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Indications for tracheostomy in paediatric patients at a tertiary referral centre, Inkosi Albert Luthuli Hospital (IALCH).

By

Dr. Phumelele Bongiwe Nokwazi Kissi

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for the degree of MMed
in the Department of Otorhinolaryngology and Head and Neck Surgery
School of Clinical Medicine
College of Health Sciences
University of KwaZulu-Natal
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As the candidate's supervisor, I have/have not approved this thesis for submission.

Signed: 
Name: Dr. Tesuven Krishna Naidu
Date: 04 September 2018

Declaration

I, Dr. Phumelele Bongiwe Nokwazi Kissi declare that:

- (i) The research reported in this dissertation, except where otherwise indicated, is my original work.
- (ii) This dissertation has not been submitted for any degree or examination at any other university.
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Dedication

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I would like to extend heartfelt gratitude to the following people who have positively contributed towards my research.

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- 2) Dr Basil Enicker, HOD of the department of Neurosurgery at IALCH, for guidance and support during the infant stages of the research project.

Overview of the thesis

The paediatric tracheostomy is an uncommon procedure, with higher mortality and morbidity rates than the adult tracheostomy. The procedure itself is technically more demanding than in adults due to the smaller more pliable trachea and the limited operating field. The paediatric tracheostomy is performed with a different technique than that of an adult tracheostomy, with a formal stoma is fashioned by suturing the tracheal wall to the skin with maturation sutures in addition to safety stay sutures placed in the tracheal wall. The considerations include the growing anatomy of a child and attention is placed on preventing accidental decannulation and preventing long term damage to the growing anatomy of a child.

With the increased availability of Paediatric intensive Care Units (PICU), and high trauma burden in children in Durban, South Africa, we plan to determine what the most common indication for performing a tracheostomy in a paediatric population. This will be done by a retrospective chart review of all cases requiring tracheostomy at IALCH between the period of 2004 to 2016. An in-depth analysis of the charts will provide insight in to the most common pathology requiring a tracheostomy and with that knowledge we can add value to the existing Paediatric tracheostomy Care programme at IALCH. This information gathered will further assist in establishing a support system for the parents of a child with a tracheostomy.

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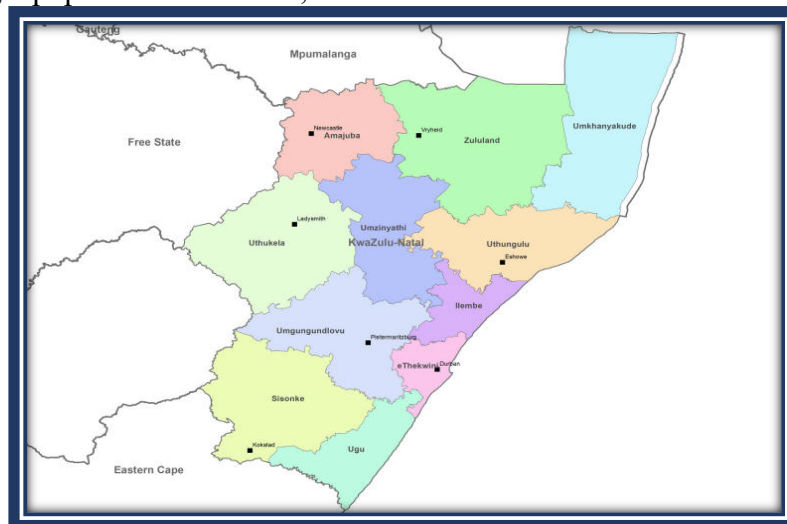
Chapter 1: The Review of the Literature

Introduction

A tracheostomy is a surgically created airway, to bypass upper airway obstruction. A tracheostomy tube is subsequently placed in the airway to maintain patency. Management of a child with a tracheostomy mandates a multidisciplinary team approach, the team comprising of a speech therapist, an occupational therapist, paediatricians, otorhinolaryngologists and most importantly the home care giver. Arguably the most important member in this team is the home care giver, having to be involved in medical care with no necessary medical training. They are the point of contact and advocate for the paediatric patient, with insight and understanding of the challenges anticipated on discharge. In the ideal setting, children with a tracheostomy can be discharged home safely only when round-the-clock supervision and a safe environment with access to health care are guaranteed. These conditions may not be met in resource-poor settings. When one cannot provide around the clock home nursing care for all children with tracheostomies, the home care giver becomes key in providing much needed care.

Groenendijk et al ^[1] explored the topic of paediatric tracheostomy and ventilation home care, in a resource poor setting, in South Africa (RSA) and concluded that, it is not always possible to establish an ideal home setting, but it is possible to provide a child with a tracheostomy safe home environment, provided caregivers are adequately trained and supported. Mortality rate, an important outcome, was not associated with any socio-economic circumstance.

The province of KwaZulu-Natal (KZN), in RSA, is divided into eleven health districts. The major urban centres are Durban and Empangeni on the coasts, Pietermaritzburg, the capital, in the midlands; and Ladysmith and Newcastle in the northwest of the province. Inkosi Albert Luthuli Central Hospital (IALCH) is a level 1 referral unit in KZN, servicing a population of 10.267,300 million ^[2].



Map of KZN Health Districts

As a quaternary care centre, IALCH also hosts specialist neonatologists, neonatal intensive care, paediatric intensive care, specialist paediatricians in cardiology, pulmonology, cardiothoracic, oncology, neurology and neurosurgery. This allows for a setting of all complex paediatric medical and surgical cases to be managed in one institution. This setting often obligates collaborative management in complex paediatric cases. IALCH is the only institution in KZN able to manage complex paediatric airway cases. Paediatric tracheostomies are thus performed here often for a variety of indications.

Critical Literature review

In the mid 1800, physician Armand Trousseau popularised the tracheostomy procedure whilst treating many diphtheria associated upper airway obstruction cases ^[3]. In the subsequent years, the indication for tracheostomy has significantly changed in keeping with technological and medical developments. In the 1970s, the most common indication for tracheostomy in children was acute inflammatory airway obstruction, namely laryngotracheobronchitis and epiglottitis ^[3]. Later years, the most common indication became chronic ventilator dependence and upper airway obstruction (congenital or acquired) and neurological impairment ^[4]. The materials used to make the endotracheal tubes has also improved from rubber and sterling silver to polyvinyl chloride. These changes have reduced the laryngeal damage associated with long term intubation, and thus reducing the frequency of this as an indication for tracheostomy. Neonatal intensive care units (NICU's) have provided the alternative to tracheostomy by way of long term intubation. NICU's and the complication of subglottic stenosis, has become an important indication for tracheostomy.

Interest has grown in the topic of paediatric tracheostomy indications, particularly in view of evolving medical technology and advances in care. Parrilla, C. et al ^[3] reviewed trends in paediatric tracheostomies, and identified a decrease number of tracheostomies performed in their assessment period (1 November 1998 – 30 November 2004). They identified upper airway obstruction as the main indicator and ventilator failure for a multitude of medical reasons. Trauma, as an indication, was identified in one of the 38 cases in their 6-year period of assessment. Perez-Ruiz, E. et al ^[5] in a multi-centre prospective study, assessed 249 cases requiring tracheostomy and the main indicator, by 62.6%, was prolonged ventilation for ventilator failure. Of the various underlying conditions leading to tracheostomy for ventilator failure, 50.6% was due to neurological disorders, followed by respiratory disorders at 39.3%. There were no cases of trauma, and only 4 cases of Juvenile onset recurrent respiratory papillomatosis (JORRP).

Hadfield, P.J. et al ^[6] reported on the changing indications of paediatric tracheostomy over a period of 8 years (1993 – 2001) and identified prolonged ventilation for neuromuscular and respiratory failure (26%) as the most common indication, followed by upper airway obstruction due to subglottic stenosis at 20%. Of interest in their series of 362 cases, was an initial increase in the number of tracheostomies performed in the 8-year period attributing this to conditions such as subglottic and tracheal stenosis, respiratory papillomatosis, caustic alkali ingestion and craniofacial syndromes.

The improvement in paediatric care facilities and the subsequent survival of patients with conditions that would not have been compatible with life has seen the advent of the

“technology dependent paediatric patient’ [7]. These children are emerging as an indication for tracheostomy and requiring ongoing tracheostomy care.

The aim of this study is to assess the indications for tracheostomy in our setting and to assess if there has been a significant change in the trend in indications in 12-year study period.

Research Question

- What is the most common indication for tracheostomy in a paediatric patient (age less than 13) at a tertiary referral centre, IALCH, in Durban, South Africa?
- Are there any changes or trends identifiable in the two-adjacent time: 2004 – 2010 (Group A) and 2011 – 2016 (Group B)?

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Chapter 2: A submission ready manuscript

Indications for tracheostomy in paediatric patients at a tertiary referral centre, Inkosi Albert Luthuli Hospital (IALCH).

P.B.N. Kissi, MBCHB, FC ORL (SA)

Department of Otorhinolaryngology, Head and Neck Surgery, School of Clinical Medicine, College of Health Sciences, Nelson Mandela School of Medicine, University of Kwa Zulu Natal, Durban, South Africa

Corresponding author: Dr. P.B.N. Kissi (bongiwekissi@gmail.com)

Background: Paediatric tracheostomy procedure is not common place. The procedure is technically more demanding in view of the smaller operating field and a growing patient. The changes in technology and medical advances, has resulted in a change in the reasons for performing tracheostomy in the paediatric patient.

Objectives: This study is done to investigate the current indications of tracheostomy in the paediatric population in IALCH, and to assess if those indications are similar or different from those described in the literature. The acquired information will assist in policy drafting and planning for the management of a tracheostomised paediatric patient.

Methods: Paediatric patients included were <13 years old. The study covered 12 years, January 2004 - 31 December 2016. Patients were identified from a retrospective database search for the tracheostomy procedure code in operative notes at Inkosi Albert Luthuli Central Hospital, Durban, South Africa. Data collected included demographics, primary diagnosis, indication for tracheostomy, referral hospital.

Results: A total of 318 tracheostomies were performed during the 12-year study period. There were 194 (61%) male and 124 (39%) females. Group A (years 2004 – 2010) had 152 cases and Group B (Years 2011 – 2016) had 165 tracheostomies performed. Overall, the most common indication for tracheostomy was prolonged ventilation at 39% followed by upper airway obstruction at 35%. The most common primary diagnosis in the patients receiving tracheostomy for prolonged ventilation, was trauma at 69%.

Conclusion: The predominant indications for tracheostomy in our institution are prolonged ventilation and upper airway obstruction. The latter has been seen throughout literature for many years, although the underlying cause for it is no longer infective but rather syndromic conditions. Under prolonged ventilation, the underlying primary diagnosis was trauma. Trauma emerging as an important, previously unrecognised, cause for performing paediatric tracheostomies. This is likely an indication of the severity of trauma seen in low to medium income countries.

Introduction

The paediatric tracheostomy procedure is different and more complicated procedure when compared to the adult tracheostomy. The decision to perform a tracheostomy on a child, is taken with consideration of the indications, subsequent follow up care and decannulation plan considered and prepared for accordingly.

Management of a child with a tracheostomy mandates a multidisciplinary team approach, the team comprising of a speech therapist, an occupational therapist, paediatricians, otorhinolaryngologists and most importantly the home care guardian. Arguably the most important member in this team, is the home care guardian. Having to be involved in medical care with no necessary medical training. They are the point of contact and advocate for the paediatric patient, with insight and understanding of the challenges anticipated on discharge. Delivery of tracheostomy ventilation at home for children is considered a 'high risk, high stakes intervention'.^[8] In the ideal setting, children with a tracheostomy can be discharged home safely only when round-the-clock supervision and a safe environment with access to health care are guaranteed. These conditions may not be met in resource-poor settings. When one cannot provide around the clock home nursing care for all children with tracheostomies, the home care giver becomes key in providing much needed care.

Groenendijk et al^[1] explored the topic of paediatric tracheostomy and ventilation home care, in a resource poor setting, in South Africa (RSA) and concluded that, it is not always possible to establish an ideal home setting, but it is possible to provide a child with a tracheostomy safe home environment, provided caregivers are adequately trained and supported. Mortality rate, an important indicator, was not associated with any socio-economic circumstance.

As a quaternary care centre, IALCH houses specialist neonatologists, neonatal intensive care, paediatric intensive care, trauma surgeons' specialist paediatricians in cardiology, pulmonology, cardiothoracic, oncology, neurology and neurosurgery. This allows for a setting of all complex paediatric medical and surgical cases to be managed in one institution. This setting often allows for collaborative management in complex paediatric cases. IALCH is the only institution in KZN able to manage complex paediatric airway cases. Paediatric tracheostomies are thus performed for a variety of indications at IALCH.

In the mid 1800, physician Armand Trousseau popularized the procedure whilst treating many diphtheria associated upper airway obstruction cases^[3]. In the subsequent years, the indication for tracheostomy has significantly changed in keeping with technological and medical developments. In the 1970s, the most common indication for tracheostomy in children was acute inflammatory airway obstruction, namely laryngotracheobronchitis and epiglottitis^[3]. Later years the most common indication became chronic ventilator dependence and congenital or acquired upper airway obstruction and neurological impairment^[4]. The materials used to make the endotracheal tubes has improved from rubber and sterling silver, to polyvinyl chloride. These have reduced the laryngeal damage related to long term intubation, subsequently reducing the frequency of this as an indication for tracheostomy. Neonatal intensive care units have provided the alternative to tracheostomy by way of long term intubation. Children, who otherwise survived, due to congenital malformations, immaturity, neuromuscular disorders, now with availability of prolonged ventilation have a chance.^[9] This, along with its complication of subglottic stenosis, has become an important indication for tracheostomy.

The aim of this study is to assess the indications for tracheostomy in our setting and to assess if there has been a significant change in the trend in indications in 12-year study period.

Methods

For this quantitative, descriptive chart review, all participants, under the age of 13 years old, with a tracheostomy performed at IALCH, Kwa Zulu Natal, South Africa during 1 January 2004 to 31 December 2016 were enrolled in the study.

The information was collected with permission from IALCH management and Biomedical Ethics review committee (BREC). Patients were identified using theatre records for the code for the tracheostomy procedure, using specialised computer software system Speedminor®. All relevant inpatient and outpatient medical records were collected and reviewed.

Data was collected using commercially available software packages, (Microsoft excel, 2007) software, and parameters collected included demographic profile, primary diagnosis, referring hospital, primary care team, indications for tracheostomy, as seen in appendix 4. A descriptive analysis was further performed with the use of statistical software package ((Statistical package for Social Sciences) SPSS. Participants were divided into two groups, the first Group A, consisting of patients operated on between 2004 and 2010, and the second, Group B, composed of those operated from 2011 to 2016.

The Questions to answer therefore are:

1. What is the number of tracheostomies performed overall and within each group?
2. What is the most common indication for tracheostomy overall and in each group?
3. Which department performs the greatest number of tracheostomies?

Patients who had a primary diagnosis of UAO included those with physical obstruction such as, juvenile onset recurrent respiratory papilloma (JORRP), foreign body aspiration, subglottic stenosis, laryngomalacia or a head and neck mass resulting in obstruction. Those in the infection category included patients who had been admitted with diagnosis of infective disorder, like tuberculosis (meningitis or disseminated TB), complicated sinusitis, diphtheria and tetanus. Syndromic group included syndromes as primary diagnosis such as Pierre Robin, Treacher Collins, Pfeiffer. Medical category included those who were primarily admitted with the cardiac, neurological, and respiratory disorders, namely chronic lung disease, status epilepticus, meningomyelocele. Patients who had multiple indications were classified by their primary indication.

SYNDROMIC (N=47)	UAO (N=69)	ONCOLOGY (N=47)	TRAUMA (N=99)	MEDICAL (N=17)	INFECTIVE (N=39)
Pierre Robin	JORRP	Astrocytoma	TBI from PVA	Meningomyelocele	HIV / Aids
Rubenstein Taybi	Cystic Hygroma	Ependymoma	Fall	Chronic lung disease	TB (Meningitis, disseminated, tuberculoma)
Elfin	Haemangioma (FOM, Glottic)	Glioblastoma	Burns	Status epilepticus	Complicated sinusitis
Pfeiffer	Fused TMJ	Leukaemia	Snake bite	Tetralogy of Fallot	Pneumonia
Prada Willi	SGS	Medulloblastoma	Corrosive ingestion	AVSD	Diphtheria
Reeman Sheldon	BVCP	Meningioma	Near drowning		Tetanus
Treacher Collins	Laryngomalacia	Pontine glioma	Stabbed neck		Nosocomial sepsis
Soto syndrome	FB Aspiration	Oral cavity teratoma	Non-accidental injury		
Crouzon		Neuroblastoma	Domestic accident		
Klinefelter		Myofibroblastoma			

Primary Diagnosis: Conditions included

Table 1: Conditions included in primary diagnosis.

Indications for tracheostomy however, were grouped as prolonged ventilation, upper airway obstruction, failed cricoid split and cranial nerve pathology. This grouping is similar to Ogilvie et al [4]. Those categories already incorporated in primary diagnosis, were not included to avoid duplication.

Results

During the overall 12-year study period a total of 318 tracheostomies were performed, of which, 194 were male and 124 were female. One hundred and fifty-three were treated during 2004 – 2010 (group A), and 165 in the period 2010 – 2016 (group B). The majority at 36% (N= 114), were from the ages of 5 and 10 years old, followed closely by those aged less than 1 year old, at 32% (N=101), as per chart 1.

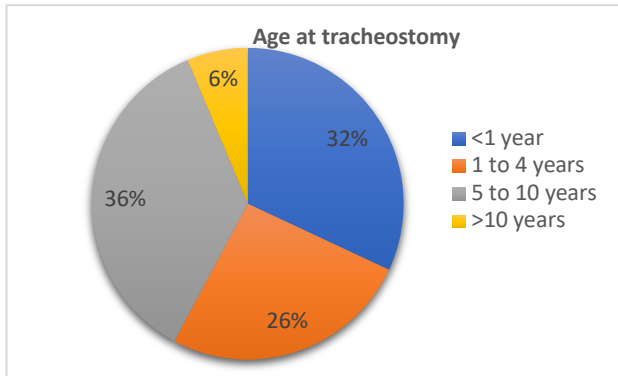


Chart 1: Age at time of tracheostomy

The most common indication for tracheostomy over the 12-year period was prolonged ventilation 48% (N=152) followed by upper airway obstruction 38% (N=120). When assessing the two groups independently, in Group A, upper airway obstruction (N=66) and prolonged ventilation (N=66) were equally the highest indication at 43% each and in Group B, it was prolonged ventilation at 52% (N= 86). When comparing Group, A and Group B, in terms of indication for tracheostomy, we found prolonged ventilation and upper airway obstruction were similar distribution.

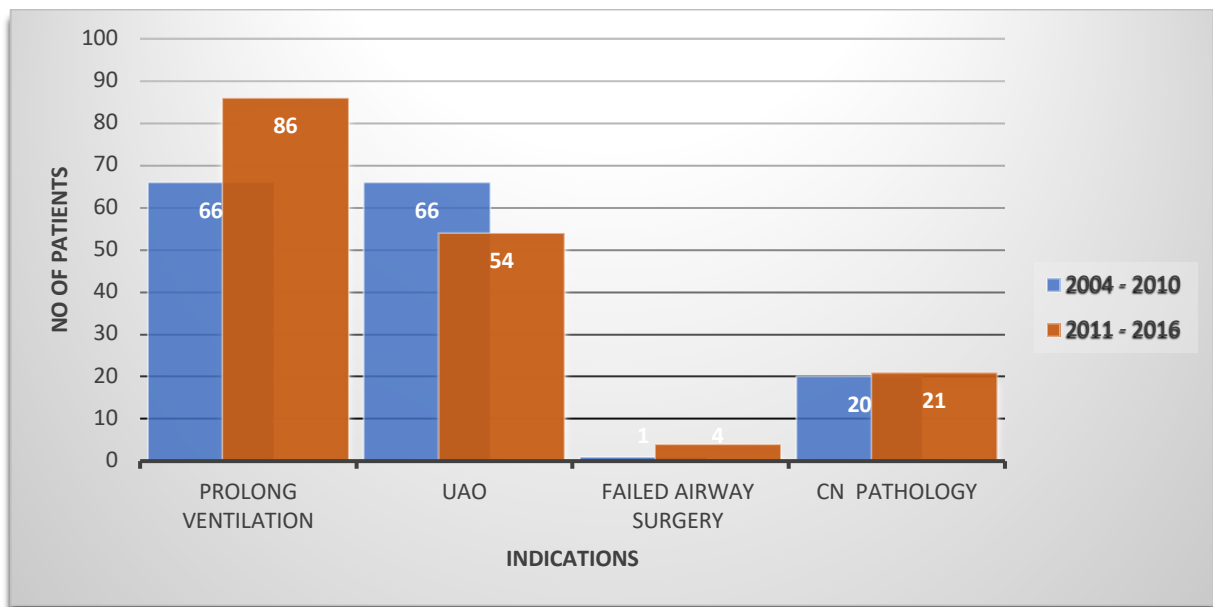


Table 2: Distribution of indication of tracheostomy 2004 - 2016

For prolonged ventilation however, there was a statistically significant increase in group B as shown in Table 2.

In our study, the most common indication for tracheostomy was prolonged ventilation, with the underlying primary diagnosis of trauma. When reviewing the number of cases or trauma in each year, the distribution is seen in chart 2. Ranging in Group A from 3 cases in 2005, to

as high as 13 in 2010, and in Group B from 1 case in 2011 to as high as 12 in 2014. There is an increase in the number of tracheostomies performed for trauma in Group B (2011 – 2016). This trend is statistically significant at $p < 0.05$.

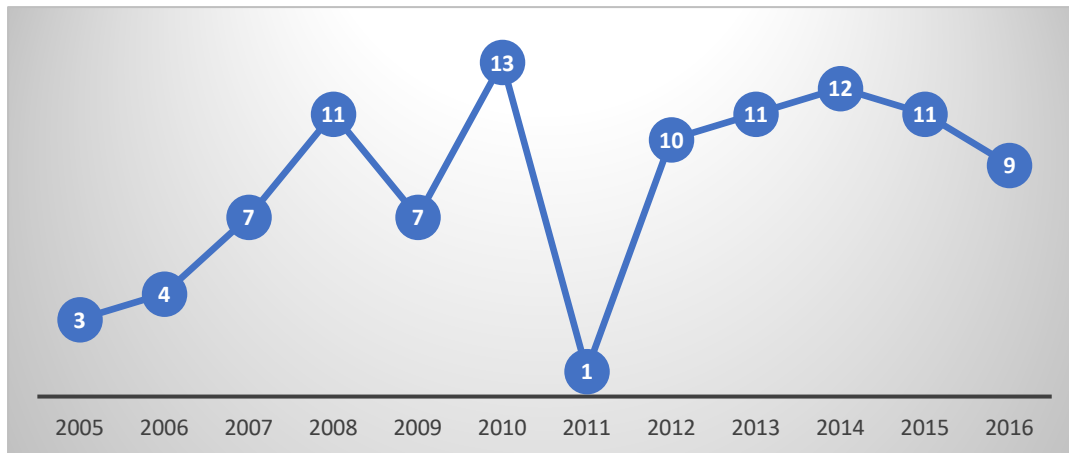


Chart 2: Number of tracheostomies performed for trauma each year of study

The most common primary diagnosis over the 12-year period was trauma, 31% (N=99), followed by UAO 22% (N=69) syndromic and oncology at 15% (N= 47) each and infective 12% (N=39), and medical 5% (N=17). When reviewing the number of cases of trauma in each year, we note a drastic rise in number of tracheostomies performed in 2005 to 2006, from 7 to 21. The highest number overall, was performed in 2014, with 36 procedures. When assessing the mechanism of trauma, the distribution is as shown in table 3. Traumatic brain injury from paedestrian vehicle accidents, predominate.

No. of cases	Mechanism of trauma
79	Traumatic brain injury from Paedestrian vehicle accident
3	Fall from Height
4	Burns
2	Snake Bite
3	Corrosive ingestion
1	Gunshot to head
1	Stabbed neck
1	Near drowning
3	Domestic accident: Rubble fell on patient; table fell on patient
2	Non accidental injury: attempted hanging, and physical assault
99	Total

Table 3: Mechanism of trauma

The primary care team for those children ultimately needing tracheostomy was neurosurgery, accepting 30% (N=96) followed by the critical care team and ENT at 22% (N=72) and 16% (N= 52) respectively. The unit performing most of the paediatric tracheostomies is the Departments of Otorhinolaryngology, Neurosurgery and Trauma at 66.6% (N=210), 18.2%

(N= 58) and 11% (N=36) respectively. The remaining tracheostomies were performed by paediatric surgery department 1.3% (N=4), Cardiothoracic department 1.5% (N=5), and plastic surgery department 1% (N=3). The rate of decannulation and complications was difficult to assess as it was poorly recorded, due to some decannulations being performed at other hospitals with ENT Departments, other than IALCH.

Discussion

Interest has grown in the topic of paediatric tracheostomy indications, particularly in view of evolving medical technology and advances in care.

In developed countries, acute epiglottitis and laryngotracheobronchitis are no longer the main reason for performing a tracheostomy due to the increasing use of the endotracheal intubation, availability of PICU's. The trend has moved to most tracheostomies being performed electively and being kept for longer period of time. This shift can also be attributed to various other medical innovations, which have resulted in an increased survival of neonates and infants with complex anomalies and chronic diseases.^[11]

Parrilla, C. et al ^[3] reviewed trends in paediatric tracheostomies during the period of 1 November 1998 – 30 November 2004 and found a reduction in the number of tracheostomies performed in their assessment period. They identified upper airway obstruction as the main indication in this period and second was ventilation failure for a variety of medical reasons. Trauma, as an indication, was only identified in one of the 38 cases in the 6-year study period. Perez-Ruiz, E. et al ^[5] in a multi-centre prospective study, assessed 249 paediatric cases requiring tracheostomy and the main indication, by 62.6%, was prolonged ventilation for ventilation failure. Of the underlying conditions leading to ventilation failure, 50.6% was due to neurological disorders, followed by respiratory disorders at 39.3%. There were no cases of trauma, and only 4 cases of JORRP.

Author	Years	No of tracheostomies	Most common indication	%
Ozmen [13]	1968 -2005	282	UAO	72%
Ogilvie [4]	1982 -2011	251	UAO	33%
Carron [10]	1988 -1998	204	Neurological impairment	27.5%
Butnaru [12]	1996 - 2001	46	UAO	43%
Parrilla [3]	1998 -2004	38	Neuromuscular/ respiratory	44.7%
Lele	2003 -2015	99	Neurological impairment	48%
Perez – Ruiz [5]	2008 -2009	249	Prolonged ventilation	62.6%

Table 4: Literature review

The “technology dependent paediatric patient” ^[7] is a development noted with the improvement of paediatric intensive care facilities and longer life expectancy for conditions that otherwise would not have survived. These patients seem to emerge in literature as an increasing group requiring tracheostomy procedure and out of hospital tracheostomy care ^[7]

The literature reveals that the majority of tracheostomies are performed in children under 1 year old. This could likely be explained by the increasing survival rates among premature and syndromic patients and the higher severity of obstructive problems at this age. Our series showed a different picture. We found the most common age range at time for tracheostomy was ages 5-10, at 36% , as per Chart 1, and this in keeping with the age most at risk for severe traumatic brain injury from pedestrians vehicle accidents as per Naidoo et al. [14]. In our study, the most common indication for tracheostomy was prolonged ventilation, with the underlying primary diagnosis of trauma. Chart 2 shows the number of cases of trauma in each year ranging from 3 to 13. Table 3 shows that paedestrian vehicle accidents were significantly the most common mechanism of injury in the trauma category. The table further illustrates the remaining mechanisms of trauma in our cohort. Hyder et al suggest that South Africa is the most dangerous place to live for a child in view of the high mortality rates associated with trauma. [15] .

In 1998, the Road Accident Report claimed that in 1998, almost 900 000 vehicles were involved in road accidents, 49% of deaths due to MVA in children occurred among pedestrians, and 37% among passengers. Most children are transported in taxis in the form of minibuses. Young children are held on the adult's lap (where there is no taxi fare) until around 4 years of age, when they are permitted to sit on a seat (if the adult can pay for the seat). There are no seatbelts, and no child protection seats in taxis. [16] Our institution has a level one trauma centre and is also the only centre in KZN where complex paediatric airway cases can be managed. IALCH also houses the only Neurosurgical unit in KZN.

The primary diagnosis was grouped as syndromic, upper airway obstruction (UAO), oncology, trauma, medical (cardiology, central nervous system, respiratory) and infective. This grouping was chosen, based on the admission investigations and diagnosis. As per Carron et al [10], the significance of separating the primary diagnosis patients into a trauma group, is the higher age at the time of tracheotomy. If the trauma group were eliminated as a distinct entity, the patient with cervical spinal cord injury or traumatic brain injury could be included in the neurological, and those with airway trauma could be placed in the UAO group, thus significantly changing the meaning of the data. [10].

Interestingly, indications associated with pathogens, such as *C. diphtheriae* or epiglottis due to *H. influenzae*, have disappeared from the statistics over the last 10 years although papillomavirus persists , as it does in other studies [6][17]. We found that both Diphtheria and Papilloma virus, causing JORRP, were present in our cohort.

In our institution, the first tracheostomy change is performed on day five. The primary care giver is engaged regarding tracheostomy care and receives training for the duration of their stay in hospital. Groenendijk et al [1] investigated ventilation home care for paediatric patients with tracheostomies in a resource poor setting, in South Africa (RSA) and found that the mortality rate of was not associated with any socio-economic circumstance. Adequate training however, has been shown to significantly reduce complications.

Once adequate tracheostomy care training is achieved, and the patient no longer requires tertiary level care, children are often stepped down to a lower level hospital for continued care, and possible decannulation at base hospital if an ENT department is available. This step-down approach made it difficult to collect further information regarding decannulation rates and long-term tracheostomy complications.

There are several limitations of this study due to the retrospective nature of the review. Classifying the patients into indication groups relies on the pre and post-operative documentation, which can vary depending on the individual surgeon performing the tracheostomy. Many patients also had co-existing diagnosis, which can influence the final decision to perform a tracheostomy.

Conclusion

The use of vaccines and improvements in medical technology has led to a drastic change in the demographic profile of the paediatric patient requiring a tracheostomy. In our institution the most common indication for tracheostomy was prolonged ventilation and of interest, is the underlying diagnosis leading to tracheostomy. Trauma, mostly paedestrian vehicle accidents, is emerging as a significant primary diagnosis for paediatric patients requiring tracheostomies. This finding is different from the literature examined, which found syndromic and neurological impairments as the underlying causes, thus mandating us to explore the reasons children have such a high rate of TBI and address the multi-disciplinary needs of these patients that have a variety of problems.

Study limitations:

The retrospective nature of the study meant that certain data could not be collected, due to it being missing. The patients that had been referred to other institutions with tracheostomy in situ, meant that we could not collect data on decannulation rates and complications occurring outside IALCH. The study was a retrospective study, thus subject to variation in management. The time taken to decide for a tracheostomy and primary surgeons may vary. This study only seeks to assess tracheostomies performed in children at IALCH, thus excluding private health care sector patients in the province and tracheostomies performed in paediatrics at other public health care institutions in KZN.

Recommendations:

Having identified trauma as the most common indication for performing a tracheostomy in children at IALCH, which serves KZN, we recommend:

For IALCH:

- 1) We recommend further studies into the demographics of patients presenting with TBI with the aim of identifying any modifiable risk factors for the patients.
- 2) We recommend inclusion in the management of severe TBI patients, an early tracheostomy care training for the identified home care giver.

For KZN Health Department.

- 1) We recommend wide spread community-based education regarding the dangers of PVA, to the community with the aim of increasing seat belt usage and protection of the at-risk children in public transportation.
- 2) A province wide data base of all paediatric patients with tracheostomy to be able to maximize tracking and ensure that no patients are lost to follow up.

Reference

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Appendices

Appendix 1: The final Study Protocol

PROTOCOL NUMBER:

BE669/17
For office use only



BIOMEDICAL RESEARCH ETHICS COMMITTEE

EXPEDITED APPLICATION FORM¹

Application to the UKZN Research Ethics Committee
for ethics review of new research projects
(For research on human participants)

NATURE OF STUDY					
Quantitative					
Type of Study: (please tick)	Epidemiological	Observational clinical study	Experimental	Observational	
	Retrospective Chart Review X	Prospective Chart Review	Laboratory study on stored samples	Audit	Other:(Specify)
1. THE PROTOCOL FOR STUDY					
Full title of research project: <i>(Please DO NOT use abbreviations or acronyms)</i> Indications for tracheostomy in the paediatric patient at a tertiary referral centre: Inkosi Albert Luthuli Hospital					
1.2 Where will the Research be carried out? (Hospital, clinic etc.). Hospital, Inkosi Albert Luthuli Hospital (IALCH)					
1.3 Aims (what you hope to achieve) and objectives (how you will achieve your aims) of study: To determine the indications for tracheostomy in the paediatric patient at IALCH over the period: <ul style="list-style-type: none"> • 1 January 2004 - 31 December 2016 • To ascertain if there are any changes or trends identifiable in the two adjacent time periods: 2004 – 2010 and 2011 – 2016. 					
1.4 Hypothesis to be tested, or Research Question to be answered: What is the most common indication for tracheostomy in the paediatric patients managed at a tertiary referral centre (IALCH), in KwaZulu Natal, South Africa.					
1.5 Summary of the proposal research methodology (restrict to 100 words) The study will be an observational, descriptive chart review of the data collected from the medical charts of the paediatric patients (13 years old) who have had tracheostomy performed at Inkosi Albert Luthuli hospital (IALCH) during the period of January 2004 – December 2016. Inkosi Albert Luthuli Hospital is a paperless hospital and the digitally stored data will be interrogated with access to the hospitals specialised software Speed minor.					
1.6 Keywords (for database):					

paediatric, tracheostomy, indications, paediatric airway,

1.7 Background and Literature Review (maximum 1 page):

Tracheostomy in the adult population is a topic well studied, with well-established indications and outcomes. Tracheostomy in the paediatric population, however, is a daunting undertaking, with recent literature suggesting that the indications have dramatically evolved in the last 30 years.

In the 1970s, the most common indication for tracheostomy in children was acute inflammatory airway obstruction, namely laryngotracheobronchitis and epiglottitis. (1)

With developments in medicine, the indications for tracheostomy in paediatrics, naturally expand to accommodate the development in modern medicine.

Neonatal intensive care units have provided the alternative to tracheostomy by way of long-term intubation. Ironically, long-term intubation itself became an important indication for tracheostomy combined with subglottic stenosis. (8) Advances in material for endotracheal intubation, from rubber and sterling silver to polyvinyl chloride tubes, have reduced the laryngeal damage related to long-term intubation, subsequently reducing the frequency of this as an indication for tracheostomy. (9)

The tracheostomy procedure in the paediatric population also carries a higher mortality, morbidity and complication rate (2) and thus indications for paediatric tracheostomy requires careful consideration.

In South Africa, a low- middle income country, 59.5% of children live in poverty, 35.1% live in a household without an employed adult. (3) South Africa has the dubious label of being the most dangerous place in the world for a child, (4) and along with infection, trauma is rising as a significant factor in consideration in all child care.

The combination of high incidents of trauma to a child and the low socio-economic setting make it a dangerous, less than ideal environment for children. Children often form a small group of trauma patient that are often neglected and forgotten. Although the burden of disease in paediatric trauma is not quantified, we do know that the post illness rehabilitation process, is one that involves a multi-disciplinary approach and is costly.

Naidoo et al, undertook to assess the paediatric admissions at a tertiary trauma intensive care unit, in Durban, South Africa, to determine the commonest causes of injury and outcome. They used the Injury Severity Score, an anatomical scoring system that provides an overall score for patients with multiple injuries. They found that of all the admissions, 54.1% were in the profound injury severity score, with this category containing 92% of the deaths.

Of the 181 injured children, 112 (61.9%) had traumatic brain injury, of the 26 who died 23 (88.4%) had associated head trauma, and in 18 deaths severe traumatic brain injury was the primary cause. (4)

Motor vehicle collisions are the major cause of severe morbidity and mortality. The majority involve pedestrians, and traumatic brain injury accounts for up to 80% of childhood trauma deaths. (6)(7)

Such severely traumatized patients undergo prolonged periods of multidisciplinary management and in this article, they undertook to analyze the paediatric admissions in a prospective database of paediatric admissions to a level 1 (tertiary) trauma intensive care unit to determine the commonest causes of injury, severity of injury. They found that pedestrian motor vehicle accidents were the most common reason paediatrics visited the intensive care unit. These severe injuries would result in prolonged ICU stays and thus quite often be candidates for tracheostomy.

The tracheostomy procedure itself is technically more demanding than in an adult due to the smaller, more pliable trachea and to the limited extension of the operating field. (1) Management of such a child requires a

multidisciplinary team, including speech therapist, occupational therapist, paediatricians, otorhinolaryngologists and the primary care giver. In the ideal setting children with a tracheostomy can be discharged home safely only when round-the-clock supervision and a safe environment with access to health care are guaranteed. These conditions may not be met in resource-poor settings. When one cannot provide home -around the clock home nursing care for all children with tracheostomies, the primary care giver becomes the guardian of at home care.

Groenendijk et al explored the topic of paediatric tracheostomy and ventilation home care, in a resource poor setting and concluded that, it is not always possible to establish an ideal home setting in South Africa. It is however, possible to provide a child with a tracheostomy safe home environment, provided caregivers are adequately trained and supported. Mortality rate, an important outcome, was not associated with any socio-economic circumstances. (5)

Despite difficult socio-economic circumstances, discharging children home with a tracheostomy is feasible if the primary care giver is adequately trained and supported.

IALCH is a central hospital in Durban, South Africa, servicing a population of 10.92 million. It is the only central hospital in KwaZulu Natal, with the ability to manage complex paediatric airway emergencies and provide its follow up.

The Paediatric unit has services for specialised paediatric care with a 14 bed paediatric icu.

We aim to assess the indications of tracheostomy in the paediatric population, of the preceding 12 years (2004 - 2016) and to compare 2 adjacent periods (2004 – 2010, and 2011 – 2016). Here we will assess If there is a change in the trend of indications for tracheostomies in the two-time periods.

This study will provide the following benefit:

1. Quantify the most common indication for trauma at our institution. This is a currently unknown entity in our population.
2. Assist in inter departmental collaborative efforts to ensure that all paediatric patients with tracheostomy are enrolled in the paediatric tracheostomy follow up clinic.
3. This study will assist in IALCH Hospital policy making, to ensure that upon discharge for a patient with tracheostomy there is a decannulation plan documented for all paediatric patients.
4. Pave the way for future studies i.e.: a) Establish a IALCH decannulation protocol as currently the UK and USA Paediatric tracheostomy decannulation protocol are not fully appropriate for our patient demographic. b) Paediatric tracheostomy care Education amongst nursing staff: to establish an ongoing educational programme to improve comfort levels in all paediatric nursing staff, managing children with tracheostomies.

1.8 Key References:

(Give approximately 5 key references)

1. Parrilla, C. et al., 2007. Current trends in paediatric tracheostomies. International Journal of Pediatric Otorhinolaryngology.
R.F. Wetmore, S.D. Handler, W.P. Potsic, Paediatric tracheostomy: experience during the past decade, Ann. Otol. Rhinol. Laryngol. 91 (1982) 628—632.)

3. child gauge

Naidoo, N. & Muckart, D.J., 2015. The wrong and wounding road: Paediatric polytrauma admitted to a level 1 trauma intensive care unit over a 5-year period. South African Medical Journal.

5. Groenendijk, I. et al., 2016. Paediatric tracheostomy and ventilation home care with challenging socio-economic circumstances in South Africa. International Journal of Pediatric Otorhinolaryngology.

2. PLAN OF INVESTIGATION FOR STUDY

* In the case of Higher Degrees, please state name and School of person consulted regarding the design:
Design discussed with Dr T.K. Naidu (Supervisor)
ENT Department

2.1	Is this a retrospective chart review with no human contact?	Yes	X	No	
2.2	Is this a study of stored tissue?	Yes		No	X
2.3	Are host genetic factors being studied?	Yes		No	X

How many hours per week will the PI devote to this project? 12 HOURS
(Timetable the project in terms of the resources and time available)

Describe in detail your data collection methods for the research project

The data will be collected in a Microsoft Excel Spread Sheet with the following parameters measured:

- Patient demographic (age, race & gender)
- Referral hospital
- Referral district
- Primary care team
- Primary diagnosis
- Secondary diagnosis
- Indication of tracheostomy
- Date of tracheostomy
- Day or night
- Elective or emergency
- Date of decannulation
- Unit performing tracheostomy
- Complications
- Mortality

The collected data will be stored in a password protected external hard drive.

3. STATISTICAL PLANNING AND DATA ANALYSIS

3.1	Has this project been approved by a professional statistician? If No, please justify.	Yes		No	X
-----	--	-----	--	----	---

3.2 If answered "yes" to (3.1), provide the name of the statistician:

Please provide a brief overview of statistical and data analytic considerations, including:

participants will include all patients with tracheostomies performed at Inkosi Albert Luthuli Hospital in the specified time period. Further statistical analytical consideration will be discussed with the professional statistician. The sampling will be by Simple Random Sampling, with a sample size of 120. An appointment with Mr. Walter Sibanda (UKZN Biostatistics) has been scheduled.

3.4 For *qualitative* studies: What is the framework/approach to be used for analysis of the data?

PARTICIPANTS IN THE STUDY

Is this a multi-national study? Yes No X

(If yes, state collaborating countries)

List all sites in South Africa in which the project will be carried i.e. geographic location (e.g. KwaZulu-Natal) and type of place (e.g. hospital, clinic, schools, community etc).

Source: <i>(Please indicate number per group)</i>	Inpatients	Outpatients	Volunteers
--	------------	-------------	------------

Age (human studies) <i>(Please indicate number per group)</i>	Neonates (<28 days) X	Infants (1-11 month) X	Children (1-12 years) X	Adolescent (13-17 years)	Adults
--	--------------------------	---------------------------	----------------------------	--------------------------	--------

4.5 Is there a control group(s)? Yes No X

4.6 Demographic profile of participants *(please tick ALL appropriate boxes below.)*

4.6.1 Gender: Female Male

4.6.2 Population Group: Black Coloured Indian White

4.6.3 Language Group/s: Specify.....

4.7 Describe the recruitment process in detail for all groups.
All patients recorded as having a tracheostomy performed at Inkosi Albert Luthuli Hospital will be included.

4.8 Will incentives be offered to facilitate recruitment?
(If yes, describe in detail)

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	N/A	<input checked="" type="checkbox"/> X
-----	--------------------------	----	--------------------------	-----	---------------------------------------

Will participants be reimbursed in some way for participation?
(If yes, describe in detail) See SA DoH Guidelines on BREC Website

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	N/A	<input checked="" type="checkbox"/> X
-----	--------------------------	----	--------------------------	-----	---------------------------------------

Will reimbursement for participants and investigators be in accordance with:
(If no, please explain)
Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa: Department of Health (2006) and;
Ethics in Health Research: Principles, Structures and Processes: (2015)
Current SA DoH Guidance on reimbursement *(See BREC website)*

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	N/A	<input checked="" type="checkbox"/> X
-----	--------------------------	----	--------------------------	-----	---------------------------------------

Will participants be insured against research related injury? <i>(If yes, please provide details; If no, please provide rationale)</i> <i>Mandatory for Clinical Trials</i>	Yes		No		N/A	X
---	-----	--	----	--	-----	---

4.12 List in detail the inclusion and exclusion criteria.

Inclusion criteria:
 Paediatric tracheostomy: below 12 years
 Tracheotomy performed at IALCH between 01/01/2004 – 31/12/2015

Exclusion criteria
 Tracheostomy performed at another institution
 Age above 12

Appendix 2:

The Guidelines for Authorship for the Journal selected for submission of the Manuscript

<http://www.samj.org.za/index.php/samj/about/submissions>

General article format / Layout

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

General:

- Manuscripts must be written in UK English.
- The manuscript must be in Microsoft Word format. Text must be single-spaced, in 12-point Times New Roman font and contain no unnecessary formatting (such as text in boxes).
- 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)'.
- Include sections on Acknowledgements, Conflict of Interest, Author Contributions and Funding sources. If none is applicable, please state 'none'.
- Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and hemoglobin (g/dL).
- Litres is denoted with an uppercase L e.g. 'mL' for millilitres).

- Units should be preceded by a space (except for % and oC), e.g. '40 kg' and '20 cm' but

'50%' and '19oC'.

- Please be sure to insert proper symbols e.g. μ not u for micro, α not a for alpha, β not B

for beta, etc.

- 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.

- 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.

Research

Guideline word limit: 4 000 words

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 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 clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. 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, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

XLIII

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text.

Do not replicate data in tables and in text.

Structured abstract

- This should be 250-400 words, with the following recommended 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 intervention, primary and secondary outcomes, 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, include recommendations for further study/actions.
- Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors.
- Do not include any references in the abstracts.

[Here](#) is an example of a good abstract.

Main article

All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.

The following are additional heading or section options that may appear within these:

- Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed
- Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.

- Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.
- Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioral, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc) that may have an impact on the study results. Clearly define how participants were enrolled and describe selection and exclusion criteria.
- Interventions (within Methods): what, how, when and for how long. Typically for randomised controlled trials, crossover trials, and before and after studies.
- Main outcome measures (within Methods): those as planned in the protocol, and those ultimately measured. Explain differences, if any.

Results

- Start with description of the population and sample. Include key characteristics of comparison groups.
- Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.
- Do not replicate data in tables and in text.
- If presenting mean and standard deviations, specify this clearly. Our house style is to

present this as follows:

XLIV

- E.g.: The mean (SD) birth weight was 2 500 (1 210) g. Do not use the \pm symbol for mean (SD).
- Leave interpretation to the Discussion section. The Results section should just report the findings as per the Methods section.

Discussion

Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:

- Statement of principal findings

- Strengths and weaknesses of the study
- Contribution to the body of knowledge
- Strengths and weaknesses in relation to other studies
- The meaning of the study – e.g. what this study means to clinicians and policymakers
- Unanswered questions and recommendations for future research

Conclusions

This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.

Appendix 3:

1) Ethical approvals Biomedical Research Ethics Committee



07 February 2018

Dr PBN Ndebele (201295352)
School of Clinical Medicine
College of Health Sciences
bongibabe@yahoo.com

Dear Dr Ndebele

Protocol: Indications for tracheostomy in the paediatric patient at a tertiary centre: Inkosi Albert Luthuli Hospital. Degree: MMed BREC Ref No: BE669/17

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 22 November 2017.

The study was provisionally approved pending appropriate responses to queries raised. Your response received on 02 February 2018 to BREC correspondence dated 12 December 2017 has been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 07 February 2018.

This approval is valid for one year from 07 February 2018. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be RATIFIED by a full Committee at its next meeting taking place on 13 March 2018.

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

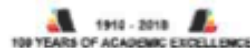

Professor V Rambiritch
Deputy Chair: Biomedical Research Ethics Committee

cc postgraduate administrator: konar@ukzn.ac.za
cc supervisor: Tesuzeni@gmail.com

Biomedical Research Ethics Committee
Professor J Tsoka-Gwegweni (Chair)
Westville Campus, Govan Mbeki Building
Postal Address: Private Bag X54001, Durban 4000

Telephone: +27 (0) 31 260 2486 Facsimile: +27 (0) 31 260 4809 Email: brec@ukzn.ac.za

Website: <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>



RELATIONSHIP COLLEGE  Ethnoscience  Human Sciences  Medical Research  Pharmaceutical Sciences  Westville

2) DOH Provincial approval



health
Department:
Health
PROVINCE OF KWAZULU-NATAL

Physical Address: 330 Langalibalele Street, Pietermaritzburg
Postal Address: Private Bag X9051
Tel: 033 395 2805/ 3189/ 3123 Fax: 033 394 3762
Email: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

DIRECTORATE:

Health Research & Knowledge
Management

HRKM Ref: 009/18
NHRD Ref: KZ_201801_016

Date: 26 January 2018
Dear Dr PBN Ndebele
UKZN

Approval of research

1. The research proposal titled '**Indications for tracheostomy in the paediatric patient at a tertiary referral centre**' was reviewed by the KwaZulu-Natal Department of Health.

The proposal is hereby **approved** for research to be undertaken at Inkosi Albert Luthuli Central Hospital.

2. You are requested to take note of the following:
 - a. Make the necessary arrangement with the identified facility before commencing with your research project.
 - b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.
3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mr X. Xaba on 033-395 2805.

Yours Sincerely

Dr E Lutge

Chairperson, Health Research Committee

Date: 31/9/18

Appendix 4: Data collection tool

AGE IN YEARS	<1
	1 - 2
	3 - 5
	5 - 12
GENDER	Male
	Female
RACE	Black
	White
	Coloured
	Indian
REFERRAL HOSPITAL	
HEALTH DISTRICT	
PRIMARY CARE TEAM	
PRIMARY DIAGNOSIS	
SECONDARY DIAGNOSIS	
INDICATION FOR TRACHEOSTOMY	
DATE OF TRACHEOSTOMY	
DAY / NIGHT	
ELECTIVE / EMERGENCY	
DATE OF DECANNULATION	
UNIT PERFORMING TRACHEOSTOMY	
COMPLICATIONS	
MORTALITY	

Appendix 5:

Raw data

THE_FACILITY	THE_APPTID	THE_CASENO	THE_PROCCODE	THE_URNID
IAL	I040610041	I040610041	31600	1
IAL	I040707042	I040707042	31600	1
IAL	I040715045	I040715045	31600	1
IAL	I060130013	I060130013	31600	1
IAL	I060709002	I060709002	31600	1
IAL	I060214029	I060214029	31600	1
IAL	I060412044	I060412044	31603	1
IAL	I060926020	I060926020	31603	1
IAL	I061122040	I061122040	31600	1
IAL	I061003030	I061003030	31600	1
IAL	I070226015	I070226015	31600	1
IAL	I060912034	I060912034	31600	2
IAL	I070213036	I070213036	31603	1
IAL	I061102026	I061102026	31600	1
IAL	I071105029	I071105029	31603	1
IAL	I070709008	I070709008	31600	1
IAL	I071018029	I071018029	31600	1
IAL	I071010039	I071010039	31600	1
IAL	I070912033	I070912033	31600	1
IAL	I071128045	I071128045	31603	1
IAL	I080206016	I080206016	31600	1
IAL	I080417014	I080417014	31600	1
IAL	I080124011	I080124011	31600	1
IAL	I080408030	I080408030	31600	1
IAL	I080429013	I080429013	31600	1
IAL	I080722049	I080722049	31603	1
IAL	I090316035	I090316035	31600	1
IAL	I080922030	I080922030	31603	1
IAL	I080625026	I080625026	31603	1
IAL	I080811016	I080811016	31603	1
IAL	I081217007	I081217007	31603	1
IAL	I081024019	I081024019	31603	1
IAL	I080922026	I080922026	31603	1
IAL	I080813028	I080813028	31603	1
IAL	I081124037	I081124037	31603	1
IAL	I090210046	I090210046	31600	1
IAL	I090214004	I090214004	31600	1
IAL	I090630005	I090630005	31603	1
IAL	I090820041	I090820041	31600	2
IAL	I091106021	I091106021	31603	1
IAL	I090911011	I090911011	31600	1
IAL	I100503018	I100503018	31600	1
IAL	I100325038	I100325038	31600	1
IAL	I100328001	I100328001	31600	1
IAL	I100426025	I100426025	31603	2
IAL	I110402002	I110402002	31600	1
IAL	I101104019	I101104019	31600	1
IAL	I100722045	I100722045	31730	2

