



Northern Ireland Trauma Audit

February 2016

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Dedicated to the memory of Dr. John Hinds

Member and supporter of NITA, colleague, friend and outstanding clinician

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Introduction

Major Trauma in Context

In the United Kingdom, trauma kills approximately 16,000 people per year¹ and is the leading cause of death in those aged under 40². This figure includes Northern Ireland's 79 road deaths in 2014. For each person killed another two will survive with permanent or serious disability³. In the nineties and in the first decade of this century, reports highlighted serious failings in the care provided to major trauma patients across the UK²⁻⁵. In response, clinical and organisational innovation, in addition to financial investment, has resulted in the creation of regional trauma networks in England and Wales. The implementation of a systematic approach to the care of trauma patients has produced expeditious and dramatic improvements in the standard of care and in mortality⁶.

Whilst trauma networks have numerous components, influencing the patient journey from the point of injury to rehabilitation, the adoption of a robust framework for audit, quality improvement and research is fundamental. In England and Wales this has largely been centered on data from the Trauma Audit Research Network (TARN). TARN and its predecessor the Major Trauma Outcome Study (MTOS) have been collecting data on severely injured trauma patients in England, Wales and the Republic of Ireland for 25 years. This data has been instrumental in informing the design of trauma systems in the UK, as well as offering institutions a solid base for quality improvement and affording researchers an important tool for developing the science of trauma care. Similar registry projects exist in Scotland (Scottish Trauma Audit Group), mainland Europe (e.g. Trauma Register – Deutsche Gesellschaft für Unfallchirurgie, EuroTARN) and the United States (National Trauma Data Bank). Historically, no hospital, or hospital trust, in Northern Ireland has regularly contributed data on trauma patients to a trauma audit or registry.

On the subject of trauma care, policy makers and commissioners in Northern Ireland have recently taken positive action in announcing their commitment to develop a regionalised trauma system. Unfortunately, due to an absence of reliable local data, the majority of the planning for this process must be based on extrapolation and opinion. Several years ago,

recognising this to be the case, a cohort of clinicians lobbied for an opportunity to develop the local evidence base. Given the number of separate acute hospitals and Health and Social Care Trusts in Northern Ireland it was felt that, at the time, a combined effort to submit data to TARN across all sites was unlikely to be feasible. With the support of the Chief Medical Officer, it was decided that a locally driven regional audit would assist in developing evidence in the interim. Thus the Northern Ireland Trauma Audit was born.

The Northern Ireland Trauma Audit

The genesis of the Northern Ireland Trauma Audit (NITA) occurred in 2011 after a successful local meeting, convened to advance the case for developing a regional trauma network. The outline for a regional audit was supported in its infancy by both the Chief Medical Officer, Dr. Michael McBride and Mr. Edwin Poots MLA, at the time Minister for Health, Social Services and Public Safety at the Northern Ireland Assembly. Subsequently, the Guidelines and Audit Implementation Network (GAIN) were approached for support and funding. In late 2013, GAIN approved an application to fund the first Northern Ireland Trauma Audit.

Organisation of the Audit

With mentorship and advice from the team at GAIN, a management committee, representing stakeholders from across the region, was assembled to assist in the preparations for a one-year comprehensive audit programme. Funding permitted the appointment of a full-time nurse to support the project and facilitated the purchase of injury scoring codes and the creation of a custom database.

After a pilot period in February/March 2014 the audit went live in April 2014. The day to day progress of the audit was overseen by the audit coordinator, the lead investigator and the chair of the audit management committee. The audit management committee met bi-monthly during the conduct of the audit. No meetings took place after August 2014.

Challenges and Outcomes

In July 2014 the audit co-ordinator post became vacant. This resulted in the suspension of data collection whilst a recruitment and appointment exercise was carried out. With great

regret and deep frustration this process was unsuccessful and ultimately led to the withdrawal of funding in 2015.

Given the progress occurring in mid-2015 around the development of major trauma services, a decision was made not to seek to recommence the audit but, instead, it was agreed that the data collected in the first four months of the audit should be analysed and presented. Firstly, it was hoped that this work, if provided in a timely fashion, would at the very least give those planning for a regional major trauma network some hard data. Secondly, with new funding announced by the Department of Health, Social Services and Public Safety in 2015, Northern Ireland⁷ could rapidly begin to contribute data to TARN.

What is presented below falls short of that envisaged at the beginning of this project. Despite this, the data presented is timely, it is original (in the sense that it is the first available regional data for at least 10 years) and it is methodologically robust.

Methodology

Participating Services/Hospitals

- Northern Ireland Ambulance Service
- The Coroners Service for Northern Ireland
- Belfast Health and Social Care Trust
 - Royal Victoria Hospital
 - The Mater Hospital
- South Eastern Health and Social Care Trust
 - Ulster Hospital
- Southern Health and Social Care Trust
 - Craigavon Area Hospital
 - Daisy Hill Hospital
- Western Health and Social Care Trust
 - The South West Acute Hospital
 - Altnagelvin Area Hospital
- Northern Health and Social Care Trust
 - Antrim Area Hospital
 - The Causeway Hospital

Subject Selection

The target population was adult patients (≥ 16 years) suffering from serious multi-region injury or complex single region injury. This may be defined by an Injury Severity Score (ISS) ≥ 16 . As an ISS is a retrospective measurement, the following inclusion and exclusion criteria were used to determine initial eligibility.

Inclusion Criteria

- All trauma patients aged ≥ 16 years
- Who fulfilled the following length of stay criteria;

Admissions whose length of stay is ≥ 72 hours
OR
Patients admitted to a critical care setting, regardless of length of stay
OR
Deaths of patients occurring in hospital, including the Emergency Department
OR
Patients transferred to another hospital for specialist care or to a critical care bed

Patients matching the descriptors above were screened against the exclusion criteria.

Exclusion Criteria

- Injuries older than 1 week
- Isolated burn injuries
- Isolated smoke inhalation
- Death or injury caused exclusively by asphyxiation, such as hanging or drowning, with no anatomical injury
- Hypothermia in isolation

The following are excluded when occurring in isolation;

- Lacerations, puncture wounds or bites with no underlying injury
- Loss of consciousness where not accompanied by brain injury or fracture
- Simple or stable facial fractures

- Neck of femur, intertrochanteric, sub-trochanteric or greater trochanteric femur fractures in those aged ≥ 65 years
- Foot or hand fractures, multiple or open
- Closed unilateral limb fractures or dislocations
- Single pubic rami fractures in those aged ≥ 65 years

Patient Identification

Patient identification occurred at the first receiving Emergency Department. Departments screened all patients presenting after injury. Those patients, who were admitted to hospital, were transferred to a second unit or died in the department were allocated a unique identifier.

The audit co-ordinator was responsible for collating weekly returns from each department for further follow-up. Weekly returns were initially screened against the study inclusion and exclusion criteria. Those that were ineligible for inclusion were removed from the process at this point.

Tracking

Patients admitted to the first receiving hospital or transferred to a second institution retained their unique identifier as part of their in-patient notes.

Patients who were subsequently transferred or died within 30 days, were notified by the in-patient team to the audit co-ordinator. Patients discharged before 30 days, were notified by the in-patient team to the audit co-ordinator.

Follow-Up

At day 30 post admission, the audit co-ordinator began the follow up process for each patient.

All patients identified, who passed screening against the inclusion and exclusion criteria, were included in the audit. Retrospective extraction of prospectively collected data was performed using in-patient notes and relevant electronic clinical systems. This information was compiled using a standardised proforma. Anonymisation occurred at this point.

Audit proformas were held centrally and inputted into an existing database to facilitate analysis and injury severity scoring.

Final follow-up (including additional data extraction) occurred during the period September – October, 2015.

Analysis and Scoring

Primarily, collated data relating to the principal audit standards (detailed below) were tabulated. Additionally, a large number of secondary data points were inputted to a database (NITA Protocol, Appendix B).

Injury scoring was carried out using the Abbreviated Injury Scale 2005 (Update 2008)⁸. For each patient all documented injuries were scored. Where applicable post-mortem reports were utilised to assist this process. Subsequently, these scores were used to calculate an Injury Severity Score⁹. A combination of Injury Severity Scores and patient data were also used to calculate a probability of survival for each individual using Ps14¹⁰.

Primary Audit Standards

The audit's primary standards were agreed by committee prior to commencement, as were the expectant compliance targets for each. They are outlined in detail below:

- 1. All Major Trauma Patients should have a pre-alert provided by the pre-hospital care service to the receiving unit.**

Evidence

'Ambulance trusts and emergency departments should have clear guidelines for the use of pre-alerts in the severely injured patient population. The ambulance crew should be able to speak directly to clinical staff in the receiving emergency department to ensure an appropriate clinical response is available immediately.'

NCEPOD, 2007

Target: 95%

- 2. All Major Trauma Patients should be received and managed by a Consultant in the Emergency Department.**

Evidence

'A consultant must be the team leader for the management of the severely injured patient.'

NCEPOD, 2007

Target: 95%

3. Computed tomography (CT) imaging of the head should be performed (that is, imaging carried out and results analysed) within 1 hour of the request having been received by the radiology department in those patients where imaging is requested because of any of the risk factors listed:

- GCS less than 13 on initial assessment in the emergency department
- Suspected open or depressed skull fracture
- Any sign of basal skull fracture
- More than one episode of vomiting
- Post-traumatic seizure
- Coagulopathy
- Focal neurological deficit

Evidence

NICE Clinical Guideline 56, Head Injury, 2007

Target: 95%

4. On-call consultant radiologists should provide the final report on the major trauma patient within 1 hour of CT image acquisition.

Evidence

Royal College of Radiologists, Standards of practice and guidance for trauma radiology in severely injured patients, 2010

Target: 95%

5. Patients with signs of shock (SBP < 90 on attendance, Lactate >4 mmol/L) and an abdominal injury AIS ≥ 3 should have a laparotomy commenced and/or an abdominal/pan CT scan within one hour of attendance.

Evidence

'An immediate response from a senior general surgeon of sufficient experience to perform life-saving emergency laparotomy is essential'

RCS/BOA, Better care for the severely injured, 2000

Target: 95%

6. Patients with severe head injury (AIS ≥3) should be transferred (if no onsite availability) to a setting with 24-hour on-site access to NICU, regardless of whether they require surgical intervention.

Evidence

'All patients with severe head injury should be transferred to a neurosurgical/critical care centre irrespective of the requirement for surgical intervention'

NCEPOD, 2007

Target: 90%

- 7. Patients with open limb fractures should be surgically managed by a consultant orthopaedic and/or plastic surgeon within 24 hours of attendance.**

Evidence

'All patients with high energy open fractures should receive the following care; ...soft tissue and bone excision (debridement) is performed by senior plastic and orthopaedic surgeons working together on scheduled trauma operating lists within normal working hours and within 24 hours of the injury'

BOA/BAPRAS Indicators for the Management of Open Lower Limb Fractures, 2009

Target: 95%

- 8. Patients with unstable pelvic fractures should have a pelvic binder applied within 30 minutes of attendance.**

Evidence

Expert opinion and BOAST 3, 2008

Target: 95%

- 9. The management of patients with spinal injuries AIS \geq 3 should be referred /discussed with the Spinal Injuries service before leaving the first receiving ED.**

Evidence

'Immediate referral must be made to the appropriate spinal injury service if there is evidence of partial or complete spinal cord or cauda equina lesion'

RCS/BOA Standard 13.5

Target: 95%

- 10. The rate of survival amongst major trauma patients, calculated using an appropriate methodology, should be no less than a suitable UK comparator.**

Evidence

Expert Opinion

Regulatory, Ethical and Legal Considerations

GAIN

GAIN funded the audit which was progressed in accordance with GAIN standard operating procedures. The decision to approve, continue or terminate the audit rested at all times with GAIN. No substantive amendment was made to the protocol, with the exception of decisions surrounding the reporting of mortality data. This was approved by GAIN.

Trust Audit Approval

Approval and assistance was sought from the relevant audit and governance departments in each participating Health and Social Care Trust. At the time of the audit all procedures and regulations were complied with including the use of confidentiality agreement and the uses of honorary contracts were applicable.

Data Protection

The confidentiality of patient identifiable data was maintained at all times in accordance with GAIN and local standard operating procedures.

No documents submitted for analysis were identifiable; subjects were identified by a subject ID number only.

All audit data will be destroyed after a period of no more than 6 calendar months after publication of the final report.

Results

1.1 Overview

The audit enrolled patients between the 1st April, 2014 and the 31st July, 2014. Patients were identified using the criteria set out in the audit protocol (Appendix B). During the period studied, 205 patients met the initial screening criteria (fig. 1). One hundred and seventeen individuals were excluded after formal injury scoring, with a further 4 excluded after note review (all due to a non-traumatic aetiology). Finally, 84 patients were included in the analysis.

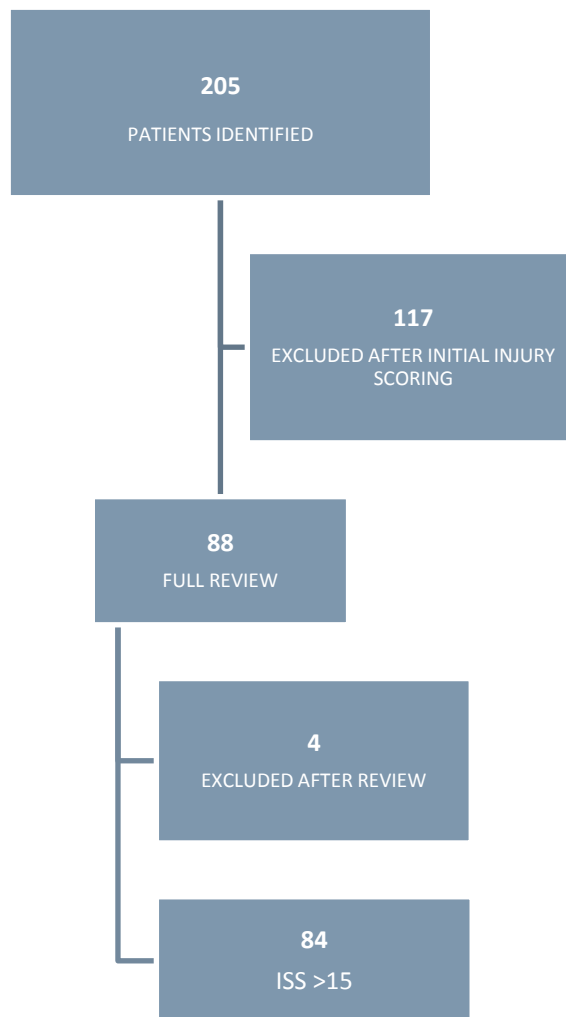


Figure 1. Enrollment flow chart

1.2 Epidemiology

The median age amongst patients enrolled in the audit was 46 (28 – 65) years. The oldest patient studied was 86, whilst 27% of patients were aged 65 or older. The vast majority of those included were male (76%). Males tended to be younger, mean age being 44.7 vs. 54.3 years, although this was not statistically significant ($p=0.101$).

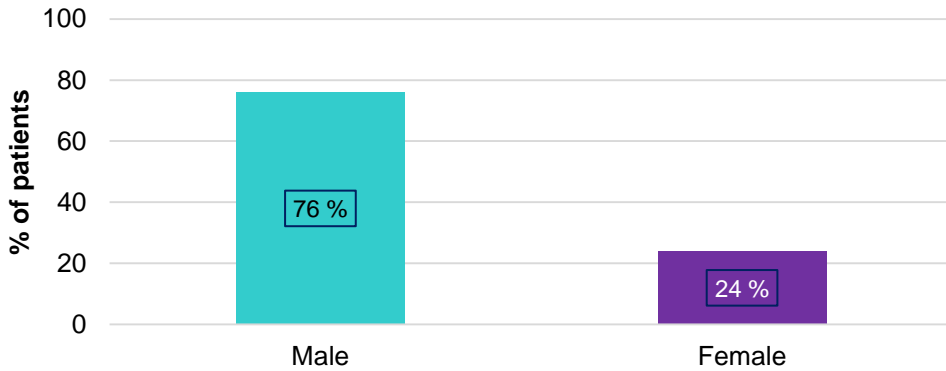


Figure 2. Patient gender

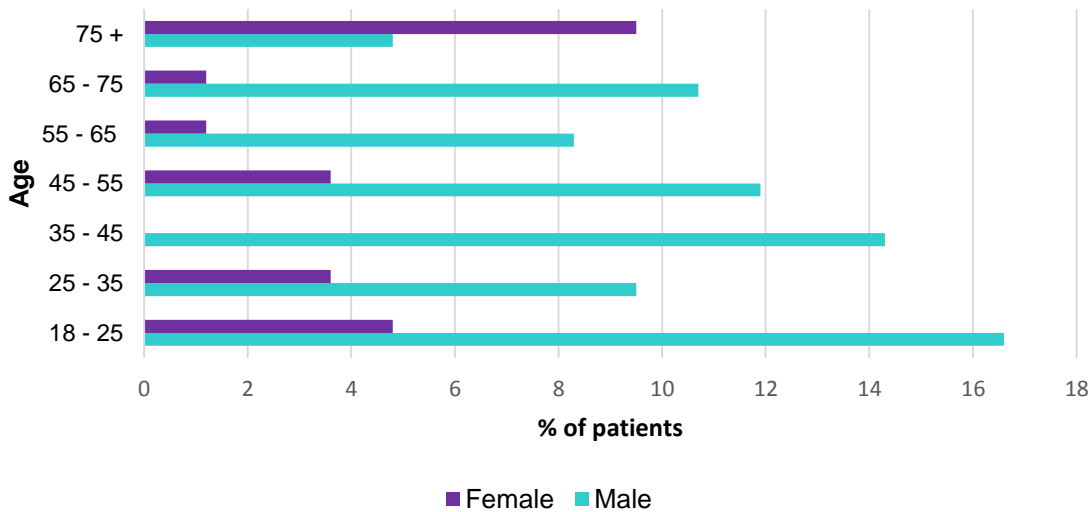


Figure 3. Percentage of patients by age group

Temporal distribution

Cases were evenly distributed across the four months in the study period; April – 21 patients, May – 20 patients, June – 24 patients, and July – 19 patients. Some variation was seen in the weekday of injury, with an observed downturn in cases presenting on

Saturdays (fig. 4). On closer examination of the dataset this appears to be accounted for by a significant number of patients presenting in the early hours of Sunday morning.

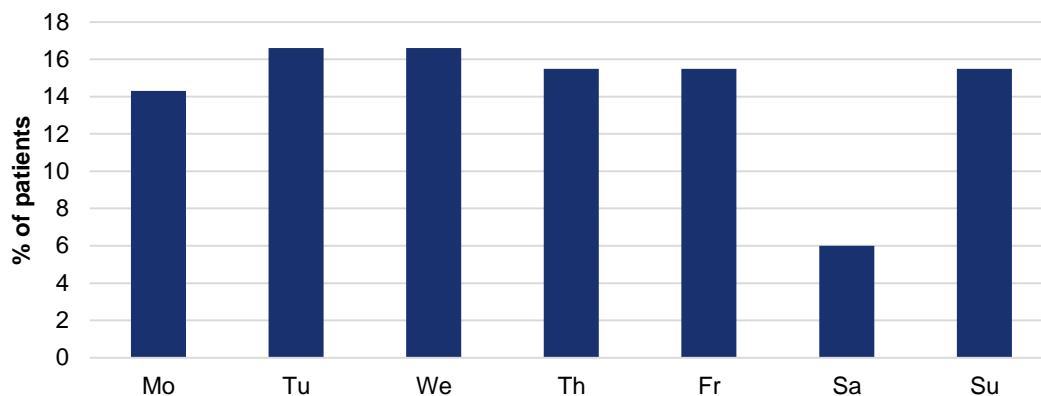


Figure 4. Day of injury

The distribution of cases by time of presentation to Emergency Departments is displayed in figure 5. In total, 76% of patients presented within the hours of 08:00 to 00:00. The hours between 15:00 and 19:00 account for a full third of all cases in the audit.

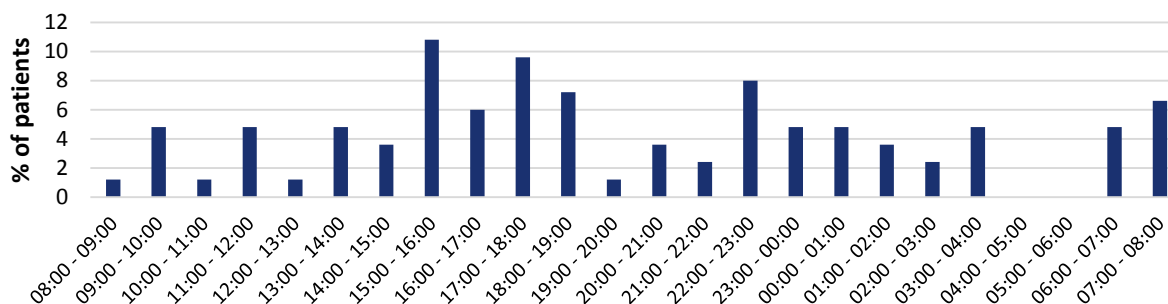
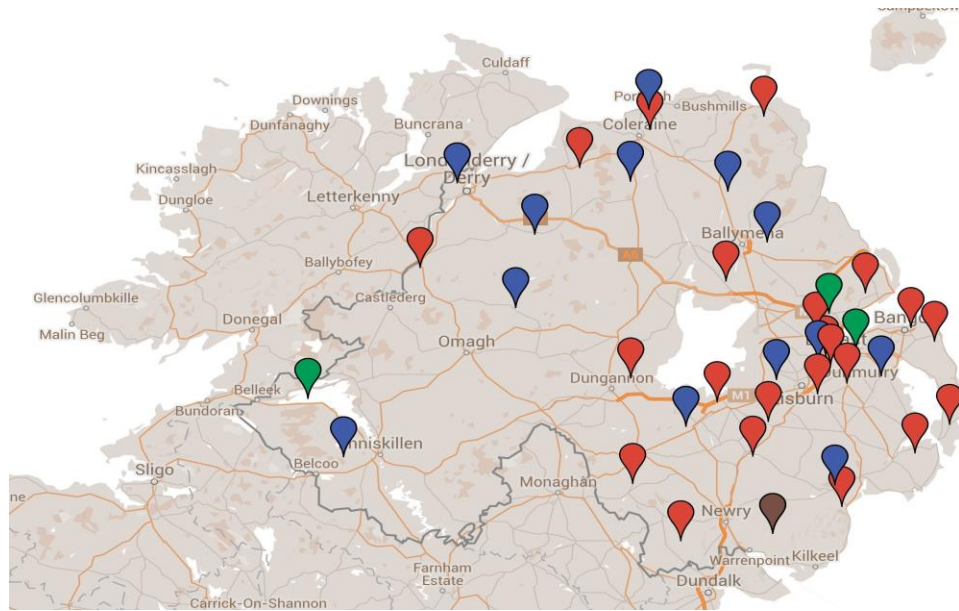


Figure 5. Presentation to Emergency Departments by time of day

Spatial distribution

For those patients with a valid incident postcode (n=61*) the location of injury is mapped in figure 6. Of the incidents with postcode data, 42 (69%) occurred within 60 minutes driving time of the Royal Victoria Hospital (RVH), Belfast. Where incidents occurred beyond 60 minutes driving time of the RVH (n=19), 14 of these patients were injured within 60 minutes driving time of Altnagelvin Area Hospital. In total, 92% of patients were injured within 60 minutes of either hospital. For illustrative purposes, figure 7 shows an isochron map of 60 minutes driving time from the Royal Victoria Hospital.



* Red - 1 case (n=22x1), Blue - 2 cases (n=13 x2), Green - 3 cases (n=3x3), Brown - 4 cases (n=1x4)

Figure 6. Incident postcode map: Location of incident by number of patients with valid incident post code (n=61)

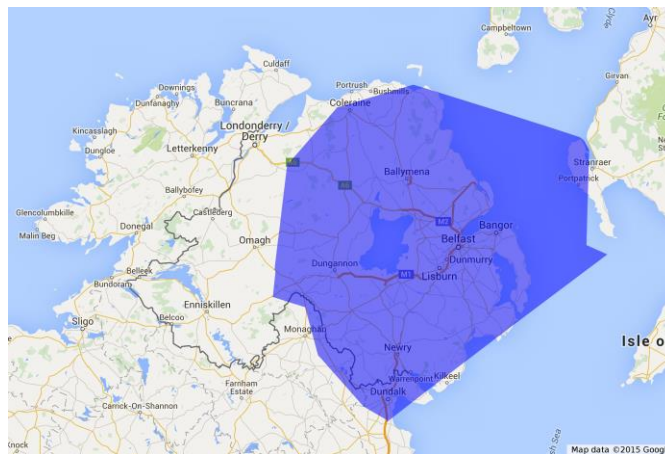


Figure 7. Isochron map of 60 minutes driving time from the Royal Victoria Hospital, Belfast

Mechanism of injury

The vast majority of patients sustained a blunt injury (fig. 8), with only 7% of patients having a penetrating mechanism. Road traffic collisions remain the single largest cause of injury (fig. 9), closely followed by falls from height. Of the 41 road traffic collision incidents, 12 were motorcyclists (29%). Importantly, in those aged 65 years or older, falls from height represent the leading cause of injury (55%).

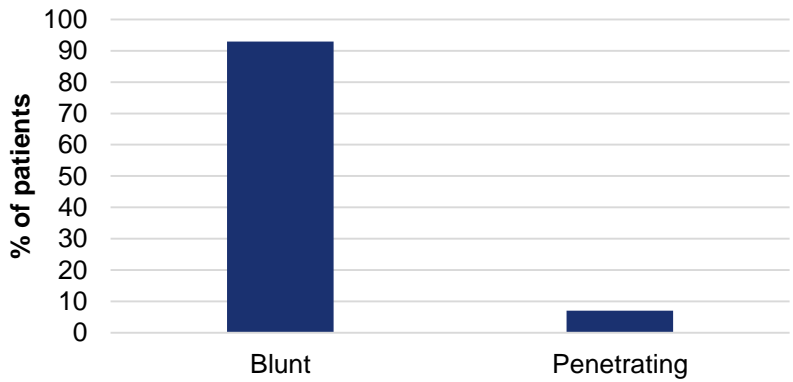


Figure 8. The incidence of blunt versus penetrating trauma

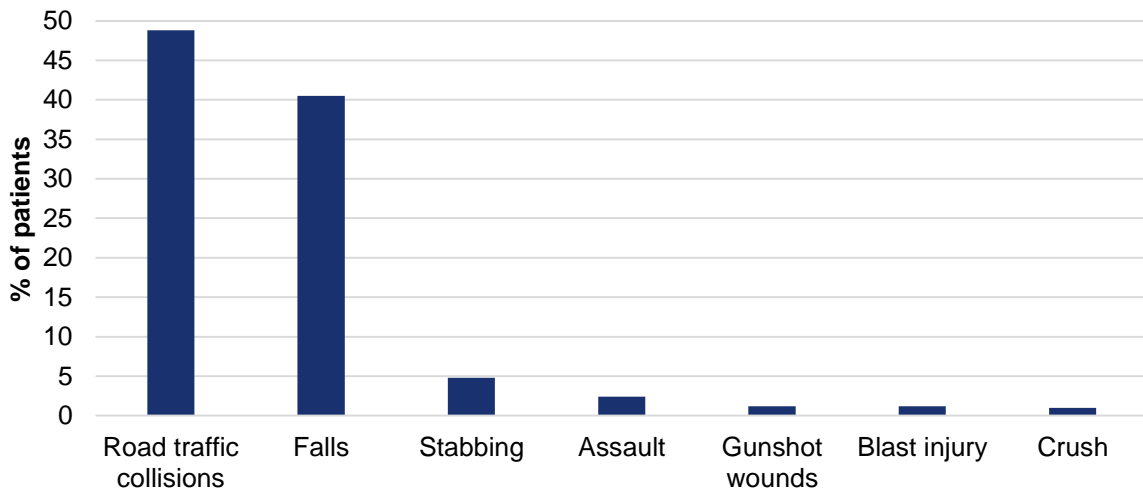


Figure 9. Mechanism of injury

1.3 Pre-hospital Care

Almost all patients, 82 (98%), received some form of pre-hospital care. The majority of which was from a Northern Ireland Ambulance Service (NIAS) paramedic crew (87%). A smaller cohort of patients received a higher level of care at scene, in all cases from a British Association of Immediate Care Society (BASICS) physician (11%). Two patients (2%) self-presented to Emergency Departments.

Where patients received pre-hospital care, the median on-scene time was 24 (17 – 33) minutes. Only 3 patients were transported to hospital by helicopter in this cohort. The median scene to hospital time in those transported by road ambulance was 17 (13 – 29) minutes.

Of the 82 patients attended by NIAS, 59 (71%) were pre-alerted to the receiving Emergency Department. A significant number of patients exhibited deranged physiology in the field; 38% had a GCS < 9, whilst 5 patients were transported in traumatic cardiac arrest.

1.4 Emergency Departments

Nine Emergency Departments submitted data to the audit (all originally planned). The distribution of cases is shown in figure 11. Two hospitals, the Royal Victoria Hospital and Antrim Area Hospital, accounted for 44% of cases submitted. On a trust basis, the Belfast Health and Social Care Trust saw the largest number of major trauma cases, followed by the Northern Health and Social Care Trust (table 1).

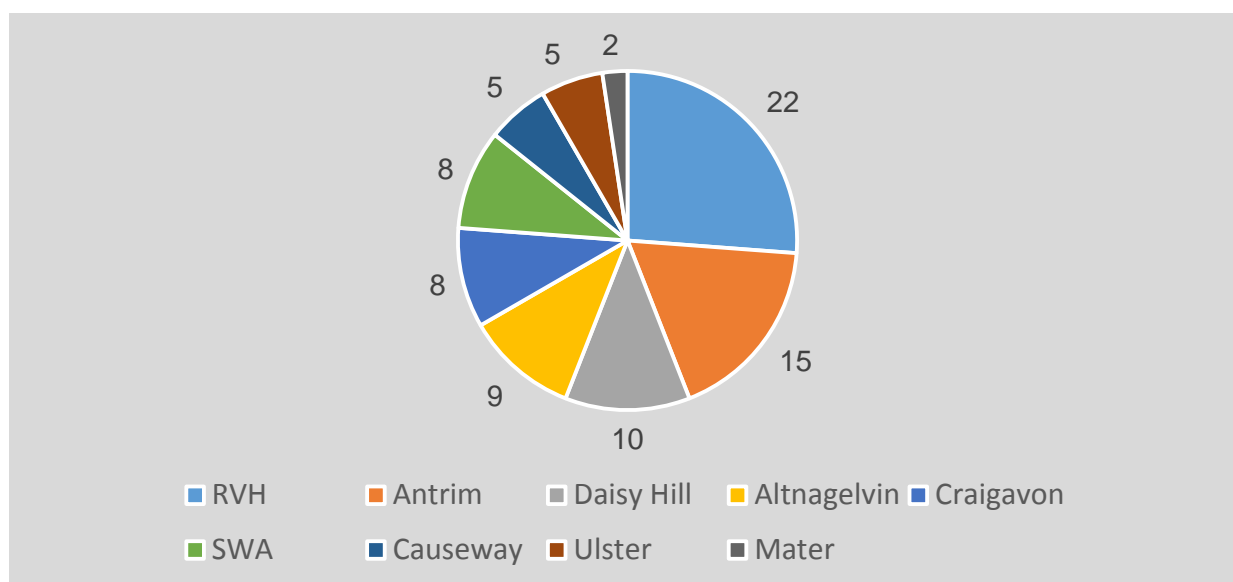


Figure 10. Number of major trauma cases by receiving Emergency Department

HSC TRUST	NUMBER OF CASES	PERCENTAGE OF TOTAL CASES
Belfast HSC Trust (RVH & Mater)	24	28%
Northern HSC Trust (Antrim & Causeway)	20	24%
Southern HSC Trust (Daisy Hill & Craigavon)	18	22%
Western HSC Trust (Altnagelvin & SWA)	17	21%
South Eastern HSC Trust (Ulster)	5	6%

Table 1. Distribution of major trauma cases by Health and Social Care Trust

The majority of patients were received and managed by a consultant in the Emergency Department (66%).

Only two patients were received by a Senior House Officer (fig. 12). Nine patients, managed by a trainee or career grade doctor, presented during core hours (08:00 – 18:00).

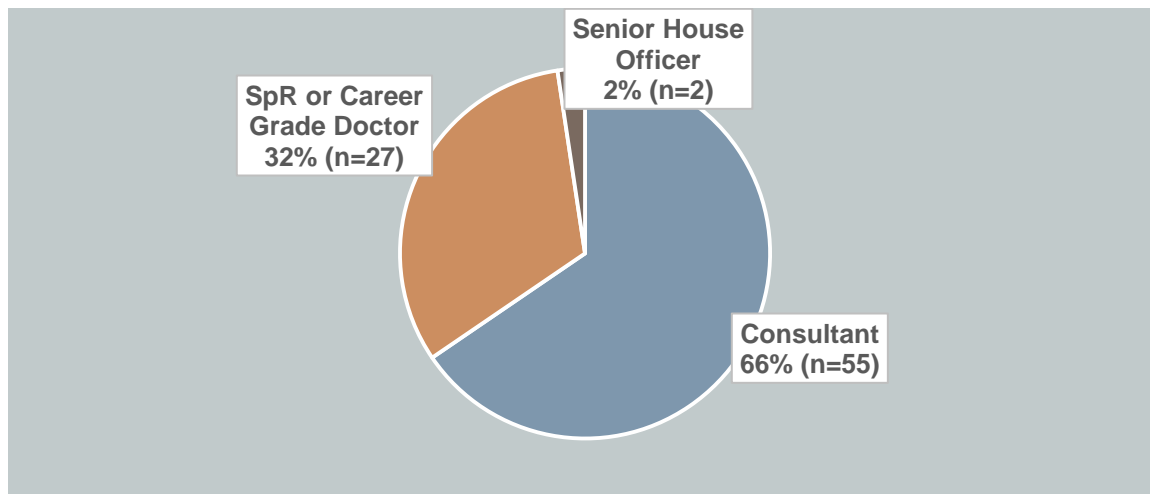


Figure 11. Grade of most senior doctor receiving patient in the Emergency Department

A significant proportion of patients required advanced airway management in the Emergency Department, with 39% of patients undergoing intubation and ventilation. After excluding those with isolated head injury, 46% of patients with multi-system injury received Tranexamic Acid in the Emergency Department.

The median time spent by patients in the Emergency Department was 240 minutes (161 – 377 minutes). This is broken down by Emergency Department in table 2. The longest time spent by a patient in an Emergency Department was 1015 minutes.

Hospital	Number of cases	Median ED Time (IQR)
Royal Victoria Hospital	22	261 (156 – 374) mins
Mater Hospital	2	262 (262 – 262) mins
Antrim Area Hospital	15	268 (215 – 418) mins
Causeway Hospital	5	188 (127 – 239) mins
Daisy Hill Hospital	10	197 (147 – 265) mins
Craigavon Area Hospital	8	262 (169 – 391) mins
Altnagelvin Area Hospital	9	289 (233 – 490) mins
South West Acute Hospital	8	183 (160 – 231) mins
Ulster Hospital	5	331 (267 - 528) mins

Table 2. Number of cases and median time spent in the Emergency Department by receiving hospital

1.5 Imaging

Computed tomography (CT) imaging of trauma patients in the resuscitation phase was carried out in the majority of cases with 74 out of 84 (88%) patients undergoing some form of scanning from the Emergency Department. Of those, 39 (53%) had a whole-body CT. Also of note is the trend away from plain imaging of the cervical spine in the context of head injury. Seventeen patients underwent CT imaging of the head and cervical spine with only 2 patients having an isolated CT scan of the head. Additionally, only 6 patients (7%) in this cohort had plain imaging of the cervical spine in the Emergency Department.

The median time from arrival at an Emergency Department to first CT imaging was 56 (39 – 75) minutes across the cohort. This is presented for individual receiving hospitals in table 3. No patient in this cohort underwent an interventional radiological procedure in the first 24 hours, despite the facility being available at a number of sites.

Of the 45 patients in the cohort with a moderate or severe chest injury (AIS \geq 3), 21 (47%) had a chest radiograph performed in the Emergency Department. Only 12 (14%) patients had pelvic radiographs performed.

Hospital	Number Of Patients Undergoing Ct Imaging	Median Time To First Scan (Iqr)
Royal Victoria Hospital	20	63 (45 – 81) mins
Mater Hospital	2	76 (75 – 76) mins
Antrim Area Hospital	12	54 (50 – 77) mins
Causeway Hospital	5	51 (45 – 91) mins
Daisy Hill Hospital	8	37 (25 – 56) mins
Craigavon Area Hospital	7	61 (44 – 157) mins
Altnagelvin Area Hospital	9	56 (47 – 75) mins
South West Acute Hospital	7	37 (34 – 55) mins
Ulster Hospital	4	55 (43 – 84) mins

Table 3. Median time to first CT scan by receiving hospital

1.6 Surgical Intervention

The rate of emergent surgery in this cohort was less than 20%. In total, 5 emergent laparotomies were performed in addition to 2 throacotomies and 1 combined procedure. All of these patients presented within core working hours (08:00 – 18:00) and all involved both consultant surgical and anaesthetic input. A further 7 emergent neurosurgical procedures were carried out. In contrast all of these patients presented outside of core working hours.

A large number of patients underwent operative orthopaedic intervention after injury. Eight orthopaedic procedures were performed within 24 hours of admission to hospital.

1.7 Critical Care

(Based on the Levels of Critical Care for Adults, Intensive Care Society 2009¹¹).

Of the 84 patients included in the cohort, 25 (30%) subsequently required level 3 care (level 3: Intensive care Unit (ICU)). These patients had a median ICU length of stay of 6 (2 – 19) days. A further 11 patients (13%) required level 2 care (level 2: High Dependency Unit (HDU)), with a median stay of 3 (2 – 6) days. In total, these patients account for 342 critical care bed days. The Regional Intensive Care Unit (RICU) at the Royal Victoria Hospital received 17 direct to ICU transfers from referring hospitals. This represents 28% of all major trauma cases presenting outside of the Belfast HSC Trust in the study period.

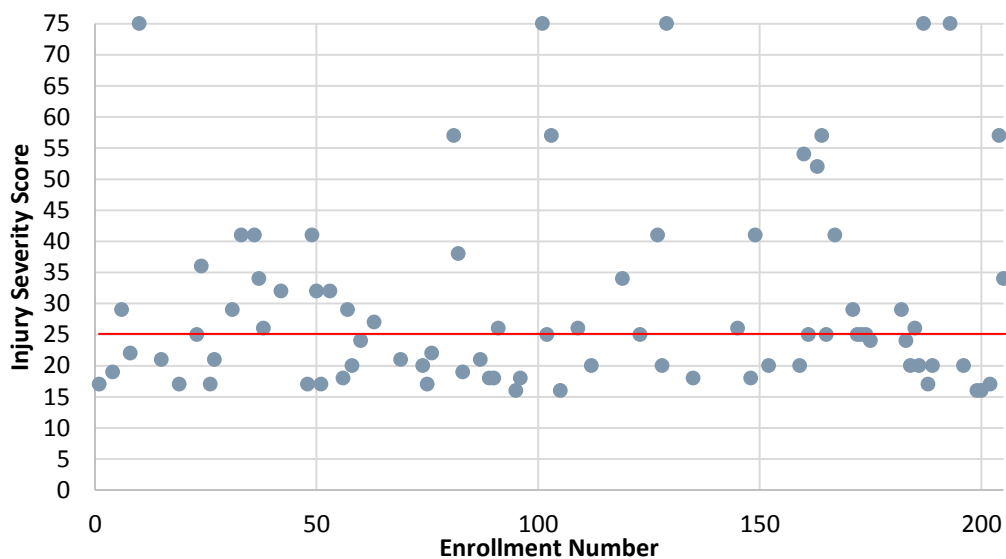


Figure 12. Scattergram of Injury Severity Scores (red line indicates the median value)

1.8 Injury Severity

The median Injury Severity Score⁹ (ISS) across the audit was 25 (20 – 34). The distribution of Injury Severity Scores are shown in figure 13. On review of postmortem studies 3 patients were judged to have sustained an unsurvivable injury and have severity scores of 75. Scattergrams of Abbreviated Injury Scale (AIS) score distributions for head and neck, face, chest, abdomen and extremities are presented below (fig. 13). Of note, 18 patients (21%) presented with isolated severe head injury.

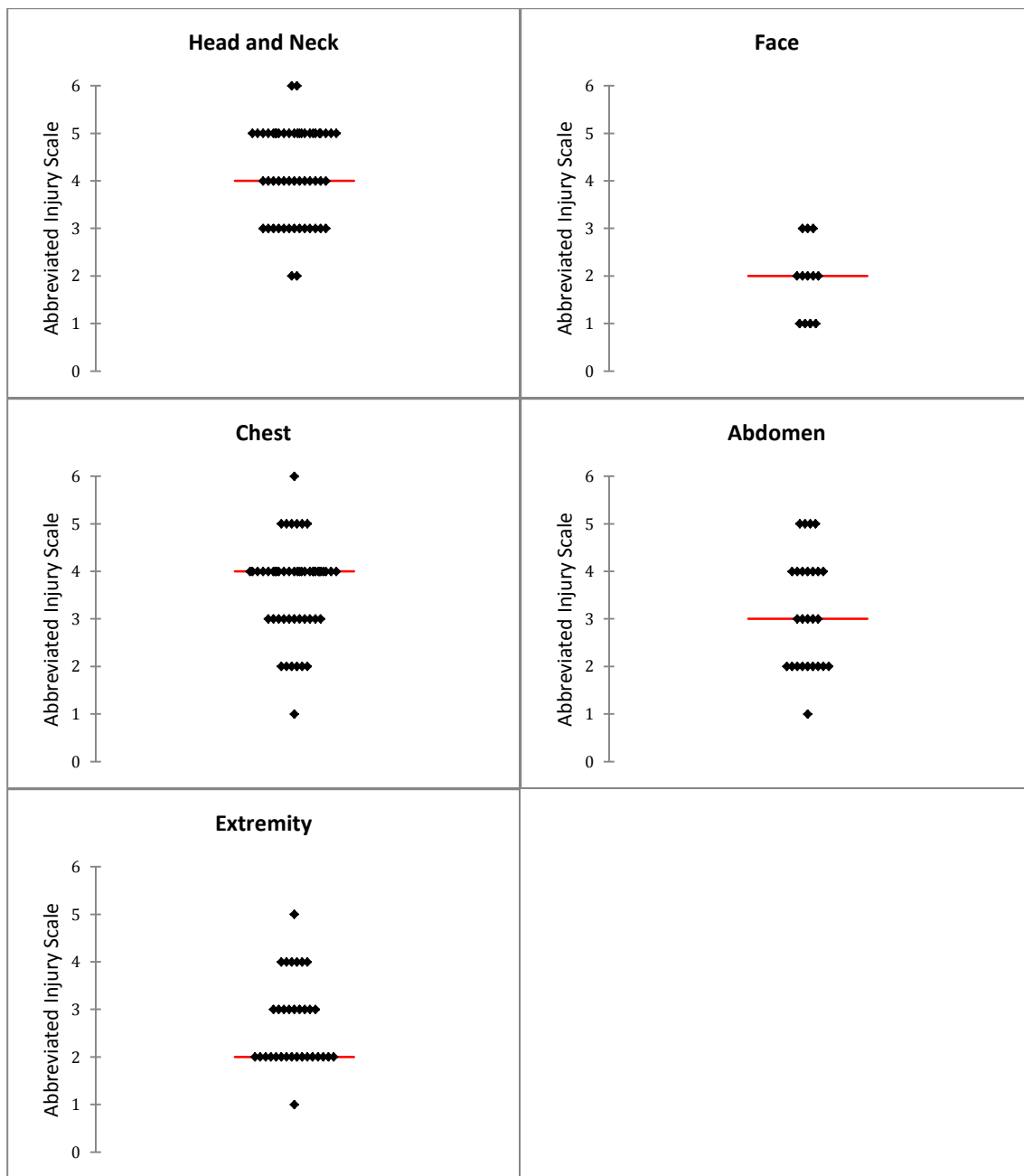


Figure 13. Scattergrams of Abbreviated Injury Scale scores by body area (red line indicates median)

1.9 Hospital length of stay and inter-hospital transfer

The median length of in-patient stay was 14 (7 – 29) days. The longest hospital admission in this cohort was 164 days. These data do not include admissions to the Regional Acquired Brain Injury Unit at Musgrave Park Hospital, Belfast. Analysis extending to the rehabilitation phase was not planned under the pre-defined protocol.

Twenty-seven patients required inter-hospital transfer in this study. As already described, 17 of these transfers were from outside the Belfast HSC Trust to the Regional Intensive Care Unit at the Royal Victoria Hospital, Belfast. Of those transferred to RICU, 10 had a severe head injury (AIS \geq 3). A further 7 patients were to non-critical care beds at the Royal Victoria Hospital; 5 patients to the fractures service (one of these after a prior transfer from Causeway Hospital to Altnagelvin) and 2 patients to neurosurgical beds.

Two critical care transfers occurred outside of the Belfast HSC Trust, one patient from Daisy Hill Hospital to Craigavon and one patient from the South West Acute Hospital to Altnagelvin. One patient was transferred as an in-patient from the Royal Victoria Hospital to the Ulster Hospital for maxillofacial surgery.

In sum, 40% of all patients initially received in Emergency Departments outside of the Belfast HSC Trust required secondary transfer to the Royal Victoria Hospital. Some 32% of all patients sustaining major trauma required at least one secondary movement. The vast majority of which were critical care transfers (70%).

1.10 Mortality

There were 21 deaths in the cohort, giving a crude all-cause mortality of 25%. Eleven patients died in the Emergency Department, 5 of whom presented in traumatic cardiac arrest. Four patients died within the first 24 hours of admission and 2 more within 72 hours. Three patients died within the first week of admission and one final patient died within 2 weeks. Amongst fatalities, two-thirds had a very severe head injury (AIS \geq 5). Only one patient died after having undergone emergency surgery.

2.0 Audit standards

Compliance against audit standards is set out below (table 4).

No.	Description	Compliance	Compliance standard
1	All Major Trauma Patients should have a pre-alert provided by the pre-hospital care service to the receiving unit	71%	95%
2	All Major Trauma Patients should be received and managed by a Consultant in the Emergency Department	66%	95%
3	Computed tomography (CT) imaging of the head should be performed within 1 hour of the request	60%	95%
4**	On-call consultant radiologists should provide the final report on the major trauma patient within 1 hour of CT image acquisition	NA	NA
5	Patients with signs of shock (SBP < 90 on attendance, Lactate >4 mmol/L) and an abdominal injury AIS ≥ 3 should have a laparotomy commenced and/or an abdominal/pan CT scan within one hour of attendance	33%	95%
6	Patients with severe head injury (AIS ≥3) should be transferred (if no onsite availability) to a setting with 24-hour on-site access to NICU, regardless of whether they require surgical intervention	46%	90%
7	Patients with open limb fractures should be surgically managed by a consultant orthopaedic and/or plastic surgeon within 24 hours of attendance	100%	95%
8	Patients with unstable pelvic fractures should have a pelvic binder applied within 30 minutes of attendance	85%	95%
9	The management of patients with spinal injuries AIS ≥ 3 should be referred/discussed with the Spinal Injuries service before leaving the first receiving ED	100%	95%
10**	The rate of survival amongst major trauma patients, calculated using an appropriate methodology, should be no less than a suitable UK comparator	NA	NA

Table 4. Compliance against audit standards

**Note. Standard 4 is omitted from the report due to incomplete data. Standard 10 is omitted from the report due to the limitations outlined in the methodology.

Discussion and Conclusions

The data presented in this report is the first publically available information on the epidemiology and outcome of major trauma in Northern Ireland since 2004. To the best of our knowledge it also represents the only systematically collected prospective regional data available. Prior to discussing the implications of this data it would seem wise to discuss weaknesses in the audit.

Limitations

Although the audit was conducted *per protocol* the planned one-year duration of data collection was not achieved. Beyond a simple reduction in the sample size this poses several problems. The most important factor and perhaps the most difficult to adjust for is the seasonal variation in the incidence of major trauma. This variation alters with individual mechanisms having different seasons for peak incidence. This is almost impossible to correct for. A large data set and in truth data from several years is required to properly and fairly examine mortality as an outcome. It is with this in mind that we have not used this data to comment on mortality or survival beyond a brief and crude description. As some hospitals have contributed relatively low numbers we have not compared measures on a hospital by hospital basis unless clinically and/or statistically relevant.

This audit is party to all of the limitations of trauma registries and large audit projects, including the limitations of a definition of major trauma based on an injury severity score, incomplete data and the difficulties in ensuring total patient capture. Despite these limitations the audit retains a number of strengths and the majority of the areas examined have produced reliable data

Discussion

Several publications, including the recent Deloitte HEMS report¹², have attempted to produce estimates of the annual number of patients sustaining major trauma (ISS >15) in Northern Ireland. These papers have quoted a number in excess of 500. A very simple and crude extrapolation of our data produces a figure of 254 patients per year. There are few good estimates of the incidence of major trauma by an ISS definition in the literature¹³. One

example is a paper from Northern Ireland, published in 1995 on a 1990 – 1991 dataset, describing an incidence of 23.2 cases per 100,000 population¹⁴. Another UK cohort, reported on at a similar time, gave an estimate of 19 cases per 100,000¹⁵. Most recently, the Scottish Trauma Audit Group (STAG) have provided data from 2012 which would give Scotland a crude incidence of around 14.1 cases per 100,000 population¹⁶.

Method	Incidence (per 100,000)	Estm. cases per year in NI
McNicholl et al. (1995), Northern Ireland	23.2	431
Gorman et al. (1995), Wales	19.0	352
Scottish Trauma Audit Group (2012), Scotland	14.1	262
Northern Ireland Trauma Audit (2014), extrapolation	13.6	254

Table 5. Published estimates of the incidence of major trauma (ISS >15), with a projection based on the current population of Northern Ireland [1,856,168 (2015)]

This analysis suggests that estimates in excess of 500 cases per year can reasonably be discounted. Furthermore, given the decline in the number of road traffic fatalities and the end of the troubles, it seems sensible to conclude that 400 cases per year appears to represent a significant overestimate.

Data from both TARN¹⁷ and STAG¹⁸ are broadly consistent with the age and gender make up in our audit. TARN have reported a mean age of 54 years in 2013 which compares to 47 years in our cohort, whilst STAG report a median age of 50 years in 2013/14 which compares to 46 years in our cohort. Similarly, both TARN and STAG complement our suggestion that the trauma population is aging. In 2013, TARN reports that 27% of patients were aged over 75 and in 2013/14 25% of the patients in the STAG dataset were aged over 70. NITA reports that 27% of patients were aged over 65. Males predominate in our data set, as they do in the large TARN and STAG cohorts, accounting for 76%, 68% and 70% respectively.

Not only is the age profile changing but the leading causes of injury also appear to have changed. In our cohort falls caused 40% of all injuries. This compares to 39% in the recent TARN publication¹⁷. In what would appear to be a linked phenomenon, the majority of major trauma patients in our cohort presented in normal working hours, with only 25% of patients arriving to an Emergency Department after midnight and before 08:00. As would be expected there is little variability in weekdays but a spike clustered in the early hours of Sunday mornings.

The spatial distribution of trauma in this audit is likely to be of interest to many, although the analysis is limited by incomplete incident postcode data (n=61 cases with incident location information out of 84 cases). Despite this it is clear that in the current configuration of services, scene to hospital time is short, on average 17 minutes (for those conveyed by ambulance). The median call to hospital time is also reasonably placed at 59 minutes. Within the limitations of our mapping technique it appears that a large proportion of the population are injured within a conceivable 60 minutes driving time of the Royal Victoria Hospital, Belfast. This work requires further exploration and validation. The rate of pre-alert is broadly similar to that reported by STAG in 2014, 71% vs. 70%. There was little variation by receiving hospital.

It is notable that over 1 in 10 major trauma patients had benefited from the input of a pre-hospital care physician at the scene of injury. This work is conducted in Northern Ireland in large part by BASICS (known as British Association for Immediate Care), a volunteer organisation.

It is worth noting that distribution of cases by hospital is spread out across several sites. By trust area, the Belfast, Northern, Southern and Western Health and Social Care Trusts see broadly similar numbers of major trauma patients, with a smaller number in the South Eastern area. It is worth noting that some historical locally agreed bypass protocols are in operation between the Northern Ireland Ambulance Service and some hospital's which may influence the distribution of patients, particularly between the Belfast and South Eastern Health and Social Care Trusts.

Less encouraging is the average time spent by a major trauma patient in the Emergency Department. A median time of 240 minutes is concerning to the authors, especially given the third quartile extends to 370 minutes. These findings require investigation and validation. Within Emergency Departments further work is also required to identify reasons for the low uptake in the use of tranexamic acid in these patients which was below 50% across the cohort.

With regards to imaging in the acute phase of major trauma the data presents a mixed picture. There has clearly been a high take up of whole body CT and it is reassuring to note the easy availability of imaging across all hospitals. As regards to the average time it takes for a patient to get to CT, whilst many Major Trauma Centres in mainland Great Britain have taken impressive steps to reduce this figure, the times presented here are not without that which would be recognisable to other hospitals receiving trauma patients in the UK.

The rate of inter-hospital transfer, particularly to specialist neurosurgical, orthopaedic and critical care services in the Royal Victoria Hospital was high. For every five patients presenting outside of Belfast after major trauma, two will require transfer to the Royal Victoria Hospital early in their journey. Whilst a number of individual services have highlighted this in the past, this appears to be the first time that this has been documented across the whole system. Particular recognition must be made of the burden that this places on the Regional Intensive Care Unit.

The severity of injury (median ISS 25) in this cohort is perhaps a little higher than expected and it is the author's contention that this likely represents some unidentified patients at the lower end of the spectrum, especially isolated head injury in the elderly. Isolated head injury is an especial feature of this cohort with those sustaining an isolated severe head injury (AIS \geq 3) being older by a decade than the whole (58 years vs. 47 years). The median length of stay compares to that reported by STAG in 2013/14, 14 days vs. 17 days. Of note are the 342 critical care bed days accounted for by just 73 patients.

The limitations of this analysis have already been clearly stated, although it is worth reiterating the cautionary note on the interpretation of crude mortality rates in such a small sample.

Conclusions

Despite the limitations of the audit, which have been discussed, this is a robust study of major trauma patients from injury to hospital discharge. This information can assist those undertaking the design of a regional trauma network for Northern Ireland. We are reassured, that in large part our findings mirror those of much larger and well established trauma registries in the UK. We have highlighted the importance of an ageing trauma population and the challenges of changing mechanisms of injury. It is worth noting that in respect of motorcyclists and major trauma, professional racing may account for a disproportionate number of cases. We are reassured by the low incidence of penetrating trauma in our community.

This report highlights areas of interest which require further examination in the near future. We have suggested that the majority of patients could be taken directly to a Major Trauma Centre (if it is designated as the Royal Victoria hospital), within an acceptable time frame, this clearly requires development. We have noted the long periods that patients appear to remain in Emergency Departments; it is of importance that this is addressed. We have also documented the high rate of inter-hospital transfer and the burdens this places on a number of services.

In summary, there is much in this report for clinicians and services to be proud of and clearly a number of areas of good practice which can be further developed within the context of a regional trauma system. There are also areas which require improvement. It is equally clear that several of these would be addressed within a high functioning system.

Recommendations

- Northern Ireland should begin to submit data on trauma patients to the Trauma Audit Research Network (TARN) at the earliest opportunity. This should occur independently of the continuing development of a regional trauma network.
- Within this process, Northern Ireland should retain the ability to present and analyse this data on a regional basis. This may be achieved by retaining the Northern Ireland Trauma Audit (NITA) entity under the auspices of a regional trauma network.
- Data generated by the measures above, in addition to the data presented in this report, should be used to direct the process of developing a regional trauma network. It is important that any design be based on the best available local data.
- Thought should be given to how a public health approach could be used to influence two epidemiological trends noted in this report, namely, the high incidence of falls amongst older trauma patients and the disproportionate number of motorcyclists involved in road traffic collisions.
- The Northern Ireland Ambulance service, in conjunction with other stakeholders, should take forward more detailed work on the spatial distribution of trauma patients. This work would be invaluable in informing the design of a network.
- Efforts should be directed to improve patient access to advanced pre-hospital care. A public consultation examining the potential for a helicopter based pre-hospital care service is ongoing. The data presented as part of this report should be carefully examined as part of that process.
- Regionally, work should be conducted to identify why the average time spent by major trauma patients in Emergency Departments is so long and to set out ways in which this may be improved.
- All hospitals currently receiving major trauma patients should seek to identify areas of care where protocolisation may improve standards and performance. Suggested themes include, common documentation, the management of major haemorrhage and trauma imaging. Collaboration between trusts may be useful in developing regional protocols/ guidelines and policies.
- The issues associated with the inter-hospital transfer and repatriation of major trauma patients should be addressed at a system level. This report highlights the large number of transfers across the system which have previously been described at a service level.

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In addition to the expert panel members and their deputies we received valuable comment and input via email from various specialties including Neurosurgery and Trauma and Orthopaedics.

NITA

Northern Ireland Major Trauma Audit
Protocol

March 2014



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Document History

Version	Date	Comment	Author(s)
V 1.1	01.05.2012	Draft	JM
V 1.2	20.11.2012	Draft	JM
V 2.1	07.07.2013	Draft	JM
V 3.1	16.02.2014	Draft	JM
V 4.1	27.03.2014	Final	JM

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1. Introduction

1.1 Background

Trauma kills 16,000 people in the United Kingdom every year¹. The majority of these deaths are amongst young people, with trauma being the leading cause of death in those aged under 40². For each of these deaths two further people face permanent or serious disability³. This represents a significant public health challenge, yet there has been no discernible improvement in outcome after serious injury since 1994⁴.

This fact has since been recognised by the NHS in England & Wales, which has developed a process of system redesign and quality improvement, centred on the creation of regional trauma networks. Evidence from across the globe suggests that the implementation of these networks may reduce mortality by at least 15%⁵.

Recently, stakeholders within Northern Ireland have expressed a desire to examine the provision of care for the seriously injured with a view to designing a regional equivalent of the trauma networks being established in England & Wales.

1.1.1 What is Trauma/Major Trauma?

Trauma is a disease. It has its own epidemiology, prevention, pathology, management, investigation, treatment and rehabilitation.

Annually trauma affects 135 million people around the world, killing 5.8 million and leaving 50 million moderately or severely disabled⁶. Importantly it is one of the few diseases for which mortality is increasing^{7,8}. The annual cost associated with managing trauma in the UK is estimated at £1.6 billion, representing ~7% of the NHS budget⁹.

The term 'trauma' may describe any form of injury e.g. a fractured ankle or a lacerated arm, whereas major trauma describes those with injuries which may cause death or severe disability. This is not to say that more moderate injury in certain groups, or particular injuries requiring specialist management, may not also represent major trauma¹⁰.

For the purposes of research and governance, major trauma is defined as an Injury Severity Score (ISS) >15¹¹. This is a useful measure, which is calculated by scoring and summing patient's individual injuries. Unfortunately it is retrospective and therefore clinically unhelpful.

The incidence of major trauma (ISS>15) is estimated at 27-33 patients per 100,000 population per year¹². In Northern Ireland we do not know what this figure may be due to the lack of available data.

1.1.2 What is a Regional Trauma System?

The concept of a regional trauma system is based on the public health model. The system exists to manage all available resources in a co-ordinated and focused manner for a particular population. The system includes pre-hospital care, injury prevention programmes, acute hospitals, the major trauma centre and other functions such as education, research, governance and rehabilitation.

Major trauma patients are treated in the major trauma centre, whilst less severely injured patients are managed by acute hospitals (trauma units). In order for this to work there must be a robust triage tool in place, with the addition of protocols for inters hospital transfer. At the other end of the continuum, in the rehabilitation phase, the ability to repatriate patients from the major trauma centre or trauma units must also exist.

Quality in the system is driven by education, research and a performance improvement programme, which must be mandated to implement change where necessary.

Two general formats of trauma system exist, inclusive and exclusive. Exclusive systems rely on the designation of a major trauma centre to which all trauma patients are bypassed. Inclusive systems are designed around a hub and spoke model. The major trauma centre (MTC) acts as the hub with smaller trauma units (TU) at the ends of the spokes. Both systems have been demonstrated to produce a mortality benefit, although inclusive systems appear to do it better¹³.

1.1.3 Historical Perspective

In the modern era, the development of civilian trauma systems began in the 1960's. The first examples of trauma centres were established in 1966 in Chicago and San Francisco¹⁴. Change continued to occur principally in the United States, with the first legal structure for trauma centre designation being established in Illinois in 1971¹⁵. By this time similar systems began to emerge in Europe, notably in Germany. In 1975 road traffic accidents in that country were responsible for approximately 18,000 deaths. After the introduction of a state wide trauma system that figure fell to around 7,000¹⁴.

Over the last 40 years, a 'systems' based approach to managing the severely injured has become common practice in a number of countries. This model has been consistently proven to reduce morbidity and mortality.

Unfortunately the pace of change in the UK has been much slower. In 1998 the Royal College of Surgeons (RCS) issued the first in a series of highly critical reports into trauma care in the

UK. Despite some early improvements following this publication, no reduction in mortality following major trauma was observed between 1994 and 2000⁴.

In 2000 the RCS, in conjunction with the British Orthopaedic Association (BOA), produced a further report entitled, 'Better Care for the Severely Injured'¹⁶. This continued to call attention to the poor standards of care apparent in the UK.

By 2006 a National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report was commissioned. This report, 'Trauma: Who Cares?'² was damning, citing that, in the cases examined by them 60% of patients received a standard of care which was defined as 'less than good practice'. A further report by the National Audit Office (NAO) into trauma care in England, published in 2010, estimated that mortality was 20% higher for major trauma patients in the UK than those in the US¹⁷.

Prior to the NAO report, a move towards change had already begun in England and Wales. In many regards London has led the way, the Framework for Action report, published in 2007, identified improvement in major trauma care as a priority for the capital¹⁸. This has since developed into the UK's first fully operational major trauma system.

1.2 Rationale

In order to develop and deliver better care for the severely injured it is essential to understand the regional epidemiology of major trauma, the standard and quality of care that is currently delivered and the likely resource implications of any future change. A regional audit which captures and examines each major trauma patient from injury to discharge represents the most comprehensive and efficient means of providing this information.

2 Audit Objectives

2.1 Primary Objectives

The primary objective of the audit is to establish and then compare the rate of survival amongst major trauma patients within NI against the UK average, as determined by the TARN database.

2.2 Secondary Objectives

The audit aims to achieve a number of secondary objectives;

1. To audit current practice against a number of national recommendations, widely felt to represent quality within a trauma system (principal audit standards).
2. To audit current practice against a number of process based indicators of quality (secondary audit standards).
3. To establish the epidemiology of major trauma within Northern Ireland.
4. To establish the temporal and spatial distribution of major trauma within Northern Ireland.
5. To establish the institutional capacity for managing major trauma.

3 Audit Description

NITA is designed to run for one calendar year across all acute hospitals within NI. It aims to capture all major trauma patients at entry to the system, whether that be in the pre-hospital arena or on presentation to an Emergency Department.

3.1 Design

Prospective, multi-centre, multi-specialty audit.

Two components;

1. Prospective patient data collection/case note review
2. Institutional questionnaire

3.2 Participating Hospital/Services

- Northern Ireland Ambulance Service
- Belfast Health and Social Care Trust
 - Royal Victoria Hospital
 - Mater Hospital
- South Eastern Health and Social Care Trust
 - Ulster Hospital
- Southern Health and Social Care Trust
 - Craigavon Area Hospital
 - Daisy Hill Hospital
- Western Health and Social Care Trust

- The South West Acute Hospital
- Altnagelvin Hospital
- Northern Health and Social Care Trust
 - Antrim Area Hospital
 - The Causeway Hospital

4. Audit Methods

4.1 Subject Selection

The target population is adult patients suffering from serious multi-region injury or complex single region injury. This may be defined by an Injury Severity Score (ISS) ≥ 16 . As ISS is a retrospective measurement, the following inclusion and exclusion criteria will be used to determine initial eligibility.

4.1.1 Inclusion Criteria

- All Trauma Patients aged ≥ 16 years
- Who fulfil the following length of stay criteria;

Admissions whose length of stay is ≥ 72 hours
OR
Patients admitted to a critical care setting, regardless of length of stay
OR
Deaths of patients occurring in hospital, including the Emergency Department
OR
Patients transferred to another hospital for specialist care or to a critical care bed

Patients matching the descriptors above will be screened against the exclusion criteria.

4.1.2 Exclusion Criteria

- Injuries older than 1 week
- Isolated burn injuries
- Isolated smoke inhalation
- Death or injury caused exclusively by asphyxiation, such as hanging or drowning, with no anatomical injury

- Hypothermia in isolation

The following are excluded when occurring in isolation;

- Lacerations, puncture wounds or bites with no underlying injury
- Loss of consciousness where not accompanied by brain injury or fracture
- Simple or stable facial fractures
- Neck of femur, Intertrochanteric, Subtrochanteric or Greater Trochanteric Femur fractures in those aged ≥ 65 years
- Foot or hand fractures, multiple or open
- Closed unilateral limb fractures or dislocations
- Single pubic rami fractures in those aged ≥ 65 years

4.2 Procedures and Measurements

4.2.1 Patient Identification

Patient identification will occur at the first receiving Emergency Department. Departments will screen all patients presenting after injury. Those patients, who are admitted to hospital, are transferred to a second unit or die in the department will be allocated a unique identifier.

The audit co-ordinator will be responsible for collating weekly returns from each department for further follow-up.

Weekly returns will be initially screened against the study inclusion and exclusion criteria. Those that are ineligible for inclusion will be removed from the process at this point.

4.2.2 Tracking

Patients admitted to the first receiving hospital or transferred to a second institution will retain their unique identifier as part of their in-patient notes.

If the patient is subsequently transferred or dies within 30 days, the responsible in-patient team will be prompted to inform the audit co-ordinator.

If the patient is discharged before 30 days, the responsible in-patient team will be prompted to inform the audit co-ordinator.

4.2.3 Follow-up

At day 30 post admission the audit co-ordinator will begin the follow up process for each patient.

If the patient has been discharged or has died prior to this date, in-patient notes will be requested for screening and data extraction.

If the patient remains in hospital a site visit will be made by the audit co-ordinator in order to undertake screening and data extraction at this point.

4.2.4 Analysis and Scoring

All patients identified, who pass screening against the inclusion and exclusion criteria, will be included in the audit. Retrospective extraction of prospectively collected data will be performed using in-patient notes and relevant electronic clinical systems. This information will be compiled using a standardised proforma. Patients identified for inclusion in the audit will have their records anonymised on the proforma.

Audit proformas will be held centrally and inputted into an existing database to facilitate analysis and injury severity scoring.

4.3 End-point Management

4.3.1 Primary Audit Standards

1 All Major Trauma Patients should have a pre-alert provided by the pre-hospital care service to the receiving unit.

Evidence

'Ambulance trusts and emergency departments should have clear guidelines for the use of pre-alerts in the severely injured patient population. The ambulance crew should be able to speak directly to clinical staff in the receiving emergency department to ensure an appropriate clinical response is available immediately.'

NCEPOD, 2007

Target: 95%

2 All Major Trauma Patients should be received and managed by a Consultant in the Emergency Department.

Evidence

'A consultant must be the team leader for the management of the severely injured patient.'

NCEPOD, 2007

Target: 95%

3 Computed tomography (CT) imaging of the head should be performed (that is, imaging carried out and results analysed) within 1 hour of the request having been received by the radiology department in those patients where imaging is requested because of any of the risk factors listed:

- GCS less than 13 on initial assessment in the emergency department
- Suspected open or depressed skull fracture
- Any sign of basal skull fracture
- More than one episode of vomiting
- Post-traumatic seizure
- Coagulopathy
- Focal neurological deficit

Evidence

NICE Clinical Guideline 56, Head Injury, 2007

Target: 95%

4 On-call consultant radiologists should provide the final report on the major trauma patient within 1 hour of CT image acquisition.

Evidence

Royal College of Radiologists, Standards of practice and guidance for trauma radiology in severely injured patients, 2010

Target: 95%

5 Patients with signs of shock (SBP < 90 on attendance, Lactate >4 mmol/L) and an abdominal injury AIS ≥ 3 should have a laparotomy commenced and/or an abdominal/pan CT scan within one hour of attendance.

Evidence

'An immediate response from a senior general surgeon of sufficient experience to perform life-saving emergency laparotomy is essential'

RCS/BOA, Better care for the severely injured, 2000

Target: 95%

6 Patients with severe head injury (AIS ≥3) should be transferred (if no onsite availability) to a setting with 24-hour on-site access to NICU, regardless of whether they require surgical intervention.

Evidence

'All patients with severe head injury should be transferred to a neurosurgical/critical care centre irrespective of the requirement for surgical intervention'

NCEPOD, 2007

Target: 90%

7 Patients with open limb fractures should be surgically managed by a consultant orthopaedic and/or plastic surgeon within 24 hours of attendance.

Evidence

'All patients with high energy open fractures should receive the following care; ...soft tissue and bone excision (debridement) is performed by senior plastic and orthopaedic surgeons working together on scheduled trauma operating lists within normal working hours and within 24 hours of the injury'

BOA/BAPRAS Indicators for the Management of Open Lower Limb Fractures, 2009

Target: 95%

8 Patients with unstable pelvic fractures should have a pelvic binder applied within 30 minutes of attendance.

Evidence

Expert opinion and BOAST 3, 2008

Target: 95%

9 The management of patients with spinal injuries AIS \geq 3 should be referred /discussed with the Spinal Injuries service before leaving the first receiving ED.

Evidence

'Immediate referral must be made to the appropriate spinal injury service if there is evidence of partial or complete spinal cord or cauda equina lesion'

RCS/BOA Standard 13.5

Target: 95%

10 The rate of survival amongst major trauma patients, calculated using an appropriate methodology, should be no less than a suitable UK comparator.

Evidence

Expert Opinion

4.3.2 Process Data

Pre-hospital

1. Time spent at scene
2. Transport time
3. Pre-hospital care interventions
4. Level of care at scene

Emergency Department

5. Time spent in Emergency Department
6. Emergency Department interventions (including use of point of care ultrasound)

7. Emergency Department initial observations
8. Emergency Department attendants

Imaging

9. Plain imaging – region
10. Plain imaging – time
11. CT imaging – region
12. CT imaging – time
13. Interventional radiology – procedure
14. Interventional radiology – time

Operations

15. Operation – procedure
16. Operation – start time/date
17. Operation – end time/date
18. Operation – grade of surgeon
19. Operation – grade of anaesthetist

Critical Care

20. Length of stay
21. Ventilator days

Ward

22. Length of stay

Transfusion

23. Use of a massive transfusion protocol
24. PRBC – Number and timing
25. FFP – Number and timing
26. Platelets – Number and timing
27. Cryoprecipitate – Number and timing
28. Synthetic products – Number and timing

4.3.3 Epidemiological Data

1. Distribution by gender
2. Distribution by age
3. Mechanism of injury
4. Injury intent
5. Injury Severity Score
6. Crude and standardised mortality rates

4.3.4 Temporal/Spatial Data

1. Location of injury
2. Daily activity
3. Weekly activity
4. Monthly activity

5. Regulatory, Legal and Ethical Considerations

5.1 Regulatory Considerations

5.1.1 GAIN

GAIN will act as the audit Sponsor. The audit will progress in accordance with GAIN standard operating procedures. The decision to approve, continue or terminate the audit rests with the Sponsor. Any subsequent change to the audit protocol must have prior approval from the Sponsor.

5.1.2 Trust Audit Approval

Approval and assistance shall be sought from the relevant audit departments in each participating Health and Social Care Trust. Statistical advice and support for the audit will also be sought from the Clinical Research Support Centre.

5.1.3 Audit Management Committee

The Audit Management Committee (AMC) will be set up by the NITA Chair. The AMC will convene on a bi-monthly basis and will discuss the progress and other practical aspects of the audit.

The day-to-day management of the audit will be co-ordinated through the audit co-ordinator and lead investigator.

5.2 Ethical Considerations

No ethical approval is required for this audit.

5.3 Legal Considerations

5.3.1 Data Protection

The audit co-ordinator will preserve the confidentiality of patient identifiable data in accordance with local standard operating procedures.

No documents submitted for analysis will be identifiable, subjects will be identified by a subject ID number only. Documents that are not anonymized should be kept in a strictly confidential file by the lead investigator.

The investigator shall permit direct access to subjects' records and source documents for the purposes of monitoring, auditing, or inspection by GAIN.

6. Administrative Considerations

6.1 Data Collection and Input

Data collection and input is the ultimate responsibility of the principal investigator. Collection will be principally performed by the audit co-ordinator with appropriate clerical support. Data input will be provided by a clerical support officer.

6.2 Quality Assurance

A monitoring plan will be devised and described in detail in the audit manual by the audit co-ordinator. Audit Monitors will visit all sites where the audit will take place to ensure compliance with the protocol and to ensure local regulatory adherence. Communication with sites by telephone, mail and email will also be made as necessary. Training sessions will be organised for all site staff at the beginning of the audit and then as appropriate. The approved version of the protocol should be followed at all times.

6.3 Publication Policy

All publications and presentations relating to the audit will be authorised by the Audit Management Group. Authorship will be determined according to the internationally agreed criteria for authorship (www.icmje.org).

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