Mortalities in the neonatal unit: After-hours compared with normal working hours at Pelonomi Tertiary Hospital over a 1-year period (January 2017 to December 2017).

By investigator:

Dr S.E Duba
Registrar: Department of Paediatrics and Child Health, Faculty of Health Sciences
University of the Free State
Student number: 2015345859

Study Leader:

Dr J.J Van Rooyen
MBChB, MMed (Paeds), FCPaed (SA)
Consultant: Department of Paediatrics and Child Health, Faculty of Health Sciences
University of the Free State

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Declaration

I, Sithembiso Duba, declare that the coursework Master's Degree mini-dissertation that I herewith submit in a publishable manuscript format for the Master's Degree qualification in Paediatrics at the University of the Free State is my independent work, and that I have not previously submitted it for a qualification at another institution of higher education.

Author contributions

	Affiliation	Role
Duba,S.E	Department of Paediatrics and Child Health Faculty of Health Sciences University of the Free State	Study conception and design, acquisition of data, interpretation of data, drafting the article
Van Rooyen, J.J.	Department of Paediatrics and Child Health Faculty of Health Sciences University of the Free State	Supervision, study conception and design, revising critically for clinical content, give final approval of the version to be submitted
Van Zyl, R	Department of Paediatrics and Child Health Faculty of Health Sciences University of the Free State	Review manuscript
Bouwer, A.S.	Department of Paediatrics and Child Health Faculty of Health Sciences University of the Free State	Design of the manuscript, drafting the article, revising critically
Van Rooyen, C.	Department of Biostatistics, University of the Free Sate	Analysis of data

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Table of contents

1. Abstract

Background: Neonatal mortality remains one of the leading causes of under-5-mortality in South Africa. South Africa has not reached the Millennium Development Goals targets for 2015 as set out by the WHO. The leading causes for neonatal mortality remains immaturity related (48.1%), complications of hypoxia (24.2%) and infections (11.2%). According to the PPIP and CHPIP program data, many of these deaths do have avoidable factors that are administrative and staff related. If there is a difference found in mortalities when comparing normal working hours with after-hours, then it is possible that administrative and staffing differences for these hours could be a reason for differences seen. This could assist relevant stakeholders to optimize allocation of resources (including staffing) as well as guide further research to investigate possible reasons for differences in mortalities for different time intervals.

Objectives: This research set out to investigate whether or not there are differences in the number of neonatal mortalities at Pelonomi Tertiary Hospital, Bloemfontein, when comparing normal working hours with after-hours. If there are differences, then to determine if there are differences in the avoidable factors involved in these mortalities (according to the PPIP and CHPIP data).

Method: This was a descriptive, cross-sectional study. The total number of mortalities (January 2017 – December 2017) for normal working hours and after-hours were investigated, and avoidable factors (according to PPIP and CHPIP codes) for these mortalities were compared.

Results: A total number of 103 neonatal mortalities for this time period were included in this study. More deaths occurred after-hours (16:00 – 07:30 on weekday, whole weekends and whole public holidays) when compared to normal working hours (all other weekdays 07:30 – 16:00) (n=67, 65.05% *vs* n=36, 34.95%). When the time frames are divided into after-hours (any day 16:00 – 07:30) and normal working hours (any day 07:30 – 16:00), more deaths occurred after-hours (n=55, 53.4%). Most of *these* (any day) after-hour mortalities occurred between 16:00 and 00:00 (n=31, 56.4%). The most common causes of death for these neonates reflect the same causes as the national PPIP/CHPIP data, being 1. Infection related (n=26, 25.24%), 2. multi-organ immaturity (n=21, 20.39%) and 3.Complications of hypoxia (n=18, 17.48%). There were no major differences in administrative and staff-related avoidable factors when comparing these different time intervals.

Conclusion: This study confirms that during this time period there were more neonatal deaths occurring after-hours when compared to normal working hours at Pelonomi Tertiary Hospital, Bloemfontein. Due to the design of this study we could not conclude whether or not these differences are statistically significant. To optimize allocation of limited resources and staffing, the researcher concludes that further research to determine the factors which may contribute to these differences in mortalities for different time intervals is warranted.

2. Key words: Neonatal mortality; After-hours; Normal working hours; Mortality differences; Avoidable factors; Resource and staffing allocation;

3. List of Abbreviations

BPD	- Bronchopulmonary Dysplasia
C/S	- Caesarean Section
CHPIP	- Child Healthcare Problem Identification Program
ELBW	- Extremely low birth weight
ENND	- Early Neonatal Death
ENMR	- Early Neonatal Mortality Rate
FS	- Free State
FSDOH	- Free State Department of Health
IUGR	- Intra-uterine growth restriction
IUD	- Intra-uterine death
IVH	- Intraventricular haemorrhage
LNND	- Late Neonatal Death
NAPEMMCO	- National Perinatal Morbidity and Mortality committee
NHCU	- Neonatal High Care Unit
NICU	- Neonatal Intensive Care Unit
NMR	- Neonatal Mortality Rate
NVD	- Normal Vaginal Delivery
PPIP	- Perinatal Problem Identification Program
ROP	- Retinopathy of Prematurity
UAH	- Universitas Academic Hospital
UFS	- University of the Free State
WHO	- World Health Organization

4. List of Appendices

A – Letter of approval from the HSREC
B – Permission from the FSDOH
C – Permission from the Head of Department (Paediatrics)
D – Data Capture Sheet
E – Avoidable factors according to the PPIP/CHPIP programs
F – Turnitin report
G - Author guidelines (South African journal of child health)
H – Original Approved protocol (attached separately as PDF)

5. Chapter 1

5.1 Introduction and Summary

This research paper investigated if there were any differences in neonatal mortality during normal working hours compared to after-hours. If there are differences in the number of mortalities that occur during normal working hours when compared to after-hours, then there is the possibility that there could be differences in administrative (and staffing) when comparing these different time intervals. Possible reasons therefore could then be addressed and prevented. With this study we could reflect on whether our quality of care remains the same when we are challenged with managing a unit with less healthcare workers after hours. It's more difficult to comment on the nursing allocation as it fluctuates and getting accurate numbers for every day over a 1 year period would be challenging and could possibly be done in future. The results can assist the Department of Health with decision making in terms of allocation of staff and resources, including the fair distribution after-hours.

Another consideration in the possible differences in mortalities and avoidable factors at different times of day, are the possible medico-legal risks involved. The National Department of Health spends millions of Rands annually on payments for medical negligence. Thus, it is important to know if there are any factors that lead to neonatal mortality that could be prevented.

Variations in deaths according to day of the week and time of the day isn't a new concept and has been reported with different objectives. Internationally, neonatology is one of many fields with different outcomes according to the day of the week or after hours, but there is no comparative study for South Africa. Other speciality fields also affected include neurosurgery and paediatric surgery. Some studies looked at outcomes according to the time a patient is admitted or the time a neonate is born. With the strains on financial resources that the Department of Health is currently facing, it is important that we review how we are allocating resources, including the distribution of human resources. It is important to know whether we distributing our human resources optimally, thus the researcher has decided to look at neonatal deaths after hours and comparing them with normal hours of the day.

The reason these hours have been chosen is because that is the time when the ratio of doctors- and nurses-to-patients change. During normal working hours there are 3 registrars, 2 interns and 2 consultants in the unit of Pelonomi Hospital on average. After-hours' staff include 1 registrar and 1 intern in the unit, as well as a consultant available telephonically. The average number of patients per day in the neonatal HCU at Pelonomi hospital is 37.4. That gives a doctor-to-patient ratio of 1:6 during normal working hours and a ratio of 1:18.7 after-hours (combined stats as obtained from the neonatal HCU).

In this study, the researcher investigated if there is a difference in mortality during different times of the day and week at the Neonatal HCU of Pelonomi Tertiary Hospital. This was done by a retrospective review of neonatal deaths over a one-year period. The following associated factors were also evaluated: 1) Day of the week that the death occurred, 2) Time of the day

that the death occurred, and 3) Associated avoidable factors. A retrospective data review of the Meditech system (the internal hospital record keeping system) and the PPIP/CHPIP data for these deaths were done.

5.2 Literature review

According to the World Health Organization (WHO) a neonatal death is defined as a death after a live birth that occurs during the first 28 completed days of life. This can be further subdivided into early neonatal deaths (deaths between 0 and 7 completed days of life) and late neonatal deaths (deaths after 7 days to 28 completed days of life). (1)

In South Africa, the Millennium Development Goal 4 of reducing childhood mortality by two thirds by 2015 have not been reached. There are more or less 130 million babies born worldwide annually. Of those, almost 4 million will die within the neonatal period. The highest risk period for neonatal deaths remains the first day of life. Most of these deaths will be early neonatal deaths, with the most common causes being due to prematurity (40%) and other complications of asphyxia (23%). These numbers were based on the previous (2011 – 2012) Saving Babies Report. In 2009 South Africa had a higher NMR than the baseline reported in 2009, with no reduction in rates between 2001 and 2008. (2,3)

According to the Millennium Development Goals Country Report, South Africa ended with an infant mortality rate of 23.6 (target was 18) and an NMR of 11 per 1000 live births in 2013. The new goals by the WHO in the Sustainable Developmental Goals (number 3) in 2015 has set the following targets: "*By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births*". (4)

The Saving Babies Report of 2014 – 2016, compiled by the National Perinatal Morbidity and Mortality committee (NAPEMMCO), indicated that the most common causes for neonatal deaths remains immaturity related (48.1%), followed by hypoxia (24.2%), and infection (11.2%). There were many administrative reasons stated as possible avoidable causes for these mortalities including inadequate number of nurses or doctors on duty, lack of transport, anaesthetic delays, as well as personnel being too junior to manage patients. (5)

If there are differences in the number of mortalities that occur during normal working hours when compared to after hours, then there is the possibility that there could be differences in administrative (and staffing) problems when comparing these different time intervals.

There have been various studies that investigated differences in mortality and outcomes at different times of the day and week. Some of these studies also looked at differences in mortality and other outcomes according to the timing of birth. (During vs after-hours). Most

of these studies found differences in mortalities and outcomes at different times of the day and days of the week.

One of the earlier studies was done in rural Arkansas from 1974-1975 by Mangold, W. D et al. Here they looked at the neonatal mortalities on different days of the week but at the same time they looked at the number of deliveries on the different days of the week. They found that most of the deliveries occurred from Tuesday through Friday with a peak on Tuesdays. The weekends had the lowest percentages of deliveries with the least on Sundays. Despite Sundays having the least deliveries, it had the highest neonatal deaths. This was attributed to 3 factors: 1. Less staff on Sundays (no specific numbers given) 2. More emergency obstetrics, and 3. More non-white patients delivering low birthweight neonates on Sundays. Even with these differences they were unable to conclude whether this was due to staffing issues or more obstetric emergencies on Sundays. (6)

In New South Wales, Australia, a retrospective study between 2000 and 2006 included private and public patients (total 501). Their main aim was predicting the cumulative risk of death during hospitalization by looking at the weekend, weekday and diurnal mortality risks. All age groups were included in this study. They found a clear increase in mortalities with weekend admissions and also worse outcomes after-hours. (7)

In another retrospective neonatal study by Erik A. Jensen et al between 2002 and 2009 in the USA, they looked at the association between off peak hour (12am to 6.59am) births and later neonatal morbidity (bronchopulmonary dysplasia, retinopathy of prematurity, grade 3 or 4 intraventricular haemorrhage) and mortality among very low birth weight infants. 47 617 neonates were born during this time, and of these 9317 (19.6%) were born during off-peak hours. The rest were born at peak hours (7am to 11.59pm). Off-peak hours were associated with a higher frequency of death, intraventricular haemorrhage (IVH) (39% higher), bronchopulmonary dysplasia (BPD) (16% higher) and retinopathy of prematurity (ROP) (8%). Once risk adjustment for different maternal, infant and hospital level factors were done, the only off-peak association was increased risk of severe (grade 3 or 4) IVH. More extensive studies have been suggested. (8)

In the Netherlands Ronald Gijsen et al did a 2012 retrospective study looking at the off-hour's perinatal outcome from 2003 to 2007. There was a total of 449 714 infants born at 28 completed weeks (or later) that were included in the study. The outcome measures were mortality, severe birth trauma, low Apgar score and admission to neonatal intensive care unit (NICU). Emergency deliveries in the evenings were associated with an increased risk of adverse perinatal outcome when compared with emergency deliveries during the day, but no change in outcomes were observed over weekends. Between 126 - 141 cases a year of adverse perinatal outcomes could be attributed to evening effects. 21 of these cases lead to intrauterine deaths and early neonatal deaths. The poorer outcomes at night were mainly attributed to the diminished number of staff in the evenings. This however could not explain why over weekends (day vs night) the outcomes were the same (even though the staffing was also limited). (9)

In Canada from between 1985 and 1998 Zhong-Cheng Luo et al did an extensive study that included over three million babies by looking at the risks involved in stillbirths and early neonatal deaths by day of the week of the deliveries that took place. They compared weekday data against the weekend data and they found a much higher risk of stillbirths on the weekend despite the higher number of babies that were born during the week compared with the weekend. Of note is that the differences in the two groups were not statistically significant once adjusted for gestational age. (10)

There was also a study done by Ibrahimou et al in 2012, they looked at twins born over weekends from 1989 to 2002. This was done by an obstetrics team. They compared weekday twins' deliveries with weekend twins' deliveries. They also looked at the maternal age to see if this played a role. The results they found were as follow: twin deliveries to mothers who were below the age of eighteen years had 35% higher risk of dying if they were born on the weekend but if the mothers were older the risk did not increase. (11)

There are also many studies in other speciality fields that looked at differences in mortalities and outcomes when comparing different times of the day and week. The findings were mostly similar to those of the neonatal studies.

A retrospective study looking at complications following tracheoesophageal repair was done by Peeters B. et al from 2005-2010. They looked at intraoperative complication's which might include desaturation and pneumothorax. They then also looked at post-operative complications especially leaks or strictures. They found that the patients who had procedures done after-hours had a significant higher risk of having anastomotic leaks. (12)

In a paediatric neurosurgery retrospective study done by Virendra Desai et al from 2011 to 2014 with 710 patients investigated the effect of performing surgery over weekends and after-hours. Their aim was to look at possible differences in their mortality and morbidity. They subsequently classified their patients into three different groups of weekday regular hours, weekday after-hours and weekends. They subsequently found in their results that patients who had procedures performed after hours during the week or on the weekend had higher risk or worse outcomes in terms of morbidity and mortality compared with emergency procedures done during the week. (13)

Chaim M. Bell et al reported on over 3.5 million casualty and emergency unit admissions in Canada. They mainly looked at adult patients but the results still remained in line with the other similar studies for other disciplines. They found that patients who presented with more serious conditions were more likely to die if they were admitted on a weekend. (14)

In a paediatric intensive care unit in the Netherlands, Peeters et al investigated patients admitted in two different ICU centers from 2003 to 2007. They did a prospective observational study to compare mortalities when patients were admitted after-hours compared to office hours admissions. The definition for after-hours used here was between 18:00 and 08:00 Saturdays, Sundays and public holidays. In this study they didn't note any difference in their standardized mortality rate. This despite a difference in the experience of staff that covers the unit during these different time slots. (15)

In Canada from between January 1996 and October 1997 Lee et al. did a retrospective study to look at the variation in mortalities among neonate's ≤32 weeks. They had a total number of 5192 patients who were admitted to their different neonatal intensive care units. They looked at different variables like gender, congenital anomalies, gestational age, and birth weight amongst other risk factors. Once they adjusted for risk factors they still found that the early neonatal mortality odds were 60% higher if the neonate was admitted at night compared with a neonate that was admitted during the day. (16)

Another New South Wales study investigated neonates. They reviewed a total of 8654 admissions between 1992 and 2002. Their main objective was to see if there was a difference in mortalities and morbidities after hours in their centers. Risk factors considered were low Apgar at 5 minutes, lack of maternal antenatal corticosteroids, male gender and small-for-gestational age. The results (once adjusted) for the different risk factors showed no difference between after-hour admissions and office-hour admissions. (17)

In a Nigerian study, an obstetric team led by Nwosu et al. did a retrospective study over a ten year period between 1998 and 2007. They had a total number of 3934 mortalities that were analysed over this time period and included all disciplines and all age groups. They also wanted to see if there was a difference between weekday and weekend hospital deaths. The results in the labour and intensive care units had a higher ratio of deaths on the weekends. In the other wards and disciplines there was no difference in mortalities when they compared weekdays and the weekend. (18)

With these studies quoted above there are varying results, a number of them show after-hours and weekend admissions being associated with poorer outcomes. Some of them show that association with poorer outcomes there are more mortalities on weekends and after hours. There were also a few studies which showed no difference when comparing after hours, office hours or normal working hours and the weekend. These were mainly retrospective studies. These studies were from various parts of the world including developing and developed countries, emphasizing that this identified problem exists despite differences in the quality and quantity of resources available.

Another important burden is the cost of litigation to the Department of Health. It's highest in obstetrics, neonatology and orthopaedics in South Africa. The money to finance litigation in South Africa comes out of the annual budget of the National Department of Health. This diverts resources from other health services. It is therefore important that we find ways to

decrease the cost of litigation. One of the ways to do this is to decrease the number of avoidable neonatal deaths, as this is one of the causes of high litigation. Between 2010 and 2014 the total amount paid out due to litigation was close to 500 million Rand for the whole country. There was still five billion Rand in pending claims in KZN alone. The amounts already paid out do not consider the ongoing cases of those years or when families come back five years down the line with lawyers claiming for malpractice or negligence. For 2016 alone, there was 40 million Rand allocated for the entire country as contingent liability (cases still to be paid out). This is not a problem that is isolated to the public sector. The private sector has seen a sharp rise in litigation and thus their MPS (medical protection society) insurance costs showed an increase of 14% per year between 2009 and 2015. These pay-outs increased by 132% from 2009 as compared to 2010. (19)

The ever-increasing pay-outs leads to a cycle where pay-outs are made using the National and Provincial Departments of Health's budgets. This leads to less financial resources to adequately manage other patients, with ever increasing cases of litigation. This cycle will continue unless we are proactive in preventing litigation. It is important that we identify all the underlying causes (especially avoidable reasons) for mortalities so that we can improve healthcare in South Africa as a whole, and use the limited resources available to us where they are most needed.

5.3 Research question

This research paper set out to investigate whether or not there is a difference in mortality for the neonatal population at Pelonomi Tertiary Hospital for normal working hours, compared to after-hours. The secondary question was to see if there are any differences in avoidable factors (as defined by the PPIP/CHPIP program data) for these mortalities.

5.4 Aims

By identifying possible differences in mortality and possible differences in avoidable factors, it can assist the relevant role players with decisions on distribution of resources (including human resources). The results of this study can also assist and guide future research in this field.

5.5 Objectives

In order to address the research questions, the following objectives were pursued:

- Do a literature review to identify current knowledge on this research question.
- To quantify and compare neonatal mortalities in the unit during a normal working day and after-hour shifts (data collection from Meditech and PPIP/CHPIP data).
- To determine the prevalence of avoidable factors of neonatal mortalities during a normal working day and after hour shifts (Data collection sheet – Appendix D).

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6. Chapter 2

6.1 Abstract

Background: Neonatal mortality remains one of the leading causes of under-5-mortality in South Africa. South Africa has not reached the Millennium Development Goals targets for 2015 as set out by the WHO. The leading causes for neonatal mortality remains immaturity related (48.1%), complications of hypoxia (24.2%) and infections (11.2%). According to the PPIP and CHPIP program data, many of these deaths do have avoidable factors that are administrative and staff related. If there is a difference found in mortalities when comparing normal working hours with after-hours, then it is possible that administrative and staffing differences for these hours could be a reason for differences seen. This could assist relevant stakeholders to optimize allocation of resources (including staffing) as well as guide further research to investigate possible reasons for differences in mortalities for different time intervals.

Objectives: This research set out to investigate whether or not there are differences in the number of neonatal mortalities at Pelonomi Tertiary Hospital, Bloemfontein, when comparing normal working hours with after-hours. If there are differences, then to determine if there are differences in the avoidable factors involved in these mortalities (according to the PPIP and CHPIP data).

Method: This was a descriptive, cross-sectional study. The total number of mortalities (January 2017 – December 2017) for normal working hours and after-hours were investigated, and avoidable factors (according to PPIP and CHPIP codes) for these mortalities were compared.

Results: A total number of 103 neonatal mortalities for this time period were included in this study. More deaths occurred after-hours (16:00 – 07:30 on weekday, whole weekends and whole public holidays) when compared to normal working hours (all other weekdays 07:30 – 16:00) (n=67, 65.05% *vs* n=36, 34.95%). When the time frames are divided into after-hours (any day 16:00 – 07:30) and normal working hours (any day 07:30 – 16:00), more deaths occurred after-hours (n=55, 53.4%). Most of *these* (any day) after-hour mortalities occurred between 16:00 and 00:00 (n=31, 56.4%). The most common causes of death for these neonates reflect the same causes as the national PPIP/CHPIP data, being 1. Infection related (n=26, 25.24%), 2. multi-organ immaturity (n=21, 20.39%) and 3.Complications of hypoxia (n=18, 17.48%). There were no major differences in administrative and staff-related avoidable factors when comparing these different time intervals

Conclusion: This study confirms that during this time period there were more neonatal deaths occurring after-hours when compared to normal working hours at Pelonomi Tertiary Hospital, Bloemfontein. Due to the design of this study we could not conclude whether or not these differences are statistically significant. To optimize allocation of limited resources and staffing, the researcher concludes that further research to determine the factors which may contribute to these differences in mortalities for different time intervals is warranted.

6.2 Introduction and Summary

This research paper investigated if there were any differences in neonatal mortality during normal working hours compared to after-hours. If there are differences in the number of mortalities that occur during normal working hours when compared to after-hours, then there is the possibility that there could be differences in administrative (and staffing) when comparing these different time intervals. Possible reasons therefore could then be addressed and prevented. With this study we could reflect on whether our quality of care remains the same when we are challenged with managing a unit with less doctors after hours. It's more difficult to comment on the nursing allocation as it fluctuates and getting accurate numbers for every day over a 1 year period would be challenging and could possibly be done in future. The results can assist the Department of Health with decision making in terms of allocation of staff and resources, including the fair distribution after-hours.

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The reason these hours have been chosen is because that is the time when the ratio of doctors- and nurses-to-patients change. During normal working hours there are 3 registrars, 2 interns and 2 consultants in the unit of Pelonomi Hospital on average. After-hours' staff include 1 registrar and 1 intern in the unit, as well as a consultant available telephonically. The average number of patients per day in the neonatal HCU at Pelonomi hospital is 37.4. That gives a doctor-to-patient ratio of 1:6 during normal working hours and a ratio of 1:18.7 after-hours (combined stats as obtained from the neonatal HCU).

In this study, the researcher investigated if there is a difference in mortality during different times of the day and week at the Neonatal HCU of Pelonomi Tertiary Hospital. This was done by a retrospective review of neonatal deaths over a one-year period. The following associated factors were also evaluated: 1) Day of the week that the death occurred, 2) Time of the day that the death occurred, and 3) Associated avoidable factors. A retrospective data review of

the Meditech system (the internal hospital record keeping system) and the PPIP/CHPIP data for these deaths were done.

6.3 Literature review

According to the World Health Organization (WHO) a neonatal death is defined as a death after a live birth that occurs during the first 28 completed days of life. This can be further subdivided into early neonatal deaths (deaths between 0 and 7 completed days of life) and late neonatal deaths (deaths after 7 days to 28 completed days of life). (1)

In South Africa, the Millennium Development Goal 4 of reducing childhood mortality by two thirds by 2015 have not been reached. There are more or less 130 million babies born worldwide annually. Of those, almost 4 million will die within the neonatal period. The highest risk period for neonatal deaths remains the first day of life. Most of these deaths will be early neonatal deaths, with the most common causes being due to prematurity (40%) and other complications of asphyxia (23%). These numbers were based on the previous (2011 – 2012) Saving Babies Report. In 2009 South Africa had a higher NMR than the baseline reported in 2009, with no reduction in rates between 2001 and 2008. (2,3)

According to the Millennium Development Goals Country Report, South Africa ended with an infant mortality rate of 23.6 (target was 18) and an NMR of 11 per 1000 live births in 2013. The new goals by the WHO in the Sustainable Developmental Goals (number 3) in 2015 has set the following targets: "*By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births*". (4)

The Saving Babies Report of 2014 – 2016, compiled by the National Perinatal Morbidity and Mortality committee (NAPEMMCO), indicated that the most common causes for neonatal deaths remains immaturity related (48.1%), followed by hypoxia (24.2%), and infection (11.2%). There were many administrative reasons stated as possible avoidable causes for these mortalities including inadequate number of nurses or doctors on duty, lack of transport, anaesthetic delays, as well as personnel being too junior to manage patients. (5)

If there are differences in the number of mortalities that occur during normal working hours when compared to after hours, then there is the possibility that there could be differences in administrative (and staffing) problems when comparing these different time intervals.

There have been various studies that investigated differences in mortality and outcomes at different times of the day and week. Some of these studies also looked at differences in mortality and other outcomes according to the timing of birth. (During vs after-hours). Most

of these studies found differences in mortalities and outcomes at different times of the day and days of the week.

One of the earlier studies was done in rural Arkansas from 1974-1975 by Mangold, W. D et al. Here they looked at the neonatal mortalities on different days of the week but at the same time they looked at the number of deliveries on the different days of the week. They found that most of the deliveries occurred from Tuesday through Friday with a peak on Tuesdays. The weekends had the lowest percentages of deliveries with the least on Sundays. Despite Sundays having the least deliveries, it had the highest neonatal deaths. This was attributed to 3 factors: 1. Less staff on Sundays (no specific numbers given) 2. More emergency obstetrics, and 3. More non-white patients delivering low birthweight neonates on Sundays. Even with these differences they were unable to conclude whether this was due to staffing issues or more obstetric emergencies on Sundays. (6)

In New South Wales, Australia, a retrospective study between 2000 and 2006 included private and public patients (total 501). Their main aim was predicting the cumulative risk of death during hospitalization by looking at the weekend, weekday and diurnal mortality risks. All age groups were included in this study. They found a clear increase in mortalities with weekend admissions and also worse outcomes after-hours. (7)

In another retrospective neonatal study by Erik A. Jensen et al between 2002 and 2009 in the USA, they looked at the association between off peak hour (12am to 6.59am) births and later neonatal morbidity (bronchopulmonary dysplasia, retinopathy of prematurity, grade 3 or 4 intraventricular haemorrhage) and mortality among very low birth weight infants. 47 617 neonates were born during this time, and of these 9317 (19.6%) were born during off-peak hours. The rest were born at peak hours (7am to 11.59pm). Off-peak hours were associated with a higher frequency of death, intraventricular haemorrhage (IVH) (39% higher), bronchopulmonary dysplasia (BPD) (16% higher) and retinopathy of prematurity (ROP) (8%). Once risk adjustment for different maternal, infant and hospital level factors were done, the only off-peak association was increased risk of severe (grade 3 or 4) IVH. More extensive studies have been suggested. (8)

In the Netherlands Ronald Gijsen et al did a 2012 retrospective study looking at the off-hour's perinatal outcome from 2003 to 2007. There was a total of 449 714 infants born at 28 completed weeks (or later) that were included in the study. The outcome measures were mortality, severe birth trauma, low Apgar score and admission to neonatal intensive care unit (NICU). Emergency deliveries in the evenings were associated with an increased risk of adverse perinatal outcome when compared with emergency deliveries during the day, but no change in outcomes were observed over weekends. Between 126 - 141 cases a year of adverse perinatal outcomes could be attributed to evening effects. 21 of these cases lead to intrauterine deaths and early neonatal deaths. The poorer outcomes at night were mainly attributed to the diminished number of staff in the evenings. This however could not explain why over weekends (day vs night) the outcomes were the same (even though the staffing was also limited). (9)

In Canada from between 1985 and 1998 Zhong-Cheng Luo et al did an extensive study that included over three million babies by looking at the risks involved in stillbirths and early neonatal deaths by day of the week of the deliveries that took place. They compared weekday data against the weekend data and they found a much higher risk of stillbirths on the weekend despite the higher number of babies that were born during the week compared with the weekend. Of note is that the differences in the two groups were not statistically significant once adjusted for gestational age. (10)

There was also a study done by Ibrahimou et al in 2012, they looked at twins born over weekends from 1989 to 2002. This was done by an obstetrics team. They compared weekday twins' deliveries with weekend twins' deliveries. They also looked at the maternal age to see if this played a role. The results they found were as follow: twin deliveries to mothers who were below the age of eighteen years had 35% higher risk of dying if they were born on the weekend but if the mothers were older the risk did not increase. (11)

There are also many studies in other speciality fields that looked at differences in mortalities and outcomes when comparing different times of the day and week. The findings were mostly similar to those of the neonatal studies.

A retrospective study looking at complications following tracheoesophageal repair was done by Peeters B. et al from 2005-2010. They looked at intraoperative complication's which might include desaturation and pneumothorax. They then also looked at post-operative complications especially leaks or strictures. They found that the patients who had procedures done after-hours had a significant higher risk of having anastomotic leaks. (12)

In a paediatric neurosurgery retrospective study done by Virendra Desai et al from 2011 to 2014 with 710 patients investigated the effect of performing surgery over weekends and after-hours. Their aim was to look at possible differences in their mortality and morbidity. They subsequently classified their patients into three different groups of weekday regular hours, weekday after-hours and weekends. They subsequently found in their results that patients who had procedures performed after hours during the week or on the weekend had higher risk or worse outcomes in terms of morbidity and mortality compared with emergency procedures done during the week. (13)

Chaim M. Bell et al reported on at over 3.5 million casualty and emergency unit admissions in Canada. They mainly looked at adult patients but the results still remained in line with the other similar studies for other disciplines. They found that patients who presented with more serious conditions were more likely to die if they were admitted on a weekend. (14)

In a paediatric intensive care unit in the Netherlands, Peeters et al investigated patients admitted in two different ICU centers from 2003 to 2007. They did a prospective observational

study to compare mortalities when patients were admitted after-hours compared to office hours admissions. The definition for after-hours used here was between 18:00 and 08:00 Saturdays, Sundays and public holidays. In this study they didn't note any difference in their standardized mortality rate. This despite a difference in the experience of staff that covers the unit during these different time slots. (15)

In Canada from between January 1996 and October 1997 Lee et al. did a retrospective study to look at the variation in mortalities among neonate's ≤32 weeks. They had a total number of 5192 patients who were admitted to their different neonatal intensive care units. They looked at different variables like gender, congenital anomalies, gestational age, and birth weight amongst other risk factors. Once they adjusted for risk factors they still found that the early neonatal mortality odds were 60% higher if the neonate was admitted at night compared with a neonate that was admitted during the day. (16)

Another New South Wales study investigated neonates. They reviewed a total of 8654 admissions between 1992 and 2002. Their main objective was to see if there was a difference in mortalities and morbidities after hours in their centers. Risk factors considered were low Apgar at 5 minutes, lack of maternal antenatal corticosteroids, male gender and small-for-gestational age. The results (once adjusted) for the different risk factors showed no difference between after-hour admissions and office-hour admissions. (17)

In a Nigerian study, an obstetric team led by Nwosu et al. did a retrospective study over a ten year period between 1998 and 2007. They had a total number of 3934 mortalities that were analysed over this time period and included all disciplines and all age groups. They also wanted to see if there was a difference between weekday and weekend hospital deaths. The results in the labour and intensive care units had a higher ratio of deaths on the weekends. In the other wards and disciplines there was no difference in mortalities when they compared weekdays and the weekend. (18)

With these studies quoted above there are varying results, a number of them show after-hours and weekend admissions being associated with poorer outcomes. Some of them show that association with poorer outcomes there are more mortalities on weekends and after hours. There were also a few studies which showed no difference when comparing after hours, office hours or normal working hours and the weekend. These were mainly retrospective studies. These studies were from various parts of the world including developing and developed countries, emphasizing that this identified problem exists despite differences in the quality and quantity of resources available.

Another important burden is the cost of litigation to the Department of Health. It's highest in obstetrics, neonatology and orthopaedics in South Africa. The money to finance litigation in South Africa comes out of the annual budget of the National Department of Health. This diverts resources from other health services. It is therefore important that we find ways to decrease the cost of litigation. One of the ways to do this is to decrease the number of avoidable neonatal deaths, as this is one of the causes of high litigation. Between 2010 and

2014 the total amount paid out due to litigation was close to 500 million Rand for the whole country. There was still five billion Rand in pending claims in KZN alone. The amounts already paid out do not consider the ongoing cases of those years or when families come back five years down the line with lawyers claiming for malpractice or negligence. For 2016 alone, there was 40 million Rand allocated for the entire country as contingent liability (cases still to be paid out). This is not a problem that is isolated to the public sector. The private sector has seen a sharp rise in litigation and thus their MPS (medical protection society) insurance costs showed an increase of 14% per year between 2009 and 2015. These pay-outs increased by 132% from 2009 as compared to 2010. (19)
The ever-increasing pay-outs leads to a cycle where pay-outs are made using the National and Provincial Departments of Health's budgets. This leads to less financial resources to adequately manage other patients, with ever increasing cases of litigation. This cycle will continue unless we are proactive in preventing litigation. It is important that we identify all the underlying causes (especially avoidable reasons) for mortalities so that we can improve healthcare in South Africa as a whole, and use the limited resources available to us where they are most needed.

6.4 Research methods

6.4.1 Research question

This research paper set out to investigate whether or not there is a difference in mortality for the neonatal population at Pelonomi Tertiary Hospital for normal working hours, compared to after-hours. The secondary question was to see if there are any differences in avoidable factors (as defined by the PPIP/CHPIP program data) for these mortalities.

6.4.2 Aims

By identifying possible differences in mortality and possible differences in avoidable factors, it can assist the relevant role players with decisions on distribution of resources (including human resources). The results of this study can also assist and guide future research in this field.

6.4.3 Objectives

In order to address the research questions, the following objectives were pursued:

- Do a literature review to identify current knowledge on this research question.
- To quantify and compare neonatal mortalities in the unit during a normal working day and after-hour shifts (data collection from Meditech and PPIP/CHPIP data).

- To determine the prevalence of avoidable factors of neonatal mortalities during a normal working day and after hour shifts (Data collection sheet – Appendix D).

6.4.4 Study Site

The Neonatal high care unit at Pelonomi Tertiary Hospital is situated in Bloemfontein in the Free State Province. This is a 34-bed unit (that often needs to accommodate up to more than 50 patients) which functions as a high care unit and a neonatal intensive care unit, including mechanical ventilation of neonates. The unit has two consultants, three or four registrars and two interns working in the unit during normal working hours (07:30 to 16:00). One registrar and one intern are on site after-hours (16:00-07:30) with a consultant available telephonically who will come to the unit if required.

6.4.5 Study Design

This was a descriptive, cross-sectional study. The total number of mortalities for normal working hours and after-hours (as defined below) were investigated, as well as a comparison of the avoidable factors (according to PPIP codes) for these mortalities.

6.4.6 Study Participants and Sample Size

Inclusion criteria: All neonates who demised in the Pelonomi Tertiary Hospital Neonatal High Care Unit in Bloemfontein for the period of January 2017 to December 2017 were included in the study. Infants who demised after the 28th day of life, but were still admitted to the neonatal unit at that time, were also included.
Exclusion criteria: Patients with incomplete information or data in their records to complete the data sheet were not included in this study.

6.4.7 Pilot Study

Once approval for this research was granted, a pilot study was conducted. Five cases meeting the inclusion criteria for this study were assessed by completing the data capture sheet (Appendix D). The data sheet and information required was deemed sufficient by the Department of Biostatistics to continue with the research.

6.4.8 Collection and Analysis of Data

Information for all neonatal deaths are captured by the registrars and consultants by means of PPIP/CHPIP data forms and Meditech summaries. All neonatal deaths for the study period were identified by the investigator. All information required was captured on a data form (see appendix D) by the investigator. This information was used to answer the research questions and address the objectives of this study.
Collected data was analysed by a biostatistician at the Department of Biostatistics, University of the Free State. Scaled data was measured as continuous variables, whereas ordinal or

nominal data was analysed as categorical data. Continuous data was summarized as a mean, median, standard deviation or ranges as appropriate. Categorical data was presented as percentages or frequencies.

6.4.9 Ethical considerations

A research protocol was submitted for approval to the Health Science Research Ethics Committee of the Faculty of Health Sciences at the University of the Free State prior to commencing the research. Upon approval from the committee an application for approval was submitted to the Free State Department of Health, which was granted. Informed consent was not applicable in this study. Data collected for included had no identifiable information thus confidentiality was ensured. Consent to perform research in the Department of Paediatrics was obtained in writing from the Head of Paediatrics at the University of the Free State.

6.5 Results

A total of 104 mortality cases were identified for the period of this study, with one patient excluded due to lack of data(a time of death was missing for this patient) (n=103).
Demographical data distribution according to gestation at birth (Table 1) shows that most mortalities occurred for patients between 28 – 33 weeks gestation (n=48, 46.60%). According to the birthweight distribution (Table 2), most mortalities occurred for patients of extreme low birthweight (<1000g) (n=40, 38.83%). More males (n=58, 56.31%) demised during this time period.

Table 1: Gestation at birth

Gestation at birth	Frequency (n)	Percentage (%)
<28 weeks	26	25.24
28-33 weeks	48	46.60
34-37 weeks	8	7.77
≥38 weeks	21	20.39
Total	103	100

Table 2: Birthweight

Birthweight	Frequency (n)	Percentage (%)
<1000g	40	38.83
1000g – 1499g	28	27.18
1500g – 2499g	13	12.62
≥2500g	22	21.36
Total	103	100

Table 3: Gender

Gender	Frequency (n)	Percentage %
Female	45	43.69
Male	58	56.31
Total	103	100

The distribution of mortalities according to time of death were divided into normal working hours (07:30 to 16:00 during week days) and after-hours (16:00 – 07:30 week days, whole weekend and whole public holidays) (Table 4). Most of the deaths occurred after hours (n=67, 65.05%).

Table 4: Time of death

Time of death	Frequency (n)	Percentage (%)
After-hours	67	65.05
Normal working hours	36	34.95
Total	103	100

When after-hours included weekends and public holidays (16:00 – 07:30, any day) and compared to normal working hours for any day (07:30 – 16:00, any day) (Table 5), the amount of mortalities were almost equally distributed (n=55, 53.4%). The timing of *these* after-hour deaths were further sub-divided into different time brackets (Table 5), with most (of the after-hour deaths) occurring between 16:00 and 00:00.

Table: 5 Breakdown of time death (any day)

Time of death	Frequency (n)	Percentage (%)
07:30 – 16:00	48	46.60
16:00 – 00:00	31	30.10
00:00 – 07:30	24	23.30
Total	103	100

The distribution according to the cause of death are noted in Table 6. Only one cause of death was documented and captured per patient, as per PPIP/CHPIP guidelines (final cause of death). The most common causes were infection related (n=26, 25.24%), extreme immaturity (n=21, 20.39%) and hypoxic ischemic encephalopathy (n=18, 17.48%). – correlating with most common causes of neonatal mortalities for national PPIP/CHPIP data.

Table: 6 Final cause of death

Final cause of death	Frequency	Percentage
Infection related	26	25.24
Multi- organ immaturity	21	20.39
Hypoxic ischemic encephalopathy	18	17.48
Pulmonary haemorrhage	10	9.71
IVH	9	8.74
Respiratory distress syndrome	8	7.77
Chromosomal abnormality	4	3.88
Congenital cardiovascular abnormality	2	1.94
Congenital respiratory abnormality	1	0.97
Congenital Central nervous system abnormality	1	0.97
Kernicterus	1	0.97
Neonatal encephalopathy	1	0.97
Sub aponeurotic bleed	1	0.97
Total	103	100%

Most of the deaths had identifiable avoidable factors (n=93, 90.29%) (Table 7). These avoidable factors were specified (and further subdivided) in Table 8 according to the PPIP/CHPIP codes. The most frequent occurring avoidable factor was due to patient related factors (n=83, 89.25%). These factors include: not initiating antenatal care, booking late in pregnancy, inappropriate and late responses to medical problems and other maternal behaviours (See Appendix E how all these categories are subdivided according to PPIP/CHPIP guidelines). It is to be noted that every mortality could have more than one avoidable factor identified, and that an identified avoidable factor does not accurately relate to whether or not a death could have been avoided.

Table: 7 Avoidable factors identified for the deaths

Avoidable factors	Frequency (n)	Percentage (%)
Yes	93	90.29
No	10	9.71
Total	103	100

Table: 8 Avoidable factors according to PPIP/CHPIP category.

Avoidable factor	Frequency (n)	Percentage (%) *
Patient related	83	89.25
Admin related	11	11.83
Healthcare - antenatal	15	16.13
Healthcare - labour related	13	13.98
Healthcare - post-delivery related	32	34.41

*Total percentage does not add up to 100 as more than one avoidable factor was present in some patients. The percentage (%) is calculated using the total number of patients with avoidable factors identified.

In Table 9 the avoidable factors were correlated for the time of death. These hours were divided into normal working hours (07:30 – 16:00 weekdays) and after-hours (16:00 – 07:30 weekdays, whole weekends and whole public holidays). The number of avoidable factors identified were almost equally distributed for after-hours (n=60/67, 89.55% of total after hour deaths) and normal working hours (n=33/36, 91.67% of total normal working hour deaths). The same correlations were seen if these avoidable factors were further subdivided into the different categories as previously stated in table 8, with no major differences in any of these categories whether the death occurred after hours or not (Tables 10 – 14).

Table 9: Time of death correlated with avoidable factors

	Avoidable	Avoidable	
Time of death	Yes	No	Total **P VALUE
After-hours (n) (%)	60 89.55	7 10.45	67 100
Normal working hours (n) (%)	33 91.67	3 8.33	36 100
Total	93	10	103

Table 10: Time of death correlated with patient related factors

	Patient related	Patient related	
Time of death	No	Yes	Total
After hours (n) (%)	8 13.33	52 86.67	60 100
Normal working hours (n) (%)	 2 6.06	 31 93.94	 33 100
Total (n)	10	83	93

Table 11: After hours death correlated with admin related factors

	Admin related	Admin related	
Time of death	No	Yes	Total
After hours (n) (%)	53 88.33	7 11.67	60 100
Normal working hours (n) (%)	 29 87.88	 4 12.12	 33 100
Total (n)	82	11	93

Table 12: After hours death correlated with healthcare antenatal

	Antenatal related factors	Antenatal related factors	
Time of death	No	Yes	Total
After hours (n) (%)	50 83.3	10 16.67	60 100
Normal working hours (n) (y)	 28 84.85	 5 15.15	 33 100
Total (n)	78	15	93

Table 13: After hours deaths correlated with healthcare workers in labour

	Healthcare worker while in labour	Healthcare worker while in labour	
Time of death	No	Yes	Total **p value
After hours (n) (%)	51 85.00	9 15	60 100
Normal working hours (n) (%)	 29 87.88	 4 12.12	 33 100
Total (n)	80	13	93

Table 14: After hours deaths correlated with healthcare worker post-delivery

	Healthcare worker post-delivery	Healthcare worker post-delivery	Total ***p value
Time of death	No	Yes	
After hours (n) (%)	39 65	21 35	60 100
Normal working hours (n) (%)	 22 66.67	 11 33.33	 33 100
Total (n)	61	32	93

6.6 Discussion

This study confirms that there are more neonatal mortalities occurring after-hours compared to normal working hours for the time period of this study in the Neonatal High Care Unit, Pelonomi Tertiary Hospital. Due to the design of this study, it could not be concluded whether or not these numbers are statistically significant. The findings of this research are similar when compared to other neonatal units internationally. When these after hours are subdivided further (Table 5), there is the finding of peak mortalities during early evening hours (16:00 – 00:00), and lowest in the morning (00:00 – 07:30). This is similar to the study done by Coiera et al (7). To confidently conclude why this phenomenon occurs is difficult to establish by means of observational data, as there are many confounders related to this concern.

There are many reasons that can be speculated for the results of this research project. Firstly, this might be explained by the available healthcare services during these times. The quantity of resources and staffing provided might not necessarily equally distributed for a full 24 hours. The quantity, or total amount of staff, that is allocated for these different hours is different in all our units. This includes nursing staff, doctors and other support staff and departments (for example radiology and cleaning services). It's also important to note that emergency medical services might have less number of staff after-hours. The fact that there were less mortalities for after-hours when a whole weekend and public holiday is subdivided into normal working hours (07:30 – 16:30 any day) and after-hours (16:00 – 07:30 any day) could be due to the following reason: there is still more staff in the unit, during the day for any of these days. The limitation for this speculation is that due to the design of this study, these factors were not accounted for as variables, and cannot confidently be related to attributable factors for these findings. The factors that need to be considered but were not the primary objective of the research were that there might have been times where overcrowding in the unit , as previously mentioned it's a 34 bed unit and there are times where this capacity is exceeded, this will change the staff to patient ratio.

Secondly, the quality of services provided might not be the same as provided during normal working hours. Doctors and nurses have to perform physical tasks during a time of expected diurnal rest periods and these tasks might be done less efficiently than during normal working hours, especially during periods when doctors are awake for more than 24hours. This could then lead to increased risk of errors and avoidable factors. The limitation of proving these findings are the same as stated above, and at this stage only to be speculated on.

Thirdly, another possible reason might be due to the confounder of the indication for delivery or admission. Many deliveries occurring after hours is performed due to deteriorating maternal condition. This automatically puts the neonate at risk for certain complications, including prematurity and birth asphyxia with their subsequent and related complications and increased risk of morbidity and mortality. There are many studies for neonatal units looking at mortality (occurring any time) when compared to time of delivery for this specific reason. Our study did not specify time of delivery, as many mortalities occur many hours - if not days - after delivery, increasing the number of confounders.

When analyzing the demographics of the study population of this study, it is to be noted that there was a discrepancy in the mortalities occurring in the groups of <1000g when compared to the comparable gestational age (<28 weeks). This might be due to a large number of these infants suffering from intrauterine growth restriction, or reflect the possibility that gestational age measurements are inaccurate. Most of the deaths occurred in the ELBW group that is a similar finding to the Saving Babies report. Unfortunately, there is still a large number of mortalities for patients >2500g, and is mostly asphyxia/HIE related. The causes of deaths are similar to the national PPIP findings reported in the Saving Babies Report, with most mortalities occurring due to immaturity, infections and asphyxia related complications. The distribution of the mortalities according to weight then is as expected when compared to the cause of death. If one does expect a difference in the cause of death when correlated to the time of death, it is to be remembered that the causes captured on the PPIP/CHPIP forms are always documented as the underlying or primary cause (that is the disease process). This then does not account for events and situations leading up to the immediate time surrounding death. Thus, events like inadequate resuscitations, medication errors, lack of standard medical care etc. are not specified and accounted for, as that could have been an explanation for time differences.

When looking at these specific avoidable factors and the correlation of the avoidable factors to the time of death, it does not reveal any major differences. Whether or not there were avoidable factors present, or when these factors were specified for time of death, did not reveal any differences. When one does consider that a possible explanation for differences in time of death could be quantity of staff available, it is to be noted that this specific variable is rarely, if ever, captured as an avoidable factor on the PPIP forms (see Appendix E – specified as insufficient nurses or doctors on duty). Other staff and administrative variables are rarely accurately or completely captured due to inadequate note keeping. The possibility also exists that when staff members do feel that lack, or quality, of care from their side contributed to a patient's death, this will not be documented as such. The fact that most avoidable factors are patient related is a similar finding to the Saving Babies report. All mortalities can have more than one avoidable factor, and having an avoidable factor identified does not mean that that death was avoidable in itself, or the actual cause of the death. For these reasons, and inherently due to the design of this study, these confounders and variables could not be confidently linked to the time differences in mortality.

6.7 Conclusion

Neonatal mortalities are one of the critical indicators of the quality of health care systems. If there are differences in mortalities during different times of day, then quality of healthcare provided during these times should be reassessed. This study confirms that there are differences in mortalities when comparing time differences for the period of his study. This is vital as it's then important to investigate and do further research as to where and why these problems do occur. In addressing these problems, the government could make substantial savings in terms of appropriate and effective allocation of resources and funds. The costs involved in the appointment of the adequate number of staffing, whether doctors or nurses, as well as their training to improve quality of care, can be significantly less than the costs involved in medico-legal cases and litigation. To give evidence-based advice and suggestions to the management of hospitals, it's important to thus design research and investigations that would specifically answer the questions and limitations as set out in the discussion of this research paper. This would also include more vigilant capturing of avoidable factors (in terms of admin and staff related factors) on the PPIP/CHPIP forms. This is the first study of its kind at Pelonomi hospital with findings that are similar to other units across the world facing similar challenges in terms of staffing and resource allocation. Our findings might then already be enough to hold the appropriate structures and management accountable to address these issues faced in our neonatal units. The researcher concludes that to optimize allocation of limited resources and staffing, and to prevent unnecessary costs incurred with medico-legal cases, further research to determine the factors which may contribute to these differences in mortalities for different time intervals is warranted.

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7. Appendices

A – Letter of approval from HSREC

Health Sciences Research Ethics

01-Mar-2019

Dear **Dr Sithembiso Duba**

Ethics Clearance: **Neonatal mortality: after hours compared with normal working hours at Pelonomi Hospital over a 1-year period (January to December 2017).**

Principal Investigator: **Dr Sithembiso Duba**

Department: **Paediatrics and Child Health Department (Bloemfontein Campus)**

APPLICATION APPROVED

Please ensure that you read the whole document

With reference to your application for ethical clearance with the Faculty of Health Sciences, I am pleased to inform you on behalf of the Health Sciences Research Ethics Committee that you have been granted ethical clearance for your project.

Your ethical clearance number, to be used in all correspondence is:**UFSHSD2018/0794/2603**

The ethical clearance number is valid for research conducted for one year from issuance. Should you require more time to complete this research, please apply for an extension. We request that any changes that may take place during the course of your research project be submitted to the HSREC for approval to ensure we are kept up to date with your progress and any ethical implications that may arise. This includes any serious adverse events and/or termination of the study.

A progress report should be submitted within one year of approval, and annually for long term studies. A final report should be submitted at the completion of the study. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National

Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP (2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical

Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

For any questions or concerns, please feel free to contact HSREC Administration: 0514017794/5 or email EthicsFHS@ufs.ac.za.

Thank you for submitting this proposal for ethical clearance and we wish you every success with your research.

Yours Sincerelv

Dr. SM Le Grange

Chair : Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | E: ethicsfhs@ufs.ac.za
IRB 00006240; REC 230408-011; IORG0005187; FWA00012784
Block D, Dean's Division, Room D104 | P.O. Box/Posbus 339 (Internal Post Box G40) | Bloemfontein 9300 | South Africa
www.ufs.ac.za

B- Permission from FSDOH

health
Department of Health
FREE STATE PROVINCE

29 January 2019

Dr. S Duba
Dept. of Peadiatrics and Child Health
Faculty of Health Sciences
UFS

Dear Dr. S Duba

Subject: Mortalities in the neonatal unit: after hours compared with normal working hours at Pelonomi Hospital over a 1-year period (January 2017 to December 2017)

- Please ensure that you read the whole document, Permission is hereby granted for the above – mentioned research on the following conditions:
- Serious Adverse events to be reported to the Free State department of health and/ or termination of the study
- Ascertain that your data collection exercise neither interferes with the day to day running of the Pelonomi Hospital nor the performance of duties by the respondents or health care workers.
- Confidentiality of information will be ensured and please do not obtain information regarding the identity of the participants.
- **Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).**
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of Free State and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the University of Free State and to Free State Department of Health.
- **Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to** sebeelats@fshealth.gov.za **before you commence with the study**
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution manager/CEOs on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are encouraged to present your study findings/results at the Free State Provincial health research day
- Future research will only be granted permission if correct procedures are followed see http://nhrd.hst.org.za

Trust you find the above in order.

Kind Regards

Dr D Motau
HEAD: HEALTH
Date: 29/01/19

Head : Health
PO Box 227, Bloemfotein, 9300
4th Floor, Executive Suite, Bophelo House, cnr Maitland and, Harvey Road, Bloemfotein
Tel: (051) 408 1646 Fax: (051) 408 1556 e-mail:khusemj@fshealth.gov.za@fshealth.gov.za/chikobvup@fsh...lth.gov.za
www.fs.gov.za

C – Permission head of department Peadiatrics

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[redacted]

17 May 2018

Prof N Mofolo

Head: School of Medicine

University of the Free State

Cc

Me M du Randt

Dr E le Grange

Dear Prof Mofolo

RE: ACCEPTANCE RESEARCH PROJECT DR S DUBA

TITLE: NEONATAL MORTALITY: AFTER HOURS COMPARED WITH NORMAL WORKING HOURS AT PELONOMI HOSPITAL OVER A 1-YEAR PERIOD

I hereby confirm that I approve the study design, sampling, methods and objectives of the study.

He is committed to complete this research project for the completion of his MMed degree.
Sincerely,

PROF SC Brown
ACTING HEAD: DEPARTMENT OF PAEDIATRICS AND CHILD HEALTH
FACULTY OF HEALTH SCIENCES
UNIVERSITY OF THE FREE STATE

Department of Paediatrics and Child Health / Departement Pediatrie en Kindergesondheid
205 Nelson Mandela Drive/Rylaan, Park West/Parkwes, Bloemfontein 9301, South Africa/Suid-Afrika
P.O. Box/Posbus 339 (G69), Bloemfontein 9300, South Africa/Suid-Afrika, www.ufs.ac.za, F: +27(0)51 444 3230
Prof A Venter: T: +27 (0)51 405 3181, E: Gnpdav@ufs.ac.za / Prof DK Stones: T: +27 (0)51 405 2820, E: StonesDK@ufs.ac.za
Prof SC Brown: T: +27 (0)51 405 3254, E: Gnpdscb@ufs.ac.za / Dr A van der Vyver: T: +27 (0)51 405 3184, E: Gnpdavdv@ufs.ac.za

D – Data Capture Sheet

Mortality data form:

	INFORMATION NEEDED	INFORMATION COLLECTED
Study number		
Gestation	1. <28 weeks=1 2. 28–33 weeks and 6 days =2 3.34-37 weeks and 6 days =3 4. 38 weeks =4	
Birthweight	<1000g=1 1000-1499g=2 1500-2499g=3 2500 and ≥4	
Date of Birth	DD/MM/YY	
Time of Birth	24 hr. clock	
After-hours or weekend?	Yes=0;No=1	
Public holiday?	Yes=0;No=1	
Gender	female (1) Male (2)	
Date of Death	DD/MM/YY	
Time of Death	24 hour clock	
After-hours or weekend?	Yes=0;No=1	
Public holiday?	Yes=0;No=1	
Age at Death	In days	
Final cause of Neonatal Death as captured on PPIP or CHPIP	Specify as coded in PPIP or CHPIP	
Was this death avoidable?	Yes=0;No=1	
Avoidable factors	Specify as coded in PPIP or CHPIP	
	Patient related	
	Administration related	
	Healthcare worker - In antenatal care - In labour - Post delivery	

E – Avoidable factors according to PPIP/CHPIP programs

Codes & description: Avoidable and modifiable factors according to the PPIP and CHPIP program

Code Description

0100 PATIENT ASSOCIATED
0101 Never initiated antenatal care
0102 Booked late in pregnancy
0103 Infrequent visits to antenatal clinic
0104 Inappropriate response to rupture of membranes
0105 Inappropriate response to antepartum haemorrhage
0106 Inappropriate response to poor fetal movements
0107 Delay in seeking medical attention during labour
0108 Attempted termination of pregnancy
0109 Failed to return on prescribed date
0110 Declines admission/treatment for personal/social reasons
0111 Partner/Family declines admission/treatment
0112 Assault
0113 Alcohol abuse
0114 Smoking
0115 Delay in seeking help when baby ill
0116 Infanticide
0117 Abandoned baby
0199 Other

0200 ADMINISTRATIVE PROBLEMS
0201 Lack of transport - Home to institution
0202 Lack of transport - Institution to institution
0203 No syphilis screening performed at hospital / clinic
0204 Result of syphilis screening not returned to hospital/clinic
0205 Inadequate facilities/equipment in neonatal unit/nursery
0206 Inadequate theatre facilities
0207 Inadequate resuscitation equipment
0208 Insufficient blood / blood products available
0209 Personnel not sufficiently trained to manage the patient
0210 Personnel too junior to manage the patient
0211 No dedicated high risk ANC at referral hospital
0212 Insufficient nurses on duty to manage the patient adequately
0213 Insufficient doctors available to manage the patient
0214 Anaesthetic delay
0215 No Motherhood card issued
0216 No on-site syphilis testing available

0217 No accessible neonatal ICU bed with ventilator
0218 Staff rotation too rapid
0219 Lack of adequate neonatal transport
0299 Other

0300 MEDICAL PERSONNEL ASSOCIATED
0301 Medical personnel overestimated fetal size
0302 Medical personnel underestimated fetal size 0303
No response to history of stillbirths, abruptio etc.
0304 No response to maternal glycosuria
0305 No response to poor uterine fundal growth
0306 No response to maternal hypertension
0307 No antenatal response to abnormal fetal lie
0308 No response to positive syphilis serology test
0309 Poor progress in labour, but partogram not used
0310 Poor progress in labour, but partogram not used correctly
0311 Poor progress in labour - partogram interpreted incorrectly
0312 Fetal distress not detected intrapartum; fetus monitored
0313 Fetal distress not detected intrapartum; fetus not monitored
0314 Management of 2nd stage: prolonged with no intervention
0315 Management of 2nd stage: inappropriate use of forceps
0316 Management of 2nd stage: inappropriate use of vacuum
0317 Delay in medical personnel calling for expert assistance
0318 Delay in referring patient for secondary/tertiary treatment
0319 No response to apparent postterm pregnancy
0320 Neonatal care: inadequate monitoring
0321 Neonatal resuscitation inadequate
0322 Neonatal care: management plan inadequate
0323 Baby sent home inappropriately
0324 No response to history of poor fetal movement
0325 Breech presentation not diagnosed until late in labour
0326 Multiple pregnancy not diagnosed intrapartum
0327 Physical examination of patient at clinic incomplete
0328 Doctor did not respond to call
0329 Delay in doctor responding to call
0330 Iatrogenic delivery for no real reason
0331 Nosocomial infection
0332 Multiple pregnancy not diagnosed antenatally
0333 GP did not give card/letter about antenatal care
0334 Fetal distress not detected antenatally; fetus monitored
0335 Fetal distress not detected antepartum; fetus not monitored
0336 Baby managed incorrectly at Hospital/Clinic
0337 Inadequate / No advice given to mother
0338 Antenatal steroids not given
0339 Incorrect management of antepartum haemorrhage
0340 Incorrect management of premature labour
0341 Incorrect management of cord prolapse
0399 Other

0400 INSUFFICIENT NOTES TO COMMENT ON AVOIDABLE FACTORS
0401 Insufficient notes
0402 File missing
0403 Antenatal card lost

Family / Caregiver		
Timing	F101	Infrequent clinic attendance
	F102	Delay in seeking care
Recognition	F103	Caregiver did not realise severity of illness
	F104	Caregiver refusing treatment
	F105	Home treatment with negative effect on the child, e.g. enema
Immunisations	F106	Never immunised / behind with immunisations
Nutrition	F107	Inappropriate nutrition
RTHC	F108	Not present / referral letter lost
Consents / Returns	F109	Declining HIV test
	F110	Did not arrive on day of referral / did not keep appointment
Other	F189	Other modifiable factor concerning caregiver / family (specify)
Insufficient Information	F190	Insufficient information / notes on caregiver / family care

Clinic / Ambulatory Care: Clinical Personnel		
Case Assessment	P301	Insufficient assessment for acute respiratory infection / LRTI
	P302	IMCI not used for patient assessment
	P304	Insufficient assessment for failure to thrive
	P309	Other insufficient assessment (specify)
Monitoring	P311	No weight / other inappropriate use of RTHC
	P312	O_2 saturation (at Community Health Centre)
	P319	Other insufficient monitoring (specify)
Case Management	P321	No appropriate stat antibiotics / antibiotics for acute infection
	P322	No TB contact treatment
	P323	Insufficient fluid management for gastro-enteritis with dehydration
	P324	Insufficient investigations done
	P325	IMCI not used for case management
Delay in Referring - Acute	P331	Delay in referring acute respiratory infection
	P332	Delay in referring gastro-enteritis with dehydration
	P333	Delay in referring other acute problem (specify)
Delay in Referring - Chronic	P341	Delay in referring failure to thrive
	P342	Delay in referring chronic cough
	P343	Delay in referring chronic diarrhoea
Other	P379	Other modifiable factor - clinical personnel at clinic level (specify)
Inappropriate Care by GP	P380	Inappropriate care / late referral from Private Sector
Insufficient Information	P390	Insufficient notes
Clinic / Ambulatory Care: Administration		
Lack of Transport	C211	Home to Institution
	C213	Clinic / CHC to Hospital
Lack of Access	C222	Lack of clinic / limited opening times
	C224	Lack of high care beds / resuscitation area
Barriers	C227	Barriers to entry to healthcare
Lack of Personnel	C231	Lack of professional nurse at clinic
	C239	Other lack of personnel (specify)
Communication	C241	Communication problems: Staff to caregiver
	C249	Staff to staff communication problem at clinic or between clinic and hospital
Lack of Drugs, IV fluids etc	C254	O_2 supply / equipment
	C255	Antibiotics
	C256	Other lack of drugs, IV fluids (specify)
Laboratory	C258	Basic laboratory investigation not available (e.g. blood glucose)
Lack of Equipment	C261	Pulse oxymeter (at CHC)
	C262	Suction
	C263	Lack of other equipment (specify)
Lack of Policy	C271	Concerning short-stay for paediatric patients at health care centre
	C279	Other lack of protocol / policy (specify)
Insufficient Information	C290	Insufficient notes

Admission and Emergency (Hospital): Clinical Personnel		
Case Assessment	P401	History taking incomplete
	P402	Physical examination incomplete
	P403	Respiratory rate not taken, respiratory distress not noticed
	P404	Assessment of shock / dehydration insufficient
	P405	Appropriate investigations not done (blood, x-ray, other)
	P406	Results of investigations not noted
	P407	Not classified as critically ill by nurse / danger signs not noticed
	P409	Other insufficient case assessment (specify)
Monitoring	P411	Respiratory rate
	P412	O_2 saturation
	P413	Blood glucose
	P414	Shock
	P415	Level of consciousness, convulsions
	P419	Other insufficient monitoring (specify)
Case Management	P421	Shock not treated appropriately (e.g. intra-osseus line)
	P422	Airway obstruction not managed appropriately
	P423	Appropriate O_2 therapy not prescribed / not recorded / not given
	P424	Convulsions not managed appropriately
	P425	Appropriate antibiotics not prescribed
	P426	Other insufficient case management (specify)
Insufficient Information	P490	Insufficient notes
Admission and Emergency (Hospital): Administrators		
Lack of Transport	A211	Home to Institution
	A214	Hospital to Referral Hospital / Institution to Institution
Lack of Access	A223	Lack of hospital beds / ward overcrowded
	A224	Lack of high care beds / resuscitation area
	A225	Lack of infant / paediatric ICU facilities
Barriers	A227	Barriers to entry to healthcare
Lack of Personnel	A232	Lack of professional nurse at hospital (specify: day / night / week end)
	A233	Lack of senior doctors (post Community Service)
	A239	Other lack of personnel (specify)
Communication	A242	Staff to caregiver
	A243	Doctor not called for critically ill child
	A245	Doctor to doctor (e.g. no hand over of critically ill patient)
	A246	Doctor called, but did not respond / did not come
	A249	Other staff to staff communication problem (specify)
Lack of Drugs, IV Fluids etc	A254	O_2 supply / equipment
	A255	Antibiotics
	A256	Other lack of drugs, IV fluids (specify)
	A257	Lack of blood products
Laboratory	A258	Basic laboratory investigation not available
Lack of Equipment	A261	Pulse oxymeter
	A262	Suction
	A263	Lack of other equipment (specify)
Lack of Policy	A273	Lack of case management protocol
	A279	Other lack of protocol / policy (specify)
Insufficient Information	A290	Insufficient notes

Ward (Hospital): Clinical Personnel		
Case Assessment	P501	Physical examination incomplete
	P502	Appropriate investigations not done
	P504	Results of investigations not traced / not noted (including x-rays)
	P507	LRTI / ARI not responding to treatment, not reassessed
	P508	Other condition not responding to treatment, not reassessed
	P509	Patient not seen during week-end / public holiday
	P510	Insufficient case assessment / management at previous admission / OPD visit
Monitoring	P521	Respiratory rate / O_2 saturation
	P523	Blood glucose
	P524	Shock
	P525	Level of consciousness, convulsions
	P526	Electrolytes
	P529	Other insufficient monitoring (specify)
Case Management	P531	Appropriate O_2 therapy not prescribed / not recorded / not given
	P532	Convulsions not managed appropriately
	P533	Appropriate change / addition of antibiotics / TB Rx not prescribed
	P534	Appropriate blood product not prescribed
	P535	Other appropriate treatment not prescribed (specify)
	P536	Other case management protocol not followed (specify)
	P537	No team decision for terminal care
	P538	Prescribed treatment not given
Delay in Calling for Senior Opinion	P601	Community Service Doctor / Intern did not call senior Medical Officer
	P602	MO at peripheral hospital did not call provincial hospital / referral hosp
	P603	Other delay in calling for senior opinion
Delay in Referring	P611	To provincial hospital / referral hospital for coma / CT scan
	P612	To provincial hospital / referral hospital for other problem
	P613	Other delay in referring
IV Fluids / Intake-Output	P621	No prescription for IV fluids
	P622	IV fluids not monitored / not recorded appropriately
	P623	Too much / too little / incorrect type of IV fluids prescribed / given
	P624	No appropriate intake-output charting done
Feeding / NG Tube	P631	NG tube feedings not prescribed
	P632	NG tube feedings not recorded / given
	P633	Other appropriate feedings not recorded / not given
	P634	Problems with NG tube feedings (e.g. cough, cyanosis)
Other	P689	Other modifiable factor (specify)
Insufficient Information	P690	Insufficient notes

Ward (Hospital): Administrators		
Lack of Transport	W214	Hospital to Referral Hospital
Lack of Access	W223	Lack of hospital beds / ward overcrowded
	W224	Lack of high care beds / resuscitation area
	W225	Lack of infant / paediatric ICU facilities
Lack of Personnel	W232	Lack of professional nurse at hospital (specify: day / night / week-end)
	W233	Lack of senior doctors (post Community Service)
	W239	Other lack of personnel (specify)
Communication	W242	Staff to caregiver
	W243	Doctor not called for critically ill child
	W245	Doctor to doctor (*e.g.* no handover of critically ill patient)
	W246	Doctor called, but did not respond / did not come
	W249	Other staff to staff communication problem (specify)
Lack of Drugs, IV etc	W254	O_2 supply / equipment
	W255	Antibiotics
	W256	Other lack of drugs, IV fluids (specify)
	W257	Lack of blood products
Laboratory	W258	Basic laboratory investigation not available
Lack of Equipment	W261	Pulse oxymeter
	W262	Suction
	W263	Lack of other equipment (specify)
Lack of Food / Milk	W269	Lack of food / milk
Lack of Policy	W272	For weekend / holiday ward rounds
	W273	Lack of case management protocol
	W279	Other lack of protocol / policy (specify)
Insufficient Information	W290	Insufficient notes

F – Turnitin report

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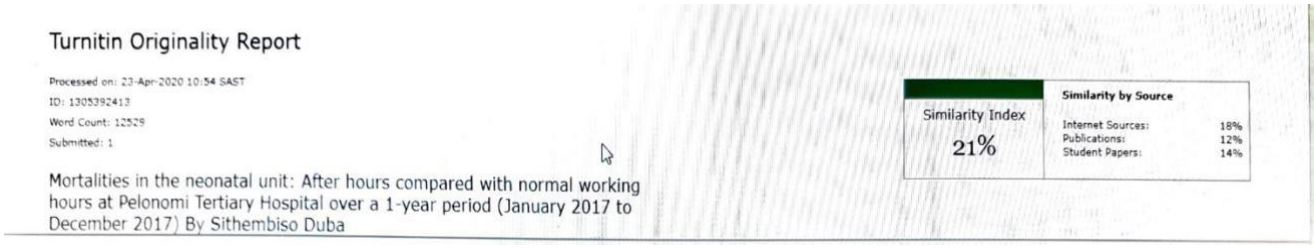

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