderate dizziness when in the department with just one patient feeling severely unbalanced. Again eight cases had no records.

Forty-five (23.9%) recruits had mild to moderate nausea and 2 were severely nauseated when in the department. Six cases had no records for this.

All of the patients not accounted for above did not complain of any of these symptoms.

Twelve patients (6.4%) also complained of new onset of a visual disturbance following their injury, seven of which were unilateral and five bilateral. This was mostly a blurring of vision and there were no reported cases of permanent visual disturbance at the progress interviews.

12.4 Unable to contact group

The basic demographics of the 166 patients that were not contacted were analysed separately.

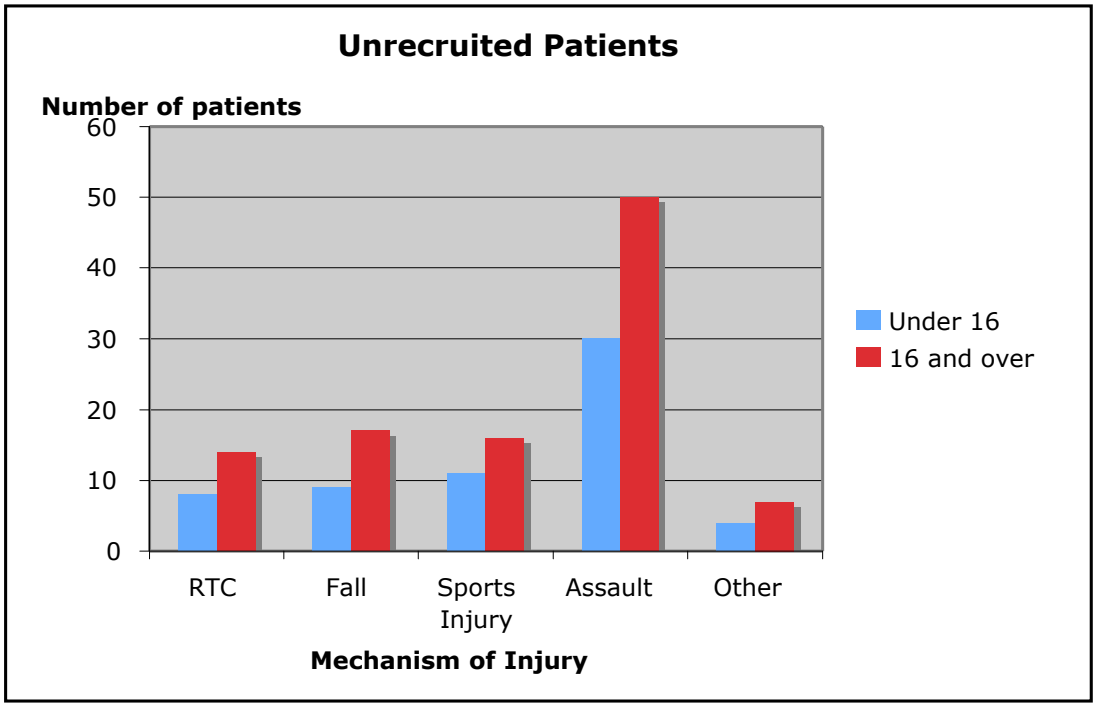
In total 62 patients were under the age of sixteen with the remaining 104 aged sixteen or over. In theory all of those under sixteen should still be in full-time education. If this was the case and the ratio of less than sixteen years to older patients in education is consistent (64:36) then the expected number of eligible patients missed is:

62 + (36/64 x 62) = 62 + 35 = 97

Using this figure, the calculated recruitment rate for this study was 66.0% (188/ [188+97] = 0.66) with a 95% confidence interval of 60-71%.

The mechanism of injury for this group as a whole is represented in the figure below.

Table 12.3

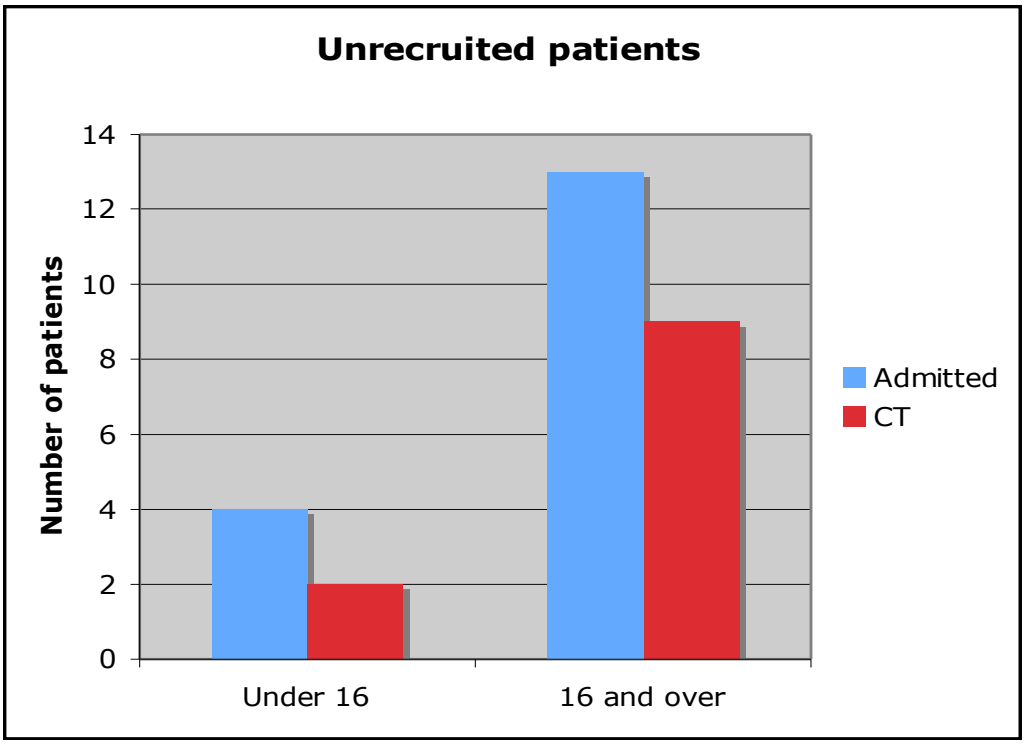


Only one patient was recorded as having a GCS of less than 15 on attendance to the department. The documented GCS was 14 and the patient was intoxicated and admitted for observation following a normal CT scan.

The number of patients admitted and referred for CT scan is shown figure 3.5. All admitted patients except one were admitted to the ward (not HDU or ICU). The exception was taken directly to theatre for management of extra-cranial injuries following a RTC.

Only one of the CT scans was positive with a basal skull fracture identified but no intracranial pathology. This patient was GCS 15 throughout their time in the emergency department.

Table 12.4



13. Follow up

13.1 Progress Interviews

Interviews were performed by telephone using the pre-designed outcome questionnaire. Initially it was thought that it would be easy to contact all patients around one month after their injury. Delays ensued for the initial interviews, however. Patient details were not always correct and often they were not present at the time of phone call. In total 108 extra phone calls were made to those potential recruits who were actually not in full-time education.

The timing of these interviews was between one and three months after the subject's head injury, with any patient not contacted by the three-month cut-off being excluded. At the outset of progress interview data collection, no endpoint was determined for time after the injury for the interview to take place. It became apparent that this provided a poorly defined set of results and so the three-month time limit was implemented.

The mean time to progress interview was 58 days with a range from 23 to 122 days. The longest delay being before it had been decided to exclude those not contacted by the end of three-month window.

13.2 Progress Interview Results

Of the 188 recruits, **142** (75.5%) had no problems at the progress interview, between one and three months following their injury.

30 (16%) were suffering mild symptoms but denied that they were affecting their life at all – the majority of these suffering headaches or scarring subsequent to their injury.

16 of the 188 (8.5%) could only be classified as having made a moderate recovery following their injury.

Whilst the interview could be performed with patient or parent (or both together), a proportion of parents were not happy with an unknown interviewer talking to their child without supervision – despite information about the project being given to them (in department or by post). Objections by parents for an exclusive interview with their child could not, therefore, be ignored.

A breakdown of the results showed that 100 interviews were performed with the patient alone, 85 with the carer or parent and 3 were with both together. The outcomes were proportionally the same within the three groups.

Table 13.1

Outcomes from progress interviews

Person Interviewed (Percent)	Outcome 5b	Outcome 5a	Outcome 4b (or worse)	**TOTAL**
Patient Alone	76 (76.0)	15 (15.0)	9 (9.0)	**100**
Parent/ Carer	64 (75.3)	14 (16.5)	7 (8.2)	**85**
Patient & Carer	2 (66.7)	1 (33.3)	0 (0)	**3**
TOTAL	**142 (75.5)**	**30 (16.0)**	**16 (8.5)**	**188**

13.3 Progress Interviews by mechanism of injury

A breakdown of outcomes at the progress interview relative to the mechanism of initial injury was performed. The results are shown in table 13.2.

The two groups with the highest proportion of subjects suffering disability were those involved in a Road Traffic Collision (15%) and those assaulted (13%). No patients injured whilst participating in sports appeared to be suffering any significant difficulties at the time of their progress interview, with only five (13%) suffering minor symptoms.

Table 13.2

Breakdown of progress interview results by mechanism of injury

Mechanism of Injury	Good Recovery (5b)	Good Recovery (5a)	Moderate Recovery (4b)	**TOTAL**
RTC	18 (70%)	4 (15%)	4 (15%)	**26**
Fall	20 (69%)	8 (28%)	1 (3%)	**29**
Sports Injury	34 (87%)	5 (13%)	0	**39**
Assault	63 (74%)	11 (13%)	11 (13%)	**85**
Other	7 (78%)	2 (22%)	0	**9**
	142 (75.5%)	**30 (16.0%)**	**16 (8.5%)**	**188**

(Percentages shown for each mechanism of injury)

13.4 Outcome Interview

The 16 who had only made a moderate recovery at the progress interview were contacted again, between six and nine months following the initial injury, for a second interview or outcome interview.

The median time from injury to outcome interview was 206 days with a range from 181 to 266 days.

Four of these sixteen were lost to follow-up.

For these four patients, all attempts to contact them again were unsuccessful and so the GP was contacted to establish the need for ongoing medical input as a result of their injury problems. None had contacted their GP as a direct result of any ongoing disability or symptoms.

Only one of those interviewed after six months had completely recovered with no residual effects. Six of those in the 4b category at the progress interview had improved to category 5a whilst the other five were still describing significant difficulties in returning to their normal life.

Eleven (5.85%) of those initially recruited continued to suffer ongoing symptoms six months following their head injury. Five (2.66%) of these continued to suffer disability as a direct result of the injury.

Nine of the eleven (82%) recruits still suffering symptoms at the outcome interview were assaulted as their initial mechanism of injury.

Nine of the eleven recruits still suffering symptoms were discharged directly from the emergency department, five from six (83.3%) in category 5a and four from five (80%) in category 4b.

14. Schoolwork

14.1 Progress Interviews

During the interview process subjects were questioned about their schoolwork. They were asked if they felt that their work in general had been affected by the injury. They were then asked about specific areas that could reflect difficulties at school. Examples of commonly occurring problems are:

Longer to think through problems;

Forgetfulness (short-term memory difficulties);

Difficulty concentrating in class;

Work seeming more difficult / concepts harder to understand;

Visual problems (blurred / double vision)

Special needs and additional support were also asked about.

One of the recruits had subsequently been excluded from school but this was not directly related to the head injury sustained.

All subjects who denied any problems at the progress interview also denied any difficulties at school or that their schoolwork had been affected by the injury.

Of the 46 subjects who were suffering some degree of symptoms at the progress interview, only nine claimed that in general their schoolwork had been affected. However, ten of this group claimed to have problems with forgetfulness (short-term memory), one of which considered it a severe problem. The rest of these results are summarised in the table 14.1.

Table 14.1

School related problems at progress interview

Problems (%)	Short-term memory	Longer to think	Work more difficult	Poor Concentration	Understand Concepts	Blurred vision	Double vision
None	31 (67.4%)	35 (76.1%)	35 (76.1%)	31 (67.4%)	35 (76.1%)	33 (71.7%)	39 (84.8%)
Mild/ Moderate	9 (19.6%)	5 (10.9%)	4 (8.7%)	9 (19.6%)	4 (8.7%)	8 (17.4%)	2 (4.3%)
Severe	1 (2.1%)	0	1 (2.1%)	0	0	0	0
Missing	5 (10.9%)	6 (13.0%)	6 (13.0%)	6 (13.0%)	7 (15.2%)	5 (10.9%)	5 (10.9%)
Total	46	46	46	46	46	46	46

Six subjects were receiving additional help at school (two having one-to-one teaching, three having extra tutorials, and one given extra time for work). Four of this group had previously required additional support in school with only one of these four claimed that the support requirements had increased. This indicates that three in total required extra support as a result of the injury.

These data would suggest a lack of insight with regard to the effect of small disabilities, such as short-term memory loss, on overall schoolwork by the patients involved.

14.2 Affected schoolwork related to KOSCHI category

The progress interview categorisation of all subjects grouped sixteen recruits as category 4b and a further thirty recruits as 5a with all others fully recovered (5b).

With specific reference to affected schoolwork, eight of the nine subjects who claimed to be having difficulties after one month were classified as category 4b with the other as 5a because, on further questioning, the problems specifically suffered at school did not appear to have increased since the head injury. Two category 4b patients had not returned to school at the time of the progress interview, one as a direct result of the injury and the other as he was still on the hospital ward.

Table 14.2 shows the specific school related problems suffered by those patients categorised as 4b at the time of the progress interview. The figures for each problem area represent the majority of all the difficulties highlighted in table 14.1, which shows that most of the school problems at the progress interview were in those with other ongoing problems.

Table 14.2

School related problems in category 4b patients at progress interview

Problems (%)	Short-term memory	Longer to think	Work more difficult	Poor Concentration	Understand Concepts	Blurred vision	Double vision
None	6 (37.5%)	10 (62.5%)	10 (62.5%)	7 (43.8%)	11 (68.8%)	11 (68.8%)	14 (87.5%)
Mild/ Moderate	9 (56.2%)	5 (31.2%)	4 (25.0%)	8 (50.0%)	3 (18.8%)	5 (31.2%)	2 (12.5%)
Severe	1 (6.2%)	0	1(6.2%)	0	0	0	0
Missing	0	1(6.2%)	1(6.2%)	1 (6.2%)	2 (12.5%)	0	0
Total	16	16	16	16	16	16	16

14.3 Time off school

The length of time, in days, off school following the injury was analysed at different categorical cut-off points, to demonstrate any link with a poor outcome. These were three, five, seven and fourteen days.

In the analysis for problems after one month, a cut off of three days was found to be significant but this did not carry through to predict problems after six months. In fact none of the selected time periods off school was predictive of a poor outcome after six months.

Table 14.3

Regression analysis of factors predictive of poor progress interview

	S.E.	Wald	df	Sig.	Exp(B)	95.0% C.I.for EXP(B)	
						Lower	Upper
Admitted (Y/N)	.639	.215	1	.643	.744	.213	2.600
PTA (Y/N)	.604	1.464	1	.226	2.076	.636	6.776
GCS 15 vs. <15	.971	1.002	1	.317	.378	.056	2.536
LOC (Y/N)	.487	.736	1	.391	.658	.253	1.711
Assaulted (Y/N)	.393	.203	1	.653	.838	.388	1.810
Initial dizziness (Y/N)	.503	.289	1	.591	1.311	.489	3.513
Initial headache (Y/N)	.396	.369	1	.543	1.272	.585	2.766
Initial nausea (Y/N)	.474	1.475	1	.225	.562	.222	1.424
Gender (M/F)	.410	.639	1	.424	.721	.323	1.609
Return to school 3/7	.425	3.980	1	.046	.429	.186	.985
Constant	.991	.698	1	.404	2.288		

N=174 (131 with no symptoms, 43 with symptoms)

Nagelkerke $R^2 = 0.076$

14.4 Outcome interviews

Outcome interviews were performed with twelve of the original patients. Again they were questioned about their current schoolwork as well as other areas (see methods). Of these twelve patients only four claimed that the injury was still having an effect on their schoolwork. The specific complaints are shown in table 14.4, which includes the missing outcome interview numbers.

Table 14.4

School related problems at outcome interview

Problems (%)	Short-term memory	Longer to think	Work more difficult	Poor Concentration	Understand Concepts	Blurred vision	Double vision
None	6 (37.5%)	10 (62.5%)	10 (62.5%)	10 (62.5%)	11 (68.8%)	12 (75.0%)	11 (68.8%)
Mild/ Moderate	6 (37.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	1 (6.2%)	0	1 (6.2%)
Severe	0	0	0	0	0	0	0
Missing	4 (25.0%)	4 (25.0%)	4 (25.0%)	4 (25.0%)	4 (25.0%)	4 (25.0%)	4 (25.0%)
Total	16	16	16	16	16	16	16

With specific regard to the requirement for additional support at school, all twelve of those interviewed described some extra help, eleven of them having extra tutorials and one given extra time with work. Only one of the twelve admitted to the need for additional support prior to the injury with requirements having increased since the injury. This might suggest a delay until school problems manifest themselves following injury when compared with the progress interview results.

14.5 Behavioural and Mood disturbances

Academic performance is just one aspect of schooling and specific questioning on aspects of cognitive function may not investigate with sufficient range other influences on school performance. The interviews covered aspects of behaviour and mood, specifically affecting home life but some of these can have an indirect effect on school performance [17].

14.5a Behaviour

Patients were specifically asked about feelings of frustration, hyperactivity, and temper outbursts and comparison with any of these behaviours prior to the injury. Those who were followed up to the outcome interview, as a group, improved in their behavioural symptoms over time.

Table 14.5

Number of patients with behavioural problems at progress and outcome interviews

	Temper outbursts		Hyperactivity		Frustration	
	1/12	6/12	1/12	6/12	1/12	6/12
Never	5(31.2%)	6(50.0%)	10(62.5%)	9(75.0%)	5(31.2%)	7(58.3%)
Occasionally	10(62.5%)	6(50.0%)	5(31.2%)	2(16.7%)	11(68.8%)	5(41.7%)
Constantly	1(6.2%)	0	1(6.2%)	1(8.3%)	0	0
TOTAL	16	12	16	12	16	12

14.5b Mood

Patients were questioned about their perception of anxiety levels, any change in their sense of humour and any overall mood changes they had noticed, all of which could potentially affect schoolwork indirectly. Again there appeared to be an overall improvement over time in the group followed up to the outcome interview, but nobody commented that they felt these problems were causing difficulties at school.

Table 14.6

Number of patients with alterations in mood at progress and outcome interviews

Problems	Mood		Sense of humour		Anxiety	
	1/12	6/12	1/12	6/12	1/12	6/12
Normal	8(50.0%)	7(58.3%)	10(62.5%)	10(83.3%)	6(37.5%)	9(75.0%)
Altered*	7(43.8%)	4(33.3%)	6(37.5%)	2(16.7%)	8(50.0%)	3(25.0%)
Depressed#	1(6.2%)	1(8.3%)	0	0	2(12.5%)	0
TOTAL	16	12	16	12	16	12

* For anxiety read mild/moderate levels

For anxiety read severe levels

15.1 Logistic Regression Analysis

Using the SPSS (v.14) database tools, potential predictive factors for poor outcome were analysed with logistic regression methods.

15.2 Primary analysis

The primary analysis was on the outcome group still suffering symptoms after six months. This was eleven of our recruits.

Binary Logistic regression analysis revealed two potential predictors of poor outcome after six months. These were:

- Assaulted as the mechanism of injury (when dichotomised in to assaulted or not assaulted for analysis purposes)
- A GCS <15 at presentation (GCS 15 vs. GCS <15)

Table 15.1

Binary Logistic Regression model for poor outcome after six months

	S.E.	Wald	df	Sig.	Exp(B)	95.0% C.I.for EXP(B)	
						Lower	Upper
Admitted (Y/N)	1.865	1.227	1	.268	.127	.003	4.901
PTA (Y/N)	1.064	.059	1	.807	1.296	.161	10.441
LOC (Y/N)	.905	1.581	1	.209	3.121	.529	18.403
Assaulted (Y/N)	1.058	5.134	1	.023	11.006	1.382	87.614
Initial dizziness (Y/N)	.989	.507	1	.476	.495	.071	3.434
Initial headache (Y/N)	.847	1.318	1	.251	2.645	.503	13.920
Initial nausea (Y/N)	1.138	.827	1	.363	2.815	.302	26.201
GCS (15 vs. <15)	2.076	4.551	1	.033	83.789	1.433	4898.572
Gender (M/F)	.779	.456	1	.500	.591	.128	2.721
Constant	1.476	13.412	1	.000	.004		

Significant variables highlighted in red. N=174 (163 no symptoms, 11 with symptoms)
Nagelkerke $R^2 = 0.214$

15.3 Outcome relative to CT scanning

Regression analysis with abnormal CT findings instead of a reduced GCS at presentation does not show any significant predictive value for poor outcome at six months. The two categories were analysed separately as one was dependent on the other. When included in the same model neither factor shows any significant predictive power.

Table 15.2

Regression analysis with abnormal CT findings

	S.E.	Wald	df	Sig.	Exp(B)	95.0% C.I.for EXP(B)	
						Lower	Upper
Admitted (Y/N)	6859.474	.000	1	.998	.000	.000	.
PTA (Y/N)	1.231	2.145	1	.143	6.062	.543	67.623
LOC (Y/N)	1.148	.016	1	.900	1.156	.122	10.961
Assaulted (Y/N)	1.317	5.640	1	.018	22.822	1.727	301.601
Initial dizziness (Y/N)	1.103	.533	1	.465	.447	.051	3.882
Initial headache (Y/N)	.936	.953	1	.329	2.494	.398	15.633
Initial nausea (Y/N)	5120.225	.000	1	.997	.000	.000	.
Gender (M/F)	.817	.555	1	.456	.544	.110	2.698
Abnormal CT (Y/N)	8559.736	.000	1	.996	.000	.000	.

Non-significant findings in blue. N=178 (167 no symptoms, 11 with symptoms)

Nagelkerke $R^2 = 0.359$

A further analysis was performed with the requirement for CT scan if the NICE CT guidelines had been applied as a categorical factor. Again this did not demonstrate any statistically significant link to a poor outcome at either one or six months.

Table 15.3

Regression analysis of NICE CT requirements and poor outcome

	S.E.	Wald	df	Sig.	Exp(B)	95.0% C.I.for EXP(B)	
						Lower	Upper
Admitted (Y/N)	1.230	.275	1	.600	.525	.047	5.852
PTA (Y/N)	1.060	.074	1	.786	1.334	.167	10.641
CT required (Y/N)	1.460	2.079	1	.149	8.208	.469	143.492
LOC (Y/N)	.928	.236	1	.627	1.570	.255	9.687
Assaulted (Y/N)	.999	5.250	1	.022	9.857	1.392	69.786
Initial dizziness (Y/N)	.894	.164	1	.685	.696	.121	4.017
Initial headache (Y/N)	.760	.551	1	.458	1.758	.396	7.800
Initial nausea (Y/N)	.962	.176	1	.675	1.497	.227	9.868
Constant	1.307	14.493	1	.000	.007		

15.4 Analysis of patients presenting with GCS 15

The analysis was then repeated for only those patients with an assessment GCS of 15. This demonstrated no additional features at presentation that could predict a poor outcome after six months.

Table 15.4

Regression analysis for patients presenting with GCS 15

	B	S.E.	Wald	df	Sig.	Exp(B)	95.0% C.I.for EXP(B)	
							Lower	Upper
Assaulted (Y/N)	-2.593	1.257	4.25	1	.03	.075	.006	.879
LOC (Y/N)	.026	1.188	.000	1	.98	1.026	.100	10.52
Admitted (Y/N)	19.190	7389.50	.000	1	.99	21580945	.000	.
PTA (Y/N)	-1.716	1.302	1.73	1	.18	.180	.014	2.308
Initial dizziness (Y/N)	-.462	1.184	.152	1	.69	.630	.062	6.415
Initial headache (Y/N)	.732	.900	.662	1	.41	2.080	.356	12.14
Initial nausea (Y/N)	18.246	5336.32	.000	1	.99	83994105	.000	.
Constant	-37.895	9114.88	.000	1	.99	.000		

N=166 (157 no symptoms, 9 with symptoms) Nagelkerke R^2 = 0.265

The mechanism of injury being assault, as opposed to any other mechanism, was again significant for this group of patients.

Loss of consciousness and any period of post-traumatic amnesia were not significant predictors of a poor outcome, however. In fact, of those who presented with an assessment GCS of 15, had no history of concussion or amnesia and were not admitted, 6/115 (5.2%) went on to a poor outcome after six months. This was over half of those in the poor outcome group (6/11=54.5%).

Any patient complaining of symptoms (RPQ-3 scale) at presentation were also excluded from the next analysis, which then revealed that there was still 4/11 (36.4%) with problems after six months.

15.5 Secondary Analysis

Secondary analysis was performed on those patients suffering some degree of symptoms after one month. This was 46 (24.5%) of our recruits.

Separately analysed were those with only a moderate recovery (category 4b) after one month. This was 16 (8.5%) of our patients.

No statistically significant association was shown between the assessment GCS or mechanism of injury and the presence of symptoms after one month, as previously demonstrated with the six-month outcome results. The initially abnormal CT findings were also not predictive of problems at the progress interview stage.

Table 15.5

Regression analysis of progress interview presence of symptoms

	B	S.E.	Wald	df	Sig.	Exp(B)	95.0% C.I.for EXP(B)	
							Lower	Upper
Gender (M/F)	-.425	.403	1.110	1	.292	.654	.297	1.441
Assaulted (Y/N)	-.186	.385	.232	1	.630	.831	.391	1.766
LOC (Y/N)	-.346	.477	.528	1	.468	.707	.278	1.801
GCS (15 vs. <15)	-.895	.948	.891	1	.345	.409	.064	2.621
Admitted (Y/N)	-.322	.615	.274	1	.601	.725	.217	2.420
PTA (Y/N)	.607	.585	1.074	1	.300	1.834	.582	5.776
Initial dizziness	.314	.495	.402	1	.526	1.369	.519	3.611
Initial headache	.261	.392	.443	1	.506	1.298	.602	2.801
Initial nausea	-.557	.462	1.449	1	.229	.573	.232	1.419
Constant	.185	.919	.040	1	.841	1.203		

N= 174 (131 no symptoms, 43 with symptoms) Nagelkerke $R^2 = 0.045$

This was also the case when the analysis was repeated for the moderate recovery group at one month.

Table 15.6

Regression analysis of progress interview moderate recovery

	B	S.E.	Wald	df	Sig.	Exp(B)	95.0% C.I.for EXP(B)	
							Lower	Upper
Gender (M/F)	-.764	.595	1.649	1	.199	.466	.145	1.495
Assaulted (Y/N)	-1.108	.642	2.975	1	.085	.330	.094	1.163
LOC (Y/N)	-.828	.693	1.424	1	.233	.437	.112	1.702
GCS (15 vs. <15)	-1.938	1.350	2.061	1	.151	.144	.010	2.030
Admitted (Y/N)	-.056	1.099	.003	1	.960	.946	.110	8.146
PTA (Y/N)	.786	.949	.686	1	.408	2.195	.342	14.09
Initial dizziness	-.260	.735	.125	1	.724	.771	.183	3.256
Initial headache	.282	.611	.213	1	.645	1.325	.400	4.389
Initial nausea	-.069	.729	.009	1	.925	.934	.224	3.897
Constant	.564	1.230	.210	1	.647	1.758		

N=174 (158 no symptoms, 16 with symptoms) Nagelkerke R^2 = 0.110

Logistic regression analysis revealed no statistically significant presentation parameters that could predict the presence of symptoms at this stage.

When all clinical severity parameters were removed from the analysis (PTA, LOC, reduced GCS, admitted) then the percentage of patients still experiencing difficulties after one month was 24.3% (28/115) [95% CI 17-33%]. Expanding this to exclude all of those with symptoms (RPQ-3 scale) at presentation as well, there were 27.7% (15/55) [95% CI 16-40%] patients with problems at one month.

15.6 School problems analysis

The data obtained from the progress interviews were analysed with specific reference to poor outcome after six months. The danger with this technique is interpretation of the results as they may demonstrate that those with problems go on to have problems that are not necessarily clinically significant, even if statistical analysis demonstrates some significant results. The idea behind this analysis was to identify any potential factors that may add to a decision making process for referral on to specialist services. If specific factors are demonstrated at presentation and then others at a routine follow-up does this add statistical weight to the referral decision?

The data illustrated below identify two factors from the schoolwork-focused section of the progress interview that appear significant predictors of a poor outcome after six months. These are complaints of forgetfulness or short-term memory loss, and the need for extra assistance with schoolwork (regardless of whether there were any previous requirements).

Table 15.7

Regression analysis of school complaints against six-month outcomes

	B	S.E.	Wald	df	Sig.	Exp(B)	95.0% C.I.for EXP(B)	
							Lower	Upper
Work affected	-2.854	2.259	1.59	1	.206	.058	.001	4.822
Require assistance	4.601	1.930	5.68	1	.017	99.570	2.266	4374.841
Blurred vision	-4.823	2.823	2.92	1	.087	.008	.000	2.032
Poor concentration	3.822	2.327	2.69	1	.101	45.696	.477	4374.295
Difficulty with concepts	-9.703	17939.7	.000	1	1.00	.000	.000	.
Increased difficulty of work	5.588	46350.6	.000	1	1.00	267.069	.000	.
Double vision	-63.03	31356.1	.000	1	.998	.000	.000	.
Excluded	.517	9.875	.003	1	.958	1.677	.000	4269288
More forgetful	8.555	2.708	9.98	1	.002	5190.56	25.73	1046825
Increased needs	3.466	10.000	.120	1	.729	32.019	.000	1040849
Previous needs	-.527	2.115	.062	1	.803	.590	.009	37.313
Longer to think	14.07	40192.9	.000	1	1.00	1296471	.000	.
Constant	-6.454	2.563	6.34	1	.012	.002		

N=187 (177 no symptoms, 10 with symptoms) Nagelkerke R^2 = 0.810

The emotional and social sections of the interview have not been analysed in a similar way for reasons of concern over the clinical significance (see discussion section).

15.7 Lost to follow-up patients

Although four of the recruits were lost to follow-up, the primary analysis was using the 'best' case scenario, i.e. all four of these patients had completely recovered, producing 'negative' outcome results.

Limited analysis of the results was performed for the 'worst' case scenario, i.e. all four of these patients were still suffering functional effects from the injury. Hypothetical as these results are, they show that the reduction of GCS at presentation is no longer a significant factor in the prediction of a poor outcome whereas the mechanism of injury as assault is still significant. Eleven of the fifteen hypothetical positives were assaulted to sustain their injury.

Table 15.8

Inclusion of lost to follow-up patients

	B	S.E.	Wald	df	Sig.	Exp(B)	95.0% C.I. for Exp(B)	
							Lower	Upper
Gender (M/F)	-.603	.632	.912	1	.340	.547	.158	1.888
Initial dizziness	-.345	.759	.207	1	.649	.708	.160	3.134
Initial headache	.528	.652	.656	1	.418	1.695	.473	6.078
Initial nausea	-.241	.751	.104	1	.748	.785	.180	3.419
Assaulted (Y/N)	-1.465	.701	4.371	1	.037	.231	.058	.912
LOC (Y/N)	-1.083	.727	2.217	1	.136	.339	.081	1.408
GCS (15 vs. <15)	-1.982	1.386	2.046	1	.153	.138	.009	2.083
PTA (Y/N)	.725	.973	.555	1	.456	2.064	.307	13.902
Admitted (Y/N)	-.006	1.129	.000	1	.996	.994	.109	9.089
Constant	.755	1.295	.340	1	.560	2.128		

N=174 (159 no symptoms, 15 with symptoms) Nagelkerke R^2 = 0.136

16. T.I.S.W.A.S. (**T**esting for **I**ncreased **S**100B in **W**ee **A**fter **S**ignificant head injury)

Urinary S100B study

In total, 35 patients were recruited for this study from the paediatric area of the emergency department at Hull Royal Infirmary between February and June 2005.

16.1 Subject Group

Twenty patients were recruited in the subject group (that is they had suffered a head injury within twelve hours of presenting to the department). Of these, fourteen were male.

Seven of the subject group had had a witnessed period of unconsciousness following their injury.

On arrival to the emergency department sixteen subjects had a Glasgow Coma Score of 15/15. The remaining four had a GCS of 14, 10, 7 and 6. Of these three were admitted to critical care beds due to the severity of their injuries. The fourth was admitted to the ward for observation. All other patients were discharged directly from the emergency department.

Of the subject group S100B results, five were measurable above the minimum of 0.02µg/L for our analyser.

There was no correlation between the presentation GCS or injury sustained and the urinary S100B result.

Table 16.1

Subject Group (Injuries, GCS and S100B results)

Age in years	GCS	Main injury sustained	S100B result (µg/L)
0	**6**	Subdural haematoma	**0.06**
1	**7**	Skull #	0.00
2	15	Laceration (head)	**0.05**
2	15	Haematoma (head)	0.00
2	15	None	0.00
4	15	Laceration (head)	0.02
4	15	Laceration (head)	0.00
7	15	Laceration (head)	0.00
7	**14**	None documented	0.02
8	15	Laceration (head)	0.00
9	15		0.00
9	15	Haematoma (other)	**0.07**
10	15	STI limb	0.00
10	15	Haematoma (head)	**0.05**
11	15	Haematoma (head)	0.00
11	15	Laceration (head)	0.02
12	15	Laceration (head)	0.02
12	**10**	Limb #	0.00
13	15	Laceration (head)	**0.03**
13	15	Haematoma (other)	0.02

16.2 Control Group

A further fifteen recruits were included for the control group and these were matched for age and sex with the subject group. Of these recruits, eleven were male and three female. One of the data collection sheets was lost for the control group but the sample collected was still analysed as part of a batch analysis.

All patients in the control group had suffered an isolated limb injury. Five had suffered a fracture and the remaining nine for whom we had data had only soft tissue injuries. All control subjects had a GCS of 15/15.

Table 16.2

Control Group (Injuries, GCS and S100B results)

Age in years	GCS	Main injury sustained	S100B result (µg/L)
1	15	Limb #	**0.04**
1	15	Limb #	0.02
4	15	STI limb	**0.03**
6	15	Limb #	**0.09**
6	15	Limb #	**0.05**
8	15	Limb #	**0.06**
10	15	STI Limb	**0.03**
11	15	STI Limb	**0.03**
12	15	STI Limb	**0.03**
12	15	STI Limb	**0.05**
12	15	Laceration (other)	**0.07**
12	15	STI Limb	**0.03**
13	15	STI Limb	**0.03**
13	15	STI Limb	**0.03**

All S100B results > 0.02µg/L are highlighted in bold for both tables.
GCS of <15/15 are highlighted in red in the subject group table.

16.3 Subject and Control Group Comparison

The two groups by design were matched for age and gender in order to create a case-control study.

Further analysis revealed no significant difference between the two groups in height, weight or delay from time of injury to collection of the urine sample. This analysis was performed with the Mann-Whitney U test using SPSS for Windows (v11.5). Included below are the data for these three variables.

Table 16.3

Median values for height, weight and delay to sample time

	Height (cm)	Weight (kg)	Delay to Sample time (minutes)
Subject Group (Range)	118 (60-158)	27.3 (4.0-69.1)	78 (24-312)
Control Group (Range)	142 (80-164)	35.4 (10.0-53.3)	135 (30-369)
Z statistic	-1.469	-0.802	-1.028
2-tailed significance	0.142	0.423	0.304

16.4 S100B results comparison

In the subject group the range of results was from undetectable to 0.07μg/L with the minimum detectable level for our analyser being 0.02μg/L. The range for the control group was from 0.02-0.09μg/L.

Using the Mann-Whitney U test a significant difference was established between the two groups but this was in the opposite direction for our hypothesis, which is urinary S100B concentrations were higher in the control group, and therefore not regarded as a clinically significant finding within the realms of this study.

Discussion

17. Clinical Question

A sixteen-year old boy, presents to the emergency department, in the early evening following an assault. Allegedly someone else's fault, he has been punched to the head and face with some minor body blows. There is no good history of loss of consciousness and he is not complaining of nausea, dizziness or vomiting. Following application of the NICE CT head guidelines he does not warrant a scan but does complain of headache and feeling tired. In two months time he starts his GCSE exams with future options dependent on the results. His parents are concerned – what do you say to them?

Are his schoolwork and forthcoming exam results likely to be affected by this "minor" head injury?

Can we predict whether he will suffer problems from this assault?

If we could, what would we do about it?

One of the objectives of these studies was to attempt to identify any prognostic indicators that may be applicable to the emergency department, for post-concussive symptoms and persistent post-injury problems. The importance of this research, in light of previous work, was the inclusion of patients discharged directly from the emergency department. Between 100 and 300 cases per 100,000 population per year are admitted following head injury with an estimated 80% of these classified as mild [73]. It has been estimated that the number discharged directly from the emergency department is 4-8 times this number [74], approximately 80% of all head injured patients.

Also included, in contrast to some previous emergency department head injury research [19, 20], were patients under the influence of alcohol and drugs.

The first study was aimed at a select sub-group of patients considered important because of the potential impact that even a brief period of post-injury symptoms might have. This sub-group was children and young adults in full-time education and a secondary analysis of effects of head injury on school progress, as perceived by the subject, was performed.

17.1 Important findings

Six months following attendance to Hull Royal Infirmary Emergency Department with any head injury, nearly 6% (95% CI 3.3-10.2%) of the selected patients continued to suffer some symptoms with almost 3% suffering disabilities that continued to affect their daily activities, brought on by the head injury.

The incidence of post-concussive symptoms after six months, in the adolescent population in full-time education, was less than previously reported in children and adults presenting to an emergency department following any head injury [19, 20, 22].

These results show a 17% (95% CI 13-20%) difference from the mean of three previous emergency department studies looking at outcomes following head injury [19, 20, 22].

All of the subjects followed up to six months after their injury continued to require additional support at school with half of these students complaining of short-term memory problems.

One quarter of patients discharged directly from the emergency department had not completely recovered one month after their injury.

Six of the eleven (54.5%) patients with symptoms after six months – and 28/46 (60.9%) after one month - displayed none of the conventional clinical parameters suggestive of significant brain injury at presentation. These include loss of consciousness, amnesia, need for admission or reduced GCS.

Four of the eleven (36.4%) patients after six months – and 15/46 (32.6%) after one month - not only had no conventional clinical parameters at presentation but also had no symptoms (headache, dizziness or nausea/vomiting) when in the emergency department

Extrapolating these data would suggest that up to half of the patients with post-concussive symptoms, at six months, could have been missed in previous studies that did not include all patients presenting to the emergency department.

Even without looking at the clinical parameters and symptoms, the fact that 13/16 (81.25%) with disability after one month - and 38/46 (82.6%) with any symptoms after one month - had been discharged directly from the emergency department would suggest that only identifying and following those admitted to hospital grossly misrepresents the scale of problems following head injury.

After six months, 4/5 (80%) subjects with disability and 9/11 (82%) with any symptoms had been discharged directly from the emergency department.

18. Predictors of outcome

The factors, identifiable at presentation, relating to poor outcome six months after injury for this study group were:

A Glasgow Coma Score of less than 15 at presentation and

Having sustained the head injury from an assault.

18.1 Glasgow Coma Score

In his review of mild head trauma, Binder comments on the prediction of outcome relative to acute injury characteristics, quoting previous work in this area [75]. He describes significant links between outcomes and reduced GCS, post-traumatic amnesia and length of coma, in particular quoting data from Levin [76]. A study of more severely injured patients (admission GCS 9-14) by van der Naalt[71] linked outcomes – of symptom reporting and return to work - to initial PTA duration more closely than initial GCS. The authors excluded all patients with an initial GCS of 15.

The literature exploring outcomes for mild head injury patients often groups together those patients presenting with a GCS 13-15 [4, 11, 22, 23]. Bazarian, in attempting to identify predictors of PCS in the emergency department population, isolated only those patients with a GCS of 15, in order that they may complete the battery of neurobehavioural tests being investigated [19, 53]. None of these studies compared those with GCS 15 to reduced GCS (<15) as with this study. The findings in this group would suggest that future studies of mild head injury outcomes analyse these inception cohorts separately.

18.2 Mechanism of Injury

A large proportion of patients presenting to Hull Royal Infirmary Emergency Department following head injury in this age group did so as a result of an alleged assault – 85 from the 188 (45%) recruited patients and 80 from 166 (48%) potential recruits that were unable to be contacted.

These figures are considerably higher than previously documented by Ponsford [22] (1%) and Hawley [77] (4.8%) in the under sixteen population and Thornhill [11] (34%), Wade [4] (12%) and Bazarian [53] (1.4%) in the adult population.

This discrepancy may be due to the exclusion of patients under the influence of alcohol and drugs in a number of these studies, alcohol often being associated with aggressive behaviour and violence. Dikmen [21] noted that these influences may act as a confounding factor in those patients who might otherwise have a GCS of 15 following their head injury. As such they suggested that future studies incorporate intoxicants in to the study design – as in this case.

Wade and Thornhill did not look at those discharged directly from the emergency department but only at those admitted. Minor head injury patients, for example those attending following an assault, would commonly be dealt with by emergency department staff and subsequently discharged.

This does appear a significant finding as 82% (9/11) of those with a poor outcome after six months were assaulted as their original injury. Taking the assaulted group in isolation 10.6% (9/85) patients developed problems lasting six months. The question of whether this could be a potential causative factor for post injury symptoms is discussed later in this section.

Other mechanisms of injury were analysed separately and compared to all other groups in order to establish if any similar link to poor outcome existed.

Injury from a motor vehicle accident (MVA) - or Road Traffic Collision (RTC) - has previously been suggested as a causative factor [19] in the development of PCS, although this was not supported by Wade in 1998 [4]. This was specifically shown not to have any link with a poor outcome in this study group.

Injury during sporting activities contributed 39 (21%) of the recruits to this study, of which only five (2.6%) described mild symptoms at the progress interview. All of those questioned had returned to the sport in which they were injured and none described a reduction in performance. The low incidence of any problems in the sports injury group is consistent with previous findings [4, 19], although Wade had only 11/218 (5%) patients injured whilst participating in sports. An argument proposed for a large psychological component to post-concussive symptoms is that those injured during sporting activities have a degree of expectation of injury and are more driven to return to their sports and, as such, suffer to a lesser degree than those injured in an unexpected manner, for example an assault. Although not designed to prove this theory, the figures from this study may add support to this argument.

19. Previously identified prognostic factors

Other factors, previously identified in the literature as predictive of poor outcome following head injury, did not produce a statistically significant impact on this study group of patients. Specifically analysed were loss of consciousness [53], post-traumatic amnesia [18, 76], gender [53], need for admission[18], and the presence of headache, dizziness or nausea at presentation [20].

Separate analyses were performed for the need for CT scan (by application of the NICE guidelines) and abnormal CT scan as predictive factors for poor outcome at both one and six months. These showed no significant predictive role in the development of a poor outcome related to CT scanning in the emergency department.

Insufficient data were collected on previous head injury, any illnesses and the digit span forward test, all of which have previously shown to have some prognostic significance [22, 53].

Previous recruitment strategies have excluded factors that potentially influence the outcome of those recruits in question and, as such, have limited study cohorts to include only small proportions of the total number of head injured patients. De Kruijk [20] recruited less than 10% (107/1125) of the total head injured cohort identified whilst Bazarian [53] recruited only around 19% (83/425) both of which were not representative of the head injury population attending the respective emergency departments.

Whilst 188 recruits from all 715 head injured patients identified (in the 13-21 year old age-group) is only 26%, the estimated value of 65% recruitment of eligible head injured patients for this study was calculated using a denominator from excluding those based on a criterion that has not been shown to influence outcome, that is currently in full-time education.

The six month follow-up rate for this study was 75% (12/16) which compares well to both of the aforementioned studies, de Kruijk following up 69% (74/107) to six months and Bazarian 78% (65/83) for the same period, although the numbers are considerably smaller. Ponsford reported a follow-up rate of only 62% (84/136) at three months in the adult population when assessing the impact of intervention two weeks and three months after injury [23].

Both Thornhill [11] and Wade [4] quote a recruitment rate of about 70% whilst Hawley [77] gives a figure of 63% for those contacted within two years of injury, all of whom looked at admitted patients and did not exclude patients because of the presence of potential confounding factors. Using these figures, this study is comparable to such studies.

20. Progress Interviews

One month following attendance to Hull Royal Infirmary Emergency Department as a result of any head injury, nearly one quarter of patients continued to suffer some symptoms, of which a third continued to suffer considerable difficulties restricting a return to their usual life.

This figure of 25% of patients with post-concussive symptoms, after one month, was lower than previously described. Whilst Ponsford [22] quoted a figure of 20% of patients with persistent symptoms this was at the three-month follow-up interviews in their study in children in Melbourne. Interestingly, this group was not found to perform worse on neuropsychological testing when compared with the rest of the group, which will be discussed later in this section.

An emergency department cohort of adult patients in Rochester, USA, studied by Bazarian [19], showed a one month PCS rate of 58% following mild head injury and a three month figure of 43%. The control group of orthopaedic patients did, however, demonstrate a PCS rate of 34% after one month, which will be discussed later.

An important feature of both of these studies is that the cohort of head injured patients assessed were included if they described a period of loss of consciousness, albeit brief. Bazarian did qualify this by including ten patients who had not had any loss of consciousness but they did have amnesia enabling them to be enrolled in the study.

This was not an inclusion criterion for the current study.

A review of methodological issues in the study of mild head injury by Dikmen [21] suggested that estimation of the duration of unconsciousness, which was often based on reports from untrained observers, was a potential source for measurement error owing to the fact that study inclusion criteria often use a defined period of unconsciousness, for example 30 minutes. This might result in patients being incorrectly excluded.

In fact description of an episode of unconsciousness, regardless of duration, was analysed as a potential predictive factor for poor outcome and was found not to be statistically significant.

This factor alone might explain the low recruitment rates described by other authors [19, 20] and the higher rate of PCS in their cohorts. The higher PCS rates are not necessarily due to higher numbers of patients suffering problems but a lower number of 'normal' patients being included at inception.

As mentioned earlier in the discussion, over half of the patients in the poor outcome group at both progress and outcome interviews did not have any of the conventional clinical parameters used for head injury research, which is loss of consciousness, amnesia, reduced GCS or admission to hospital. This suggests that patients without conventional parameters at presentation should be included in future research and this would increase the proportion of 'normal' patients included at inception. Increasing the number of those without problems will effectively reduce the proportion of those with problems.

21. School problems related to symptoms

The analysis of outcome results revealed that a small but significant percentage of patients, within the chosen sub-group, go on to suffer persisting symptoms following head injury. This group was selected for the fact that they are still in full-time education and so analysis of school functioning was the next logical step.

The interview asked specifically about cognitive functioning (for example forgetfulness or short-term memory loss, poor concentration, difficulty understanding concepts) as well as requirements for any additional support at school.

The results from this project showed evidence of some cognitive difficulties after six months but often this did not relate to the patients' opinion of whether their schoolwork had been affected. The difficulties described were consistent with previous research [60] in that most problems described were with short-term memory and concentration.

The poor-outcome group also all required additional support with schoolwork after six months, whether that was extra time for work or extra tutorials, which was consistent with the previous findings by Hawley [60].

Hawley had previously looked at children in Staffordshire, UK, returning to school following admission to hospital resultant from moderate to severe head injury [60]. The authors identified a significant relationship between memory problems and difficulties with schoolwork, with 94% of patients demonstrating such a link. Approximately 40% of children performed below the class average on their ability to concentrate and filter out distractions, and the parents questioned identified the main difficulties for their children as memory, concentration and learning new information.

The same study also identified an increased requirement for additional educational support amongst the head injured cohort. The authors concluded that information about head injury should be provided for the school and potential cognitive and behavioural problems highlighted.

An important design point about the interview process was to try to establish whether problems at school had deteriorated from those already present prior to the injury. All answers were subjective and, as such, a measure of perceived function, not a specific intelligence or cognitive ability measurement. The results were not comparable to a baseline of either a standardised normal or pre-injury score. In such assessments, a negative result or failure could actually be a normal for the subject in question and not a result of the injury itself. So if the interviewer asked specifically for a change from pre-injury status, the subjective responses were the patients' impressions and as such reflected the effect of any dysfunction. It is, after all, the effect of the dysfunction, resultant from the injury, which this research is aiming to identify.

If it were possible to have pre-injury functional test results and then compare these to those post-injury, a more accurate picture of events would result.

A sub-analysis was performed to identify factors from the school section of the progress interviews that may show significant correlation with those suffering symptoms after six months.

This demonstrated that both short-term memory difficulties and the need for additional assistance with work were linked with a poor outcome interview. These two factors are again consistent with the previous research by Hawley [60] as the most common problems following head injury. There is a limit to the strength of these conclusions, however, as the findings are only relevant to the cohort of recruits who were actually followed up. There may well exist a bias in that those with problems at the progress interview are those who were subsequently followed up to the outcome interview, because of those same problems.

The reason for inclusion of this sub-analysis was to draw attention to the possibility of using information gained from a standardised interview, at a set follow-up, that may stratify patients further in to risk categories and, as such, allow referral on to specialist rehabilitation services for those in the high-risk group. If this were to be of benefit patients would still require initial stratification, at the time of contact with health services, in order that a select group could be followed up formally.

22. Outcome assessment tool

The outcome criteria used were amalgamated in to a structured telephone interview. Patients' notes (or data collection forms) had to be used in order to obtain the appropriate contact information. This meant that interviewers were not blinded to the presentation complaints of those they were contacting. This could introduce an element of bias in to the process with more emphasis placed on certain elements of the interview in an attempt to elicit positive results for certain groups of patients.

No preconceptions of what presentation factors could lead to positive interview results existed when the project was conceived, so this minimised this area of potential bias.

With specific regard to allocation of progress or outcome category, this was performed by one researcher, with no reference to presentation complaints or severity of injury. It was not completely 'blinded' in that this researcher was also involved in recruitment and interview processes, but there is no reason to suspect bias in the results.

The area of interest for this study was in the prediction of problems from the emergency department. What is required is to know the cause of these post-concussion symptoms and if the group in which they will occur can be identified, to target early treatment at them. It would therefore make sense to investigate any potential indicators or predictors of PCS with a universally agreed outcome tool so that results from any head injury research can be directly compared. This standardised outcome assessment tool would then enable direct comparison of clinical parameters, biochemical markers, neuro-imaging, and neuro-physiological testing for effect in this role, and help to unify the approach to investigating this highly prevalent problem.

The most promising prospect as an universal outcome assessment tool is the GOSE via structured interview, which is both widely recognised and has been validated against a battery of different tests used with head injuries [78]. There were strong associations shown with the frequency of reported symptoms and problems on the neurobehavioural functioning scale, as well as strong correlations with the Beck depression inventory and measures of initial injury severity. The authors do comment that associations with cognitive tests were generally modest but did exist, and then conclude that the measures remain useful overall summary assessments of outcome from head injury.

Already this has been adapted for use with children in the KOSCHI [59]. The general acceptance of these outcome tools as a standard for head injury research would enable a more accurate estimation of the prevalence of post-injury problems. With this, further work can be focused on maximising the accuracy (statistically) of any decision rules that are developed as prediction models, as the current literature uses a wide range of outcome formats and so results are not easily comparable.

22.1 Potential bias using self-reporting tools

Whilst the convenience of a single outcome scale, easily completed following a standardized interview format with the patient is tempting, pitfalls of this method need to be highlighted.

Self-reporting of symptoms and the subjective decline in school performance may be picked up at interview but it is possible that insight in to behavioural problems and memory loss is lacking, which has previously been demonstrated with frontal lobe lesions [79].

Previous researchers in to school performance following brain injury have utilised information gathered from teachers and parents in order to attain a complete picture of the problems with the subject in question. This was not specifically performed in this study, however, the results have been analysed to look at the outcomes dependent on the respondent at interview. The proportions of symptomatic patients and those with only a moderate recovery at the progress interview were found to be almost exactly the same in both patient-only and parent-only response groups.

22.2 Control patients

External observers to this study have questioned the lack of control subjects amongst the recruits to compare with the head injured cohort. This approach has previously been adopted [18, 19], fuelled by concern over a proportion of non-head injured patients demonstrating post-concussive symptoms. Indeed Bazarian commented on the high percentage of orthopaedic 'controls' that demonstrated PCS one month after injury.

The outcome measures utilised for this study were designed to identify changes in symptoms and function, not just to identify the existence of such problems. The questions were asked alluding to such changes from the injury so to ask them in a non-injured cohort would be futile. The fact that orthopaedic control patients demonstrated symptoms following their injuries may give more weight to those who argue for a psychological cause of PCS, and this is discussed further in chapter 27.

23. Recruitment in the Emergency Department

Patients recruited to the main part of this study were a pre-defined sub-group of patients with a commonly occurring problem, selected at as early a stage as possible in the course of their disease process. This sub-group was selected because of the potentially long-term effects of the condition in question.

Despite a significant education program for medical and nursing staff within the department at Hull Royal Infirmary, the majority (62%) of recruited patients were contacted by the secondary method established for this study. This figure, perhaps, demonstrates the difficulties associated with emergency department research and highlights the potential requirement for dedicated research staff to approach and recruit subjects for large scale studies. Having said this, emergency department researchers in Canada are able to recruit large subject groups for internationally recognised studies examples of which include the CT head decision rules [9] and the Ottawa ankle rules [80]. This was done utilising the current workforce and was multi-centred in nature with the advantage, regarding recruitment rates, being that informed consent was not required. Perhaps an alternative attitude towards research, as demonstrated across the Atlantic, would facilitate higher quality UK-based studies within the emergency medicine community.

Recruitment of subjects for research can be made in one of two ways, retrospectively or prospectively.

23.1 Retrospective recruitment

A danger exists in retrospective recruitment in that the starting point for data collection can have a confounding influence on the end-point being investigated. For example, some head injury research looks to identify those patients admitted to hospital and then assess the outcome in this group [4, 11]. The very fact that the patient has been admitted would suggest that the nature of the injury was more severe than the average patient discharged directly. In theory, this would skew the outcome data to a produce a more significant proportion of all head injured patients being identified as poor outcome, when inclusion of all those discharged directly would reduce this proportion as, at the time of their injury, they were expected to have less problems, hence being discharged. This is supported by the current study.

Retrospective case identification and data collection is dependent on accurate record keeping in the first instance. Even if the coding system to identify a particular condition were perfectly accurate then the data available for analysis might not fit a specific pattern, i.e. relevant data may not be consistently recorded or even legible.

It can have its uses, in particular in the field of audit, where assessment of documentation or the management of patients with respect to a guideline is required. Prospective audits of these areas would focus the staff in question and possibly confound results as the staff then focus on documenting everything or managing according to the guidelines being audited.

23.2 Prospective Recruitment

Prospective recruitment is a better tool for research purposes as all subjects are investigated from the inception point, thus making the results (if valid and important) applicable to a wider cohort of patients from the same point in the disease process. Recruitment prospectively allows for identification and inclusion of patients with the target condition and, from there, the accurate collection of all relevant data being investigated. In head injury management specifically, it reduces the possibility of excluding an important cohort of patients when it comes to results analysis. In addition to use in observational studies, prospective recruitment allows assessment of interventions within the group in question.

Difficulties do exist with prospective recruitment. At the recruitment stage, patients must be made aware of the study and full information must be made available to them. Recruits must be aware of the future requirements for the study and consent to participate before any information can be gathered. Staff recruiting these patients must be educated about the study background, inclusion and exclusion criteria, data collection methods, where to leave/send the data collected and where to direct recruits if any problems arise, all prior to commencement of the study itself. Often a small pilot study can iron out any logistical difficulties and help raise awareness within the department or clinical area in question.

It is possible that valid patients are not recruited at the appropriate time for a variety of reasons and a secondary recruitment strategy may be required.

At the data collection stage, forms may be lost or incomplete, but the same ‘loss of relevant data’ problems exist with both recruitment strategies.

This study looked to maximise the prospective recruitment and attain a high follow-up rate, a problem with previous similar studies [4, 18].

Employing a primary and secondary recruitment strategy was aimed at reducing avoidable losses from recruitment and subsequent follow-up. Despite this, essential data about education or employment status were still not immediately available at the progress interview stage. This led to unnecessary phone calls in over one hundred cases, wasted time, which could have been avoided with accurate initial data collection.

Emergency department research is potentially difficult to perform well for a few reasons. Ideally, dedicated research staff would be recruiting patients and collecting data but, in order to recruit consecutive patients, a twenty-four hour presence would be required and may not recruit any patients for long stretches of time thus wasting resources. Demographic data is often collected separately to clinical data, at the “registration” phase, by reception staff and could well be incorrect or incomplete.

If emergency department staff members are used to recruit and collect data then a large-scale education program is necessary, available on different occasions to reach all staff members and with research staff available to respond to any queries or suggestions for improvement. A pilot study, as used with this project, can aid in this process but for maximal benefit requires a good feedback mechanism to the researchers in place. Additionally, a culture of research within a department, or across the specialty, will hopefully aid recruitment, as it is easy to forget about a study when time pressures exist, patient management takes priority and staff members are not accustomed to recruiting patients into trials.

24. Follow-up

Despite all the efforts to improve numbers for this study there were still 166 potential recruits who were unable to be contacted. An estimation of the effect on recruitment rate these figures had was included in the results section, and showed a worst-case rate of just 53%, with an educated estimate of 65%, calling in to question any conclusions drawn from the data.

Broad analysis of the group not recruited reveals a similar make up of subjects with regards to the mechanism of injury, presentation GCS, admission and CT scan rate. The main difference was the age groups with the 64% of recruits and only 37% of the non-recruited group under the age of sixteen. Results from the recruited group would suggest that a large proportion of those aged sixteen and over in the non-recruited group would not be eligible for inclusion, no longer being in full-time education, however, this cannot be confirmed.

Persistent post-concussive symptoms have been recorded in patients beyond one year after the injury [11, 60]. The ICD v.10 defines the condition when present within four weeks of head injury [5] and previous evidence is that cognitive impairment is unlikely to persist beyond three months [81, 82]. Follow-up beyond the three month period is necessary and beyond six months probably excessive for this study group. The objective was to identify the sub-group of patients who go on to suffer post-concussive symptoms, attempt to use the data gathered to isolate predictive factors at presentation and link these general findings with subjective school related problems. Follow-up beyond the six-month period would add little information in this respect.

An area that potentially could have been improved would be in the follow-up of those categorised as KOSCHI group 5a at the progress interview. Crouchman herself suggested that, owing to the requirements of development in child and adolescent brains, those with symptoms but who appear unaffected initially might, actually, develop more slowly than expected over the subsequent months thus making a relative deterioration, leading to a point where the symptoms begin to affect functioning [59].

Taking this in to consideration would advocate the need to follow-up those within this initial category. In general, however, patients have been found to steadily improve over time and would not be expected to deteriorate symptomatically from their initial condition [22, 83, 84].

Four patients with significant problems after one month were lost to further follow-up. This represents a quarter of those with positive findings. Every effort was made to contact these recruits, including three telephone calls at different times of the day, including the weekends, letters sent out to the contact address plus email or text messages if relevant details were available. In failing to contact them by any of these means, their primary care doctors were contacted to establish any on going concerns, or if alternative interventions had been required. This yielded no positive results and the four were subsequently considered to have completely recovered in the primary outcome analysis.

Theoretical ‘worst’ case results were included for interest, i.e. if all of these four missing patients had severe, persistent problems. The result changed the outcome analysis in that the presence of a reduced GCS at presentation was no longer a significant predictor of poor outcome after six months. The injury being caused by an assault remained significant, however. This demonstrates the large influence that small numbers have when the sample size is restricted and serves as a reminder that all conclusions should be considered carefully before action is taken.

In short the follow-up of patients for this study was long enough but cannot be described as complete. It did, however, correspond well with other similar studies in this field as mentioned earlier in the discussion.

25. Significance of this study

This research is not new in concept with regard to the incidence of post-concussive symptoms. Research in this area has been undertaken for many years [85] with a range of estimates for the proportion of head injured patients going on to suffer PCS, in particular in the mild injury group [11, 85]. Rees comments that the overall estimate of 15% may be too high in that the patient population is derived from inpatients [67] but other research including patients discharged directly from the emergency department, as in this study, estimated a higher mean incidence of 23%, albeit calculated from only three studies [19, 20, 22].

If this figure is an overestimation, and the true value is closer to the six percent identified in this study, this still represents a significant morbidity figure in actual numbers. An estimate of over one million attendances each year, to UK emergency departments, following head injury is often quoted [1]. Extrapolating this to the estimated figure of 6% results in 60,000 patients in the UK each year developing persistent post-concussive symptoms. This figure is higher than the combined number of new lung and colorectal cancers registered in 2004 (59,245 in total) [86].

The next step in this project is to repeat the analysis in a separate, independent group of patients. This is currently underway in the Manchester region with independent investigators, using the same protocols and paperwork, but is, at present, in the data collection phase.

26. Physiology vs. Psychology

It is widely recognised that a proportion of "minor" head injury patients will continue to suffer disability and symptoms beyond six months after their injury [11, 16, 51, 87, 88], whereas most physiological effects would be expected to have subsided within three months [67, 83].

As yet no explanation for this discrepancy has proven satisfactory. Are the problems suffered genuine pathological reactions to the head injury, with sub-clinical examination and investigative findings from the current battery of tests performed? Or, are the problems suffered a result of pre-existing psychological deficits that have manifest themselves clinically following injury? If this is the case – are they specific to head injury or can they occur following other injuries, for example orthopaedic injuries?

26.1 Neuropsychological testing

Other studies have attempted to isolate the symptoms attributable to the head injury from the amalgamation of reactions to any injury by using neuropsychological tests [15, 51, 67, 89]. The reasoning is that these would identify specific features related to brain and neurological function and thus could be advocated as an objective evaluation of the results of brain injury.

As these tests are aimed at the function of the brain they are not the ideal tools to differentiate between the two sides of the argument. They merely test for the presence of a specific problem but do not identify the cause of it. They will objectively identify disability when compared with either control groups or the “normal” response, but are dependent on subjective measures. A meta-analysis by Binder in 1997 identified eleven studies of mild head trauma in adults using neuropsychological testing, and compared results to control groups [90]. The results suggested a minimal identifiable impact directly related to the mild head injury and the positive predictive value calculated for this testing was well below 50%. This translates to a positive test (or below normal test) being very poorly predictive of brain injury. They concluded that clinicians were more likely to be correct when diagnosing no brain injury than when diagnosing the presence of brain injury.

It appears from the literature that brain injury does not produce a unique pattern of results; the cognitive difficulties arising may result from other injury-related factors such as stress, pain, insomnia, and mood disturbances [67]. The tests can also be confounded by pre-morbid psychological or learning difficulties or even previous head injuries, as identified by Ponsford [22]. These factors in themselves are linked to a higher risk of head injury and neuropsychological problems [21], so are the problems identified following injury actually present before the injury occurs?

If these tests go no further to explaining the anomaly that appears to exist following mild head injury then why are they used? The main reason is the role they play in monitoring and assessing recovery from head injury, particularly the severe end of the spectrum and they are used by those who primarily deal with this group of patients in rehabilitation.

The usefulness of these tests was also examined in an article by Rees [67], which reviewed articles using these tests with control groups. They were separated in to normal, uninjured controls or general trauma controls, and demonstrated that there was no significant difference in outcomes between general trauma patients and mild head injury patients when using neuropsychological measures.

26.2 Post-traumatic Disorder

The psychological burden of injury has been studied in an emergency department population in the UK, and not specifically in head injured patients. In 1990, the British Medical Journal published a study from Bristol that followed up patients with jaw fractures and compared those injured from an assault to those involved in a Road Traffic Collision [91]. The researchers demonstrated increased levels of anxiety, depression and psychiatric symptoms, three months after injury, amongst the group of assaulted patients, suggesting that the assault itself was enough to lead to poor psychological outcome. A further study by Mason in 2002, looked at post-traumatic stress reactions amongst male emergency department attenders following any injury [92]. No correlation between injury severity and psychological outcome was established. However, after six months up to 10% of patients demonstrated severe PTSD symptoms – a similar number to that from the head injured cohort in this study.

The two studies mentioned bring in to question the direct relationship between head injury and outcome demonstrated in this research, with the suggestion that any injury, not specifically head injury, will result some psychological disturbance and this is more likely following an assault. This could perhaps strengthen the case for a diagnosis of post-traumatic disorder rather than post-concussive syndrome amongst the mild head injury group, with a predominantly psychological origin to the symptoms suffered.

In the final discussion points in his article, Rees [67] highlighted the possibility of a maladaptive stress response being involved in the development of post-concussive, or post-traumatic, symptoms. He quoted articles that demonstrated MRI changes within the hippocampus of those suffering depression or post-traumatic stress disorder (PTSD) and linked these changes with previously described abnormal reactivity of the hypothalamic-pituitary-adrenal axis (HPA). In his seminar, published in the New England Journal of Medicine, McEwen [93] discusses the potentially damaging effects of stress mediators and the central role that the HPA axis has to play in mediating individual responses to stressful events.

Further to this, in 1999 the Canadian Journal of Psychiatry published two articles about Post-Traumatic Stress Disorder (PTSD), which questioned the dose-response outcomes for post-traumatic symptoms. These points were similar to questions raised in the mild traumatic brain injury literature where seemingly mild injury can produce significant disabilities, disproportionate to the initial injury.

The editor comments that trauma and PTSD do not have a simple cause and effect relationship [94] and the first article by Bowman [95] emphasizes the fact that despite evidence for high exposure levels to ‘traumatic’ events amongst the population only a small proportion go on to suffer PTSD. Bowman concludes that ‘traumatic’ event qualities play only a minor role in the development of PTSD and individual responses are more significant. The most important characteristics mentioned include long-standing traits, beliefs, and pre-event histories of psychiatric and personality disorders. These conclusions are similar in some of the head injury literature [23, 74, 75, 96].

In the same issue, Yehuda [97] looks at biological factors associated with PTSD and depression, and focuses on cortisol responses to stressful situations. In depression, the evidence is for the HPA to be resistant to increased cortisol levels (demonstrated by the dexamethasone suppression test), whilst the converse is true in PTSD patients where the HPA axis response to dexamethasone is excessive compared to normal individuals resulting in an increased suppression of cortisol secretion. In summary, depressive patients have a subdued neuroendocrine reaction to their environment whilst PTSD patients have an excessive reaction.

If pre-existing traits and characteristics play a significant role in the development of PTSD then it would suggest are these maladaptive responses are perhaps present prior to the event. If this were the case then those subjects exposed to ‘traumatic’ events that did not develop post–traumatic difficulties could be expected to have normal neuroendocrine stress responses. A potential area for future research perhaps.

27. A link to traumatic brain injury

Specific to head or traumatic brain injury, can the injury itself precipitate an abnormal neuroendocrine response by damage to the hippocampus or HPA axis?

There is well-documented evidence that traumatic brain injury can lead to the development of hypopituitarism, to varying degrees, in both children [98] and adults [99-101]. This response has been demonstrated in even mild head injury [100]. Linking together the ideas involved in the post-traumatic stress literature and endocrine literature raises the question about the role of a maladaptive pituitary response, whether acquired or pre-existing, contributing to post-concussive symptoms or even a post-traumatic disorder not specific to head injury. It may also help to explain the finding that even those patients without any conventional markers of head injury severity, persist with disabling symptoms six months after the injury has occurred.

Whether the cause for post-concussive problems is ultimately physiological, psychological, or a combination of both, the important outcome is the subjective one, as it is the patient who is suffers regardless of the cause of that suffering. The quest for a physiological trigger for PCS should persist, however, because our exploration in to this field has not yet been exhaustive. The potential to discover a treatable cause for a common problem, thus improving the quality of life for large numbers of patients, should be incentive enough for any medical researcher.

28. Future prospects

This study has looked at the commonly used assessment criteria following head injury in the emergency department. Apart from a reduced GCS at presentation and the fact that the patient had been assaulted, no significant factors that could predict outcome were identified.

Perhaps the fact that some patients without any conventional indicators of severity at presentation went on to have difficulties is a more significant finding as it demonstrates that other tools are required to aid in the derivation of any decision rules regarding follow-up of these patients.

Some of the potential future developments for investigating these patients are briefly discussed in the following chapters.

28.1 Imaging

Neuroimaging is one area, rapidly developing, and able to perhaps produce an increased understanding of microscopic changes occurring within the brain tissue resulting in clinically manifested functional changes. Computed Tomography is the gold standard for detection of intra-cranial haemorrhage in the acute setting, as discussed in the introduction, but is poorly predictive of post-concussive symptoms. Alternative modalities were reviewed by Bazarian in 2006 looking at investigation of both structural and functional neurological injury with specific focus on concussion (mild traumatic brain injury) patients [102]. These included Magnetic Resonance Imaging (MRI), functional MRI, MR Spectroscopy, Positron Emission Tomography (PET) and Single Photon Emission Computed Tomography (SPECT). In conclusion he commented that the target for these modalities would be to identify axonal injury and to link these findings with post-concussive symptoms, although he noted the limitations with more advanced technologies and widespread applicability.

28.2 Neurophysiological testing

Duff reviewed the utilisation of Quantitative Electroencephalogram (QEEG) in the assessment of post-concussion syndrome in 2004 [103], highlighting the empirical and objective qualities in discriminating various neurophysiological patterns of brain dysfunction. He acknowledged the lack of data to support conventional EEG and listed a series of studies in which QEEG was superior in detecting underlying brain lesions than conventional imaging techniques, with evidence of correlation to ongoing cognitive deficits and symptoms in those diagnosed with post-concussion syndrome. Again the question of applicability on a large scale needs to be raised.

28.3 Biochemical markers

Another area of promise for this research is in the use of biochemical markers. The idea is that head injury causes a release of proteins from damage to neuronal axons and supporting cells, such as astrocytes. These are released into the cerebro-spinal fluid and then diffuse across the blood-brain barrier to be detectable in the peripheral circulation. Bazarian included serum biomarkers in his review article [102], focusing on those with more extensive research findings including neuronal markers (neuron-specific enolase, cleaved-tau protein) and astrocyte markers (protein S100B, creatine kinase BB isoenzyme and glial fibrillary acidic protein). Most of the evidence linking serum marker levels to outcome is in research with protein S100B.

This link with outcome was formally reviewed by Townend recently, who concluded that there was insufficient evidence to support widespread adoption of testing following head injury [104]. One of the reasons for this was that no quantitative link with outcome has been consistently established although studies have identified elevated protein S100B concentrations following head injury [44, 66, 105] when compared with controls.

Incidentally, there is good correlation between ‘normal’ levels of S100B and negative findings on CT scan following head injury [46, 106].

Extensive work with protein S100B in neonates has been undertaken by Gazzolo in Italy, who has established strong correlations between elevated serum S100B concentrations and intra-ventricular haemorrhage [47] and subsequently a link between brain damage following peri-natal asphyxia and elevated urinary S100B concentrations [48]. Berger, in 2002, identified elevated S100B concentrations in the serum of closed head injury children with no elevation in the samples of control patients with extra-cranial fractures [49].

28.4 Local pilot study

Linking these areas of research together a pilot study was set-up in the paediatric area of Hull Royal Infirmary Emergency Department to investigate the theory that urinary S100B levels, measured at presentation to the emergency department, would be detectable following traumatic brain injury.

The results from the pilot study revealed that no significant difference existed between the subject and control groups despite three cases of proven, clinically significant brain injury in the subject group. Urinary protein S100B concentrations did not reach the levels previously recorded by Gazzolo [48] (highest of 0.09 µg/L compared with average, on first micturition, of 1.92 ± 0.33µg/L). In fact they were considerably lower than previous studies almost to the point of being undetectable. If, however, the low concentrations as actual figures were set aside, then the results would suggest that there is release of protein S100B to the same degree following peripheral injury as with head injury, thus rendering urinary S100B of little use as a biochemical marker in the early stages following head injury.

The reasons for the consistently low concentrations measured in this study were considered. It has previously been documented that transport time to the laboratory, with storage at room temperature, does not affect the measurement of protein S100B concentration for the same urine sample [65]. Samples were collected cleanly and uniformly for all recruits and a standard storage protocol was established with the receiving laboratory upon receipt of samples from the emergency department. Recovery procedures for samples were different to those of Italian researchers and it is certainly possible that this may have had an effect on the results, but the clinical biochemist consulted for the study was not of the opinion that this should be the case.

A simpler cause for the low concentrations was hypothesized, that the time from injury to collection of samples was not long enough for release of protein S100B from astrocytes, crossing of the blood-brain barrier, circulation around the body, filtration at the glomeruli and eventual excretion in the urine. The mean time from injury to collection was just under two hours. Even if excretion into urine were almost instant, with the bladder containing normal urine (no protein S100B) the concentrations of S100B excreted would be diluted before micturition – to almost undetectable levels.

These hypotheses would need to be tested by a more prolonged follow-up period for the two groups and serial urine measurements whilst under observation.

Potential variations for height, weight, sex and age were eliminated by the use of case-control matching, and shown to be of no significant difference. This left the study with the conclusion that there was no significant elevation of urinary S100B following traumatic brain injury that could be utilised within an emergency department in the UK.

As mentioned earlier, collection time from injury to sampling was under two hours for both groups and a recent publication, again by Berger, identified that the mean time for a peak rise in urinary protein S100B following head injury was over 55 hours, compared with fourteen hours for serum concentrations [107]. The authors also noted a link between elevated S100B concentrations, in both serum and urine, and poor outcome at both six and twelve months, as measured by a dichotomised Glasgow Outcome Score.

This latest study, published in 2006, would have been the next stage in the research plan of this thesis, had the pilot study in to urinary S100B, performed in 2005, yielded any positive results. Attempting to link clinical parameters, urinary S100B concentrations and poor outcome in those discharged from the emergency department was the ultimate goal but this was not achieved within the scope of this thesis.

Conclusion

29. Answers to the Clinical Question

So how do we answer the questions from the concerned parents from the start of this discussion?

Are his schoolwork and forthcoming exam results likely to be affected by this "minor" head injury?

Can we predict whether he will suffer problems from this assault?

If we could, what would we do about it?

The results from this study would suggest that there is about a five percent chance of persistent symptoms lasting up to six months following any head injury, but this is about ten percent amongst those assaulted. In this percentage it could be expected that extra help would be required with schoolwork. The main problems expected would be with short-term memory and concentration, but there may be problems with subsequent anxiety levels and behavioural problems both at school and home. Forewarning patient, parents and school of these problems may aid in the transition back to pre-injury functional levels and reduce the impact of any symptoms, but, as yet, there is no way of accurately predicting who will develop post-injury symptoms from the large numbers of patients attending the emergency department.

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Appendices

APPENDIX I

Glasgow Coma Scale [6]

Best Motor Response

6	Obeying commands
5	Localizing to painful stimulus
4	Withdrawal from painful stimulus
3	Flexor (decorticate)
2	Extensor (decerebrate)
1	None

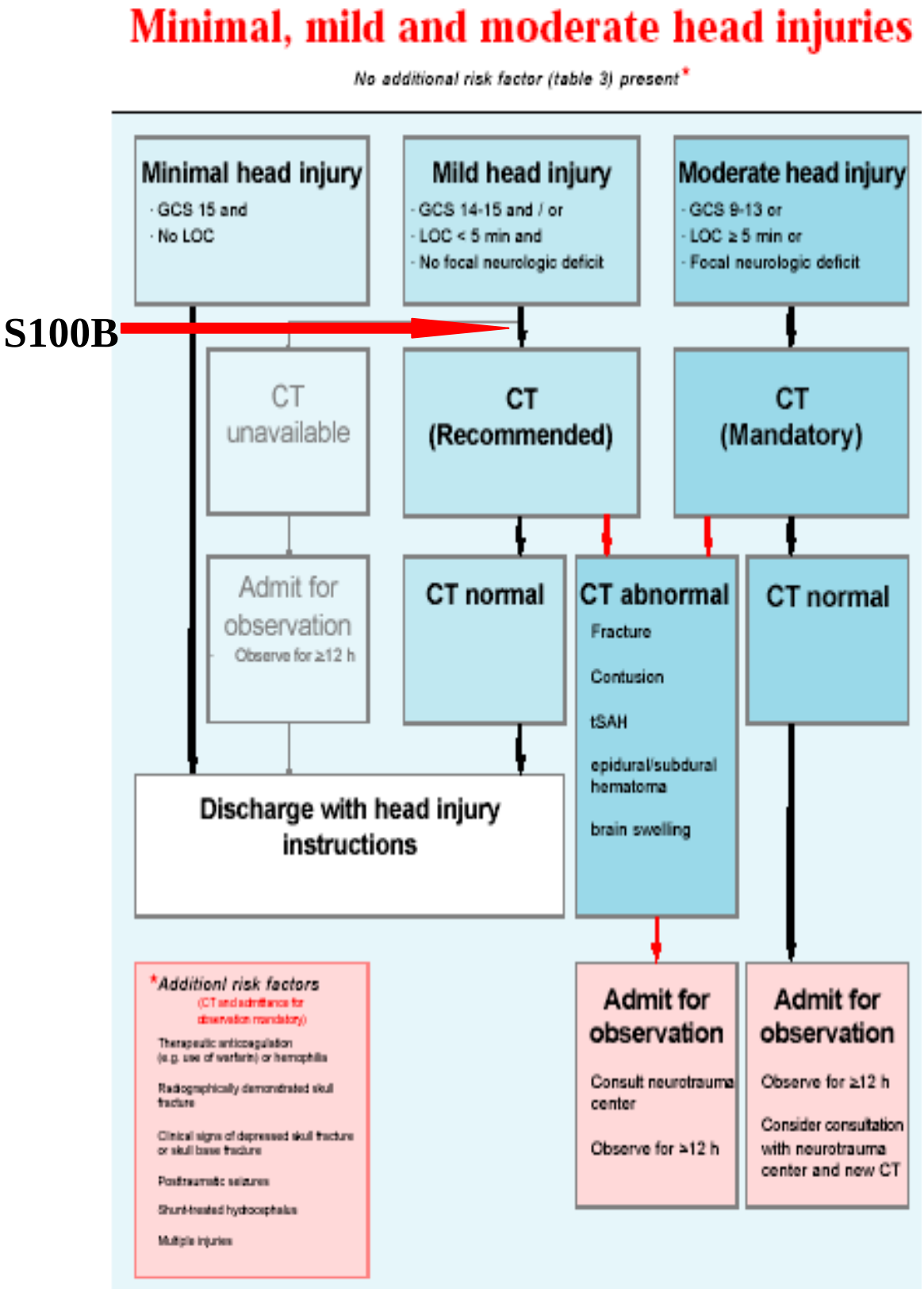
Best Verbal Response

5	Oriented
4	Confused conversation
3	Inappropriate speech
2	Incomprehensible speech
1	None

Eye Opening

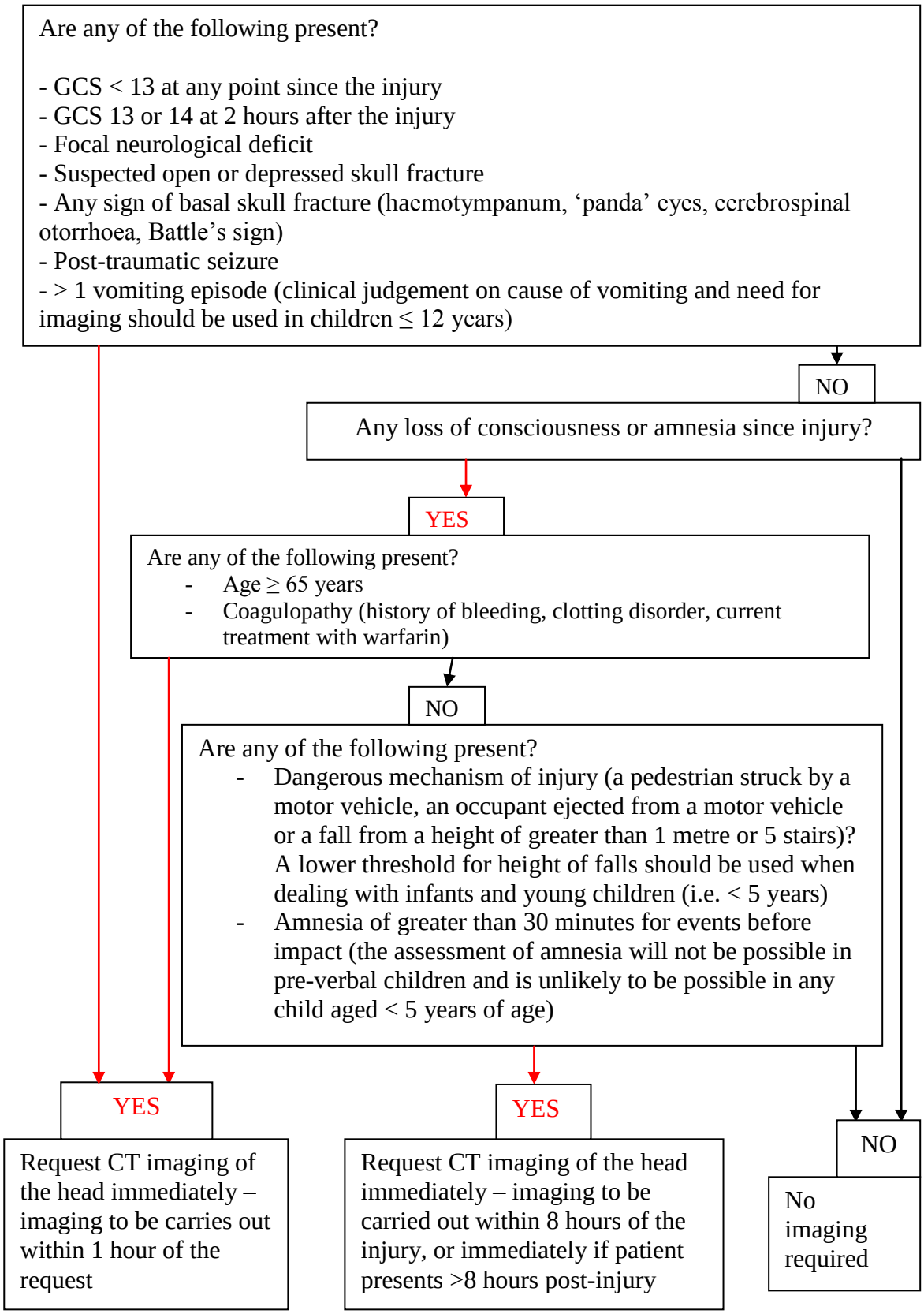
4	Spontaneous
3	Responds to voice
2	Responds to pain
1	None

APPENDIX II (Modified Scandinavian Head Injury Guidelines)



APPENDIX III

Selection of patients with a head injury for CT imaging of the head [2]



APPENDIX IV

ATLS criteria for high-energy mechanism of injury [68]

- Ejection from auto
- Death in same passenger compartment
- Pedestrian thrown or run over
- High speed auto crash*
    i. Initial speed >40mph (64kph)
    ii. Major auto deformity >20inches (50cm)
    iii. Intrusion into passenger compartment >12 inches (30cm)
- Extrication time >20 minutes
- Falls >20ft (6m)
- Rollover*
- Auto-pedestrian injury with >5mph (8kph) impact
- Motorcycle crash >20mph (32kph) or with separation of rider and bike

* Unrestrained passenger

APPENDIX V - **Proforma**

Name……**DoB**……**A/E No**……
Injury: Date……..Time…… **Presentation:** Date…….Time……
History:

Please circle:

RTC	**N/A**				
Car/Lorry		*Driver*	*Passenger*	*Pedestrian*	
Seatbelt		*Y / N / ?*	***Airbag***	*Y / N / ?*	
Motorbike		*Helmet*	*Y / N / ?*		
Bicycle		*Helmet*	*Y / N / ?*		
Speed		*<30mph*	*>30mph*	*Don't know*	
Damage to vehicle		*None*	*Minor*	*Major*	*Don't know*
Fall	**N/A**	*Trip/Slip*	*<1m*	*>1m*	*>5 steps*
Sports	**N/A**	*Headgear*	*Y / N / ?*	*Contact*	*Non-Contact*
Assault	**N/A**	*Fist*	*Feet*	*Weapon*	*Don't know*

Initial Symptoms

LOC (mins)	**No**	**Yes**	*? time*	*<5*	*5-15*	*15-30*	*>30*	**Unknown**
Amnesia (mins)	**No**	**Yes**	*? time*	*<10*	*10-30*	*30-60*	*>60*	**Unknown**
Vomiting	**No**	**<2**		**>2**				**Unknown**
Seizure	**No**	**Yes**						**Unknown**
Visual Deficit	**No**	**Yes (Old / New)**		**Unilateral**		**Bilateral**		**Unknown**
Bleeding/ Fluid	**No**	**Ears (including haemotympanum)**		**Nose**		**Elsewhere (see diagrams)**		

Current symptoms – resulting from head injury

Headache	*Absent*	*Mild / Moderate*	*Severe*	**Don't know**
Dizziness	*Absent*	*Mild / Moderate*	*Severe*	**Don't know**
Nausea	*Absent*	*Mild / Moderate*	*Severe*	**Don't know**

Previous Hx: (Please mark on normal history sheet if Collapse ?cause)
Head injury admission Y N Epilepsy/ Bleeding disorder / Anticoagulants
Other (list):.

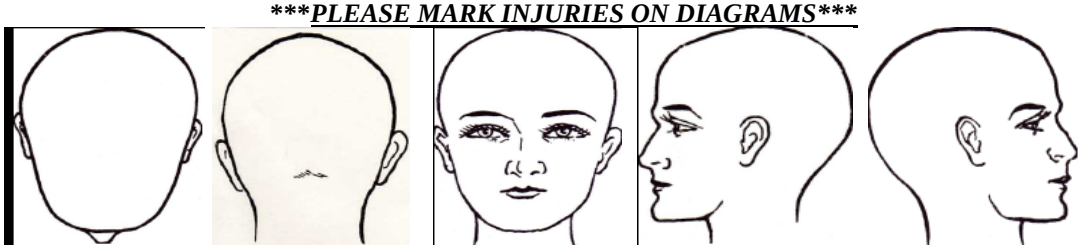
Examination:

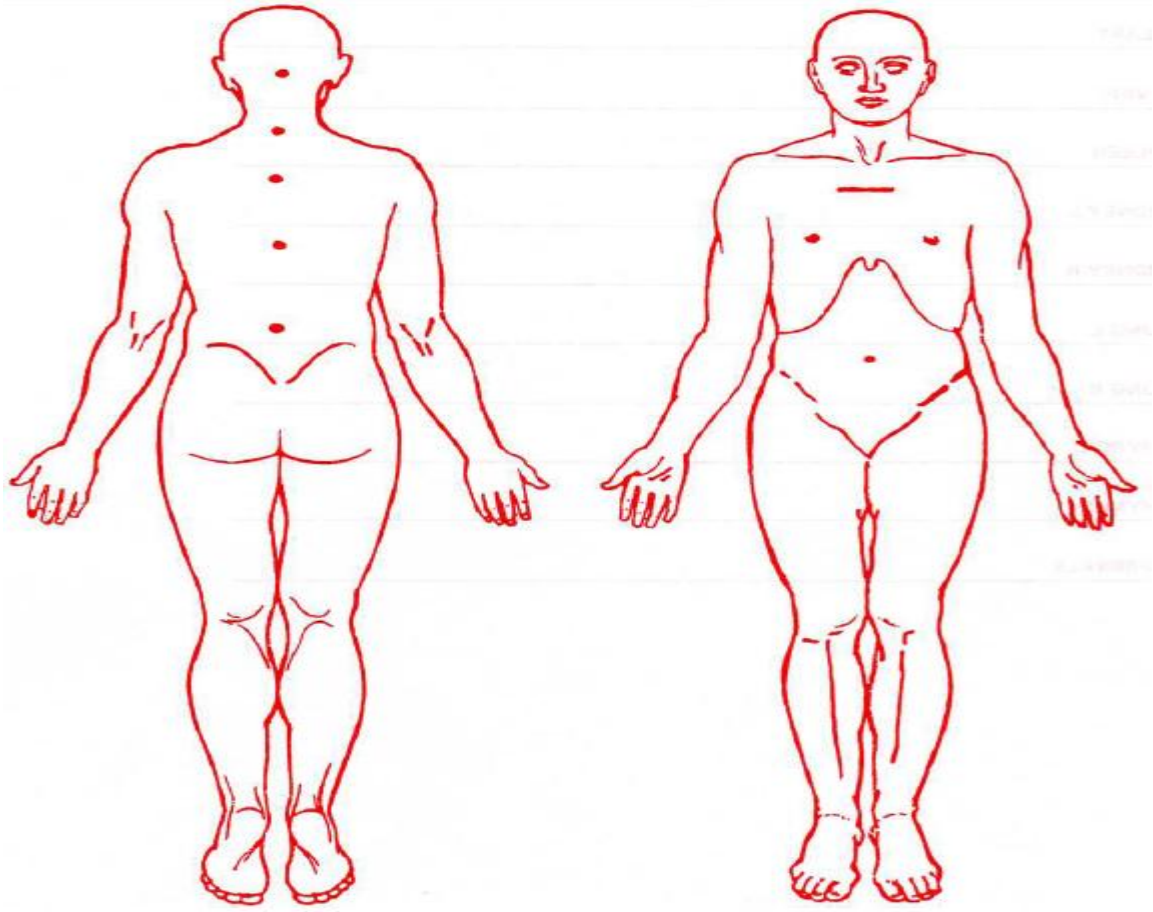
GCS: lowest since injury	**/ 15**	**HR**	**bpm**	**BP**	**mmHg**
on assessment	**/ 15**	**RR**	**/min**	**SpO2**	**%**
Alcohol ingested	**Y / N**	**BM**		**Alcometer**	

EYES	**Pupils**						***Fundoscopy***	
Right	?	Normal	Constricted	Dilated	Reactive	Fixed	*Normal*	*Abnormal*
Left	?	Normal	Constricted	Dilated	Reactive	Fixed	*Normal*	*Abnormal*

Focal Neurology No **Yes***…(describe)*
Skull# None Open Basal
Other findings:

******PLEASE MARK INJURIES ON DIAGRAMS******





Does the patient need a CT scan? **Immediately** **Within 8 hours** **No**
(Please refer to guidelines on A&E intranet page)
If in doubt- seek senior help
CT RESULT :

Is this patient suitable for the MOHICAN study? **Y** **N**
{Age 13 – 21 inclusive and in full time education}
If No: Please indicate reason why not…
If Yes:
Please ask patient to repeat in sequence and note if correct:

9 2 5 3 1 6 7 4	**Correct?**	**Y**	**N**	**not able to test**
4 7 8 3 2 1 6 9	**Correct?**	**Y**	**N**	**not able to test**

Tell the patient we would like to contact them in one month to see how they have got on.
If yes: ***(Please note contact details)***
Best method of contact:
Post (address on front sheet) Telephone……..Mobile……..Text
Email……

Doctor : **Signature:**

APPENDIX VI

Patient Information leaflet
04/2005 (2.2)

A Pilot study to estimate the incidence of disabling symptoms following mild head injury amongst children and young adults in full-time education.

We wish to invite you to take part in a research study. Before you agree please read this and ask any questions that you may have.

What is the purpose of this study?

Children and young adults with head injuries are a large number of those that come to the emergency department and some, with even mild injuries, may go on to develop problems returning to daily life. We are trying to establish the number of those discharged whom then go on to develop these problems in order to improve the service that we provide.

Why have I been invited?

You have been invited to take part because you have suffered a head injury and are in full time education.

What will happen if I decide to take part?

You will receive all the normal care.

We would like to contact you one month after discharge from hospital for a brief interview to find out how you are doing at school / college / university. This will be by one of the methods mentioned below; whichever is the best for you.

Interview / Phone call (home or mobile) / text messaging / email / by post.

The interview will involve a brief series of questions, which have been developed in previous research, to try and identify any potential problems that you may have at school / college / university because of the head injury. They will cover different aspects of daily life to produce a score that reflects the degree of your recovery.

If we find that you are having problems since the head injury then we would like to refer you on for support and inform the school / college / university nurse and your GP. We would also want to repeat the interview after six months.

You will be asked to sign a consent form stating that you agree to take part in this study.

Do I have to take part?

No, you don't have to take part and you will still be treated as usual.

Are there any risks involved?

No – the only thing that you have to do is answer a few questions in the future.

Confidentiality

The information that you have given on arrival to the department is the standard information that all patients are asked to provide.

The information that you give for the study at the initial stage and in the follow-up will be related to your head injury only and has been developed in previous research studies as indicating possible problems following such a head injury.

If any of the information that you give suggests a potential problem we would refer you on for further assessment and in such would pass on the information that you give us.

All information for this study will identify you by a unique number and will be stored on a password protected computer database – separate from the main hospital database – in a locked office within the department.

The information will be retained, until fully analysed, by the research staff involved and will be disposed of appropriately after approximately one year.

By signing the consent form you are agreeing for the above to occur.

A letter informing your GP and school nurse of your participation in this study will be forwarded unless you have any objections.

This study is organised by the Senior Lecturer in the Emergency department, **Dr Will Townend** and the research fellow for the department, **Dr Alastair Pickering.**

Contact number 01482 674052/8

Thank you for taking the time to read this information leaflet.

Patient Consent 02/2005 (1.2)

A Pilot study to estimate the incidence of disabling symptoms following mild head injury amongst children and young adults in full-time education.

LEAD RESEARCHER Dr Will Townend, Senior Lecturer in Emergency Medicine, HRI

SUBJECT ID …….....**Please initial box**

I confirm that I have read and understood the information sheet dated 02/2005 (1.2) for the above study and have had the opportunity to ask questions ☐

I understand that my participation is voluntary and will not affect their medical care or legal rights ☐

I understand that information relating to my case will be stored on a password protected database and give permission that it is only accessed by those directly involved in the study or appropriate regulatory authorities ☐

I agree to take part in this study and be contacted for interview as the study information sheet states ☐

_____ ___/___/___ _____
Name of subject (BLOCK CAPITALS) Date Signature

_____ ___/___/___ _____
Name of person giving consent Date Signature

_____ ___/___/___ _____
Researcher/ person taking consent Date Signature

APPENDIX VII

Parent Information leaflet
04/2005 (2.1)

A Pilot study to estimate the incidence of disabling symptoms following mild head injury amongst children and young adults in full-time education.

We wish to invite your child to take part in a research study. Before you agree please read this and ask any questions that you may have.

What is the purpose of this study?

Children with head injuries are a large number of those that come to the emergency department and some, with even mild injuries, may go on to develop problems returning to school. We are trying to establish the number of those discharged whom then go on to develop these problems in order to improve the service that we provide.

Why have I been invited?

You have been invited to take part because your child has suffered a head injury and is in full time education.

What will happen if I decide to take part?

Your child will receive all the normal care.

We would like to contact you one month after discharge from hospital for a brief interview to find out how your child is doing at school. This will be by one of the methods mentioned below; whichever is the best for you.

Interview / Phone call (home or mobile) / text messaging / email / by post.

The interview will involve a brief series of questions, which have been developed in previous research, to try and identify any potential problems that your child may have at school because of the head injury. They will cover different aspects of daily life to produce a score that reflects the degree of recovery of your child.

If we find that your child is having problems since the head injury then we would like to refer them on for support and inform the school nurse and GP. We would also want to repeat the interview after six months.

You will be asked to sign a consent form stating that you agree to take part in this study.

Do I have to take part?

No, you don't have to take part and your child will still be treated as usual.

Are there any risks involved?

No – the only thing that you have to do is answer a few questions in the future.

Confidentiality

The information that you have given on arrival to the department is the standard information that all patients are asked to provide.

The information that you give for the study at the initial stage and in the follow-up will be related to your child's head injury only and has been developed in previous research studies as indicating possible problems following such a head injury.

If any of the information that you give suggests a potential problem we would refer your child on for further assessment and in such would pass on the information that you give us.

All information for this study will identify your child by a unique number and will be stored on a password protected computer database – separate from the main hospital database – in a locked office within the department.

The information will be retained, until fully analysed, by the research staff involved and will be disposed of appropriately after approximately one year.

By signing the consent form you are agreeing for the above to occur.

A letter informing your GP and school nurse of your participation in this study will be forwarded unless you have any objections.

This study is organised by the Senior Lecturer in the Emergency department, **Dr Will Townend** and the research fellow for the department (currently working as a registrar), **Dr Alastair Pickering.**

Contact number 01482 674052/8

Thank you for taking the time to read this information leaflet.

Parental Consent 02/2005 (1.1)

A Pilot study to estimate the incidence of disabling symptoms following mild head injury amongst children and young adults in full-time education.

LEAD RESEARCHER Dr Will Townend, Senior Lecturer in Emergency Medicine, HRI

SUBJECT ID …….....**Please initial box**

I confirm that I have read and understood the information sheet dated 02/2005 (1.1) for the above study and have had the opportunity to ask questions ☐

I understand that my child's/ my ward's participation is voluntary and will not affect their medical care or legal rights ☐

I understand that information relating to my case will be stored on a password protected database and give permission that it is only accessed by those directly involved in the study or appropriate regulatory authorities ☐

I agree to take part in this study and be contacted for interview as the study information sheet states ☐

_____ ___/___/___ _____
Name of subject (BLOCK CAPITALS) Date Signature

_____ ___/___/___ _____
Name of person giving consent Date Signature

_____ ___/___/___ _____
Researcher/ person taking consent Date Signature

APPENDIX VIII

Original Glasgow Outcome Scale[55] (GOS)

2 Death

3 Persistent Vegetative State

4 Severe Disability (conscious but disabled)

5 Moderate Disability (disabled but independent)

6 Good Recovery

Extended Glasgow Outcome Scale (GOSE)

1 Dead

2 Vegetative State

3 Lower Severe Disability

Completely dependent on others

4 Upper Severe Disability **DEPENDENT**

Dependent on others for some activities

5 Lower Moderate Disability **INDEPENDENT**

Unable to return to work

Unable to participate in social activities

6 Upper Moderate Disability

Return to work in reduced capacity

Reduced participation in social activities

7 Lower Good Recovery

Good recovery with minor social or mental deficits

8 Upper Good Recovery

APPENDIX IX

Structured interview for GOSE

CONSCIOUSNESS	
1. Is the head injured personable to obey simple commands, or say any words?	1 = No (VS) 2 = Yes

Anyone who shows ability obey even simple commands, or utter any word or communicate specifically in any other way is no longer considered to be in the vegetative state Eye movements are not reliable evidence of meaningful responsiveness. Corroborate with nursing staff. Confirmation of VS requires full assessment as in Royal College of Physician Guidelines.

INDEPENDENCE IN THE HOME	
2a Is the assistance of another person at home essential every day for some activities of daily living?	1 = No 2 = Yes

For a 'no' answer they should be able to look after themselves at home for 24 hours if necessary, though they need not actually do so. Independence includes the ability to plan for and carry out the following activities: getting washed, putting on clean clothes without prompting, preparing food for themselves, dealing with callers, and handling minor domestic crises. The person should be able to carry out activities without needing prompting or reminding, and should be capable of being left alone overnight.

2b Do they need frequent help or someone to be around at home most of the time?	1 = No (Upper SD) 2 = Yes (Lower SD)

For a 'No' answer they should be able to look after themselves at home for up to 8 hours during the day if necessary, though they need not actually do so.

2c Was assistance at home essential before the injury?	1 = No 2 = Yes

INDEPENDENCE OUTSIDE THE HOME

3a Are they able to shop without assistance? 1 = No (Upper SD)
2 = Yes

This includes being able to plan what to buy, take care of money themselves, and behave appropriately in public. They need not normally shop, but they must be able to do so.

3b Were they able to shop without assistance before the injury? 1 = No
2 = Yes

4a

They may drive or use public transport to get around. Ability to use a taxi is sufficient, provided the person can phone for it them self and instruct the driver.

4b Were they able to travel without assistance before the injury? 1 = No
2 = Yes

WORK

5a Are they currently able to work to their previous capacity? 1 = No
2 = Yes

If they were working before, then their current capacity for work should be at the same level. If they were seeking work before, then the injury should not have adversely affected their chances of obtaining work or the level of work for which they are eligible. If the patient was a student before the injury then their capacity for study should not have been affected.

5b How restricted are they?
a) Reduced work capacity. 1 = a (Upper MD)
b) Able to work only in sheltered workshop or non-competitive job, or unable to work. 2 = b(Lower MD)

5c Were they either working or seeking employment before the injury. 1 = No
2 = Yes

SOCIAL & LEISURE ACTIVITIES

6a Are they able to resume regular social and leisure activities outside home? 1 = No 2 = Yes

They need not have resumed all their previous activities, but should not be prevented by physical or mental impairment. If they have stopped the majority of activities because of loss of interest or motivation then this is also considered a disability.

6b What is the extent of restriction on their social and leisure activities?

a) Participate a bit less: at least half as often as before injury 1 = a (Lower GR)

b) Participate much less: less than half as often 2 = b (Upper MD)

c) Unable to participate: rarely, if ever, take part. 3 = c (Lower MD)

6c Did they engage in regular social and leisure activities outside home before the injury? 1 = No 2 = Yes

FAMILY & FRIENDS

7a Have there been psychological problems which have resulted in ongoing family disruption or disruption to friendships? 1 = No 2 = Yes

Typical post-traumatic personality changes: quick temper, irritability, anxiety, insensitivity to others, mood swings, depression, and unreasonable or childish behaviour.

7b What has been the extent of disruption or strain?

a) Occasional - less than weekly. 1 = a (Lower GR)

b) Frequent - once a week or more, but tolerable. 2 = b (Upper MD)

c) Constant - daily and intolerable. 3 = c (Lower MD)

7c Were there problems with family or friends before the injury? 1 = No 2 = Yes

If there were some problems before the injury, but these have become markedly worse since, then answer No

RETURN TO NORMAL LIFE

8a Are there any other current problems relating to the injury which affect daily life? 1 = No (Upper GR) 2= Yes (Lower GR)

Other Typical problems reported after head injury: headaches, dizziness, tiredness, sensitivity to noise or light, slowness, memory failures, and concentration problems.

8b Were similar problems present before the injury? 1 = No 2 = Yes

If there were some problems before the injury, but these have become markedly worse since, then answer no.

What is the most important factor in outcome?
Effects of head injury ___ Effects of illness or injury to another part of the body ___
A mixture of these ___

EPILEPSY

Since the injury has the head injured person had an epileptic fit? No / Yes
Have they been told that they are at risk of developing epilepsy? No / Yes

SCORING

Overall rating is based on the lowest outcome category indicated on the scale.

1 Dead
2 Vegetative State
3 Lower severe Disability
4 Upper Severe Disability
5 Lower moderate Disability
6 Upper Moderate Disability
7 Lower Good Recovery
8 Upper Good Recovery

APPENDIX X

KOSCHI category examples [59]

1 Death

2 Vegetative

The child is breathing spontaneously and may have sleep/wake cycles. They may have non-purposeful or reflex movements of limbs or eyes. There is no evidence of ability to communicate verbally or non-verbally or to respond to commands.

3 Severe Disability

a. The child is at least intermittently able to move part of the body/eyes to command or make purposeful movements; for example, confused child pulling at nasogastric tube, lashing out at carers, rolling over in bed. May be fully conscious and able to communicate but not yet able to carry out any self-care activities such as feeding.

b. Implies a continuing high level of dependency, but the child can assist in daily activities; for example, can feed self or walk with assistance or help to place items of clothing. Such a child is fully conscious but may still have a degree of post-traumatic amnesia.

4 Moderate Disability

a. The child is mostly independent but needs a degree of supervision/actual help for physical or behavioural problems. Such a child has overt problems; for example, 12 year old with moderate hemiplegia and dyspraxia insecure on stairs or needing help with dressing.

b. The child is age appropriately independent but has residual problems with learning/behaviour or neurological sequelae affecting function. They probably should have special needs assistance but their needs may not have been recognized/met. Children with symptoms of post-traumatic stress are likely to fall in to this category.

5 Good Recovery

a. This should only be assigned if the head injury has resulted in a new condition which does not interfere with the child's well being and/or functioning; for example,
    i. Minor headaches not interfering with social or school functioning
    ii. Abnormalities on brain scan without any detectable new problem
    iii. Prophylactic anticonvulsants in the absence of clinical seizures
    iv. Unsightly scarring of face/head likely to need cosmetic surgery at some stage
    v. Mild neurological asymmetry but no evidence of affect on function of limb. Includes isolated change in hand dominance in young child.

b. Implies that the information available is that the child has made a complete recovery with no detectable sequelae from the head injury.

APPENDIX XI

Rivermead Post Concussion Symptoms [61]

0 = Not experienced at all
1 = No more of a problem
2 = a mild problem
3 = a moderate problem
4 = a severe problem

Compared with before the accident, do you now (i.e. over the last 24 hours) suffer from:

Headaches	0	1	2	3	4
Feelings of dizziness	0	1	2	3	4
Nausea and/or vomiting	0	1	2	3	4
Noise sensitivity,					
easily upset by loud noise	0	1	2	3	4
Sleep disturbance	0	1	2	3	4
Fatigue, tiring more easily	0	1	2	3	4
Being irritable, easily angered	0	1	2	3	4
Feeling depressed or tearful	0	1	2	3	4
Feeling frustrated or impatient	0	1	2	3	4
Forgetfulness, poor memory	0	1	2	3	4
Poor concentration	0	1	2	3	4
Taking longer to think	0	1	2	3	4
Blurred vision	0	1	2	3	4
Light sensitivity,					
easily upset by bright light	0	1	2	3	4
Double vision	0	1	2	3	4
Restlessness	0	1	2	3	4

APPENDIX XII

INTERVIEW STRUCTURE

Outcome score

A/E number . ____/_____ **Study No.** _____

Date of Birth ____/____/_____

Date of injury ____/____/_____

Date of interview ____/____/_____

Sex M / F *(Please circle)*

Respondent: Patient alone Carer alone Patient and Carer
(Please circle)

Initial questions

Do you feel that you are completely back to normal following your head injury? Y N

Have you noticed any problems in returning to normal life following your head injury? Y N

Have you returned to school / college since your head injury? Y N

If yes:

a. How soon after the injury? ____ days ____weeks

b. Are you having any difficulties at school since your head injury? (e.g. work, friends, activities...) Y N

If no:

Why not? *(ensure that it is not holidays!!)*

RPCQ 3

Have you had any of the following symptoms?

headaches	none	mild/moderate	severe
dizziness	none	mild/moderate	severe
nausea/vomiting	none	mild/moderate	severe

***** TO BE COMPLETED IN ALL CASES *****

SCHOOL / COLLEGE – if returned

Has you been excluded from school / college ? Y N

Has your school / college work been affected by the injury? Y N

Have you had any of the following?

Forgetfulness	None	Mild/Moderate	Severe
Poor concentration	None	Mild/Moderate	Severe
Taking longer to think	None	Mild/Moderate	Severe
Blurred vision	None	Mild/Moderate	Severe
Double vision	None	Mild/Moderate	Severe

Is work more difficult than prior to the injury?
Not at all Slightly Definitely

Is it harder to understand concepts than prior to injury?
Not at all Slightly Definitely

Do you now require any special needs/ assistance? Y N
a. One to one teaching? ____
b. Extra tutorials? ____
c. Extra time for projects / work? ____

Did you have any special school requirements before the injury? Y N

If yes - Have they increased since the injury? Y N

SOCIAL

Do you still go out with your friends as before the injury? Y N
Have there been any changes in behaviour since the injury?

Temper outbursts / irritability	none	occ.	constant
Impatience / frustration	none	occ.	constant
Hyperactivity/ restlessness	none	occ.	constant

Have there been any noticeable changes in the following?

Sense of humour	Normal	Altered	None
Mood	Normal	Altered	Depressed
Anxiety	None	Mild/ Mod.	Severe
Motivation	Normal	Lacking	Absent
Tearful	Not at all	Occasionally	All the time

HOME

Has the injury required any changes in the home situation? Y N
(parental job change, rehousing needs, extra home-help, ...)

Any sleeping problems? Y N

tiredness	none	occasional	frequent
nightmares	none	occasional	frequent
sleepwalking	none	occasional	frequent

Is there any residual scarring / deformity from the injury? Y N
has this affected them at all Y N
will it require any future surgery Y N

Have you noticed any problems with increased sensitivity to light since the head injury? None Mild/Moderate Severe

Have you noticed any problems with increased sensitivity to noise since the head injury? None Mild/Moderate Severe

Has any anti-epileptic medication been started / or has the patient had any seizures? Y N

SPORTS

Has the patient returned to sport? Y N

at the same level _____
in a lower standard team _____
not at all _____

If not why not? – *(Remember that this may be due to a peripheral injury!!)*

On returning to sport is it

as easy to play as before the injury _____
more difficult to play than before _____
extremely difficult to return to prior level _____

If not returned to prior level is the difficulty with:

fitness not at all slightly mostly
skills not at all slightly mostly
concentration not at all slightly mostly
training not at all slightly mostly
motivation not at all slightly mostly

Has the patient returned to the sport in which they sustained the injury? Y N

Have they altered their approach to the sport? Y N

Wearing extra protection Y N
Less aggressive / competitive Y N