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Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath Academic Hospital

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A research report (Paed 7036) submitted to the Faculty of Health Sciences, University of the Witwatersrand, in part fulfilment towards the degree of Master of Medicine in Paediatrics, in the sub-speciality of Paediatric Critical Care (MFOSPACC60)

Johannesburg 2018

Dedication

To my amazing husband Yahya Atiya,

for his undying love, exceptional patience,

and support throughout my career.

My parents, Shabeer and Amina

for their encouragement and support.

Without your sacrifice, none of this would ever have been possible.

And my Grandparents

Gone, but never forgotten.

Co-author Declaration

Declaration: Student's contribution to article(s) and agreement of co-author(s)

I, Ayesha Bibi Khan, student number 9900898P, declare that this Research Report is my own work and that I contributed adequately towards research findings published in the article(s) stated below which are included in my Research Report .

Signature of Student  **Date 11 June 2018**.....

Name of Primary Supervisor Dr Shahed Omar.....

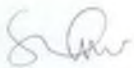
Signature of Primary Supervisor

.....  .....**Date**...11/06/2018.....

Agreement by co-authors: By signing this declaration, the co-authors listed below agree to the use of the article(s) by the student as part of his/her Thesis/Dissertation/Research Report. In cases where the student is not the 1st author of a published article, the primary supervisor must explain (under comments) why the student is entitled to use the paper for his/her degree purposes.

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Letter of Contribution

To whom it may concern

The MMed titled 'Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath Academic Hospital', in submissible format (for the Journal of Southern African Critical Care) is primarily my work.

I, Dr AB Khan, student number 9900898P, conceived the idea for this study, wrote the protocol, collected all the data personally without any assistance, calculated the statistics with some assistance from a statistician in the protocol phase and assistance from my supervisors, and I wrote the final paper.

Drs Omar and Thandrayen assisted in supervisory roles with my work. They reviewed the protocol and manuscript at each stage and provided guidance and the fine tuning and perfecting of the work being submitted. They also helped correct my statistics.

Yours Sincerely,



Ayesha Bibi Khan

Student Number 9900898P



Primary Supervisor

Dr Shahed Omar



Secondary Supervisor

Dr Kebashni Thandrayen

Acknowledgments

I would like to extend my thanks and appreciation to the following:

- My supervisor, Dr Shahed Omar, for his constructive criticism, unending enthusiasm, advice, and patience.
- My co-supervisor, Dr Kebashni Thandrayen, for her a patience and guidance.
- Professor LR Mathivha, Head of the Department of Critical Care at Chris Hani Baragwanath Hospital, for her encouragement in pursuing this career and her support with this dissertation.
- Petra Gaylard for her assistance with statistics in the protocol planning phase.
- The numerous colleagues and peers who proof-read the manuscript and for providing constructive criticism.
- Last, but never least, to my family, for their endearing love, and their unwavering support and encouragement.

ABSTRACT

Background

Intubated patients with a high tracheal tube cuff pressure (CP) are at risk of developing tracheal or subglottic stenosis. Recently an increasing number of patients have presented to our hospital with these complications.

Objectives

To determine the frequency of tracheal tube cuff pressure measurements (CPM), the range of CP and explore nursing knowledge regarding CP monitoring.

Methods

Frequency of CPM was assessed using a prospective intensive care unit (ICU) chart review. An interventional component of CPM was performed next. Finally a self-administered questionnaire was completed by nurses.

Results

Chart reviews and CPM were completed on 304 charts from 61 patients. Patients' ages ranged from one to 71 years, with a male preponderance (1.5:1). Eighty seven percent of charts did not have a documented CPM and only 12 charts had at least one measurement per shift. Only 17% of CP were within the recommended range, with 59% being low.

The nursing questionnaire was administered to 75 professional nurses with a response rate of 51%. Intensive care nursing experience ranged from 3 to 35 years with 92% being critical care trained. Seventy two percent of respondents reported measuring CP at least once per shift and knew the recommended cuff pressure range. Almost all respondents (94%) knew of at least one complication of abnormal CP.

Conclusion

Current practice requires urgent revision. Development of a nursing guideline together with in-service training may improve compliance with CPM and potentially decrease complications that arise from abnormal cuff pressures.

ARTICLE FOR SUBMISSION

Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath Academic Hospital

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Introduction

Cuffed tracheal tubes are used to prevent loss of tidal volume during positive pressure ventilation, minimize pulmonary aspiration of gastric and oral secretions, facilitate respiratory monitoring and, in the paediatric population, additionally decrease the need for repeated laryngoscopy due to incorrect tube size.[1-3]

These goals are achieved by appropriate cuff inflation. Cuff pressure (CP) should be above 25cmH_2O to prevent aspiration and below 30cmH_2O to avoid damage to surrounding structures.[4,5] Obstruction to blood flow occurs when CP exceeds capillary perfusion pressure (CPP), resulting in ischaemia of the tracheal mucosa. Impedance to flow occurs at CP ≥30cmH_2O, with total obstruction of flow ≥50cmH_2O in normotensive adult patients.[5] No paediatric studies have been done to assess CPP nor CP at which tracheal capillary blood flow is impeded. The extent of damage from increased CP is related to absolute pressure exerted by the cuff as well as the duration of exertion of this pressure (with damage to mucosa occurring within 15 minutes of exposure to high pressures), with a greater contribution being from the absolute pressure.[5,6] A wide range of injuries result from high CP, ranging from mucosal ulceration to trachea-oesophageal fistula.(6,7) Low cuff pressures also have associated risks including the development of ventilator associated pneumonia secondary to aspiration and compromised ventilation as a consequence of loss of positive pressure.(1,8)

Internationally accepted consensus guidelines for optimal CP range and frequency of cuff pressure monitoring (CPM) are lacking.[9] A local nursing guideline suggests a range of 25 – 30cmH_2O.[10] The American Heart Association Pediatric Advanced Life Support 2015 guidelines recommends the use of the manufacturers specification for appropriate cuff pressure in children under nine years and suggests a reference range of 20-25cmH_2O.[11]

CP should be measured using a manometer or pressure transducer, as other techniques such as digital palpation and minimal leak technique (MLT) in isolation have been shown, in both adult and paediatric patients, to result in CP outside the recommended range.[12-14] If pressures above 30cmH_2O are required to achieve an adequate seal, the tracheal tube is likely to be too small and replacement is recommended.[15]

Ideally, pressures should be monitored continuously using pressure transducers and displaying pressure on a monitor.[16,17] This may allow rapid adjustments to prevent time-dependant pressure complications such as mucosal injury.[6] Newer tracheal tubes may provide an alternative to prevent complications by use of foam rubber cuffs which exert lower pressures, or cuffs with pressure relief valves or pressure safety balloons.[6,19] In third world settings, where lack of resources may preclude this, the alternative is intermittent measurement of cuff pressures, preferably 6 hourly.[16] A South African nursing guideline,

suggests that cuff pressure should be measured once per shift (every 12hours), which is equivalent to twice daily, so this would be an acceptable minimum of recommended standards.[10] Pressures should be adjusted to achieve an adequate seal while keeping pressures within the recommended safety limits.[10,20]

Numerous studies have shown that cuff pressure monitoring is inadequate and cuff pressures are often higher than recommended.[20-22] Other studies have shown cuff pressure measurements are still not routinely performed.[23,24] To avoid complications of over inflation, cuff pressures need to be measured and documented regularly and routinely.[10,20,25] This requires staff awareness regarding care of cuffed tubes. Studies performed both locally and internationally highlight the lack of awareness, and misconceptions around endotracheal tube cuff pressures amongst staff in certain intensive care units.[25,26] In centres where cuff pressure awareness is high, there is still significant heterogeneity pertaining to optimal target pressures and frequency of monitoring.[9,17]

Given the lack of standardization in CPM, we undertook to investigate current practice regarding the monitoring of endotracheal/tracheostomy tube CP in our ICU. The objectives were threefold, including assessment of the frequency of CPM per day, determining if CP were within the recommended nursing guideline ranges by measurements made by the investigator and exploring nurses' knowledge regarding CP monitoring. CP were adjusted to be within the acceptable range, if the principle investigators measurement was found to be outside this range.

Methods

Methods for chart review and cuff pressure measurements

A prospective cross-sectional chart review and interventional study of CP measurements was done at the Chris Hani Baragwanath Academic Hospital (CHBAH) Main ICU which is a combined adult and paediatric multidisciplinary ICU. Ethical approval was obtained from the Human Research Ethics Committee (HREC) at the University of the Witwatersrand (clearance number M160473). Informed consent and assent, as applicable, was obtained. Consent was initially obtained from next kin, and then from patient once extubated and competent to do so.

The study period extended from 12 June 2017 to 31 July 2017. All patients who had a cuffed tracheal tube in situ for 24 hours were included, while patients who had the cuff deflated intentionally were excluded. In consultation with a statistician, a sample size of 400 patient-days (including both adult and paediatric patients), based on expected bed occupancy and intubation rate. This would yield a precision of 5.3%, was deemed adequate for this study.[18]

Demographic data, diagnostic categories and endotracheal/tracheostomy tube type and size were recorded. Frequency of cuff pressure monitoring was documented daily (CPMd) on a data collection form and captured electronically. Additionally, an independent CPM was performed by the investigator (CPMa). If this CPM was found to be outside the recommended ranges, an intervention was done using the manometer to correct the pressure, as it would be unethical not to adjust to normal rline anges if outside recommended ranges. Paediatric patients were separated into two groups: those under nine and those over nine, due to differences in recommended CP ranges. The range utilised for the purpose of the study was

25 to 30cmH_2O for patients nine years of age and older, and for those under nine years of age, 20 to 25cmH_2O.[10,11] All data was de-identified prior to analysis.

The CP was measured using an aneroid manometer made by Covidien, called a hand pressure gauge and the unit of measurement of pressure was cmH_2O. The manometer had a pressure gauge, with a bulb for inflation, a red button for deflation and a piece of tubing to connect the manometer to the bulb of the cuff of the tube. A new factory-calibrated manometer was used as per manufacturer's specifications by a single operator after appropriate training. The manometer gauge reads the pressure and the bulb and deflation buttons are used to adjust the pressure.

Methods for nursing questionnaire

A voluntary, anonymous questionnaire was distributed to the entire professional nursing compliment present in the ICU over a two-week period. The maximum number of nursing staff during the study period was estimated to be approximately 96, of which the total number of nurses was divided into four groups according to their shift allocation. The expected response rate for completion of questionnaires was predicted to be 80% thus the sample size anticipated was 76. The questionnaire was administered to each group once only and the questionnaire was collected within eight hours to minimise bias. Consent was implied by return of a completed questionnaire. The nursing questionnaire (NQ) collected information regarding demographics, education regarding cuff pressure monitoring, current practice as reported by the respondents and basic knowledge regarding CP. They were asked to place the completed questionnaire in a sealed box in the nurses' tearoom before the end of the shift.

Data analysis was carried out in Statistica version 13 (Statsoft, USA). Descriptive analysis of the categorical data was carried out by frequency and percentage tabulation, and illustrated by means of bar charts. Continuous variables were described using means and standard deviations. Linear regression was used to determine if the presence of the investigator in the unit over time introduced CPM bias. A p-value <0.05 was considered statistically significant.

Results

Results for chart review and cuff pressure measurements

A total of 304 ICU charts from 61 patients were reviewed and cuff pressures were measured. Two patients were excluded due to refusal to consent. Patients were predominantly adults and 61% were male. Only four paediatric patients under the age of nine were included (Figure 1). From these four patients 15 ICU charts were available for review. See table 1 for demographic data.

Chart review revealed no documented CPMd in 264 (87%) charts (Figure 2). Only 12 charts (4%) had a CPMd at least once per 12-hour shift as suggested by guidelines.

Investigator measurement of cuff pressures (CPMa) revealed that 83% (252/304) of the measurements were out of the recommended ranges (Figure 3).

Results for nursing questionnaire

The overall response rate of the NQ was 51% (38/75). Questions were interpreted individually and, since some respondents did not answer all questions, the total numbers are not 38 in all instances. All respondents were professional nurses and 92% (35/38) were

critical care certified. Only one respondent was not a permanent staff member. The mean ICU experience was 14.8 years (SD±8.6). Eight respondents did not state their number of years of ICU experience, with 87% (26/30) having ≥5years of ICU experience.

CP monitoring education was received by 76% of respondents. Knowledge of existing CP monitoring guidelines was reported by 62% (23/37) of respondents. Only 53% (20/38) reported routinely measuring cuff pressures. When asked how frequently they measured cuff pressures, 34% did not respond. Of the remainder, 48% (18/38) of the respondents reported measuring at least twice per day, 8% (3/38) measured once per day and 10% (4/38) measured at their own discretion.

In response to the method of CPM, 93% (25/27) indicated the use of a manometer, while 11 respondents did not answer the question. The local nursing CPM guideline range (25 – 30cmH_2O) was reported by 68% (26/38) of the respondents, however only seven knew the correct unit of measurement. Ninety five percent (35/37) of respondents were aware of complications of a low CP. Displacement or dislodgement of the tube was reported as a complication by 60% (22/37) of respondents. Two respondents did not answer the question regarding complications of high CP. The remaining respondents were aware of complications of a high CP.

Discussion

It is important to maintain cuff pressures within the recommended range and to prevent patient morbidity and mortality due to the complications of abnormal CPM outside these ranges.[1,6,8,27] Our data shows only a minority (17%) of CP measurements were within the recommended range. This places the majority of our patients at risk for preventable complications and this trend holds true for both adult and paediatric patients. A survey conducted in Cape Town as well as an international study also showed low rates of CPM, which may be a reflection of the lack of international consensus guidelines for CPM.[24,28]

The first arm of the study was a chart review to assess frequency of CPM documented on patient's charts in a 24-hour period. The review showed that the vast majority (87%) of patients had not had any CPM documented. Of the 40 charts with pressures monitored, only 19 (6%) had measurements done more than twice per 24-hour period, as recommended by local guidelines. However, as the national nursing guideline recommends one reading per shift, we further analyzed these charts and found that in patients with multiple readings only 12 (4%) had readings done at least once per shift. A 2004 Polish study showed that cuff pressure measurements were not done routinely in their controlled units.[24] A similar study done in Cape Town, South Africa showed only 15% of patients had readings done twice daily, with CP monitors used in 38% of their patients.[28] Of note in our study, nurses documented the CP they set rather than the reading they got when they measured the CP, so the number of inappropriate readings found by nurses could not be determined.

For the interventional arm of the study, CPMa were done on each patient with every chart review to determine if the CP was within the acceptable range (refer to the methods section).[10,11] Only 17% (52/304) were within the accepted range, with the majority (59%) being low. However if we used the reference range cited in international studies (20 - 30cmH_2O), the number of CPMa within the acceptable range improved to 36%.[9,29] Unfortunately an acceptable range for CP has yet to be validated, hence the heterogeneity in reporting locally and abroad, with some papers only stating an upper limit of pressure, commonly referenced as 30cmH_2O.[25,26] These results highlight the importance of regular

CPM, as 83% of our measurements were outside the target range, placing 83% of patients at risk for complications from inappropriate CP.

Since CPM is largely carried out by the nursing staff, it is imperative that they have a working knowledge of CP monitoring. With this in mind, a nursing questionnaire was administered to the nursing staff of our ICU. The response rate was only 51% (38/75) which may represent a reflection of the poor CPM practice found in the first part of the study. Demographics revealed a highly qualified and experienced group of nurses. Despite this, the knowledge of CPM and the practice of CPM documentation were both low. Two thirds of respondents shared the misconception that the cuff of an endotracheal tube serves the function of keeping the tube in place, and cited tube dislodgement as a complication of low CP. A similar observation was made in the study by Mol et al.[26] The overall awareness of complications of abnormal CP was high (>90%). A questionnaire done at a Flemish conference in 2014, yielded similar results: 80% of respondents had ICU degrees and 50% had >10years of experience, with 66% not knowing the CP range and a high number of respondents having awareness of complications.[29] This implies a gap in knowledge, and in respondents who have some knowledge, a gap between knowledge and its application; which has been well described in the nursing fraternity.[30] Numerous barriers exist which may explain current practice. We postulate a lack of a unit-specific evidenced-based guidelines on tracheal tube care, a lack of resources (insufficient number of manometers) and poor access to necessary equipment (manometers not at the bedside) as possible reasons. Only 76% of respondents reported receiving education on CPM, another significant barrier. While formulating and implementing an evidence-based guideline for our ICU may raise awareness regarding CPM, studies have shown that implementing protocols/guidelines are insufficient to reduce complications without ongoing educational programs to improve knowledge.[31]

Limitations of this study included a poor response rate to the NQ, with the result that the information gained was not truly representative of the nursing workforce. The questionnaire had not been piloted or validated which may have added to the value of the results obtained. Although the study period was extended, the calculated sample size to achieve a precision of 5.3% was not reached due to a lower than predicted bed occupancy rate as well as intubation rate during the study period. This reduced the power of the study, however the study still yields useful insights into our practice or lack thereof and provides the basis for changing current practice. There was a concern for introducing bias as the study progressed and the investigator was seen performing CPM in the unit resulting in change in practice. Therefore, a linear regression was performed and revealed no significant change in practice of CPM over the study period ($p=0.23$).

Conclusion

Assessment of current practice revealed that CPM is not routinely done. ICU nurses have a basic knowledge regarding CPM and risks of abnormal CP. This knowledge has not translated into practice. Although local best practice guidelines are available, an institution specific guideline together with ongoing in-service training will improve knowledge and awareness amongst nursing staff which may result in better tracheal tube care. Improved awareness and education to perform regular CPM can mitigate complications and improve patient outcomes in our ICU.

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Author contributions: Primary author, Dr AB Khan, MMed student and did all the data collection and write up with supervision from Drs Omar and Thandrayen.

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Conflicts of interest: None

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Table 1. Patient demographics according to the adult and paediatric groups (9-18 years and <9 years)

	All	Adult (≥18 years)	Paediatric patients (<18 years)	
			<9 years*	9 – 17 years
Patients, n (%)	61(100)	53 (87)	4(7)	4 (7)
Charts, n	304	251	15	38
Age in years: mean±SD	39±17.4	43.4±14	4±2.6	16±1.26
Weight in Kg: mean±SD	71.5±21	76.7±15.5	18±7.1	55±4.7
Sex, % male	61	53	5	3
Diagnostic Category n:				
Trauma	26	24	2	0
Medical	20	16	1	3
Surgical	13	11	1	1
Other†	2	2	0	0

* Recommended CP range of 20 to 25cmH_2O in <9 years

†Orthopaedic x1, Obstetrics x1

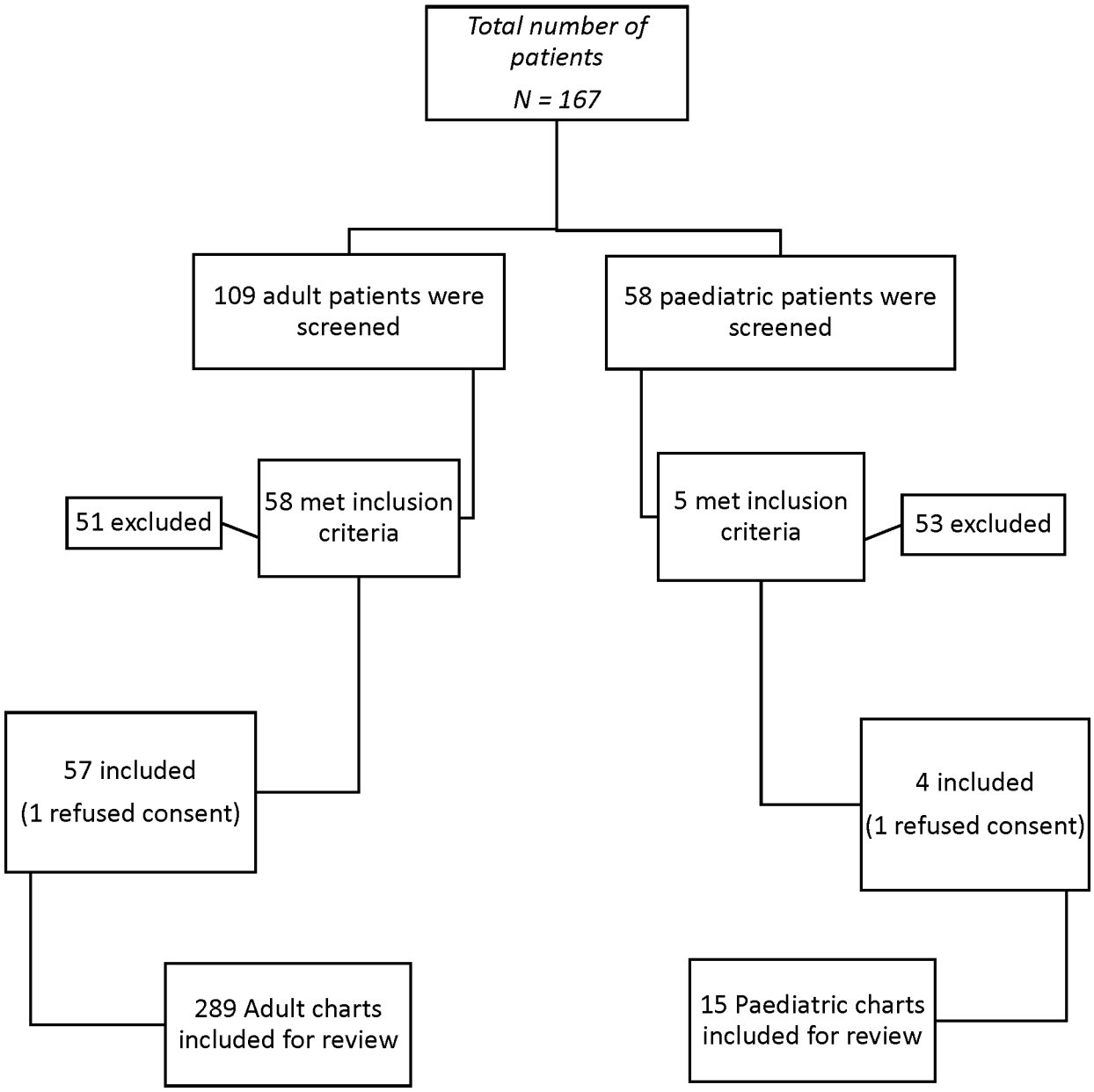


Figure 1. Flow diagram illustrating adult and paediatric patient recruitment, patient numbers and charts reviewed

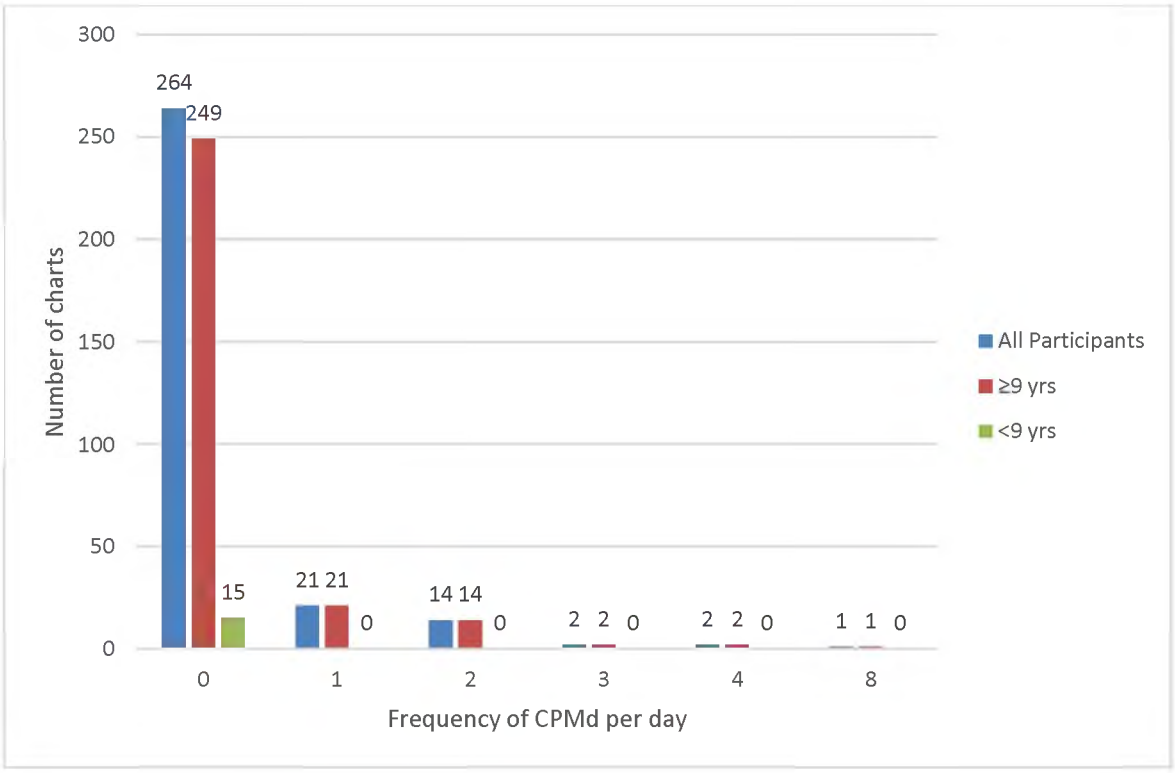


Fig. 2. Frequency of CPM documented per day.

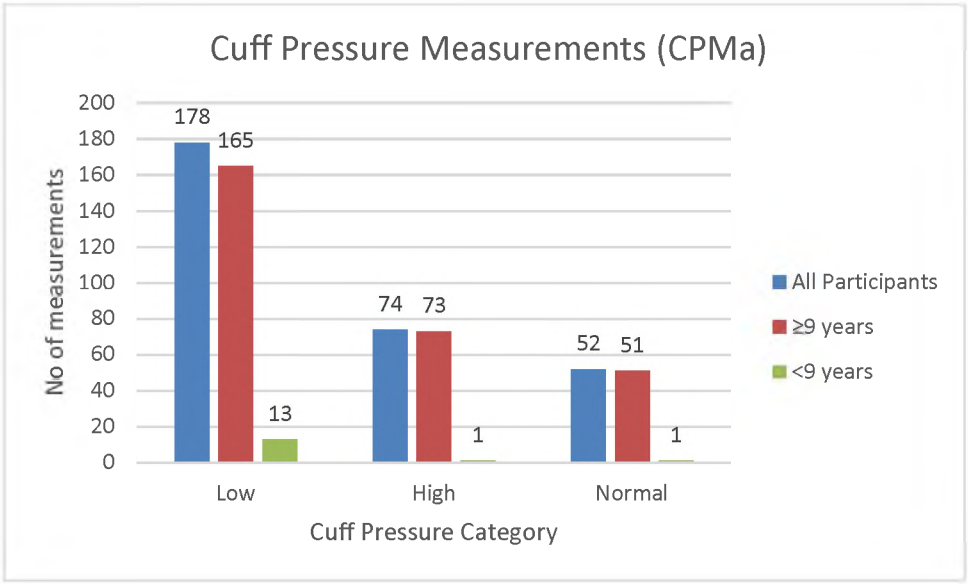


Fig. 3. CPM done by the investigator (CPMa)

Appendix A – Approved Protocol

1. Introduction

Tracheal tube cuff pressure monitoring should be routine in all patients intubated with a cuffed tube, both endotracheal tubes as well as tracheostomy tubes.[1] Tracheal tube cuff pressure monitoring is carried out by the nursing staff in Intensive Care Units (ICU). I will be conducting a study at the Chris Hani Baragwanath Academic Hospital (CHBAH) Main ICU to assess how frequently our patients' cuff pressures are being monitored, if patients' cuff pressures are in the recommended range and to assess the nursing staffs' basic knowledge regarding cuff pressure monitoring.

This study was triggered by the fact that there are seemingly a high number of patients presenting to our hospital's ENT department with tracheal or subglottic stenosis. A major risk factor for developing these conditions is over-inflation of the endotracheal tube cuff. This is an anecdotal observation. We hope that this study will help us to establish if our care is adequate or requires revision.

Further, since tracheal tube care is done by nursing staff, adequate knowledge of cuff pressure monitoring and the awareness of potential complications of cuffed tubes is imperative for nurses. The nursing questionnaire will not only determine baseline knowledge but also bring about awareness regarding this aspect of care.

2. Literature Review

Tracheal tube cuffs are used to prevent loss of tidal volume during positive pressure ventilation as well as to minimise pulmonary aspiration of gastric and oral secretions. To achieve these end points, the cuff needs to be appropriately inflated. Under inflation results in air leakage which may adversely affect mechanical ventilation and increased risk of aspiration while over inflation results in

varying degrees of damage to the surrounding tissues.[1,2,3] The use of cuffed tubes also facilitate respiratory monitoring including to correctly measure tidal volumes, lung compliance and end tidal carbon dioxide(CO_2) levels.[4] For paediatric patients, the additional benefit of a cuffed tube is a decreased need for repeated laryngoscopy due to incorrect tube size.[5,6]

The inflated cuff transmits its pressure to the surrounding structures, namely the tracheal mucosa. If the cuff pressure exceeds the capillary perfusion pressure in the tracheal mucosa, it results in decreased capillary blood flow.[1,7,8,9)] This impedance to blood flow results in ischaemia and subsequent mucosal damage. The capillary perfusion pressure in adults ranges between 20 and 30mmHg with impedance of blood flow noted at pressures of 22mmHg and total obstruction of flow in the mucosa overlying cartilage noted at pressures of 37mmHg.[1,7, 10] The recommended pressure for adult patients is below 22mmHg (30cmH_2O).[1,7,9]

The mucosal perfusion pressure reference ranges for the paediatric population have not been reported. There are also no validated recommendations available regarding the ideal endotracheal tube cuff pressures in children. A study done in paediatric patients by Dullenkopf et al showed that the overall cuff pressure required to attain an adequate seal, as determined by auscultation was 24cmH_2O.[11] The American Heart Association Pediatric Advanced Life Support 2015 guidelines recommends the use of the manufacturers specification for appropriate cuff pressure in children but does also suggest a reference range for paediatric patients of 20-25cmH_2O.[12]
Besides measuring cuff pressures using a manometer, there are two other techniques that can be used to assess adequate and safe cuff pressures.[1] The first is the minimal occlusive volume(MOV) technique which is done by deflating the cuff followed by gradual inflation of the cuff, while auscultating over the trachea, until such time that the leak is no longer audible. This is particularly useful for patients with fluctuating lung compliance. In the second technique, called the minimal leak technique, the same method for MOV is applied, followed by gradually removing air in 0.1ml

increments until the leak becomes audible. This method results in less trauma to the trachea but could allow loss of tidal volume and cause aspiration.[1] When using these methods the measured pressure should still be kept within the acceptable safe reference range. If there is a leak present at the upper limit of acceptable normal cuff pressure limits, it implies that the tube is too small and needs to be changed to a size larger than that which is presently used.[13]

The extent of damage from the overinflated cuff is related to absolute pressure exerted by the cuff as well as the duration of exertion of this pressure, with a greater contribution being from the absolute pressure.[7,9] Severity of damage is proportional to increasing pressure applied to the mucosa.[9] The types of injury include tracheitis, ulceration, tracheomalacia, tracheoesophageal fistula and cicatricial scarring with resultant tracheal stenosis.[1,14,15]
This can be avoided by routine regular measurement of tracheal tube cuff pressures and adjustment of the pressures if required so that pressures are at appropriate levels to prevent injury.

Numerous studies have shown that cuff pressure monitoring is inadequate and pressures are often higher than recommended.[2,5,16,17] To avoid complications of over inflation, cuff pressures need to be measured and documented regularly and routinely.[1,2,17] This requires staff awareness regarding care of cuffed tubes. Studies done by Mol et al in South Africa and Bhatta in the United Kingdom both highlight that lack of awareness and misconceptions around endotracheal tube cuff pressures still exist amongst staff involved in this aspect of care.[17,18] A survey in the Eastern Cape, South Africa showed that the majority of respondents did not practice evidence based medicine and furthermore only half of them monitored pressures once per shift.[19] In centres where cuff pressure awareness is high, there is still significant heterogeneity pertaining to optimal target pressures and frequency of monitoring.[20,21]

Ideally, pressures should be monitored continuously using pressure transducers and displaying pressure on a monitor.[3,21] This may allow rapid adjustments to dangerous pressure levels, decreasing patient's risk to laryngotracheal trauma secondary to cuff pressure, as damage to mucosa occurs within 15minutes of exposure to high pressures.[9] Newer tracheal tubes may provide an alternative to prevent damage by use of foam rubber cuffs which exert lower pressures or pressure relief valves or pressure safety balloons.[9,16]

In third world settings where lack of resources may preclude this, the alternative is intermittent measurement of cuff pressures, preferably 6 hourly.[3] The Nesibopho Guidelines suggest that cuff pressure should be measured once per shift, which is equivalent to twice daily, so this would be an acceptable bare minimum.[1] Pressures should be adjusted to the lowest pressure that allows for an adequate seal and should be within the recommended safety limits.[1,2]

3. Aims

The aim of the study is to determine the current practice regarding the monitoring of endotracheal/tracheostomy tube cuff pressures (cuff pressure).

4. Objectives

- To assess nursing staffs' knowledge regarding cuff pressure monitoring
- To assess frequency of cuff pressure monitoring in our unit
- To assess if cuff pressures are within the recommended safe reference ranges or levels.

5. Methodology for chart audit of cuff pressure monitoring

5.1. Study design

- A prospective cross-sectional chart review and interventional study of cuff pressure measurements.

5.2. Study location

The CHBAH Main ICU which is a combined adult and paediatric ICU that services both medical and surgical patients.

5.3. Study population

All patients in the ICU during the study period who meet the inclusion criteria listed below.

5.3.1. Inclusion Criteria

- Have a cuffed tube (endotracheal or tracheostomy) in situ for ≥ 24hrs
- Consent obtained

5.3.2. Exclusion Criteria

- Intubated for <24hours
- Intubated with a cuffed tube but cuff deflated intentionally

5.3.3. Sample size [22]

- The unit of observation is the patient-day, i.e. a patient contributes one observation to the study for each 24-hour period he/she is intubated.

- For the estimation of percentages (e.g. the percentage of patient-days for which monitoring of cuff pressures was carried out), based on a worst-case scenario (for sample size) estimate of 50%, 5% precision and the 95% confidence level, a sample size of 385 is required.
- It is estimated that in the adult side of the ICU, over a period of 30 days, at 15-bed occupancy, at a rate of 75% intubation, 337 patient-days would be observed. This corresponds to a precision of 5.3% (rather than 5.0%) and is thus adequate for the purpose of the study.
- The estimation on the paediatric side of the ICU, over a period of 30 days, at a 8-bed occupancy, at a rate of 10% intubation, an additional 24 patient-days would be observed.
- Sample size for prevalence was determined using the formula:

$$n = \frac{Z^2 P(1-P)}{d^2}$$

where n = sample size,

Z = Z-statistic for the chosen level of confidence,

P = expected prevalence or proportion

d = precision

5.4. Study period

- Chart review and pressure measurements: 1st June 2017 – 30th June 2017

5.5. Data Collection

5.5.1. Demographic data

- Age

5.5.2. Cuff Pressure Data (Appendix A)

- Review chart for last 24 hours at a set time everyday

    - Document time frame of review
- Document how many times cuff pressure was charted in 24 hours.
- Cuff pressure measurement by primary investigator
- Documentation if adjustment of cuff pressure

5.6. Method of cuff pressure measurement

- An aneroid manometer made by Covidien, called a hand pressure gauge, will be used to measure cuff pressure at the time of chart review to assess if it is in the safe range. Unit of measurement of pressure is cmH_2O.
- The manometer has a pressure gauge, with a bulb for inflation/deflation, a red button for releasing air to decrease the intracuff pressure and a piece of tubing to connect the manometer to the bulb of the cuff of the tube.
- The manometer being used does not require calibration. It has been calibrated and tested prior to leaving place of manufacture and pressures are deemed accurate as long as it is still in the warranty period. I will be using a new manometer, on loan from our local suppliers.
- To avoid inter-rater reliability errors all measurements will be performed by me. To avoid intra-rater reliability error, I will receive training from the company supplying the manometer. I will also take three consecutive measurements each on the first ten patients of study and see if they are reliable. I will repeat the measurements within thirty minutes to see if the results are reproducible.
- The pressure measured will be collected for data analysis.
- If pressures are found to be inappropriate, they will be corrected to a safe range and this will be documented on the doctors' daily progress note sheet and data collection sheet. They will not be written on the nursing chart, so as not to skew the results of the chart review arm of this study.

5.7. Data analysis

- Data will be captured using an Excel Spreadsheet and\or RedCap
- Descriptive analysis of the categorical data will be carried out by frequency and percentage tabulation, and illustrated by means of bar charts or pie charts.
- Data analysis will be carried out in SAS or Statistica.

6. Methodology for the Nursing Questionnaire

6.1. Study design

- Voluntary, anonymous self-administered questionnaire

6.2. Study location

- Academic multi-disciplinary ICU at CHBAH.
- The nursing staff in our ICU takes care of both paediatric and adult patients.

6.3. Study population

- All nurses working in the ICU who are willing to participate in the study
- The current population size of the nursing staff is 96
    - Total nursing staff is approximately 25 per shift. There are 4 shifts at CHBAH Main ICU.
    - I plan to administer the questionnaire to all sisters on the first day of their shift, over a 2week period to cover all shifts.
    - A response rate of at least 80% is anticipated, corresponding to a sample size of 76.

6.4. Study period

- Questionnaire: 2 weeks, first day of shift for each shift

  1st July 2017 – 14th July 2017

6.5. Data Collection

- Questionnaire (Appendix B) will be handed out to all nurses on duty during the study period on the first day of their shift.
- I will explain to them at their morning meeting the purpose of the study and how to complete and return the form.
- I will explain to them that the questionnaire is anonymous and voluntary.
- The questionnaire will be administered four times and on the the first day of each shift.
- Completed questionnaire to be returned in a sealed envelope placed in a sealed box in the nurses' tearoom by the end of the shift and to be collected by the investigator at the end of each of the shifts to maintain anonymity and to prevent bias.
- Completed questionnaires will be analysed to determine participants' knowledge.

6.6. Data analysis

- Data will be captured using an Excel Spreadsheet and or RedCap
- Responses will be scored against a rubric.
- Descriptive analysis of the data will be carried out by frequency and percentage tabulation, and illustrated by means of bar charts or pie charts.
- Data analysis will be carried out in Statistica version 12 (Statsoft, USA).

7. Ethics Approval:

- We are in the process of obtaining ethical approval from the Human Research Ethics Committee (HREC) at the University of the Witwatersrand..
- Consent will also be sought from the CEO of CHBAH and the Head of Department of CHBAH Main ICU.
- Consent for the chart review and cuff pressure measurements will be obtained as detailed below, as at the time of inclusion into the study patients will be intubated and likely to be sedated with/without muscle paralysis and will not be able to give consent:
    - Patient admitted and unable to sign consent and if the next of kin is available then consent will be obtained from next of kin (Appendix C). As soon as the patient is able to consent, informed consent will be obtained. At this stage, if the patient refuses, the patient is removed from the study.
    - Patient admitted and unable to sign consent. Next of kin unavailable. Consent is then obtained from the 'non study doctor", who is the attending doctor (who is not the investigator or supervisor of this research paper) who has the patient's best interest at heart (Appendix D). As soon as the next of kin is available, informed consent is obtained from the next of kin. At this stage, if the next of kin refuses, the patient is removed from the study. Further, as soon as the patient is able to, informed consent is obtained from the patient (Appendix E). At this stage, if the patient refuses, the patient is removed from the study.
    - Consent to be signed by patient if able to sign informed consent and has the right to decline at the outset. This however will be unlikely; as a patient who is intubated is vulnerable and if sedated will not have the capacity to do so.
    - Informed consent will be obtained once patient is able to sign. Consent form will have an accompanying information sheet (Appendix F).

- For the paediatric patients, defined as patients <18 years of age, consent will be obtained from their parents/legal guardian (Appendix C)
- Assent will be obtained from paediatric patients, if they have the capacity to assent (Appendix G).
- During the consenting process, a cuffed endotracheal tube will be used to demonstrate and explain to patient/next of kin what a cuff is.
- For the nursing questionnaire, consent will be implied if the form is completed and returned. An information sheet attached to the nursing questionnaire will state that participation is voluntary and anonymous and that implied consent will be used (Appendix H).

8. Timing

	Feb	Mar	April	May	June	July	Aug	Sept
Literature review								
Preparing protocol								
Protocol assessment								
Ethics application								
Collecting data								
Data analysis								
Writing up thesis								

9. Funding

- Costs anticipated include printing of questionnaires, internet usage, photocopies, time and labour for data collection and all to be borne by the primary investigator.

- The Covidien aneroid manometer used for cuff pressure measurement will be loaned to me from the supplier at no cost for the duration of the study.

10. Limitations

- Potential problem anticipated as study progresses will be that of the investigator's presence in the unit which may raise nursing awareness and change their routine practice.
- During data analysis, I will assess if documentation improved from day one of data collection to the last day of data collection.
- Nursing staff from different shifts may communicate details of questionnaire to one another. To address this I will:
    - request confidentiality when administering the questionnaire
    - only perform interviews on first day of each shift to avoid bias

11. Outcomes

It is hoped that this study will give us insight into the practices in our ICU, with a view to refining or redefining them if necessary.

I also wish to raise awareness amongst our staff regarding the importance and relevance of cuff pressure monitoring, by means of the questionnaire.

The measurement of pressures, if abnormal will serve to highlight the need to ensure we measure pressures as per recommended guidelines.

12. Publishing Intentions

I intend to publish the study in an appropriate peer reviewed journal.

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14. Appendix A

Sequence Number					
Date					
Study Identifier					
Adult (1)	Paed(2)	Age			
Gender	Male(1)	Female(2)			
Weight (Kg)		Diag Category			
Chart Review					
Period Reviewed					
Measurement Requested					
Number of times pressure documented					
Pressures documented on chart					
(in cmH_2O)					
Pressures measured by investigator					
Actual pressure value					
Adult	<25	25-30	>30		
Adults	25-30				
Paediatrics	<20	20-25	>25		
Paediatrics	20-25				
Adjustment Required	Yes	No			
Leak Present	Yes	No			
Percentage Leak					
Endotracheal T	1	Tracheostomy	2		
Tube Size					

Note: Unit of pressure measurements will be cmH_2O (as per manometer calibration).

Conversion of cmH_2O to mmHg: multiply by 0.736

15. Appendix B

Voluntary and Anonymous Nursing Questionnaire

1. Level of education

Professional Nurse	
Enrolled Nurse	
Other	

2. Do you have a critical care nursing qualification?

Yes			No	

3. Are you Agency Staff?

Yes		No	

4. How many years of ICU experience do you have?

_____

5. Have you received any education with regards to cuff pressure monitoring?

Yes		No	

6. Do you know of any guidelines or protocols regarding cuff pressure monitoring?

Yes		No	

7. Do you monitor endotracheal tube/tracheostomy tube cuff pressures routinely?

Yes		No	

If YES, then answer questions A-C but if no go to Question 7.

a. How frequently do you monitor cuff pressures?

_____

b. Which patients do you do cuff pressure measurements on?

_____

c. Which method do you use to determine if cuff pressure is appropriate and safe?

_____
_____
_____

8. What is the acceptable range for cuff pressures (Please state units and if you do not recall the units then state "I do not recall")?

_____
_____

9. Are you aware of any complications of low cuff pressures? If yes, please list.

Yes		No	

_____
_____
_____
_____

10. Are you aware of any complications of high cuff pressures? If yes, please list.

Yes		No	

_____
_____
_____
_____

THANK YOU FOR YOUR PARTICIPATION

16. Appendix C

Information Sheet for the Next of Kin/Parent/Legal Guardian:

Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath Academic Hospital.

Hello. My name is Ayesha Bibi Khan. I am an intensivist working in the Chris Hani Baragwanath Academic Hospital, Intensive Care Unit (ICU).

I would like to invite you to assist me with my MMed Research study called:

Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath academic hospital

Why am I doing this study?

Any patient who requires ventilation (lung support) need to have a tube in their trachea (windpipe) to allow the air to move in and out. This tube usually has a cuff (which is like a cushion) at the end. The cuff prevents air leaking out during ventilation. It also prevents saliva going into the lungs (aspiration) which may cause pneumonia (lung infection).

This cuff needs to be filled with air to perform this function. Once filled with air, the cuff has a pressure inside it. There is evidence to suggest that if the pressure is too high in the cuff, it can cause damage to the trachea. To prevent this damage from occurring we should be measuring the pressure in the cuff regularly.

The aim of my study is to see how often we are checking that the pressure in the cuff is within safe limits.

What would I like from participants in this study?

As your family member has a cuffed tube, I would like to ask if you would consent (give me permission, provided that when your family member is able, they agree/consent as well) for me to use the information available on their ICU charts in my study. I will review the chart and count how many times in a day the cuff pressure was recorded onto the chart. I am going to collect the information from the ICU chart to use in my study to see if we are checking as often as is recommended.

I also require permission to measure the cuff pressure myself and adjust it to normal if it is not in the recommended range.

RISKS: there will be no risk to your family member. I will be taking information from the chart and only adjusting the pressure to a safe range if it is too high or too low.

BENEFITS: If the pressure in the cuff is outside the recommended range, I will adjust it to a safe level. This will prevent damage to the tissues of the windpipe.

If our study shows that monitoring is not good enough, we will use the information to bring about change in the ICU so future patients may benefit.

VOLUNTARY: Participation is voluntary. The care your family member receives will not be affected in anyway should you choose not to participate in my study. There will be no incentives for participating in this study.

CONFIDENTIALITY: Information from the ICU chart will be identified by a unique code.

All results and information remain confidential as with all patients in the ICU. If you would like any further information, please contact me, Dr Khan on the contact number below.

May you change your mind about participating in the study?
Yes, you may do so at any time without giving any reasons. Remember that participation is completely voluntary and will not affect the quality of medical care provided in the ICU.

Thank you for taking the time to read this information sheet and for assisting me with my MMed study.

If you have any questions, please feel free to contact me:

My contact details are:

Ayesha Bibi Khan

Cell Number: 082 550 3102

Email: Ayesha.khan@wits.ac.za

Contact details of Human Research Ethics Committee (Medical) - HREC

If you have any ethical complaints or concerns about the study you may contact:

The HREC (Medical) Administrator:

Ms Zanele Ndlovu

Tel Number: 011 717 1252

Email: zanele.ndlovu@wits.ac.za

Please remember that your family member will remain anonymous. If you feel comfortable about participating in this study please read and sign the attached consent form.

Informed consent form – Next of kin

I, (full name) _____ have read the information sheet. I understand what my relative or family member will be participating in. Participation in the study is **voluntary and I consent to his/her participation,** to the use of the collected information and measurements of cuff pressure. I understand that all the information related to the study is anonymous and cannot be linked to the participant. I understand that the participant has the right to withdraw from the study at any time. I also understand that withdrawal will not affect the participant's medical management.

Name of participant_____

Relationship if next of kin _____

Signed: _____

Date: _____

Time: _____

Witness: _____

Signed: _____

Date: _____

Time: _____

Investigator: _____

Signed: _____

Date: _____

Time: _____

17. Appendix D

Information Sheet for the Non-Study Doctor of the participant:

Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath Academic Hospital.

Dear Colleague. My name is Ayesha Bibi Khan. I am an intensivist working in the Chris Hani Baragwanath Academic Hospital, Intensive Care Unit (ICU).

I would like to invite you to assist me in my MMed Research study called:

Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath academic hospital

Why am I doing this study?

Any patient who requires ventilation using a cuffed endotracheal or tracheostomy tube requires the cuff pressures to be measured. The cuff prevents air leaking out during ventilation. It also may prevent aspiration, which may cause pneumonia.

There is evidence to suggest that high cuff pressures can cause damage to the trachea. To prevent this damage from occurring we should be measuring the pressure in the cuff regularly.

The aim of my study is to see how often we are checking that the pressure in the cuff is within safe limits to prevent damage.

What would I like from participants in this study?

Given that your patient has a cuffed tube, I would like to include your patient in my study. I would like to ask if you would assent (give me permission, provided that when the patient is able, they agree/consent as well) to participate in my study. I will review the chart and count how many times in a day the cuff pressure was recorded onto the chart. I am going to collect the information from the ICU chart to use in my study to see if we are checking as often as is recommended.

I would like permission to measure the pressure and, if it is not within the recommended range adjust it to the recommended normal range.

RISKS: there will be no risk to your patient. I will be taking information from the chart and only adjust the pressures if they are abnormal.

BENEFITS: If required, the pressure will be adjusted to a safe range to prevent damage to the tracheal mucosa.

The information we get from my study may help future patients, if it shows that we are not measuring the pressures as often as we should be measuring.

VOLUNTARY: Participation is voluntary. There will be no incentives for participating in this study.

CONFIDENTIALITY: Information from your patient's chart will be identified by a unique code. No individual or identifiable information will be available in the published data. Only the researcher and supervisors will have access to the data collection sheet, which will be stored in a locked office.

All results and information remain confidential as with all patients in the ICU. If you would like any further information, please contact me, Dr Khan on the contact number below.

Thank you for taking the time to read this information sheet and for assisting me with my MMed study.

If you have any questions, please feel free to contact me:

My contact details are:

Ayesha Bibi Khan

Cell Number: 082 550 3102

Email: Ayesha.khan@wits.ac.za

Contact details of Human Research Ethics Committee (Medical) - HREC

If you have any ethical complaints or concerns about the study you may contact:

The HREC (Medical) Administrator:

Ms Zanele Ndlovu

Tel Number: 011 717 1252

Email: zanele.ndlovu@wits.ac.za

Please remember that your patient will remain anonymous. If you feel comfortable about participating in this study please read and sign the attached consent form.

Informed consent form (Non ICU physician attending to patient)

I, (full name)_____ have read the information sheet. I understand what the person under my care will be participating in. Participation in the study is **voluntary and I assent to his/her participation,** to the use of the collected information and cuff pressure measurements. I understand that all the information related to the study is anonymous and cannot be linked to the participant. I understand that the participant has the right to withdraw from the study at any time. I also understand that withdrawal will not affect the participant's medical management.

Name (Participant)_____

Name (physician) _____

Signed: _____

Date: _____

Time: _____

Witness: _____

Signed: _____

Date: _____

Time: _____

Investigator: _____

Signed: _____

Date: _____

Time: _____

18. Appendix E

Information Sheet for the participant:

Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath Academic Hospital.

Hello. My name is Ayesha Bibi Khan. I am an intensivist working in the Chris Hani Baragwanath Academic Hospital, Intensive Care Unit (ICU).

I would like to invite you to take part in my MMed Research study called:

Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath academic hospital

Why am I doing this study?

Any patient who requires ventilation (lung support) will need to have a tube in their trachea (windpipe) to allow the air to move in and out. This tube usually has a cuff (which is like a cushion) at the end. The cuff prevents air leaking out during ventilation. It also prevents saliva going into the lungs (aspiration) which may cause pneumonia (lung infection).

This cuff needs to be filled with air to perform this function. Once filled with air, the cuff has a pressure inside it. There is evidence to suggest that high pressures in cuffs can cause damage to the trachea. To prevent this damage from occurring we should be measuring the pressure in the cuff regularly.

The aim of my study is to see how often we are checking that the pressure in the cuff is within safe limits to prevent damage and also to see if the pressure is in the safe range when I measure it.

What would I like from participants in this study?

I would like to ask all patients that require a cuffed tube to provide permission for me to use the information available on their ICU charts. I will review the chart and count how many times in a day the cuff pressure was recorded onto the chart. I am going to collect information from your ICU chart to use in my study to see if we are checking as often as is recommended.

I am also asking for permission to measure the pressure in the cuff and adjust it to the recommended range. The adjustment will only be made if the pressures are too high or too low.

RISKS: there will be no risk to you. I will be taking information from your chart and only adjusting the pressure if it is not in the normal range.

BENEFITS: If your pressure is not being measured, I will measure it and adjust it. This will prevent damage to your windpipe caused by too much pressure.

The information we get from my study may help future patients, if it shows that we are not measuring the pressures as often as we should be measuring.

VOLUNTARY: Participation is voluntary. Your care will not be affected in anyway should you choose not to participate in my study. There will be no incentives for participating in this study.

CONFIDENTIALITY: Information from your chart will be identified by a unique code. No individual or identifiable information will be available in the published data. Only the researcher and supervisors will have access to the data collection sheet, which will be stored in a locked office.

All your results and information remain confidential as with all patients in the ICU. If you would like any further information, please contact me, Dr Khan on the contact number below.

May you change your mind about participating in the study?
Yes, you may do so at any time without giving any reasons. Remember that your participation is completely voluntary and will not change the way your doctor manages your disease.

Thank you for taking the time to read this information sheet and for assisting me with my MMed study.

If you have any questions, please feel free to contact me:

My contact details are:

Ayesha Bibi Khan

Cell Number: 082 550 3102

Email: Ayesha.khan@wits.ac.za

Contact details of Human Research Ethics Committee (Medical) - HREC

If you have any ethical complaints or concerns about the study you may contact:

The HREC (Medical) Administrator:

Ms Zanele Ndlovu

Tel Number: 011 717 1252

Email: zanele.ndlovu@wits.ac.za

Please remember that you will remain anonymous. If you feel comfortable about participating in this study please read and sign the attached consent form.

OR

Information Sheet for the participant for retrospective data use:

Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath Academic Hospital.

Hello. My name is Ayesha Bibi Khan. I am an intensivist working in the Chris Hani Baragwanath Academic Hospital, Intensive Care Unit (ICU).

I would like to invite you to take part in my MMed Research study called:

Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath academic hospital

Why am I doing this study?

Any patient who requires ventilation (lung support) will need to have a tube in their trachea (windpipe) to allow the air to move in and out. This tube usually has a cuff (which is like a cushion) at the end. The cuff prevents air leaking out during ventilation. It also prevents saliva going into the lungs (aspiration) which may cause pneumonia (lung infection).

This cuff needs to be filled with air to perform this function. Once filled with air, the cuff has a pressure inside it. There is evidence to suggest that high pressures in cuffs can cause damage to the trachea. To prevent this damage from occurring we should be measuring the pressure in the cuff regularly.

The aim of my study is to see how often we are checking that the pressure in the cuff is within safe limits to prevent damage and also to see if the pressure is in the safe range when I measure it.

What would I like from participants in this study?

While you were in the ICU I received consent from your family/your doctor to use your chart information in my study. I also obtained consent to measure your cuff pressure and adjust it to a safe range.

I would like to ask for your permission to use the information I took from your chart and the measurements I made in my study.

RISKS: there was no risk to you. I took information from your chart and I adjusted the pressures only when they were not in the normal range.

BENEFITS: The adjustment made prevented possible damage to your windpipe and also possible decreased your risk of having aspiration pneumonia.

The information we get from my study may help future patients, if it shows that we are not measuring the pressures as often as we should be measuring.

VOLUNTARY: Participation is voluntary. Your care will not be affected in anyway should you choose not to participate in my study. There will be no incentives for participating in this study.

CONFIDENTIALITY: Information from your chart will be identified by a unique code. No individual or identifiable information will be available in the published data. Only the researcher and supervisors will have access to the data collection sheet, which will be stored in a locked office.

All your results and information remain confidential as with all patients in the ICU. If you would like any further information, please contact me, Dr Khan on the contact number below.

May you change your mind about participating in the study?
Yes, you may do so at any time without giving any reasons. Remember that your participation is completely voluntary and will not change the way your doctor manages your disease.

Thank you for taking the time to read this information sheet and for assisting me with my MMed study.

If you have any questions, please feel free to contact me:

My contact details are:

Ayesha Bibi Khan

Cell Number: 082 550 3102

Email: Ayesha.khan@wits.ac.za

Contact details of Human Research Ethics Committee (Medical) - HREC

If you have any ethical complaints or concerns about the study you may contact:

The HREC (Medical) Administrator:

Ms Zanele Ndlovu

Tel Number: 011 717 1252

Email: zanele.ndlovu@wits.ac.za

Please remember that you will remain anonymous. If you feel comfortable about participating in this study, please read and sign the attached consent form.

Informed consent form - Participant

I, (full name) _____ have read the information sheet. I understand what my participation in the study entails and **voluntarily consent** to the use of the collected information and cuff pressure measurements. I understand that all the information related to the study is anonymous and cannot be linked to me. I understand that I have the right to withdraw from the study at any time. I also understand that my withdrawal will not affect my medical management.

Name (Participant) _____

Signed: _____

Date: _____

Time: _____

Witness: _____

Signed: _____

Date: _____

Time: _____

Investigator: _____

Signed: _____

Date: _____

Time: _____

19. Appendix F

Information sheet for children able to Assent:

Hello. My name is Ayesha Bibi Khan. I am a paediatrician who looks after children in the ICU. I work here at this hospital called the Chris Hani Baragwanath Academic Hospital.

I would like to invite you to take part in my MMed Research study called:

Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath academic hospital

Why am I doing this study?

When you are so sick that you cannot breathe on your own, we need to use a special machine called a ventilator to help you breathe. Air gets into your lungs through a tube called a windpipe. We also need to put a tube, like a big straw, into your wind pipe so the ventilator can get the air in and out for you, until you are feeling better and are able to breathe by yourself again.

This tube that we use has a balloon (which called a cuff) at the end which acts as a cushion. The tube needs the cushion so that the air we put in does not leak out the sides of the tube and so that enough air gets into your lungs. If the balloon is blown up too much it can squeeze your windpipe. We use a machine to check how much air there is in the balloon so that it does not squeeze the windpipe. The machine measures the pressure of the air in the balloon.

My study is checking on your ICU chart, how many times the pressure is measured in the balloon. We want to be sure that it is checked regularly.

What would I like from participants in this study?

I would like to ask your permission to use the information on your chart in my study. I will check the chart and count how many times in a day the pressure was recorded onto the chart.

If I see that they have not measured your pressure, I will measure it and set it to be normal so that your windpipe does not get hurt with too much pressure.

Can this hurt you?

No, it cannot. I will be taking information from your chart and only adjusting the pressure if it is not correct.

You and your parents have a choice. You do not have to take part in this study unless you want to.

CONFIDENTIALITY: Information from your chart will be identified by a unique code. No individual or identifiable information will be available in the published data. Only the researcher and supervisors will have access to the data collection sheet, which will be stored in a locked office.

All your results and information remain confidential as with all patients in the ICU. If you would like any further information, please contact me, Dr Khan on the contact number below.

May you change your mind about participating in the study?
Yes, you may do so at any time without giving any reasons. Remember that your participation is completely voluntary and will not change the way your doctor manages your disease.

Thank you for taking the time to read this information sheet and for assisting me with my MMed study.

If you have any questions please feel free to contact me:

My contact details are:

Ayesha Bibi Khan

Cell Number: 082 550 3102

Email: Ayesha.khan@wits.ac.za

Contact details of Human Research Ethics Committee (Medical) - HREC

If you have any ethical complaints or concerns about the study you may contact:

The HREC (Medical) Administrator:

Ms Zanele Ndlovu

Tel Number: 011 717 1252

Email: zanele.ndlovu@wits.ac.za

Please remember that you will remain anonymous. If you feel comfortable about participating in this study please read and sign the attached consent form.

Informed Assent form - Participant

I, (full name)_____ have read the information sheet. I understand what my participation in the study entails **voluntarily assent** to the use of the collected information and cuff pressure measurements. I understand that all the information related to the study is anonymous and cannot be linked to me. I understand that I have the right to withdraw from the study at any time. I also understand that my withdrawal will not affect my medical management.

Name (Participant) _____

Signed: _____

Date : _____

Time: _____

Witness: _____

Signed: _____

Date : _____

Time: _____

Investigator: _____

Signed: _____

Date : _____

Time: _____

20. Appendix G

Information sheet for Nursing Questionnaire:

Nursing Questionnaire

Dear Participant

My name is Ayesha Bibi Khan, I am a paediatric intensivist working in the Main ICU at Chris Hani Baragwanath Academic Hospital. I would like to invite you to participate in my study entitled:

Tracheal tube cuff pressure monitoring: Assessing current practice in critically ill patients at Chris Hani Baragwanath academic hospital

Measurement of cuff pressures in endotracheal tubes and tracheostomy tubes should be part of the care we provide to our patients. The object of this study is to assess what is our units practice regarding cuff pressure measurements which will include looking at staff awareness regarding cuff pressure measurements.

I will be using a nursing questionnaire to assess nursing awareness regarding cuff pressure measurements. The questionnaire will take approximately 15minutes to complete.

Should you wish to participate, please complete the questionnaire in the context of your practice so that the results obtained can be an accurate reflection of our current practice. Please answer the questions without help from colleagues and without referring to textbooks or the internet. This is important so that our information is accurate.

RISKS: There will not be any risk to you if you participate in the questionnaire.

BENEFITS: The results will reflect whether our practice is correct and in the best interest of the patient. The information obtained may result in in service training should it be necessary to improve patient care. It will also help prevent complications of inappropriate cuff pressures by raising awareness about cuff pressure measurements.

PARTICIPATION IS VOLUNTARY: You are not under any obligation to participate in the study. You will not be judged for not participating and you will not be penalized for not participating in my study. There will not be any incentives for participating in this study. Consent will be implied by the return of a completed questionnaire.

CONFIDENTIALITY: The questionnaire is Anonymous and no personal information will be required. You may return the questionnaire complete or incomplete to the sealed box provided and you may withdraw at any point should you wish to do so. Only the researcher and supervisors will have access to the completed questionnaires, which will be stored in a locked office. Published data will not contain any personal or identifiable information.

Thank you for taking the time to read this information sheet and for assisting me with my MMed study.

If you have any questions, please feel free to contact me:

My contact details are:

Ayesha Bibi Khan

Cell Number: 082 550 3102

Email: Ayesha.khan@wits.ac.za

Contact details of Human Research Ethics Committee (Medical) - HREC

If you have any ethical complaints or concerns about the study you may contact:

The HREC (Medical) Administrator:

Ms Zanele Ndlovu

Tel Number: 011 717 1252

Email: zanele.ndlovu@wits.ac.za

Appendix B - Ethics Clearance

R14/49 Dr Ayesha Bibi Khan

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160473

NAME: (Principal Investigator)	Dr Ayesha Bibi Khan
DEPARTMENT:	Paediatrics Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Tracheal Tube Cuff Pressure Monitoring: Assessing Current Practice in Critically Ill Patients at Chris Hani Baragwanath Academic Hospital
DATE CONSIDERED:	06/05/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Shahed Omar and Dr Kebashni Thandrayen
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	07/06/2017

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

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004,10th floor, Senate House/3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review April and will therefore be due in the month of April each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

04 July 2017

Dr Ayesha Bibi Khan
Department of Paediatrics
Chris Hani Baragwanath Academic Hospital

Sent by email to: abativa@gmail.com

Dear Dr Khan

Re: **Protocol Ref no: M160473**
Protocol Title: Tracheal Tube Cuff Pressure Monitoring: Assessing Current Practice in Critically Ill Patients at Chris Hani Baragwanath Academic Hospital
Principal Investigator: Dr Ayesha Bibi Khan
Amendment of Data Collection Sheet

This letter serves to confirm that the Chairman of the Human Research Ethics Committee (Medical) has approved the protocol amendment for the abovementioned protocol, as detailed in your letter dated 20 June 2017.

The following documents were received:

- Cover Letter dated 20 June 2017.
- Study Proposal.
- Appendix A: Data Collection Sheet.
- Appendix B: Questionnaire.
- Appendix C: Information Sheet for the Next of Kin/Parent/Legal Guardian.
- Informed Consent Form – Next of Kin.
- Appendix D: Information Sheet for the Non-Study Doctor of the Participant.
- Information Sheet for the Participant for the Retrospective Data use.
- Informed Consent Form – Participant.
- Appendix F: Information Sheet for Children able to Assent.
- Informed Assent Form – Participant.
- Appendix G: Information Sheet for Nursing Questionnaire.

Research Office Secretariat: Faculty of Health Sciences, Phillip Tobias Building, 3rd Floor, Office 302, Corner York Road and 29 Princess of Wales Terrace, Parktown, 2193 Private Bag 3, Wits 2050 | T+27 (0)11-717-1234/2656/2700/1252 E: Lebo.Moeng@wits.ac.za | Office E HREC-Medical.ResearchOffice@wits.ac.za | Website: www.wits.ac.za/research/about-our-research/ethics-and-research-integrity/

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Thank you for keeping us informed and updated.

Yours Sincerely,

L. moeng

.....

Mr Lebohang Moeng
Administrative Assistant
Human Research Ethics Committee (Medical)

UNIVERSITY OF THE WITWATERSRAND
OFFICE OF THE DEPUTY VICE CHANCELLOR RESEARCH
04 JUL 2017
RESEARCH OFFICE HREC (Medical)
JOHANNESBURG

Research Office Secretariat: Faculty of Health Sciences, Phillip Tobias Building, 3rd Floor, Office 302, Corner York Road and 29 Princess of Wales Terrace, Parktown, 2193 Private Bag 3, Wits 2050 I **T**+27 (0)11-717-1234/2656/2700/1252 **E**: Lebo.Moeng@wits.ac.za I **Office E** HREC-Medical.ResearchOffice@wits.ac.za IWebsite: www.wits.ac.za/research/about-our-research/ethics-and-research-integrity/

Appendix C – Author Guidelines for the Southern African Journal of Critical Care

Author Guidelines

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

AUTHORSHIP Named authors must consent to publication. Authorship should be based on substantial contribution to: (i) conception, design, analysis and interpretation of data; (ii) drafting or critical revision for important intellectual content; and (iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to **www.icmje.org**).
CONFLICT OF INTEREST Authors must declare all sources of support for the research and any association with a product or subject that may constitute conflict of interest.
RESEARCH ETHICS COMMITTEE APPROVAL Provide evidence of Research Ethics Committee approval of the research where relevant.
PROTECTION OF PATIENT'S RIGHTS TO PRIVACY Identifying information should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives informed written consent for publication. The patient should be shown the manuscript to be published. Refer to **www.icmje.org**.
ETHNIC CLASSIFICATION References to ethnic classification must indicate the rationale for this.

MANUSCRIPTS Shorter items are more likely to be accepted for publication, owing to space constraints and reader preferences.
Original articles not exceeding 3 000 words, with up to 6 tables or illustrations, are usually observations or research of relevance to critical care. References should preferably be limited to no more than 15. Please provide a structured abstract not exceeding 250 words, with the following recommended headings: *Background, Aims, Methods, Results,*and *Conclusion.*
Short reports or ***scientific letters***, which include case reports, side effects of drugs and brief or negative research findings should be 1500 words or less, with 1 table or illustration and no more than 6 references. Please provide an accompanying abstract not exceeding 150 words.
Editorials, Opinions, etc. should be about 1000 words and are welcome, but unless invited, will be subjected to the SAJCC peer review process.
Review articles are rarely accepted unless invited.
Letters to the editor, for publication, should be about 400 words with only one illustration or table, and must include a correspondence address.
Obituaries should be about 400 words and may be accompanied by a photograph.

MANUSCRIPT PREPARATION Refer to articles in recent issues for the presentation of headings and subheadings. If in doubt, refer to 'uniform requirements' - **www.icmje.org**.
Manuscripts must be provided in **UK English**.
Qualification, affiliation 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)'.

Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dl). Litres is denoted with a lowercase 'l' e.g. 'ml' for millilitres). Units should be preceded by a space (except for %), e.g. '40 kg' and '20 cm' but '50%'. Greater/smaller than signs (> and 40 years of age'. The same applies to ± and °, i.e. '35±6' and '19°C'.
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.
General formatting The manuscript must be in Microsoft Word or RTF document format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes, with the exception of Tables).

ILLUSTRATIONS AND TABLES If tables or illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.
Tables may be embedded in the manuscript file or provided as **'supplementary files'**. They must be numbered in Arabic numerals (1,2,3...) and referred to consecutively in the text (e.g. 'Table 1'). Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged. Tables must be cell-based (i.e. not constructed with text boxes or tabs), and accompanied by a concise title and column headings. Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.
Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'. Figure legends: Fig. 1. 'Title...' All illustrations/figures/graphs must be of **high resolution/quality**: 300 dpi or more is preferable but images must not be resized to increase resolution. Unformatted and uncompressed images must be attached as '**supplementary files**' upon submission (not embedded in the accompanying manuscript). TIFF and PNG formats are preferable; JPEG and PDF formats are accepted, but authors must be wary of image compression. Illustrations and graphs prepared in Microsoft Powerpoint or Excel must be accompanied by the original workbook.

REFERENCES Authors must verify references from the original sources. *Only complete, correctly formatted reference lists will be accepted.* Reference lists must be generated manually and **not** with the use of reference manager software. 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. First and last page, volume and issue numbers should be given.
Wherever possible, references must be accompanied by a digital object identifier (DOI) link and PubMed ID (PMID)/PubMed Central ID (PMCID). Authors are encouraged to use the DOI lookup service offered by **CrossRef**.
Journal references: Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. [http://dx.doi.org/10.1000/hgjr.182] [PMID: 2764753]
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 jun, 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: World Health Organization, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).
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)'.

PROOFS A PDF proof of an article may be sent to the corresponding author before publication to resolve remaining queries. At that stage, **only** typographical changes are permitted; the corresponding author is required, having conferred with his/her co-authors, to reply within 2 working days in order for the article to be published in the issue for which it has been scheduled.
CHANGES OF ADDRESS Please notify the Editorial Department of any contact detail changes, including email, to facilitate communication.

CPD POINTS Authors can earn up to 15 CPD CEUs for published articles. Certificates may be requested after publication of the article.

CHARGES There is no charge for the publication of manuscripts.

Submission Preparation Checklist

As part of the submission process, authors are required to check off their submission's compliance with all of the following items, and submissions may be returned to authors that do not adhere to these guidelines.

1. The submission has not been previously published, nor is it before another journal for consideration.
2. The text complies with the stylistic and bibliographic requirements in **Author Guidelines**.
3. The manuscript is in Microsoft Word or RTF document format. The text is single-spaced, in 12-point Times New Roman font, and contains no unnecessary formatting.
4. Illustrations/figures are high resolution/quality (not compressed) and in an acceptable format (preferably TIFF or PNG). These must be submitted as 'supplementary files' (not in the manuscript).
5. For illustrations/figures or tables that have been published elsewhere, the author has obtained written consent to republication from the copyright holder.
6. Where possible, references are accompanied by a digital object identifier (DOI) and PubMed ID (PMID)/PubMed Central ID (PMCID).
7. An abstract has been included where applicable.
8. The research was approved by a Research Ethics Committee (if applicable)
9. Any conflict of interest (or competing interests) is indicated by the author(s).

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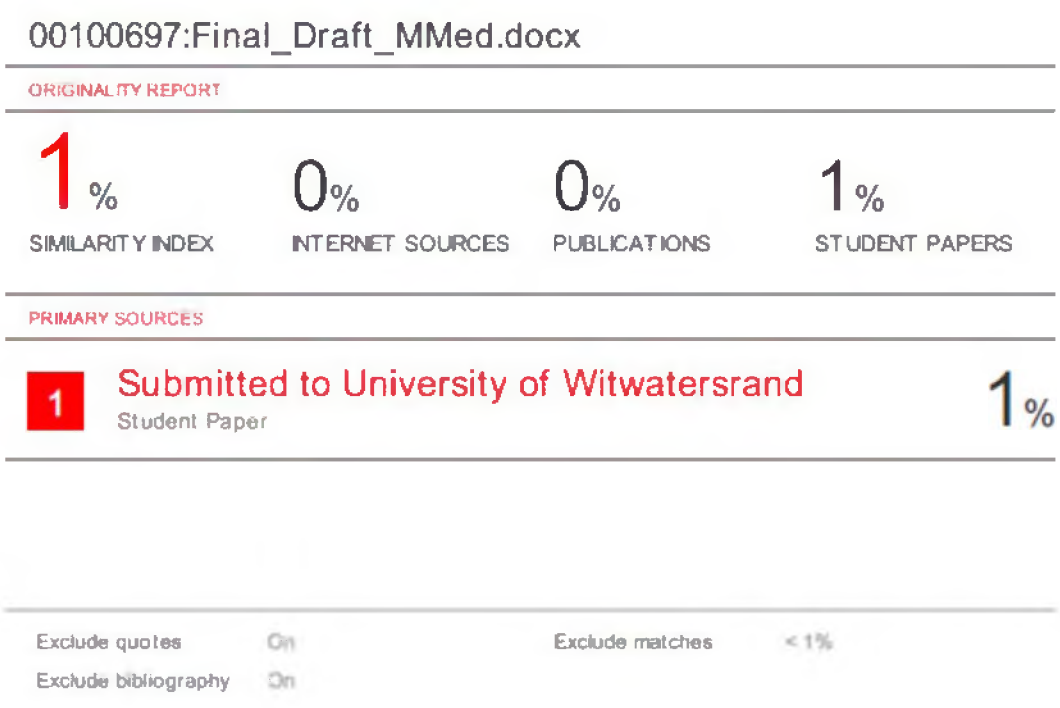
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APPENDIX D – TURNITIN REPORT



00100697:Final_Draft_MMed.docx

ORIGINALITY REPORT

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SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

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1	Submitted to University of Witwatersrand Student Paper	1%

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