Children admitted to Paediatric Intensive Care at Red Cross War Memorial Children's Hospital with Non-Accidental Injuries (2012-2020): A Retrospective Descriptive Study

A minor dissertation

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BWSLYN002

SUBMITTED TO THE UNIVERSITY OF CAPE TOWN

In fulfilment of the requirements for the degree Master of Medicine (MMed) in Paediatrics Faculty of Health Sciences University of Cape Town

Date of Submission: 26/07/2024

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Format:

- Publication ready
- Chosen journal: Southern African Journal of Critical Care
- Reference style: Vancouver

Acknowledgements:

I would like to thank my supervisors Professor Brenda Morrow and Dr Beyra Rossouw. Beyra Rossouw continued to guide me even though she was miles away on another continent. I thank her for her time and patience and for helping me with the conception of this topic which we both were passionate about.

Brenda Morrow has been a tremendous blessing and help with my MMED. She kindly agreed to assist and take over the guidance of this project. I will forever be grateful for the lessons she has taught me and for inspiring me and allowing me to fall in love with research.

I would also like to thank Carla Brown from the social work department for all her efforts to locate patient data and all her input regarding the law and social welfare of these patients. I'd also like to thank Dr Dirk Von Delft for his input regarding the trauma aspect of NAI.

I am grateful for the PICU team at Red Cross War Memorial Hospital. To Dr Claire Procter for allowing me to use her office on weekends and public holidays and to Dr Shamiel Salie for all his assistance with the PICU data base and generating statistics.

Lastly to the people who got me through this, my family. I'd like to thank my son's nanny Portia Masunda who supported me so much during this time. To my husband Adam Carpenter who continues to love, support and believe in me. And lastly to my 2-year-old son Noah who inspires me every day to be the best for my patients and for him as his Mama.

It has been a long journey, but I am grateful to God for the information we have obtained, and I hope it can be used to benefit and protect children in SA!

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Abbreviations:

CT -COMPUTERIZED TOMOGRAPHY

LST- LIFE SUSTAINING TREATMENT

MRI -MAGNETIC RESONANCE IMAGING

MV – MECHANICAL VENTILATION

NAI – NON-ACCIDENTAL INJURY

NHLS- NATIONAL HEALTH AND LABORATORY SYSTEM

PACS- PICTURE ARCHIVING AND COMMUNICATION SYSTEM

PICU - PAEDIATRIC INTENSIVE CARE UNIT

PIM SCORE: PAEDIATRIC INDEX OF MORTALITY

RCWMCH – RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL

RAMR- RISK ADJUSTED MORTALITY RATE

SA- SOUTH AFRICA

TITLE PAGE

Children admitted to Paediatric Intensive Care at Red Cross War Memorial Children's Hospital with Non-Accidental injuries (2012-2020): A Retrospective descriptive study

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Abstract

Objectives: To describe the characteristics and outcomes of patients admitted to the paediatric intensive care unit (PICU) with suspected non-accidental injury (NAI).

Methods: A retrospective descriptive study of routinely collected data from all children admitted to the PICU with suspected NAI from 1 January 2012 to 31 December 2020.

Results: Of 11345 children admitted to PICU, 42 (0.4%) patients with suspected NAI (median (IQR) age 20.3 (7.9 – 62.6) months; 61.9% male) were included in the data analysis. Most patients sustained physical injury (n=31; 73.8%) from assaults (n=19; 45.2%), and head injuries were the most common injury site (n=24; 57.1%). Of the patients, 37 (88.1%) received invasive mechanical ventilation for median 2.0 (IQR) (1.0 – 3.8) days. PICU mortality was 28.6% (n=12), with a risk adjusted mortality (observed/mean predicted mortality) of 3.2. Of the 30 PICU survivors, 7 (23.3%) were discharged with long-term disability, whilst the functional outcome of 16 (53.3%) survivors is not known.

A multivariable binary logistic regression was conducted to determine the effect of inotropes, type of NAI, mechanism of injury, injury site (head, skin – eye injuries removed from the model for reasons of collinearity), and multiple injuries on patient survival. The model was significant ($p = 0.001$) and a good fit for the data (Nagelkerke R square 0.78) and was able to correctly predict 85.7% of cases. None of the variables in the model were r found to be independently associated with survival ($p > 0.1$ for all).

Conclusions: Children who have sustained NAI represent a small proportion of PICU admissions, with higher-than-expected mortality and considerable morbidity. Patient follow-up is recommended to determine long-term functional and psychosocial outcomes.

Introduction:

The Sustainable Development Goals include a bold and clear call to eliminate violence against children by 2030 (1). The South African Children's Act No 38 of 2005 also upholds the right to safety and protection of every child (2). Despite these initiatives, it is still estimated that globally one out of two children aged between 2–17 years have experienced some form of violence (3).

Non-accidental injury (NAI) in children, also known as child abuse, is the deliberate infliction of injury with the intention to cause harm. This can be in the form of physical , sexual harm or intentional neglect (4), with females being more affected by sexual abuse than males (5). Neglect as an NAI occurs in the context where parents are able to provide for their children but choose not to do so. In the case of ill children, neglect of their health can lead worsened health status and potentially life threatening complications (6).

Perpetrators of child abuse range from strangers to extended family members, friends and parents(7, 8) . Factors predisposing to childhood NAI may include dysfunctional family structure, poverty, unemployment, intimate partner violence, single parents, and substance abuse(9).

The Optimus Study was the first study to provide representative data of lifetime prevalence of violence in South Africa (SA). By the ages of 15-17 years one third of participants had personally experienced physical abuse and 23% were exposed to violence in the home. One in five of the participants had experienced some form of sexual abuse (6). South African poverty rates are high and poverty is known to have a direct effect on child protection (10). Childhood exposure to a toxic stressful environment has been linked to the pathogenesis of long term developmental and psychological conditions as well as leading to chronic non- communicable conditions in adulthood (11, 12) (13).

Fatal child abuse is the most severe consequence of NAI and forms a proxy measure for the effectiveness of a country's child protection system (14). Filicide is term used for the killing of a child by a parent while neonaticide is the death of neonates within the first 6 days of life (15, 16). South Africa's homicide rate for children under five years of age, the most vulnerable age

for NAI, is more than six times the global incidence at an estimated and unacceptable 5.5 per 100 000 children (14, 17).

Gang related violence in SA has resulted in many neighbourhoods being unsafe areas for children (18). A homicide review showed that teenage males were the group most affected by gang related violence in South Africa (17). There have been many children falling victim to being caught in crossfire because of gang violence.

Children who are victims of recurrent NAI are at risk of higher mortality and morbidity if the non-accidental nature of injury is initially missed (19). Early clinical suspicion is key in making a diagnosis of NAI, which must be reported under South African law (2, 20, 21). Key features that should alert medical practitioners towards the diagnosis of NAI include unexplained injuries, discrepant histories, delay in seeking health care, alleged self-inflicted injuries, alleged third party injuries, sexualised behaviour and repeated injuries (22). In addition to good history and clinical examination, the use of autopsy and post mortem skeletal surveys in non-survivors may identify previously missed occult fractures and other injuries(23).

Van As et al (2016) previously described the common clinical features of NAI seen at the Trauma Unit at RCWMCH(4). Injuries included:

Skin lesions: these may be in the form of bruises of different ages, bite marks , pinch marks and circumferential bruises (4).

Burns: 10% of physical abuse results in burns. These may be cigarette burns or hot water burns(4).

Head injuries: these may range from skull fractures to intracranial bleeds. “Shaken baby syndrome” is a rapid acceleration and deceleration of the head resulting in disruption of bridging veins leading to a bleeding. Head injuries are the most common cause of death in child abuse (4, 24).

Skeletal fractures: these may occur anywhere in the body but typically are seen as transverse fractures of long bones referred to as “bucket handle” fractures.

A retrospective study by Malki et al (2014) conducted at RCWMCH a decade previously noted that the injuries inflicted on children occurred in several parts of the body however, head

injuries were the most prevalent injury type, occurring in 35.4% of cases presenting to the trauma centre (25). Furthermore, 40% of all fractures presenting to the RCWMCH Trauma Unit from 1999 – 2005 were skull fractures (26).

Emergency medical treatment, multiple hospital admissions and even death are some of the consequences of violence. Children with the most severe forms of NAI often require admission to the paediatric intensive care unit (PICU), with substantial risk of mortality and both short- and long term morbidity, as well as high associated financial and other costs (27).

There is a paucity of recent evidence on the prevalence and outcomes of children with severe NAI requiring PICU admission in South Africa. This study therefore aimed to describe the proportion of children admitted to the PICU at Red Cross War Memorial Children's Hospital (RCWMCH), Cape Town, SA, with suspected NAI; their injury patterns, mechanism of injury; PICU course and outcomes.

Methods

This was a retrospective descriptive study of routinely collected data from all infants and children admitted to the PICU with suspected NAI, as documented by a medical practitioner, between 1 January 2012 to 31 December 2020.

Setting and Participants

The study site was the RCWMCH PICU, a 22 -bedded unit multidisciplinary PICU that admits approximately 1300 patients under 13 years of age annually.

Children were eligible for inclusion in the study if they had been admitted to PICU during the study period following traumatic injury, which was suspected as being non-accidental, as documented by the attending PICU physician.

Patients were excluded if they were admitted to PICU following accidental or self-inflicted injury. Children were also excluded if they were initially suspected of having NAI on PICU admission, but the final discharge diagnosis revealed an underlying medical condition that can be fully explained the clinical presentation and/or where NAI was subsequently ruled out by the attending physician.

Data sources and collection

Ethical approval was obtained by the Departmental and Hospital Research Committees and the University of Cape Town's Faculty of Health Sciences' Human Research Ethics Committee (HREC Rec/Ref 493/2021). The requirement for written informed consent was waived given the retrospective, descriptive nature of the study, which maintained confidentiality.

Data were extracted from the PICU and Social work databases as well as the National Health Laboratory Services (NHLS) database, patient medical folders and electronic discharge reports (ECCR). Radiological reports and images were viewed using the Picture Archiving and Communication System (PACS).

Demographic data were collected on age, sex and the region in which the child lived, to identify any socio-geographic patterns associated with high rates of NAI. Documented admission characteristics included the Paediatric Index of Mortality Score (PIM2 or PIM3); the type of NAI, mechanism of injury, areas of the body involved, the place where NAI occurred and the perpetrator's relationship to the child (if known). Data related to the course of PICU admission included whether the child was mechanically ventilated, and the duration thereof, receipt of inotropes, blood products and the need for surgical intervention. PICU outcome measures were mortality, including the proportion of deaths occurring after withdrawal of life-sustaining therapy and duration of PICU stay if the patient survived. Social welfare interventions were also documented, including whether the case had been documented as being reported to child protection services, completion of Form 22 as well as evidence of previous referral to social workers and/or removal from the home.

Data analysis

Data were collected in a standardised case record form after which deidentified data were entered into a password protected MS Excel Spreadsheet and exported to SPSS Statistics (IBM version 1.0.0.1406; 2021) for analysis. Descriptive data were tested for normality using the Shapiro– Wilk W test. Continuous variables were represented as mean (SD) or median (interquartile range) according to distribution, and categorical variables as n (%). Patient characteristics were compared between PICU survivors and non-survivors using Mann Whitney U or Chi^2 tests, as appropriate. Statistically significant and clinically relevant factors identified on univariate analysis were entered into a best-fit multivariable binary regression

analysis to identify any independent associative or modifiable factors for mortality. A significance level of $p < 0.05$ was chosen.

Results

Study Population

A total of 11345 children were admitted to the PICU over the study period, of which 119 patients (1.0%) were screened for inclusion after reviewing PICU and Social Work databases for all documented cases of suspected NAI. Fifty-five (46.2%) of these children were admitted with gunshot wounds (GSW). After determining that the injuries sustained were accidental, 69 patients (including 47 with GSW and 22 with accidental injuries, drowning and poison ingestions) were subsequently excluded. A total of 42 children were therefore included in data analysis, representing 0.4% of the PICU admissions over the study period (Figure 1) with median age of 20.3 (interquartile range, IQR 7.9 – 62.6) months and 61.9% were male.

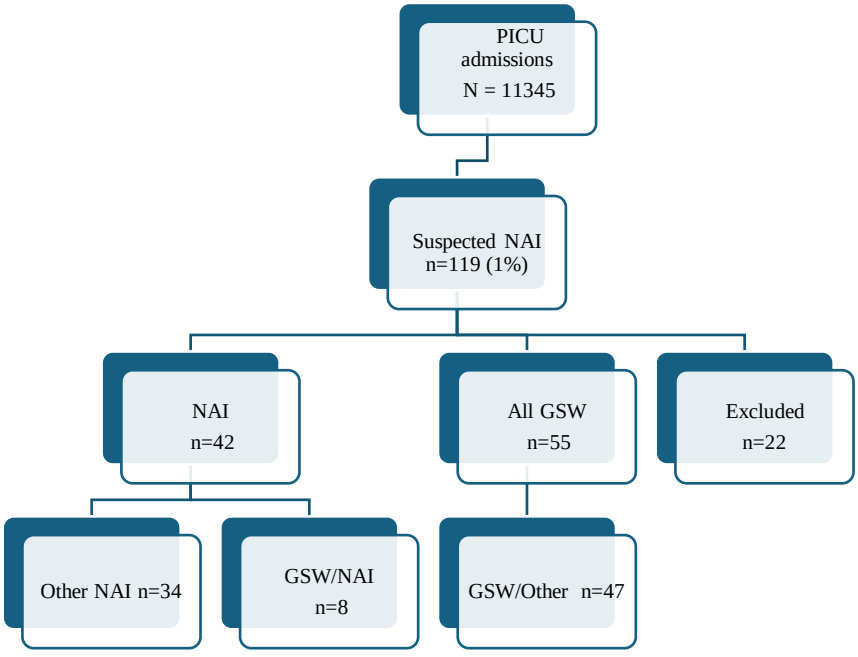

Figure 1: Flowchart of participants through the study

Most patients sustained physical injury (n=31; 73.8%) from assaults (n=19; 45.2%), with head injury (n=24; 57.1%) the most common site, followed by skin (n=23; 54.8%), polytrauma (n=17; 40.5%) and chest (n=15; 35.7%) injury (Figure 2). The two patients categorised as "Other" type of NAI were both deliberately poisoned. In most cases (n=24; 57.1%) the

perpetrator, where known, was a family member and the incident occurred in the home (n=35; 83.3%) (table 1). Most cases of NAI (n=12; 28.6%) occurred in the Klipfontein health district, followed by Micthell's Plain health sub-district (n = 8; 19%) (Figure 2). Most cases (n=35; 83.3%) were referred to Social Work for the first time during their incident admission; 7 (16.7%) children were previously known to the social work department and 2 of these patients died

During their PICU stay, most patients (n=37; 88.1%) received invasive mechanical ventilation for median (IQR) duration 2.0 (1.0 – 3.8) days. Inotropic support was required by 11 (26.2) patients; 18 (42.9%) received blood products and 23 (54.8%) underwent surgery during their PICU admission (Table 1). Various surgical disciplines were involved in the co-management of the study patient, most commonly neurosurgery, where patients with severe traumatic brain injuries had intracranial pressure and brain oxygenation monitors placed to assist with maintaining neuroprotective measures. Other surgeries that were required included laparotomies, both exploratory and damage control for visceral organ damage; vascular surgery to repair damaged bloods vessels; wound debridement for burns and orthopaedic surgery for fracture repair.

PICU mortality was 28.6% (n=12), with a PIM2 risk adjusted mortality (observed/mean predicted mortality) of 3.6. Ten of these children (83.3%) died following withdrawal of life-sustaining therapy. Of the 30 PICU survivors, seven (23.3%) were discharged with long-term disability, whilst the functional outcome of 16 (53.3%) survivors is not known.

A multivariable binary logistic regression was conducted to determine the effect of inotropes, type of NAI, mechanism of injury, injury site (head, skin – eye injuries removed from the model for reasons of collinearity), and multiple injuries on patient survival. The model was significant ($p = 0.001$) and a good fit for the data (Nagelkerke R square 0.78) and was able to correctly predict 85.7% of cases. None of the variables in the model were found to be independently associated with survival ($p > 0.1$ for all).

Table 1: Participant characteristics, PICU course and outcomes (n=42)

	All NAI **n=42**	**Survived PICU** **n=30**	**Died in PICU** **n=12**	**P**
Admission characteristics				
Age (months)	20.3 (7.9 – 62.6)	22.8 (8.1 – 62.9)	18.6 (7.6 – 18.6)	0.86
Male sex (%)	26 (61.9)	20 (66.7)	6 (50.0)	0.32
Risk of mortality	0.06 (0.03 – 0.33)	0.06 (0.03 – 0.17)	0.42 (0.03 – 0.87)	0.13

PICU course				
Invasive *MV (%)	37 (88.1)	25 (83.3)	12 (100.0)	0.13
Duration of *MV (days)	2.0 (1.0 – 3.8)	2.0 (1.0 – 3.5)	1.0 (1.0 – 5.0)	0.36
Received inotropes (%)	11 (26.2)	5 (16.7)	6 (50.0)	0.03
Received blood products (%)	18 (42.9)	13 (43.3)	5 (41.7)	0.92
Surgery while in PICU (%)	23 (54.8)	19 (63.3)	4 (33.3)	0.09
Outcome				
PICU LOS (days)	3.0 (1.8 – 6.3)	3.0 (2.0 – 7.3)	1.5 (0 – 3.8)	0.02
NAI details				
NAI occurred at home (%)	35 (83.3)	26 (86.7)	9 (75.0)	0.36
Type of NAI (%)				
Neglect	5 (11.9)	4 (13.3)	1 (8.3)	0.009
Physical	31 (73.8)	24 (80.0)	7 (58.3)	
Combination neglect/physical/ sexual	4 (9.5)	0	4 (33.3)	
Other	2 (4.8)	2 (6.7)	0	
Mechanism of injury (%)				
Burn	3 (7.1)	2 (6.7)	1 (8.3)	0.03
Gunshot	8 (19.0)	8 (26.7)	0	
Physical assault	19 (45.2)	12 (40.0)	7 (58.3)	
Poisoning	2 (4.8)	2 (6.7)	0	
Stab	4 (9.5)	4 (13.3)	0	
Combination	3 (7.1)	0	3 (25.0)	
Other	3 (7.1)	2 (6.7)	1 (8.3)	
Sites of Areas affected (%)				
Head	24 (57.1)	13 (43.3)	11 (91.7)	0.004
Skin	23 (54.8)	13 (43.3)	10 (83.3)	0.02
Eyes	9 (21.4)	3 (10.0)	6 (50.0)	0.004
Neck	3 (7.1)	3 (10.0)	0	0.41
Chest	15 (35.7)	9 (30.0)	6 (50.0)	0.22
Abdomen	13 (31.0)	10 (33.3)	3 (25.0)	0.60
Upper limb	8 (19.0)	4 (13.3)	4 (33.3)	0.14
Lower limb	9 (21.4)	6 (20.0)	3 (25.0)	0.72
Genitourinary	1 (2.4)	0	1 (8.3)	0.29 (Fisher's exact)
Spine	2 (4.8)	0	2 (16.7)	0.08 (Fisher's Exact)
Multiple injuries	17 (40.5)	9 (30.0)	8 (66.7)	0.03
Perpetrator (%)				
Family	24 (57.1)	16 (53.3)	8 (66.7)	0.81
Friend	3 (7.1)	2 (6.7)	1 (8.3)	
Gang violence	3 (7.1)	3 (10.0)	0	
Neighbour	1 (2.4)	1 (3.3)	0	
Unknown	10 (23.8)	7 (23.3	3 (25.0)	

Figure: Table comparing characteristics between survivors and non survivors

*MV=Mechanical ventilation

Continuous data are represented as median and interquartile range (IQR) and *categorical data are represented as percentage (%)*

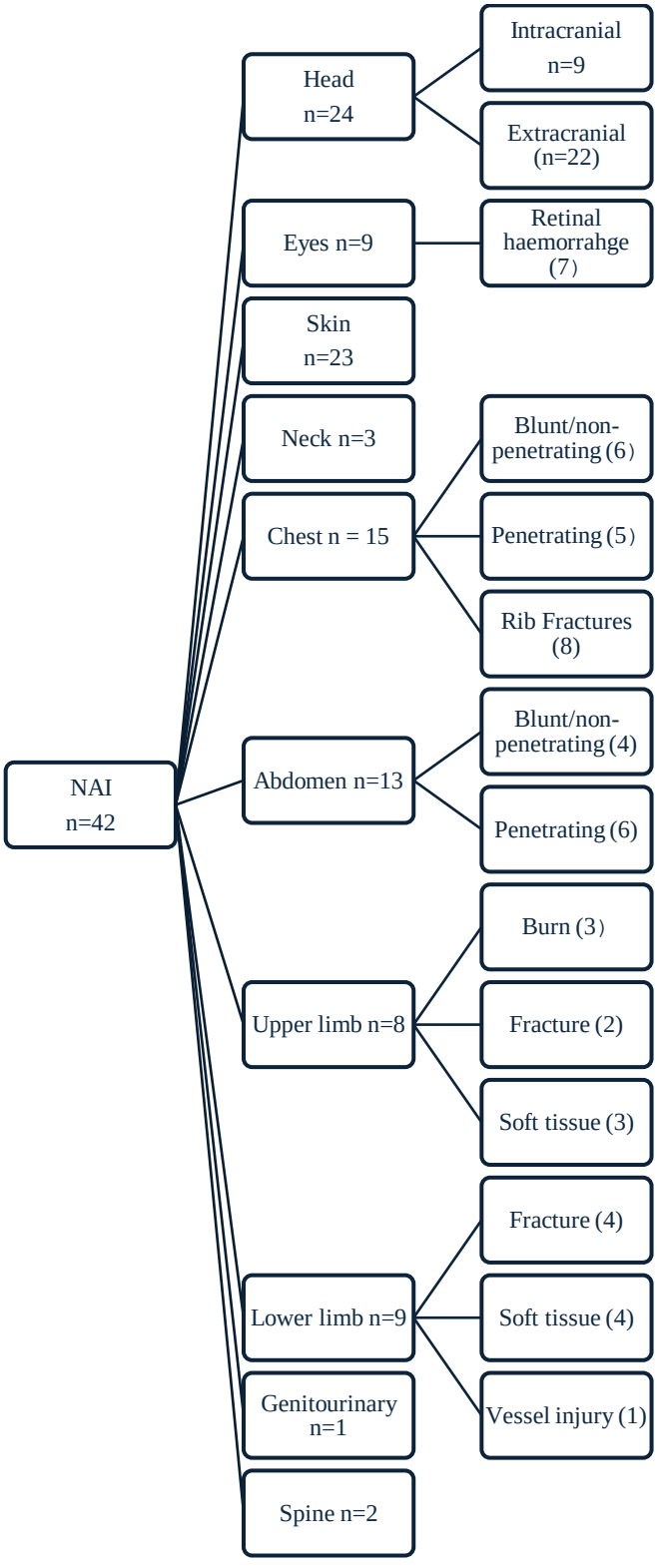

Figure 2: Sites of injury of physical assault for 42 NAI patients. Patients had injuries to multiple sites.

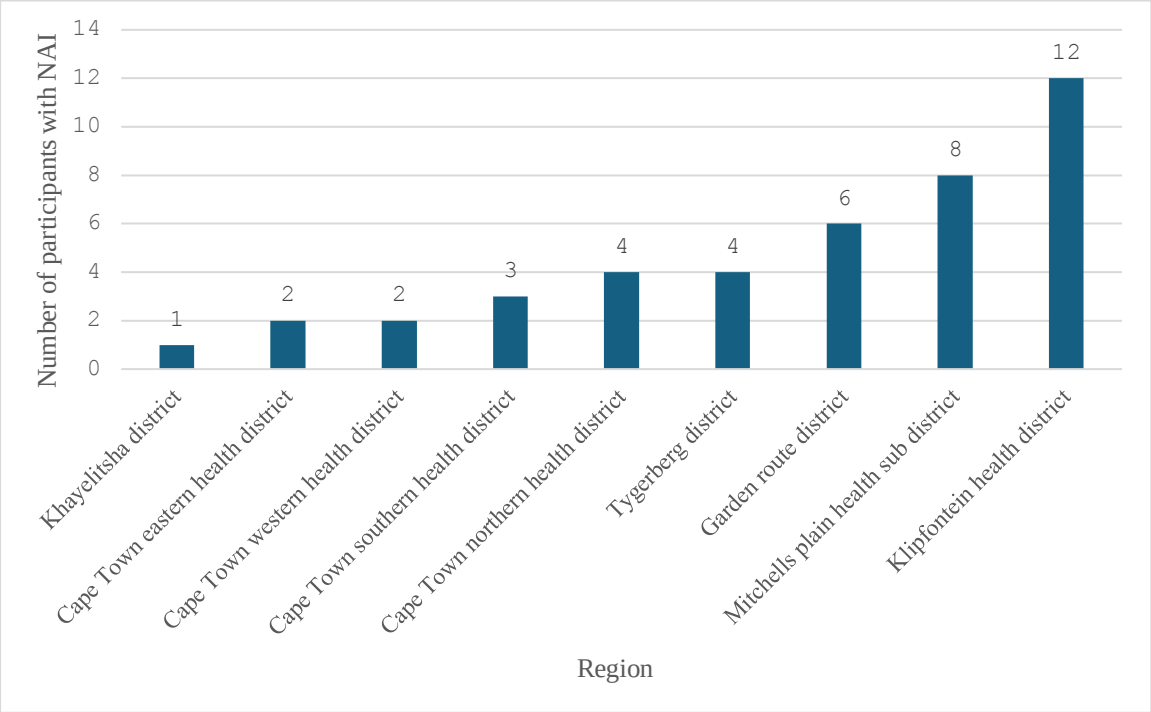

Figure 3: Geographical regions where NAI occurred

Discussion

South Africa is a middle-income country with a high unemployment rate of 32.9% (28).The high levels of criminal activity, substance abuse and gang related violence coupled with poverty make SA an unsafe place for children, even in their homes(29). Red Cross War Memorial Children's hospital, as a tertiary hospital with a mixed medical and surgical 22 bed PICU, receives all complicated trauma cases from across the Western Cape (30).

Fieggen et al (2004), reported a high incidence of children who were intentionally and unintentionally used as human shields during domestic violence in SA(29) . Child Safe is an organisation in the Western Cape that promotes the prevention of intentional and unintentional injuries of all severities through research and education and contributes to improvement (31). Despite these organizations, there remains a high incidence of childhood trauma in SA and our data confirm approximately 5 severe NAI cases per year warranting PICU admission.

The confirmed NAI cases admitted to the PICU constituted fewer than 1% of the total RCWMCH PICU admissions over the 9-year study period. This is comparable to another SA study conducted at Chris Hani Baragwanath hospital in Johannesburg that reported 1.6% of total trauma admissions to PICU were due to deliberate assault (32). Despite the relatively low proportion of NAI cases admitted to PICU, management of these cases has considerable cost implications. It is well known that PICU resources are a precious commodity in SA and the availability of beds is often a challenge to secure (30). The average cost per day at the RCWMCH PICU is approximately R13 000 and the total cost for the all the NAI patients admitted would therefore amount to an estimated R2 899 000 (223 days) over the study period; a substantial cost for a preventable condition. The 223 ICU bed days could have been utilized for curative surgical procedures and reduce that backlog on the surgical waiting list. In addition, almost a quarter of NAI survivors were known to be left with physical disability, requiring ongoing expenditure and heath resource utilisation.

It is the responsibility of and obligation of every health care worker to report child maltreatment and neglect, and all healthcare workers should be familiar with the Children's act No. 38 of 2005 and The Amended Sexual Offenses Act, including obligatory reporting requirements for all suspected NAI (2, 33). All patients in this cohort were referred to the Social Work department and appropriate forms such as J88 and Form 22 were completed. All cases were investigated and appropriately referred to police or Department of Social Development as indicated. Regular audit is recommended to ensure compliance with mandatory reporting is maintained.

In our study the average age was 20.3 months with the youngest patient being a 1- day old neonate. The under 5 year age group is known to be most commonly affected by NAI (34), owing to their physical inability to escape targeted injury and their high levels of dependence on adults. The young age of our cohort, correlates well with a 2009 South African National child homicide study, which reported that over a third or deaths due to abuse and neglect occurred in babies within the first week of life, whilst almost three quarters of cases were in children under five years of age (14).

The proximity of the RCWMCH to Klipfontein district may explain why this district had the highest rate of NAI (28.6%) in our cohort, however further research is recommended to identify potential social determinants. In the case of young children, most fatal NAI occurred in the home and the perpetrator (most often the mother) was known to the child(35) Our data confirms

this finding, with 83% of NAI events occurring in the home, and most of the perpetrators being known to the child. These findings highlight the necessity for early intervention and prevention programs targeting maternal mental health, focussed on the first 1000 days of life (36).

The most common type of NAI, occurring in over 70% of this cohort, was physical abuse, followed by intentional neglect (9% of cases). Patients with a combination of two or more types of NAIS had worse outcomes. This finding is similar to results from a cross- sectional cohort study conducted in Asia (37). It is estimated by the SA Society of Psychiatrists that a third of children under 17 years of age have experienced emotional abuse or neglect, with a higher incidence of these types of abuse amongst children who experience other NAI types such as physical and sexual assault (38). Whilst physical assault was more common in our cohort, Meinck et al (2016) estimate that childhood victims of emotional or psychological abuse have a four times greater risk of developing serious mental health illnesses later in life (39). Assessment of psychological and emotional abuse other than intentional neglect, was beyond the scope of this study. However, this aspect warrants comprehensive interdisciplinary assessment and follow up, given the long-term mental health effect.

NAI can occur and affect any site in the body. Malki et al described head injuries to be the most common affected site(25). Head injuries were the most common and most fatal injury (11 out of 12 deaths) in our cohort, mostly a consequence of physical assault. The NAI study conducted at the Addenbrooke PICU in the UK found all 15 of their study participants to have “shaken baby syndrome”(27). In this phenomenon, rapid acceleration and deceleration of the head results in disruption of bridging veins leading to intracranial and retinal haemorrhages (24). In our patient cohort, 7 (16%) of those screened were found to have evidence of retinal haemorrhage, which is strongly associated with shaken infant syndrome.

PICU mortality in our study of severe NAI was 28.6%. This is more than double the general RCWMCH PICU mortality of approximately 10% (30). The PIM2 score is an internationally validated benchmarking tool to predict mortality on PICU admission(40).The high PIM2 risk adjusted mortality of 3.6 indicates greater than predicted mortality in this group of children, with worse outcomes than were expected on admission. Over 80% of deaths in our group followed withdrawal of life-sustaining therapy due to devastating irreversible injuries.

Ballot et al (2019) described the challenges faced with withdrawal of life sustaining therapies in the South African public healthcare sector (41). According to The Royal College of

Paediatrics and Child Health (RCPCH) there are three sets of circumstances when treatment limitation can be considered; when life is limited in quantity (brainstem death, imminent death or inevitable death); when life is limited in quality (burden of treatment, burden of the condition or lack of ability to benefit); and finally informed competent refusal of treatment(42). In our study, all the patients in whom life-sustaining therapy was withdrawn fell under the "limited in quantity" category. The high mortality of this group PICU patients, compared to general PICU patients, warrants further investigation.

The long-term outcomes of this cohort of NAI survivors are beyond the scope of the study, but are likely to be substantial, with potential debilitating long term sequelae including epilepsy, cognitive dysfunction, cortical blindness motor disabilities, and psychological sequelae (39, 43). Interdisciplinary clinical follow-up of NAI survivors is therefore strongly recommended to monitor and optimise long-term functional outcomes.

Lastly, we note with concern the high proportion of children admitted to PICU following both accidental and non-accidental gunshot injury, although many were excluded from the analysis. Despite these patients not meeting the stated criteria for NAI, we presented these data to highlight the problem of gun violence in SA. Of the patients admitted with gunshot wounds who did not meet NAI criteria, the majority (n=47; 85.4%) had been caught in crossfire shootings related to gang violence. The issue of gang violence predates democracy in SA (18) and children continue to be victims, especially in the Western Cape. This study therefore highlights whether the definition of NAI should be extended to include innocent victims of crossfire.

The ongoing violence against children has and will continue to have massive implications for South Africa's economic, physical and social health. Every effort should be made to protect the future generation, the children.

Limitations

This study was a retrospective folder review and is therefore at risk of information and selection bias, being reliant on documentation in the medical folders and on the attending, clinician documenting a diagnosis of suspected NAI. We did not include children who died before admission to PICU. In addition, children admitted for other reasons, where NAI was later identified as an incidental finding, may not have been identified for inclusion in this study. This is a single centre study and therefore not generalizable to other units in or beyond South Africa.

Conclusion

Children who have sustained NAI represent a small proportion of overall PICU admissions, with higher- than-expected mortality and considerable morbidity. Gunshot wounds are relatively common, and although not all meet current NAI criteria, these results support advocacy efforts to create a gun-free South Africa. Early recognition of children who may have sustained severe NAI, based on presenting signs and injury patterns, is important to facilitate prompt referral and management. Standardised follow-up of survivors of severe NAI is recommended to determine and optimise long-term functional and psychosocial outcomes. Urgent action and policy change is needed to achieve the Sustainable Development Goal of eliminating violence against children by 2030(1).

Acknowledgements – Carla Brown, who assisted with the patient database and Dirk Von Delft for the initial assistance with conceptualising the project.

Author contribution – LB conceived the study, collected data, and wrote the initial manuscript draft; BM contributed to protocol development, data analysis, reviewed and edited manuscript drafts; BR – contributed to protocol development, reviewed and edited manuscript drafts. All authors reviewed and approved the final version of the manuscript.

Conflict of interest statement – the authors have no conflicts to declare. The study was not funded.

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Appendix A: Ethics approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

30 September 2021

HREC REF: 493/2021

Prof B Morrow
Department of Intensive Care Unit
Office D1.44 Red Cross Children's Hospital
Email: Brenda.morrow@uct.ac.za
Student: BWLSLYN002@myuct.ac.za

Dear Prof Morrow

PROJECT TITLE: CHILDREN ADMITTED TO THE RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL TO THE PAEDIATRIC INTENSIVE CARE UNIT WITH SUSPECTED NON-ACCIDENTAL INJURIES (2012-2020): A RETROSPECTIVE DESCRIPTIVE STUDY-MMED CANDIDATE-DR LYNELLE BOWES

Thank you for your response letter, addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020: 06 July 2020 & 01 July 2021.

Approval is granted for one year until the 30 September 2022.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Dr Lynelle Bowes will also be involved in this study.

Please quote the HREC REF 493/2021 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Appendix B: Current HREC renewal

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

HUMAN RESEARCH ETHICS COMMITTEE
- 6 NOV 2023
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

FHS017: Annual Progress Report / Renewal

Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registries

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.11.2024
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	6/11/2023

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	5 November 2023		
HREC REF Number	493/2021	Current Ethics Approval was granted until	30/09/2023
Protocol title	Children admitted to the Red Cross War Memorial Children's Hospital to the Paediatric Intensive Care Unit with suspected Non Accidental injuries (2012-2020): a retrospective descriptive study		
Principal Investigator	Professor Brenda Morrow		
Department / Office Internal Mail Address	brenda.morrow@uct.ac.za		
1.1 Does this protocol receive US Federal funding?		☐ Yes	x☐ No

2. Protocol status (tick ✓)

☐	Research-related activities are ongoing
X	Data collection is complete, data analysis only
Please indicate (in the block below) the titles and HREC reference numbers of any projects currently making use of the Database/registry/repository.	
Data collection and analysis are both complete, the student now needs to write up their MMed dissertation. Please see study deviation form in acknowledgement of the late submission of this renewal, and please accept my apologies!	

3. Protocol summary

Total number of records or specimens collected, reviewed or stored since the original approval		119
Total number of records or specimens collected, reviewed or stored since last progress report		79
Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report.	X Yes	☐ No

Abstract presented at Departmental Research Day (attached)

4. Signature

Signature of PI		Date	5/11/2023

Appendix C: Institutional approval

Western Cape Government
Health

DR T KERBELKER
Acting Manager: Medical Services
Red Cross War Memorial Children's Hospital
Email: Tamara.Kerbelker@westerncape.gov.za
Tel: +27 21 658 5383 Fax: +27 21 658 5006/5166

25 October 2021

Dr L Bowes
PICU

Dear Bowes,

RESEARCH: RXH: RCC 297 / WC_202110_023

PROJECT TITLE: Children admitted to Paediatric Intensive Care at Red Cross War Memorial Children's Hospital with suspected Non-Accidental injuries (2012-2020)

It is a pleasure to inform you that the hospital Research Review Committee has approved your application to conduct above-mentioned study at Red Cross War Memorial Children's Hospital.

Kindly note that this approval is subject to strict adherence to the HREC recommendations regarding research involving participants during COVID-19, dated 17 March 2020 (UCT HREC notice attached).

Yours sincerely,

DR T KERBELKER
ACTING MANAGER: MEDICAL SERVICES

Appendix D: Journal instructions to authors

Manuscript preparation

Preparing an article for anonymous review

To ensure a fair and unbiased review process, submissions may include an anonymized version of the manuscript.

Submitting a manuscript that needs additional blinding can slow down your review process, so please be sure to follow these simple guidelines as much as possible:

- An anonymous version should not contain any author, affiliation or particular institutional details that will enable identification.
- Please remove title page, acknowledgements, contact details, funding grants to a named person, and any running headers of author names.
- Mask self-citations by referring to your own work in third person.

General article format/layout

Submitted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction prior to being sent for review, which will delay publication.

General:

- Manuscripts must be written in UK English (this includes spelling).
- The manuscript must be in Microsoft Word or RTF document format. Text must be 1.5 line spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes). Pages and lines should be numbered consecutively.
- Please make your article concise, even if it is below the word limit.
- Qualifications, ***full*** affiliation (department, school/faculty, institution, city, country) and contact details of ALL authors must be provided in the manuscript and in the online submission process.
- Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.
- Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160.
- Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'
- Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.
- Medical drugs should be referred to by their generic name although the trade name may be used in brackets in the text once if unique.

If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the *only* exception. Please DO NOT use fill, format lines and so on.

Preparation notes by article type

Research

Guideline word limit: 3 000 words (excluding abstract and bibliography)

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The title of the manuscript should concisely describe the study but should not include the outcome. The introduction should be concise – no more than three paragraphs – on the background to the research question and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are to fill a gap in the literature, a logical extension of previous

work, or to answer an important question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. At the end of the introduction clearly state the aim or objective of the study. The primary and secondary outcomes should be specified.

In the Methods section describe in sufficient detail so that others would be able to replicate the study should they need to. Sections of the methods that have been described in previous publications need only be referenced. The statistical methods should be described. Where appropriate, sample size calculations should be included to demonstrate that the study is not underpowered.

Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

The discussion should be confined to an interpretation of your results with respect to your stated aim and if applicable, a comparison to the results of similar studies. The strengths and weaknesses of your study should be discussed.

The conclusion should be confined to an interpretation of the results of the study and a recommendation if applicable.

- May include up to 6 illustrations or tables.
- References should only include the most recent and relevant articles. A maximum of 30 references is advised.

Structured abstract

- This should be no more than 250 words, with the following headings:
    - **Background:** why the study is being done and how it relates to other published work.
    - **Objectives:** what the study intends to find out
    - **Methods:** must include study design, number of participants, description of the research tools/instruments, any specific analyses that were done on the data.
    - **Results:** first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
    - **Conclusion:** must be supported by the data and be aligned with the conclusion in the main text.
    - Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors. It should be able to be intelligible to the reader without referral to the main body of the article.
    - Do not include any references in the abstracts.

Here is an example of a good abstract.

***Scientific letters*/short reports**

These are shorter length, scholarly research articles of no more than 1500 words, and include case reports.

Guideline word limit: 1500 words

- Abstract: Structured, maximum 250 words, with the following headings: Background, Objectives, Methods, Results, and Conclusion.
- May include only one illustration or table
- A maximum of 15 references

Editorials

Guideline word limit: 1 000 words

These opinion or comment articles are usually commissioned but we are happy to consider and peer review unsolicited editorials. Editorials should be accessible and interesting to readers without specialist knowledge of the subject under discussion and should have an element of topicality (why is a comment on this issue relevant now?) There should be a clear message to the piece, supported by evidence.

Please make clear the type of evidence that supports each key statement, e.g.:

- expert opinion
- personal clinical experience

- observational studies
- trials
- systematic reviews.

Review articles

Narrative review articles should always be discussed with the Editor prior to submission. (Structured reviews or meta-analyses' need not be).

Guideline word limit: 4 000 words

These are welcome but should be either commissioned or discussed with the Editor before submission. A review article should provide a clear, up-to-date account of the topic and be aimed at non-specialist hospital doctors and general practitioners. They should be aligned to practice in South and/or sub-Saharan Africa and not a précis of reviews published in the international literature

Please ensure that your article includes:

- Abstract: unstructured, of about 100-150 words, explaining the review and why it is important
- Methods: Outline the sources and selection methods, including search strategy and keywords used for identifying references from online bibliographic databases. Discuss the quality of evidence.
- When writing clarify the evidence you used for key statements and the strength of the evidence. Do not present statements or opinions without such evidence, or if you have to, say that there is little or no evidence and that this is opinion. Avoid specialist jargon and abbreviations and provide advice specific to southern Africa.
- Personal details: Please supply your qualifications, position and affiliations address, telephone number and fax number, and your e-mail address; and a short personal profile (50 words) and a few words about your current fields of interest.

Correspondence (Letters to the Editor)

Guideline word limit: 400 words

Letters to the editor should relate either to a paper or article published by the SAJCC or to a topical issue of particular relevance to the journal's readership

- May include only one illustration or table
- Must include a correspondence address.

SAJCC Soapbox

Unsolicited or solicited mini-review or opinion articles on any current and/or controversial topic in the field of critical care, are invited for editorial review. The views expressed in these commentaries are not necessarily those of the SAJCC Editorial Board or of the CCSSA but do require substantiation using scholarly discourse and must be based on available scientific evidence. Articles on current issues that stimulate debate are specifically encouraged. Although topics may be on the national agenda, they should also have relevance and/or implications for the broader international audience.

Word count – between 1000 – 3000 words

Tables and figures – one table and one figure permitted

References – max 15

Obituaries

Guideline word limit: 400 words

Should be offered within the first year of the practitioner's death and may be accompanied by a photograph.

Illustrations/photos/scans

- If illustrations submitted have been published elsewhere, the author(s) should provide evidence of consent to republication obtained from the copyright holder.
- Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'.

- Each figure must have a caption/legend: Fig. 1. Description (any abbreviations in full).
- All images must be of high enough resolution/quality for print.
- All illustrations (graphs, diagrams, charts, etc.) must be in PDF form.
- Ensure all graph axes are labelled appropriately, with a heading/description and units (as necessary) indicated. Do not include decimal places if not necessary e.g. 0; 1.0; 2.0; 3.0; 4.0 etc.
- Each image must be attached individually as a 'supplementary file' upon submission (not solely embedded in the accompanying manuscript) and named Fig. 1, Fig. 2, etc.

Tables

- Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged.
- Embed/include each table in the manuscript Word file - do not provide separately as supplementary files.
- Number each table in Arabic numerals (Table 1, Table 2, etc.) consecutively as they are referred to in the text.
- Tables must be cell-based (i.e. not constructed with text boxes or tabs) and editable.
- Ensure each table has a concise title and column headings and include units where necessary.
- Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

References

NB: *Only complete, correctly formatted reference lists in Vancouver style will be accepted. If reference manager software is used, the reference list and citations in text are to be unformatted to plain text before submitting.*

- Authors must verify references from original sources.
- Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,[2] and others. [3,4-6]
- All references should be listed at the end of the article in numerical order of appearance in the Vancouver style (not alphabetical order).
- Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus.
- Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al.
- Volume and issue numbers should be given.
- First and last page, in full, should be given e.g.: 1215-1217 **not** 1215-17.
- Wherever possible, references must be accompanied by a digital object identifier (DOI) link). Authors are encouraged to use the DOI lookup service offered by CrossRef:
    - On the Crossref homepage, paste the article title into the 'Metadata search' box.
    - Look for the correct, matching article in the list of results.
    - Click Actions > Cite
    - Alongside 'url =' copy the URL between (36).
    - Provide as follows, e.g.: https://doi.org/10.7196/07294.937.98x

Some examples:

- *Journal references :* Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. DOI:10.1000/hgjr.182
- *Book references:* Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101.
- *Chapter/section in a book:* Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.
- *Internet references:* World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: WHO, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).
- Legal references
- Government Gazettes:

National Department of Health, South Africa. National Policy for Health Act, 1990 (Act No. 116 of 1990). Free primary health care services. Government Gazette No. 17507:1514. 1996.

In this example, 17507 is the Gazette Number. This is followed by :1514 - this is the notice number in this Gazette.

- Provincial Gazettes:

Gauteng Province, South Africa; Department of Agriculture, Conservation, Environment and Land Affairs. Publication of the Gauteng health care waste management draft regulations. Gauteng Provincial Gazette No. 373:3003, 2003.

- Acts:

South Africa. National Health Act No. 61 of 2003.

- Regulations to an Act:

South Africa. National Health Act of 2003. Regulations: Rendering of clinical forensic medicine services. Government Gazette No. 35099, 2012. (Published under Government Notice R176).

- Bills:

South Africa. Traditional Health Practitioners Bill, No. B66B-2003, 2006.

- Green/white papers:

South Africa. Department of Health Green Paper: National Health Insurance in South Africa. 2011.

- Case law:

Rex v Jopp and Another 1949 (4) SA 11 (N)

Rex v Jopp and Another: Name of the parties concerned

1949: Date of decision (or when the case was heard)

(4): Volume number

SA: SA Law Reports

11: Page or section number

(N): In this case Natal - where the case was heard. Similarly, (C) woud indicate Cape, (G) Gauteng, and so on.

NOTE: no. after the v

- *Other references (e.g. reports) should follow the same format:* Author(s). Title. Publisher place: Publisher name, year; pages.
- Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'.
- Unpublished observations and personal communications in the text must **not** appear in the reference list. The full name of the source person must be provided for personal communications e.g. '...(Prof. Michael Jones, personal communication)'.