FACTORS INFLUENCING OUTCOMES OF SEVERELY INJURED CHILDREN IN A SOUTH AFRICAN CONTEXT

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DECLARATION

I, Heinrich Pieter Koekemoer declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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ABSTRACT

INTRODUCTION

Paediatric trauma is a significant health burden and a leading cause of death among children in South Africa and globally.

OBJECTIVE

To determine the factors influencing the outcomes of severely injured children in a South African context.

METHODS

A retrospective study on factors influencing mortality in a paediatric cohort (≤ 14 years) admitted to the intensive care units of two hospitals in Gauteng, South Africa, from 1 January 2006 to 31 December 2013 after suffering major trauma (ISS>10).

RESULTS

The total cohort (n=166) consisted of public (n=125) and private (n=41) cohorts with actual death 15.7% (n=26) of the total cohort. There was a significant difference in probability of survival in survivors (92%) versus deaths (82%) (p=0.004). Factors that influenced the risk of mortality included time spent in the paediatric ICU [odds ratio of 0.706 (95% CI, 0.544-0.915)] and whether a patient received public or private care [odds ratio of 5.43 (95% CI, 1.178-25.012)]. Both the Injury Severity Score (p=0.004) and Revised Trauma Score (p=0.034) systems played a significant role in the ability to predict mortality.

CONCLUSION

The outcome of severe paediatric trauma is influenced by multiple factors. The strongest predictors of mortality according to this study are time spent in PICU and the private health sector; numerous limitations of this study require replication with much larger data sets using paediatric specific trauma outcome scores.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

ActDeath: Actual death

AIS: Abbreviated Injury Score

ALS: Advanced Life Support

ATLS: Advanced Trauma Life Support

BLS: Basic Life Support

CMJAH: Charlotte Maxeke Johannesburg Academic Hospital

Dr: Doctor

EDTime: Time spent in emergency department

FFH: Fall from Height

GCS: Glasgow Coma Scale

HEMS: Helicopter Emergency Medical Service

HR: Heart Rate

ILS: Intermediate Life Support

ISS: Injury Severity Score

LOCa: Level of care

MVC: Motor Vehicle Collision

PHC: Pre-Hospital Care

PHT: Pre hospital time

PICU: Paediatric Intensive Care Unit

PICUt: Time spent in Paediatric Intensive Care Unit

Ps: Probability of survival

PVC: Pedestrian Vehicle Collision

RR: Respiratory Rate

RTS: Revised Trauma Score

SBP: Systolic Blood Pressure

SD: Standard Deviation

TRISS: Trauma score - Injury Severity Score

1.0 INTRODUCTION

Paediatric trauma resulting in severe injuries is a worldwide phenomenon. An injury is defined as "the physical damage that results when a human body is suddenly subjected to energy that exceeds the threshold of physiological tolerance" (1).

The World Health Organisation released a Global Burden of Disease report in 2005 which indicated the magnitude of the impact of external injuries (mortality of more than 875000 children per year) as a cause of death among children worldwide(1). This led to a joint initiative of the United Nations Children's Emergency Fund (UNICEF), World Health Organisation, Office of the High Commissioner for Human Rights (OHCHR) and the International Labour Organisation (ILO) to draw up a list of twelve principal recommendations in an effort to stem the tide of accidental and non-accidental violence against children. The United Nations Secretary-General's core message was that all violence against children is preventable (2).

The World Health Organisation responded to the report and its recommendations by developing a 10 year plan of action over the period from 2006 to 2015 to prevent child and adolescent injury globally. The framework consisted of six main components including data and research as the initial two areas of work. One of the key objectives was to build the capacity to undertake effective interventions and to evaluate their subsequent effectiveness (3).

The South African National Burden of Disease Study (2000) showed that external causes of death (injuries) played a significant role in children aged 5 to 14 years (4). This is in keeping with the Global Burden of Disease Report findings in 2004 and 2008 (2).

To be able to evaluate the effectiveness of interventions (pre-hospital and in-hospital) in paediatric trauma management, undertaking a study to determine what factors influence the outcomes of severe paediatric trauma in South Africa is appropriate.

This study hypothesises that the severity of an acute traumatic injury determines the final mortality and morbidity irrespective of timing and type of interventions available to treat the severely injured paediatric patient.

The objectives of this study are:

- To determine whether the level of pre-hospital care makes a difference in outcome of severe paediatric traumatic injuries.
- To determine whether the time taken to transport (pre-hospital time and mode of transport) to a tertiary centre has an impact on outcome of severe paediatric traumatic injuries.
- To determine whether on scene vital signs (Glasgow Coma Scale; Systolic Blood Pressure and Respiratory Rate) are good predictors of outcome in severe paediatric trauma.
- To determine whether the amount of time spent in the emergency department has an impact on the final outcome in severe paediatric traumatic injuries.
- To determine whether the time spent in a Paediatric Intensive Care Unit (PICU) has an impact on the final outcome in severe paediatric traumatic injuries.
- To determine whether there is a difference in outcome of severely injured children in public versus private sector tertiary hospitals with equal levels of expertise available.

Potential utility:

Raising awareness about the incidence and magnitude of paediatric trauma in Gauteng, South Africa.

To serve as a source to develop guidelines for pre-hospital triage, management and transport of severely injured children.

2.0 LITERATURE REVIEW

What are the unique features of paediatric trauma in South Africa?

2.1 Significance of the problem

Unintentional injuries are a major cause of worldwide death among all age groups. More than 875 000 children less than18 years of age die every year throughout the world secondary to injuries, mostly in low- and middle-income countries (LMIC). These injuries account for at least 13% of the total burden of morbidity among children less than 15 years of age (5). According to this same report (5) from the United Nations Children's Fund, childhood injuries decreased by half in high-income countries (HIC) between 1970 and 1995. Multiple reports from low-income countries have sadly shown an increase in incidence of injuries (5). The Global Burden of Disease study published in 2013 by Naghavi et al. (6) emphasized the importance of interpersonal violence as a contributor to the likelihood of death in children and adolescents in Southern Africa. Worldwide deaths from unintentional injuries increased by almost 11% from 4.3 million deaths in 1990 to 4.8 million in 2013 (6).

2.2 Mechanism

The Red Cross War Memorial Hospital in Cape Town cared for 62,782 children between 1997 and 2006, with a total of 68,883 injuries seen in this period(7). The children were on average 5 years old and just over 60% of the cohort was male. Mechanism of injury included falls (39.8%), road traffic injuries (15.7%), burns (8.8%), and assault (7.4%). Most of these accidental injuries occurred at the house where the child was living (7). This is an indication of the variety of mechanisms of injury seen in Cape Town, South Africa.

2.3 Exclusive system

There is a need for accurate pre-hospital triage systems, and rapid transport to appropriate facilities should be mandatory. In South Africa the general trend is to transport severe paediatric injuries to the nearest, not necessarily the most appropriate facility (exclusive system) whereas it is known that inclusive systems bypassing facilities to the most appropriate level for major injuries improves survival (8,9,10,11). Inclusive trauma systems potentially play an important role in outcome of children with cervical spine injuries, as seen in a study done by Anders et al. (12) in 2014. The authors aimed to determine whether the receiving hospital of a severe cervical spinal cord injury (evidenced by altered mental status and focal neurologic findings) made a difference in outcome (12). They found that the initial receiving hospital from the scene of the accident (be it inclusive paediatric trauma centre versus exclusive local hospital) appeared to be associated with severity of final neurological outcome, proven by inclusive hospitals showing better neurological outcomes at discharge. Nirula et al. (13) sought to analyze whether initial triage of severely injured patients to a non specialised trauma centre (exclusive) was associated with an increased mortality rate. They examined database information of 1112 patients of whom 318 (29%) were initially transported to the nearest hospital. The odds of mortality were 3.8 times greater when patients were transported to the closest/non specialised facility as compared to being transported to a centre able to provide definitive care (13). An inclusive system is not formally applied and not formally legislated in South Africa. Currently injured patients are transported to the nearest hospital (exclusive) with the impact of increased mortality most keenly felt in major to severe injuries (Injury Severity Score > 10). Therefore outcomes in these severe injuries and current system of care provided are worth studying to determine the need for an inclusive system in South Africa.

2.4 High prevalence

According to a publication in 2003 by Bradshaw et al external causes of death (road traffic accidents) are especially significant in children aged 5-14 years (4). The author investigated the leading causes of death in South African children. In children aged 1-4 years, road traffic accidents caused 3.5% (boys) and 3% (girls) of deaths in the year 2000. In older children aged 5-9 years it showed 28.8% (boys) and 33% (girls) of total deaths were due to road traffic accidents. In children 10-14 years of age 18.3% (boys) and 14.9% (girls) of total deaths were related to road traffic accidents (4).

2.5 First worlds Helicopter Emergency Medical Service

In 1995 a study was done in London, England by Nicholl et al. (14) to review the impact of the London Helicopter Emergency Medical Service on survival after trauma. Differences in the nature and severity of injuries between the two cohorts (helicopter versus ambulance) were taken into account and the estimated survival rates were the same. An analysis with trauma and injury severity scores (TRISS) found 16% more deaths than predicted in the helicopter cohort as opposed to only 2% more in the ambulance cohort. There was no evidence to show a difference in survival for patients with head injury but some evidence that patients with major trauma (injury severity score ≥16) were more likely to survive if attended to by the helicopter (14). Helicopter Emergency Medical Services (HEMS) have stringent triage criteria which means that more severely and critically injured patients will be selected to be transported rapidly. This could be the reason for the small difference in survival when comparing road and helicopter transport. Stewart et al. (15) undertook a study in 2015 in

Colorado looking at the outcomes of severely injured children following different modes of transport to the receiving hospital. Of the 14405 children who were identified, 3870 were transported with a helicopter and 10535 were transported per ground ambulance. The type of transport used did not significantly affect survival, length of stay in PICU or final discharge outcomes. Transport by road was related to an almost 70% decreased length of hospital stay. A quarter of the children transported by helicopter had an Injury Severity Score of less than 10 and spent only one day in hospital (15). Transport by helicopter without good triage does not improve the outcomes of traumatically injured children independently. There is a need for more studies to determine the effect of HEMS on survival after trauma in South Africa.

2.6 Overcrowding of public sector emergency departments

In 2011 Sills et al. (16) published a retrospective study evaluating pain associated with long bone fractures in 1229 children presenting to an emergency department in Colorado, USA from November 2007- October 2008. The main outcome measures were quality measures. Good quality of care was defined as receiving appropriate treatment within 1 hour of arrival. Poor quality of care was defined as not receiving any treatment or delay in receiving treatment. The results showed that an injured child was 0.4 times as likely to receive good quality of care in an overcrowded environment as compared to 0.8 times as likely to receive good quality of care in an environment that is not overcrowded (16). This study indicated the direct impact of overcrowding on quality of care, which could possibly be one of the factors contributing to high mortality rates in paediatric trauma in South Africa as observed by Bradshaw in 2003 (In children aged 5-9 years it showed 28.8% (boys) and 33% (girls) of total deaths were due to road traffic accidents and in children 10-14 years of age 18.3% (boys) and 14.9% (girls) of total deaths were related to road traffic accidents) (4).

Overcrowding may also lead to increased time spent in the emergency department.

Time spent in the emergency department after rapid transport to a tertiary centre plays a role in the final outcome of hospitalised patients. Two separate studies have been done to support this statement. In June 2015 Evans et al. (17) completed a systematic review of rapid access models of care and their effects on delays in emergency departments. They found that prolonged time spent awaiting handover from emergency personnel to nursing staff in the emergency department led to disturbance in functioning of both the emergency department and the ambulance service. This study concluded that having a functioning rapid access model in place in a busy emergency department with a functional triage system and various levels of care on standby may be beneficial for patients by leading to less time spent in the emergency department and quicker access to appropriate medical care (17). The second study looked at the association between length of stay in the emergency department and mortality. Adam et al. (18) realised that longer waiting times spent in an emergency department was related to several poor patient outcomes which ranged from personal patient dissatisfaction to higher inpatient mortality rates. Mortality went up with extended time spent in the emergency department, showing mortality of 2.5% in those spending less than 2 hours in the emergency department and 4.5% in those spending longer than 12 hours in the emergency department ($p<0.001$) (18). The association between mortality, morbidity and length of stay in the emergency department can be due to several factors. Possible causes could be failure of triage systems leading to under diagnosing of severe injuries on arrival, inappropriate treatment with crystalloids/colloids/blood products whilst waiting for transport out of the emergency department, delay in providing invasive emergency treatment (for example neuro-protective ventilation) if a ventilator is only available in PICU, staff shortages and personnel fatigue leading to poor monitoring of critically ill patients.

2.7 Severity

Evidence in the literature to support the hypothesis that the severity of an acute traumatic injury determines the final mortality and morbidity irrespective of timing and type of interventions available to treat the severely injured paediatric patient includes a multicentre retrospective study that was done in Taiwan in 2013(19). This study by Lin et al. (19) investigated the impact of the first responder in the outcome of paediatric traumatic cardiac arrests. The study (19) concluded that among 42% of children in a total cohort of 362 who achieved sustained return of spontaneous circulation, only 10% survived to discharge and 3% had good neurologic outcomes. An initial GCS score of greater than 8 predicted a good neurologic outcome in survivors ($p = 0.008$), suggesting that a GCS of less than 8 (severe head injury) at the scene of the incident predicted poor neurologic outcome (19). Nesiama et al. (20) studied the ability of pre-hospital Glasgow Come Scale (GCS) score to predict paediatric outcomes after traumatic brain injury. The study included 185 patients. There was a strong agreement between pre-hospital and emergency department GCS scores, suggesting the use of GCS at the scene of the incident in development of pre-hospital transport destination guidelines for children with traumatic brain injuries (20). Both these studies are noted to be relatively small in sample size and hence to make definitive conclusions bigger sample groups will be needed but both suggest that by using a scoring system based on the severity of injury sustained at the scene of the incident it could be possible to predict mortality and morbidity.

3.0 METHODS

3.1 Study type

This study was a retrospective multicentre data capturing study

3.2 Study sample

Patients in the paediatric age group (≤ 14 years) admitted to the intensive care units of a Public level 1 and a Private level 1 hospital from 1 January 2006 to 31 December 2013 after suffering major trauma in Johannesburg, Gauteng, South Africa.

Inclusion was restricted to admission to the Public level 1 and Private level 1 hospitals because both have a functioning Trauma Registry, are staffed by professionals of similar level of qualification (Advanced Trauma Life Support trained), both have direct specialist supervision, have access to appropriate closed PICU's and are recognised as tertiary institutions.

Admission restricted to intensive care ensured significant injury, and allowed accounting for differentiation in outcome beyond age, vital signs and severity of injury (the major factors determining survival).

3.3 Inclusion criteria

Major trauma is commonly defined as an Injury Severity Score of ≥15. Since outcome (survival vs. death) is a major factor in this study, and the mortality of patients with an ISS of less than 10 is negligible, only patients admitted with an Injury Severity Score of ≥ 10 were included in the study (21).

The Injury Severity Score is an anatomical scoring system that provides an overall score for patients with multiple injuries. Each injury is assigned an Abbreviated Injury Score (table 1.1) and is allocated to one of six body regions (head, face, chest, abdomen, extremities – including pelvis – and external). Only the highest Abbreviated Injury Score in each body region is used. The 3 most severely injured body regions have their score squared and added together to produce the injury severity score (22).

Table 1.1 Abbreviated Injury Score scale

AIS Score	Injury
1	Minor
2	Moderate
3	Serious
4	Severe
5	Critical
6	Unsurvivable

The Revised Trauma Score (RTS) is a physiological scoring system. It is scored from the first set of data obtained on the patient, and consists of Glasgow Coma Scale, Systolic Blood Pressure and Respiratory Rate. The Revised Trauma Score is heavily weighted towards the GCS to compensate for severe head injury without multisystem injury or major physiological changes (22).

Expected survival can be calculated by using the Trauma Score - Injury Severity Scoring System (TRISS) and actual survival can be determined by discharge alive or not from PICU after a severe injury.

TRISS estimates the probability of patient survival (Ps) by taking into account the age of a patient (age index is 0 if the patient's age is below 54 years and 1 if above 55 years), anatomical injury (ISS), physiological status (RTS) and type of injury (blunt vs. penetrating injuries). Limitation to the score is that it does not take into account any pre-existing conditions. A TRISS calculator is freely obtainable from the trauma.org website (22).

3.4 Exclusion criteria

Dead on arrival, incomplete data , unable to obtain data [age, sex, GCS, systolic blood pressure, respiratory rate, injuries sustained, timing variables, outcome (survival /death)]

3.5 Study procedure

1. Data was collected at the Public level 1 Hospital by first accessing PICU admission registers from January 2006 up to December 2013. In these admission registers it was possible to identify names, hospital numbers and reason for admission. From this an excel spreadsheet was created with all trauma paediatric patients admitted from January 2006- December 2013 entered into the spreadsheet.
2. All trauma patients treated at the Public level 1 Hospital were processed through trauma casualty. For each admission a data sheet was completed. This data sheet was called "Medibank". It contained details pertaining to patient demographics (name, surname, hospital number, arrival date, gender, age, race, residential suburb) incident (date, time, where it happened, mechanism of injury, how it happened) pre-hospital (mode of transport, ambulance number, EMS service, level of care, time of arrival on scene, time spent on scene, time of arrival at hospital, on scene vitals including GCS, heart rate, respiratory rate, temp, blood pressure) and in-hospital (primary and secondary survey according to ATLS principles, injuries, treatment offered, subspecialties consulted, ongoing vital signs monitoring, time discharged from trauma casualty, destination after discharge). Each Medibank patient sheet was filed the following morning after intake and after completion of a morbidity and mortality meeting in the trauma surgery department at the Public level 1 Hospital.
3. The Medibank data sheets for the patients identified from the PICU admission registers were found in the trauma surgery files. The Medibank sheets were filed per month and year; all the months of all the years were accessible.

4. All the admissions into PICU after a traumatic injury were manually searched for through the stored Medibank files. Data captured from the Medibank data sheets included: age, sex, mechanism of injury (blunt/penetrating/burns), wounding agent, description of injuries, time of injury, total pre-hospital time, time of arrival at trauma centre, on scene vital signs (GCS, systolic Blood Pressure, respiratory rate, heart rate) level of pre-hospital care (Basic Life Support/Intermediate Life Support/Advanced Life Support/Doctor), time spent in emergency department, time to ICU.
5. Time to ICU was captured by noting the time of admission in trauma casualty and the time of admission into PICU as captured on the PICU admission registers. Time in PICU was also captured from the admission registers, when a child was discharged from PICU the date, time and destination was noted.
6. ISS was either pre-calculated by the trauma department and captured as such or calculated by capturing the specific injuries sustained from the Medibank sheets, assigning AIS scores to each injury and entering the three most severely injured body regions into the ISS calculator obtained from the trauma.org website (22). RTS was calculated by feeding the captured Medibank data (GCS, systolic BP and RR) into the respective calculator available on the trauma.org website (22).
7. The same procedure was followed at the Private level 1 Hospital. Patients were identified by accessing admission registers to PICU. The exact same Medibank data sheet was used by trauma surgeons working at the Private level 1 Hospital.
8. Patient files had to be retrieved from the files department, similar data was captured from the Medibank data sheets onto a separate excel spreadsheet. Admission and discharge from PICU was captured using PICU registers and files.

3.6 Statistical analysis

Data was captured into Microsoft Excel (23). Analysis was performed using SPSS software (24). Basic statistics were done by presenting the categorical variables in table formation. Comparisons were done by using cross tabulations for categorical variables. Cross tabulations were done using the Pearson Chi-Squared tests (if not 2x2) and Fischer exact test (if 2x2) to test for a significant result. P values of <0.05 were seen as significant. In the not 2x2 cross tabulations a warning was applicable if >20% of the cell frequencies were <5, in this case the p value could not be interpreted and hence own conclusion had to be made based on the proportions of percentages within the cohorts. Normality was tested to determine whether there is a need to use parametric or non parametric techniques for further data analysis. The Null hypothesis when testing for normality was "all is normally distributed", with alternative "not normally distributed". $P>0.05$ = normally distributed. Normality was tested by using the Kolmogorov-Smirnov test if sample size $n>50$ and the Shapiro-Wilk test if sample size $n<50$. Non parametric tests were done for data not normally distributed with multiple outliers. Comparisons were done between two cohorts by first looking at variables and doing non parametric tests (Mann-Whitney), due to all except one variable being not normally distributed. The Null hypothesis used was that there was no difference between the groups tested. ($p<0.05$ = there is a difference between groups). Multicollinearity was excluded in all independent variables (cohort, PHT, level of care, emergency department time, PICU time, ISS, RTS) in order to ensure all variables could be used in the model for logistical regression. Logistical regression was done due to dependant variables being binomial [survival (0) vs. death (1)]. The Cox and Snell R Square and Nagelkerke R Square tests were used to test the effectiveness of the logistical regression model. The Hosmer and Lemeshow Test was used to test the fit of the model, $p>0.05$ indicated a good fit model, indicating the variables were

appropriate for the model. Finally significance of logistic regression predicting likelihood of death was determined by $p<0.05$.

3.7 Ethical considerations

Permissions were obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (appendix A) as well as the Research Operations Committee of the Private level 1 Hospital (appendix B) before data collection commenced. Permission was also obtained from the Trauma Surgery Department of the Public level 1 Hospital and from the Trauma Surgery Department at the Private level 1 Hospital. There was no need for informed consent because this was a retrospective study.

3.8 Study Setting

Inclusion was restricted to admission to the Trauma Units of the Public level 1 Hospital and the Private level 1 Hospital because both had a functioning Trauma Registry, were staffed by professionals of similar level of qualification (ATLS trained), both had direct specialist supervision, had access to appropriate closed PICU's and were recognised as tertiary institutions.

4.0 RESULTS

4.1 Demographics and frequencies

Table 4.1.1 Total study cohort

	Frequency	Percent
Public	125	75.3
Private	41	24.7
Total	166	100.0

212 patients were identified in the public cohort of whom 125 had complete collectable data.

85 patients were identified in the private cohort of whom 41 had complete collectable data.

Table 4.1.2 Categorical variables including both cohorts

	Mean	Median	Std. Deviation
Age (months)	79.6	72.5	45.0
Prehospital Time (minutes)	122.2	80.0	127.2
Time in Emergency Department (minutes)	308.3	280.0	284.9
Time in Paediatric ICU (days)	4.9	3.0	6.7
Injury Severity Score	23.8	22.0	7.5
Revised Trauma Score	5.7	5.9	1.3
Probability of Survival (percentage)	84.3	91.0	16.7

4.2 Cross tabulations

Table 4.2.1 Gender distribution

			Male	Female	Total
Cohort	Public	Count	78	47	125
		% within Cohort	62.4%	37.6%	100.0%
	Private	Count	28	13	41
		% within Cohort	68.3%	31.7%	100.0%
Total		Count	106	60	166
		% within Cohort	63.9%	36.1%	100.0%

Fischer's Exact Test was done to test for significance in gender distribution between private and public cohort, a non significant p value = 0.576 ($p \geq 0.05$) was found indicating no significant difference in gender distribution between the two cohorts.

Table 4.2.2 Frequency distribution of mechanism of injury

			Blunt	Penetrating	Total
Cohort	Public	Count	121	4	125
		% within Cohort	96.8%	3.2%	100.0%
	Private	Count	40	1	41
		% within Cohort	97.6%	2.4%	100.0%
Total		Count	161	5	166
		% within Cohort	97.0%	3.0%	100.0%

Fischer's Exact Test was done to test for significant difference between mechanism of injury in the public versus the private sector, a non significant p value = 1.000 ($p \geq 0.05$) was found, indicating no significant difference in frequency of blunt versus penetrating injuries in the two cohorts.

Table 4.2.3 Distribution of wounding agent

			PVC	MVC	FFH	Crush	Assault	Total
Cohort	Public	Count	59	39	18	5	4	125
		% within Cohort	47.2%	31.2%	14.4%	4.0%	3.2%	100.0%
	Private	Count	7	23	2	6	3	41
		% within Cohort	17.1%	56.1%	4.9%	14.6%	7.3%	100.0%
Total		Count	66	62	20	11	7	166
		% within Cohort	39.8%	37.3%	12.0%	6.6%	4.2%	100.0%

Not a 2x2 crosstab thus a warning is applicable. Categories cannot be collapsed due to marked differences in wounding agents. One can clearly see the difference in incidence in PVC in public compared to private and MVC in public compared to private. Pearson Chi-Square states a p value of <0.0, indicating a significant p value but because warning value is >20%, 3 cells (30.0%) have expected count less than 5, one cannot interpret p value (24). a Further study with a bigger sample size is needed.

Table 4.2.4 Level of care

			Private Car	BLS + ILS	ALS	Dr (HEMS)	Total
Cohort	Public	Count	7	10	62	46	125
		% within Cohort	5.6%	8.0%	49.6%	36.8%	100.0%
	Private	Count	4	4	22	11	41
		% within Cohort	9.8%	9.8%	53.7%	26.8%	100.0%
Total		Count	11	14	84	57	166
		% within Cohort	6.6%	8.4%	50.6%	34.3%	100.0%

Not a 2x2 crosstab, warning is applicable: 2 cells (25.0%) have expected count less than 5. Because value is >20% one cannot interpret p value (24). Pearson Chi-Square states p-value of 0.591 ($p \geq 0.05$), indicating no significant difference between the two cohorts. Level of care

between public and private in all 4 categories (private car, BLS + ILS, ALS, HEMS) appears very similar.

Table 4.2.5 Outcome frequencies among cohorts

			Survival	Death	Total
Cohort	Public	Count	104	21	125
		% within Cohort	83.2%	16.8%	100.0%
	Private	Count	36	5	41
		% within Cohort	87.8%	12.2%	100.0%
Total		Count	140	26	166
		% within Cohort	84.3%	15.7%	100.0%

Fischer's Exact Test was done to test for significant difference between survival and death in both cohorts, result showed a non significant p value = 0.623 ($p \geq 0.05$), indicating no significant difference in frequency of survival and death between the two cohorts.

4.3 Normality

Table 4.3.1 Tests of Normality

Cohort		Kolmogorov-Smirnov			Shapiro-Wilk		
		Statistic	df	p value	Statistic	df	p value
Age	Public	0.066	125	0.200			
	Private				0.883	41	0.001
PHT	Public	0.254	125	0.000			
	Private				0.616	41	0.000
EDTime	Public	0.212	125	0.000			
	Private				0.916	41	0.005
PICUt	Public	0.264	125	0.000			
	Private				0.761	41	0.000
ISS	Public	0.151	125	0.000			
	Private				0.916	41	0.005
RTS	Public	0.122	125	0.000			
	Private				0.913	41	0.004
Ps	Public	0.221	125	0.000			
	Private				0.793	41	0.000

The Kolmogorov-Smirnov test was used if sample size n>50 (public) and the Shapiro-Wilk test was used if sample size n<50 (private). Only the age in the public cohort is normally distributed ($p>0.05$), the rest are all not normally distributed ($p<0.05$) (24).

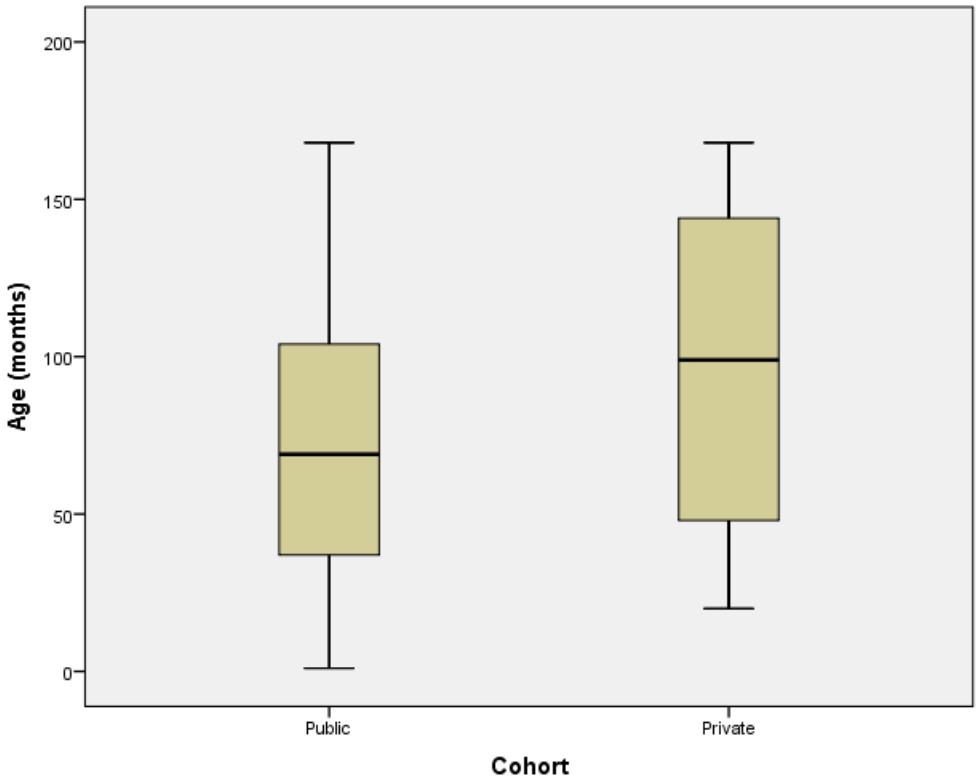

Figure 4.3.1 Age distribution

Age distribution box plot indicates normal distribution of age in both cohorts.

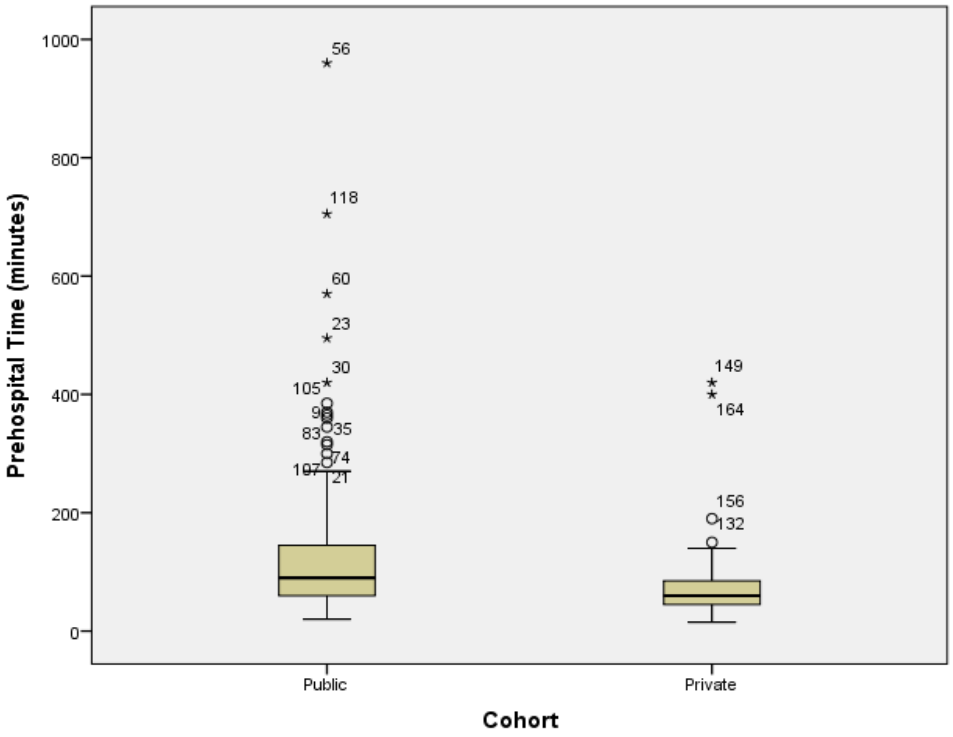

Figure 4.3.2 Pre-hospital time

Box plot indicates distribution of pre-hospital time in both cohorts is not normal.

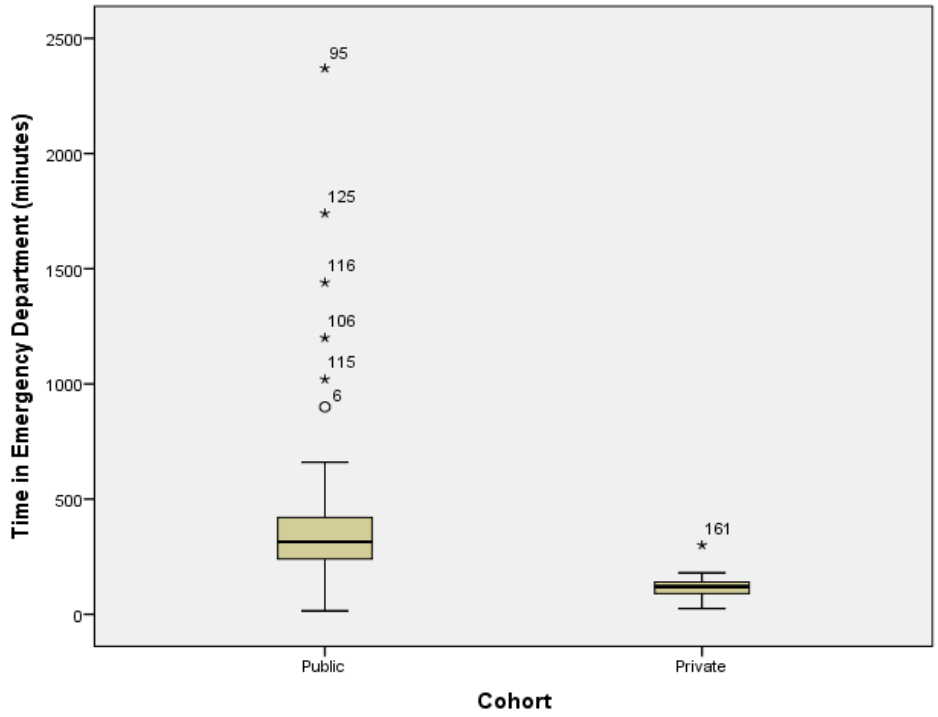

Figure 4.3.3 Time in Emergency Department

Box plot indicates distribution of time spent in emergency department in both cohorts is not normal.

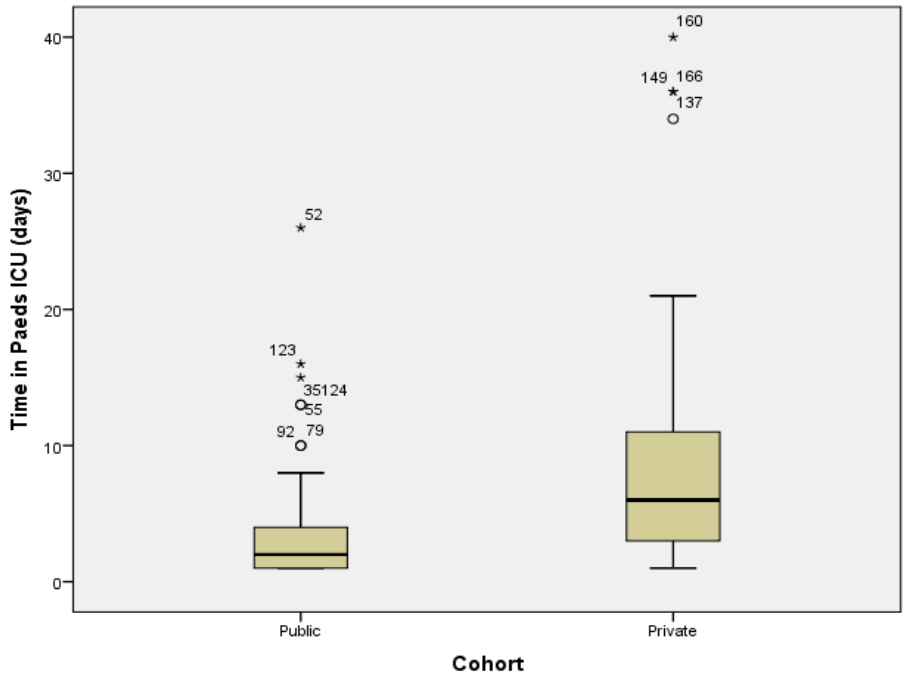

Figure 4.3.4 Time in PICU

Box plot indicates that distribution of time spent in PICU in both cohorts is not normal.

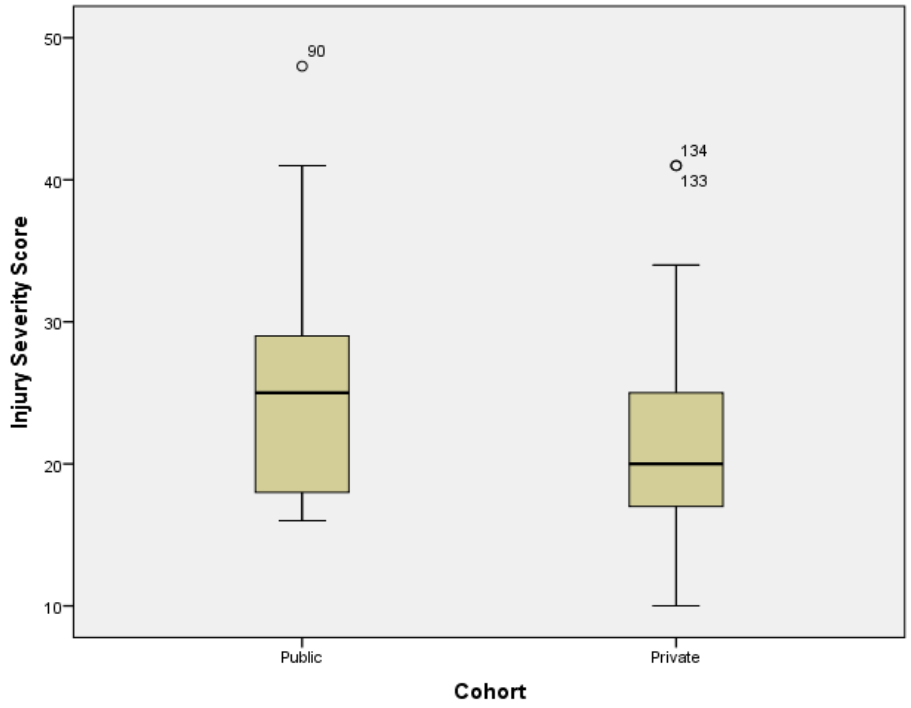

Figure 4.3.5 Injury Severity Score

Box plot indicates that distribution of Injury Severity Score in both cohorts is not normal.

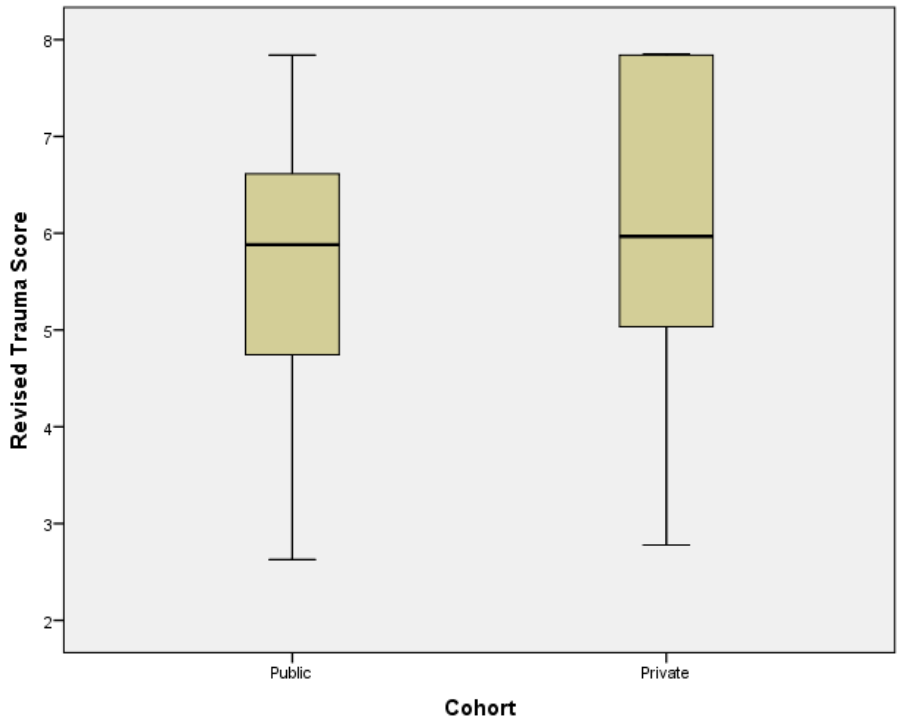

Figure 4.3.6 Revised Trauma Score

Both p values in public and private cohorts are <0.05 indicating distribution of Revised Trauma Score in public and private cohorts is not normal.

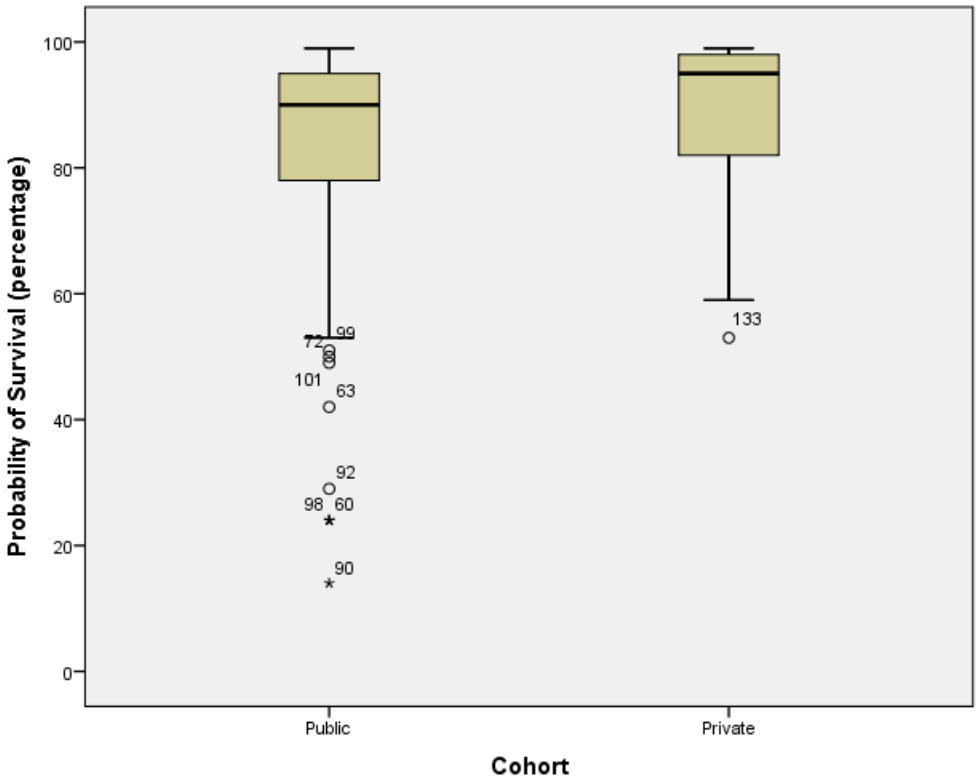

Figure 4.3.7 Probability of Survival

Box plot indicates that distribution of probability of survival in both cohorts is not normal.

Table 4.3.2 Probability of survival test of normality

ActDeath		Kolmogorov-Smirnov			Shapiro-Wilk		
		Statistic	df	p value	Statistic	df	p value
Ps	Survival	0.226	140	0.000			
	Death				0.867	26	0.003

Table 4.3.2 looks at the probability of survival versus actual death in the public versus the private cohort, showing a p value of <0.05, indicating distribution that is not normal. This was done in order to show whether a parametric or non parametric test should be used for further analysis.

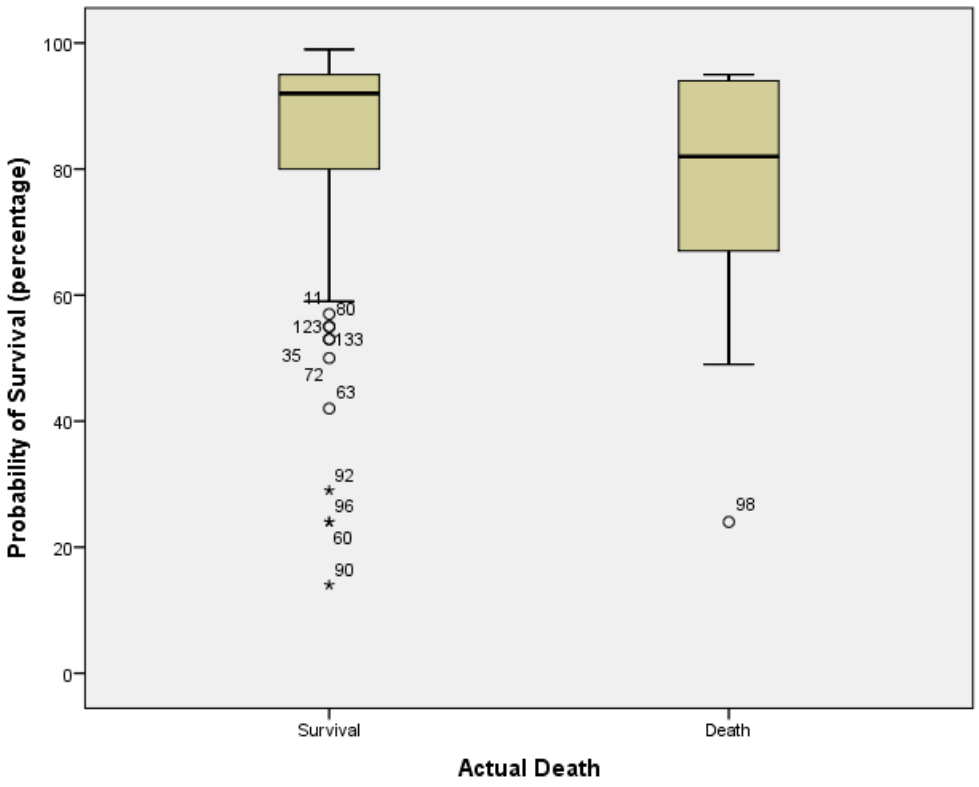

Figure 4.3.8 Probability of survival versus actual death

Box plot indicates that distribution of probability of survival in both cohorts is not normal.

4.4 Comparisons between groups

Table 4.4.1 Cohort variables tabulated

Cohort		N	Mean	Std. Deviation	Median	Mean Rank
Age	Public	125	72.4	40.3	69.0	76.8
	Private	41	101.4	51.6	99.0	103.9
PHT	Public	125	134.5	136.6	90.0	90.2
	Private	41	84.6	83.4	60.0	63.0
EDTime	Public	125	371.2	301.8	315.0	99.7
	Private	41	116.2	48.2	120.0	34.0
PICUt	Public	125	3.2	3.5	2.0	71.9
	Private	41	10.1	10.5	6.0	118.9
ISS	Public	125	24.7	7.6	25.0	89.1
	Private	41	21.1	6.9	20.0	66.5
RTS	Public	125	5.6	1.3	5.8	78.2
	Private	41	6.2	1.4	5.9	99.8
Ps	Public	125	82.8	17.7	90.0	77.2
	Private	41	88.8	12.7	95.0	102.9

Table 4.4.2 Cohort variables compared

	Mann-Whitney U	Z	p value
Age	1724.5	-3.1	**0.002**
PHT	1723.5	-3.1	**0.002**
EDTime	533.5	-7.6	**0.000**
PICUt	1107.5	-5.6	**0.000**
ISS	1864.5	-2.6	**0.009**
RTS	1896.0	-2.5	**0.012**
Ps	1768.5	-2.9	**0.003**

The Mann-Whitney U test revealed a significant difference between public and private cohorts in all the variables tested [$p < 0.05$ in all including age (median age younger in public cohort), prehospital time (median PHT longer in public sector), time in emergency department (median time in emergency department longer in public sector), time in paediatric ICU (median time in PICU longer in private sector), Injury Severity Score (median ISS

higher in public sector), Revised Trauma Score (median RTS lower in public sector), and Probability of survival(median Ps lower in public sector]

Table 4.4.3 Probability of survival tabulated

ActDeath		N	Mean	Std. Deviation	Median	Mean Rank
Ps	Survival	140	85.6	16.2	92	88.2
	Death	26	77.4	17.9	82	58.5

Table 4.4.4 Probability of survival compared

	Ps
Mann-Whitney U	1169.0
Z	-2.9
P value	**0.004**

The Mann-Whitney U test revealed a significant difference in probability if survival in those who survived compared to those who died ($p<0.004$)

4.5 Multicollinearity

Table 4.5.1 Collinearity coefficients

Model		Collinearity Statistics	
		Tolerance	VIF
[1]	Cohort	0.584	1.711
	PHT	0.931	1.075
	LOCa	0.932	1.073
	EDTime	0.822	1.217
	PICUt	0.715	1.398
	ISS	0.872	1.146
	RTS	0.875	1.142

Tolerance and VIF close to 1 indicates no problem with multicollinearity (24). Tolerance value should be as close to 1 as possible. Usually if value <0.1 it indicates possible multicollinearity. VIF should be close to 1 as well, if >10 it indicates possible problem with multicollinearity.

Table 4.5.2 Collinearity Diagnostics

Model	Eigenvalue	Condition Index	Variance Proportions							
			(Constant)	Cohort	PHT	LOCa	EDTime	PICUt	ISS	RTS
1	6.194	1.000	0.00	0.00	0.01	0.00	0.01	0.01	0.00	0.00
2	0.709	2.956	0.00	0.00	0.01	0.00	0.15	0.44	0.00	0.00
3	0.513	3.475	0.00	0.00	0.78	0.00	0.10	0.01	0.00	0.00
4	0.353	4.187	0.00	0.01	0.08	0.01	0.50	0.30	0.00	0.01
5	0.110	7.492	0.00	0.17	0.03	0.03	0.07	0.01	0.41	0.03
6	0.069	9.487	0.00	0.00	0.02	0.60	0.00	0.01	0.20	0.09
7	0.043	12.035	0.00	0.58	0.01	0.02	0.04	0.21	0.14	0.51
8	0.010	25.524	1.00	0.23	0.06	0.34	0.14	0.02	0.25	0.36

Condition index <30 indicates no problem with multicollinearity (24). If colleration is too high (>30) it indicates an ineffective model. Condition index of >15 indicates a possible problem with multicollinearity but good tolerance and VIF minimises this problem.

4.6 Logistic regression

Table 4.6.1 Dependent variable coding

Original Value	Internal Value
Survival	0
Death	1

Table 4.6.2 Categorical variable coding

		Frequency	Parameter coding (1)
Cohort	Public	125	0
	Private	41	1

Table 4.6.3 Model summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	117.928	0.146	0.251

The Cox and Snell R square test indicates that 14, 6% of the variance in the dependent variables is explained by the independent variables. Nagelkerke R Square indicates that 25.1% of the variance in the dependent variables is explained by the independent variables, thus 14.6%-25.1% of the variance in the dependent variable (survival vs. death) can be explained by the independent variables.

Table 4.6.4 Hosmer and Lemeshow Test

Step	Chi-square	df	p
1	10.280	8	0.246

Good fit is indicated by p>0.05. The p value is 0.264, indicating support for the model (24)

Table 4.6.5 Model classification table

Observed			Predicted		
			ActDeath		
			Survival	Death	Percentage Correct
Step 1	ActDeath	Survival	137	3	97.9
		Death	20	6	23.1
	Overall Percentage				86.1

Table 4.6.5 indicates that 97.9% of survivors were classified correctly as a survivor; only 23.1% were classified correctly as being dead. This indicates the difficulty in predicting death. The small sample size of actual death likely has an effect on this result. The model predicts well for survival but not so well for death.

Direct logistical regression was performed to assess the impact of factors on the likelihood of death. This model contained 7 independent variables (cohort, pre-hospital time, level of care, emergency department time, time in paediatric ICU, Injury Severity Score, Revised Trauma Score).

The full model containing all predictors was statistically significant (p<0.001) indicating that the model was able to distinguish between those who died and those who survived. The model as a whole explained that between 14.6% (Cox and Snell R square) and 25.1% (Nagelkerke R squared) of the variance in the dependant variable is explained by the independent variable, and correctly classified 86.1% of cases.

As shown in Table 4.6.6, only 4 of the independent variables made a unique statistically significant contribution to the model (cohort, time in Paediatric ICU, Injury Severity Score and Revised Trauma Score).

The strongest predictor of death was being part of the private cohort, recording an odds ratio of 5.43 (95% CI, 1.178-25.012). This indicated that patients who were part of the private cohort were 5 times more likely to die, controlling for all other factors in the model.

The odds ratio of 1.1 (95% CI,1.030-1.170) for Injury Severity Score was more than 1, indicating that for every additional point in ISS the odds of dying was 1.1 times higher, controlling for all other factors in the model.

The odds ratio of 0.68 (95% CI,0.474-0.971) for Revised Trauma Score was less than one, indicating that for every increase in score the odds of dying was 0.68 times less, controlling for all other factors in the model.

Table 4.6.6 Logistic regression predicting likelihood of death

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	p	Odds	Lower	Upper
Step 1	Cohort(1)	1.691	0.780	4.708	1	**0.030**	5.428	1.178	25.012
	PHT	-0.001	0.002	0.135	1	0.713	0.999	0.994	1.004
	LOCa	0.188	0.287	0.427	1	0.513	1.207	0.687	2.119
	EDTime	0.001	0.001	1.477	1	0.224	1.001	0.999	1.002
	PICUt	-0.349	0.133	6.923	1	**0.009**	0.706	0.544	0.915
	ISS	0.093	0.033	8.255	1	**0.004**	1.098	1.030	1.170
	RTS	-0.388	0.183	4.509	1	**0.034**	0.679	0.474	0.971
	Constant	-1.895	1.861	1.037	1	0.309	0.150		

5.0 DISCUSSION AND CONCLUSION

5.1 Demographics

The two study hospitals are both recognised as tertiary trauma institutions, one in the public sector (n=125) and one in the private sector (n=41) in Johannesburg, Gauteng, South Africa. Males are the predominant sex involved in severe traumatic injuries (64%) (table 4.2.1), comparable to the study done in Red Cross War Memorial Hospital investigating patterns of paediatric injuries in Cape Town from 1997 – 2006, where 61.7% were noted to be male (7).

The median age was 69 months in the public cohort and 99 months in the private cohort (table 4.4.1). This was found to be a significant difference between the two cohorts (p=0.002) (table 4.4.2). Younger patients involved in severe traumatic injuries in the public cohort could be due to a higher dependence on public transport and hence being required to walk to destinations (school) leading to a higher potential exposure for injury.

Blunt mechanism of injury is the major cause of severe traumatic injuries (97%) (table 4.2.2). Pedestrian vehicle collisions are the main cause of blunt injuries in the public cohort (47%) (table 4.2.3). A retrospective descriptive study done in Nigeria in 2013, another low- and middle income developing country, revealed similar findings with pedestrian vehicle collisions accounting for the most common cause of injury among older children (5-15 years) (25). In the private cohort motor vehicle collisions (56%) were the most common cause of blunt injury (table 4.2.3). This is in keeping with a retrospective chart review that was conducted on patients admitted to a New South Wales hospital in Australia from 2006-2011, revealing motor vehicle collisions as the major cause of severe traumatic brain injuries resulting in death (77%) (26). Differences in the main mechanism of injury in the two cohorts could be explained by variable ability to access different modes of transport based on level of income. Those in the private cohort are assumed to have a sustained income and hence better

access to private motor vehicle transport thus would be using it more frequently resulting in higher odds of being involved in a motor vehicle collision.

5.2 Level of pre-hospital care

In both cohorts Advanced Life Support (ALS) was the highest level of care at the majority of accident scenes (51% in total cohort), with Helicopter Emergency Medical Services (HEMS) attending 34% of the cases (table 4.2.4). At the time of the study, the Netcare 911 HEMS service was permanently staffed by a Doctor and ALS paramedic team. In 15% of cases there were no ALS rendered. The presence of medically trained assistance at the scene of an accident was determined by bystanders phoning for help by using dedicated phone lines to access call centres of a variety of emergency medical services available in South Africa. In the 15% of cases where no ALS was at the scene of the accident, 7% were transported to hospital by private car. Reasons for this can include close proximity to the hospital, a Good Samaritan willing to assist or not knowing the correct number to dial for help. In the South African pre-hospital emergency system, all ambulances were manned by two individuals. This was always a combination of Basic Life Support (BLS) and Intermediate Life Support (ILS) trained personnel. ALS paramedics had a separate response vehicle to be able to swiftly assist at various points of need. The highest level of care was BLS + ILS in the other 8% of cases not attended by ALS. This could be due to close proximity to definitive hospital care and doing a ‘scoop and run’(27) instead of waiting for ALS arrival, good triage by first responders leading to ALS standing down from responding or unavailability of ALS due to already being occupied by another call-out with unavailability of another ALS in the same area. The level of pre-hospital care did not make a significant contribution in predicting the likelihood of death in both cohorts (table 4.6.6).

5.3 Time and mode of transport

The median pre-hospital time in the public cohort was 90 minutes and in the private cohort 60 minutes (table 4.4.1). Longer pre-hospital times in the public cohort could be explained by public emergency medical services having to serve a larger community, less ambulance and emergency care worker per capita, difficult access to emergency accident scenes, potential for higher incidence of mass casualties due to public transport (taxi, bus) accidents. Even though a significant difference in pre-hospital time was indicated between the two cohorts (p= 0.002) (table 4.4.2), the total pre-hospital time made no significant contribution to predicting the likelihood of death (table 4.6.6).

5.4 Time spent in the Emergency Department

The median time in the emergency department in the public cohort was 315 minutes, and in the private cohort 120 minutes, a significant difference (p= 0.000) (table 4.4.2). The difference in the time spent in the emergency department was likely related to availability of a PICU bed for admission. The trauma casualty at the Public level 1 Hospital had very good triage systems which lead to quick response times and definitive care, the availability of an ICU bed and transport to ICU was not a controllable factor and likely the cause of prolonged stay in the emergency department whilst awaiting transfer to PICU. Time spent in the emergency department made no significant contribution to predicting the likelihood of death (table 4.6.6).

5.5 Time spent in a Paediatric Intensive Care Unit

A significant difference (p= 0.000) (table 4.4.2) in median time spent in PICU for total cohorts were found, 2 days in public and 6 days in private (table 4.4.1). The observed short stay in public PICU could be related to pressure for beds for new critically ill patients. Due to limited resources high patient turnover ensured access to care for more. Shorter stay in PICU can also be related to sufficient clinical improvement in relatively short time to allow safe discharge from PICU, or admission prognosis being guarded resulting in higher PICU mortality rates and shorter stay. This is supported by median time in PICU in public cohort survivors being 2 days as opposed to median time in PICU in public deaths being 1 day. Private cohort survivors spent a median of 7 days and deaths a median of 4 days in PICU. The longer stay in PICU for deaths in private compared to public can be an indication of a possible difference in withdrawal of care policies when appropriate in the different settings. Prolonged stay in the emergency department could also lead to shortened stay in PICU if care rendered in the emergency department is comparable to PICU care. Time spent in the PICU made a significant contribution in predicting the likelihood of death (p=0.009). An odds ratio of 0.706 (95% CI, 0.544-0.915) indicated that for every additional day in PICU patients were 0.7 times less likely to die (table 4.6.6). The question whether time spent in PICU is a valid predictor of outcome or whether it is determined by outcome still requires further investigation.

5.6 Injury Severity Score

The median ISS for public was 25 and for private 20 (table 4.4.1). The significantly higher ISS in public (p= 0.009) (table 4.4.2) could be explained by the mechanism of injury in public predominantly being pedestrian vehicle collisions (table 4.2.3) as opposed to motor vehicle collisions in private (table 4.2.3), assuming availability of modern car protective technology for example car seats, seatbelts, airbags and structural support bars in the private cohort resulting in lower ISS. The Injury Severity Score as a scoring system made a significant contribution in predicting the likelihood of death (p=0.004) (table 4.6.6). An odds ratio of 1.1 (95% CI, 1.030-1.170) indicated that for every additional point in ISS the odds of dying increased by 1.1 (table 4.6.6). An increasing ISS score is linearly associated with increased severity of injury; this is in keeping with the increased odds of mortality.

5.7 Revised Trauma Score

Median RTS in public was 5.881 and in private 5.967 (table 4.4.1), indicating a significant difference between the two cohorts (p=0.012) (table 4.4.2). RTS was calculated by using Glasgow Coma Scale, systolic blood pressure and respiratory rate (22). It was in keeping for the RTS to follow the same trend as the ISS (the expectation was to have more abnormal vital signs with increased severity of injury), but RTS in a paediatric population has limited value due to not incorporating weight and age into the calculation. Due to weight not being captured on the Medibank forms, RTS had to be used as a variable instead of the Paediatric Trauma Score. RTS as a scoring system made a significant contribution in predicting the likelihood of death (p=0.034) (table 4.6.6). A lower RTS score was associated with a decreased probability of survival; the finding of this study was in keeping with the intended RTS model (22).

5.8 Probability of Survival (Ps)

The median probability of survival (Ps) in the public cohort was 90% and in the private cohort 95% (table 4.4.1). TRISS was calculated by using ISS, RTS and age, thus a significant difference was expected and shown (p= 0.003) (table 4.4.2) due to there being a difference in the ISS and RTS in the two cohorts. A significant difference was also shown in the probability of survival in those who survived compared to those who died (p= 0.004) (table 4.4.4). Those who survived had a probability of survival of 92% compared to those who died who had a probability of survival of 82% (table 4.4.3). This indicated the expected worse probability of survival in those who died. Concern has to be raised and further detailed studies are needed to investigate why the Ps was so high for the actual deaths. Ps of higher than 50% could be classified as definitely preventable (28). TRISS has been used since the 1980's in the Major Trauma Outcome Study (American College of Surgeons Committee on Trauma). Its value as a predictor of survival or death has been shown to be from 75-90% as good as a perfect index, depending on the patient data set used (29). Problems with calculating the probability of survival include dependence on accurate calculation of ISS, accurate capturing of initial vital signs on scene to be able to calculate RTS and the TRISS calculator not being specifically designed for use with paediatric patients.

5.9 Public versus Private sector

Being part of the private cohort was the strongest predictor of death (table 4.6.6), recording an odds ratio of 5.43 (95% CI, 1.178-25.012). Reasons for this are unclear, and the finding is surprising since longer length of stay in PICU as found in the private cohort was associated with decreased odds of dying. It should be noted that the wide confidence interval suggests careful interpretation of relevance of the result and indicates the need for further studies with bigger cohorts. The use of complex statistics with small cohort groups is also a limitation in

confident interpretation of the result. One less death in the private cohort would have changed the results completely, suggesting an unreliable finding. The possibility of a potential higher risk of dying in the private cohort could perhaps be explained by exposure to less severe trauma in the private cohort compared to the public cohort (table 4.4.1 – lower median ISS) leading to trauma teams (emergency department and PICU) being less versed in management of severe paediatric trauma should the need arise. The probability of survival in the private cohort was greater than in the public cohort (table 4.4.1). In-hospital level of care was not assessed but assumed to be equivalent between private and public cohorts. The Private level 1 Hospital only employed a dedicated paediatric intensivist in January 2012 and a dedicated paediatric surgeon in September 2012. Before their arrival paediatric admissions into ICU were looked after by trauma surgeons or general surgeons with an interest in paediatric trauma and/or non-ICU trained paediatricians. Also, the Public level 1 Hospital has never had a solely dedicated Paediatric Intensive Care Unit or paediatric intensivist but still remains one of two tertiary level institutions in Johannesburg that serves as a primary care centre for paediatric trauma. Most children were looked after by paediatric surgeons and neonatologists, which remains the current situation. Further studies with bigger cohorts and more hospitals are needed to investigate this finding.

5.10 Limitations

This study was a retrospective data capturing study. Some files could not be found or were incomplete in the public cohort as well as the private cohort. The incomplete files were excluded from the study. Exclusion of these files led to relatively small numbers that matched inclusion criteria for the study.

Results were captured by hand and transcribed into electronic format onto an Excel spreadsheet, leaving opportunity for human error in transcription. The Medibank trauma sheets were completed by staff that were present at the scene of the incident as well as staff present in the emergency department. Human error could have lead to data capture errors on the trauma sheets by the respective personnel.

ISS was calculated from the final injuries captured on the trauma sheets, PICU notes and radiologic reports. It is possible that the injuries were not captured accurately or described fully or interpreted wrongfully which could lead to an inaccurate calculation of ISS.

The RTS was calculated using data captured on the trauma sheets (GCS, systolic BP and RR). Again data was exposed to human error and thus could have lead to an inaccurate representation. RTS does not take age into consideration; this could influence the results of the study (probability of survival).

The TRISS was calculated by using the RTS, ISS and age. Hence any human error as described above would lead to an inaccurate TRISS calculation. TRISS used the same coefficient for all if age <15 years, this could influence the results of the study. A difference in TRISS calculation due to errors in ISS and RTS would possibly change the final outcome of the study. TRISS has not been validated for use in the paediatric population and hence the probability of survival in children when using TRISS is questionably accurate.

It was not possible to use the Paediatric Trauma Score (PTS) due to weight not being a variable captured on the Medibank trauma sheets. PTS has been shown to be an effective predictor of severity of injury and potential for mortality (30).

Small sample sizes used with complex statistics resulting in wide confidence intervals in pertinent findings in the study is an indication that results should be interpreted with caution.

Neither of the two hospitals was accredited as a level 1 Paediatric Trauma Unit but both were accredited as a level 1 Adult Trauma Unit and still remain the primary referral centres for major paediatric trauma due to limited alternatives. Currently there is no level 1 Paediatric Trauma Unit in Gauteng, South Africa. This could have an effect on the actual survival seen in the results of the study. If similar cases were seen and treated in level 1 Paediatric Trauma Units, there could possibly be a difference in the actual survival seen.

5.11 Conclusion

Paediatric trauma is a significant health burden in South Africa and globally. The level of pre-hospital care, total pre-hospital time and time spent in the emergency department were not found to make a significant difference in the mortality of severe paediatric trauma. Factors that influenced the risk of mortality included time spent in the paediatric ICU [odds ratio of 0.706 (95% CI, 0.544-0.915)] and whether a patient received public or private care [odds ratio of 5.43 (95% CI, 1.178-25.012)]. Both the Injury Severity Score (p=0.004) and Revised Trauma Score (p=0.034) systems played a significant role in the ability to predict mortality.

The multiple factors that significantly influence the outcome disprove the hypothesis that the severity of an acute traumatic injury determines the final mortality and morbidity in severe paediatric trauma as a single entity.

The numerous limitations of this study highlights the need for replication of the study with much larger data sets investigating the impact of private paediatric severe trauma care in comparison with public paediatric severe trauma care in South Africa using paediatric specific trauma outcome scores.

APPENDIX A

M150349 Dr Heinrich Koekemoer

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150374

NAME: (Principal Investigator)	Dr Heinrich Koekemoer
DEPARTMENT:	Paediatrics Charlotte Maxeke Johannesburg Academic Hospital Netcare Union Hospital
PROJECT TITLE:	Factors Influencing the Outcome of Severe Paediatric Trauma in a South African Environment
DATE CONSIDERED:	27/03/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof J Goosen
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	08/05/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and ONE COPY returned to the Secretary in Room 10034, 10th floor Senate House, University

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX B

RESEARCH OPERATIONS COMMITTEE FINAL APPROVAL OF RESEARCH

Approval number: UNIV-2015-0022

Dr HP Koekemoer

E mail: hpkoekemoer@gmail.com

Dear Dr Koekemoer

RE: FACTORS AFFECTING THE OUTCOMES OF SEVERE PAEDIATRIC TRAUMA IN A SOUTH AFRICAN ENVIRONMENT

The above-mentioned research was reviewed by the Research Operations Committee's delegated members and it is with pleasure that we inform you that your application to conduct this research at private Hospital, has been approved, subject to the following:

i) Research may now commence with this FINAL APPROVAL from the Committee.

ii) All information regarding the Company will be treated as legally privileged and confidential.

iii) The Company's name will not be mentioned without written consent from the Committee.

iv) All legal requirements regarding patient / participant's rights and confidentiality will be complied with.

v) The research will be conducted in compliance with the GUIDELINES FOR GOOD PRACTICE IN THE CONDUCT OF CLINICAL TRIALS IN HUMAN PARTICIPANTS IN SOUTH AFRICA (2006)

vi) The Company must be furnished with a STATUS REPORT on the progress of the study at least annually on 30th September irrespective of the date of approval from the Committee as well as a FINAL REPORT with reference to intention to publish and probable journals for publication, on completion of the study.

vii) A copy of the research report will be provided to the Committee once it is finally approved by the relevant primary party or tertiary institution, or once complete or if discontinued for any reason whatsoever prior to the expected completion date.

viii) The Company has the right to implement any recommendations from the research.

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