

**NOSOCOMIAL INFECTIONS IN NEONATAL INTENSIVE CARE UNIT OF
A PUBLIC HEALTHCARE FACILITY IN SAUDI ARABIA.**

by

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DECLARATION

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I declare that the dissertation, **Nosocomial infections in neonatal intensive care unit of a public healthcare facility in Saudi Arabia** is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references.

I further declare that I submitted the dissertation to originality checking software and that it falls within the accepted requirements for originality.

Furthermore, I declare that I have not previously submitted this work, or part of it, for examination at Unisa for another qualification or at any other higher education institution.



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NOSOCOMIAL INFECTIONS IN NEONATAL INTENSIVE CARE UNIT OF A PUBLIC HEALTHCARE FACILITY IN SAUDI ARABIA

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ABSTRACT

Minimising the risks of nosocomial infections in neonatal intensive care units is an important aspect in reducing mortality rates and length of admissions. The purpose of this study was to investigate the continued occurrence of nosocomial infections in neonatal intensive care unit of a Public Healthcare facility in Saudi Arabia. The study used quantitative descriptive, cross-sectional designs and retrospective data analysis. Data collection was conducted using a self-designed checklist. The sample comprised of 138 clinical records of neonates who developed nosocomial infections during the period of 1st October 2017 to 30th September 2019. Data was analysed using IBM SPSS version 26. The results of the study showed that gestational age of less than 33+6weeks, lower birth weight less than 1000g, neonatal resuscitation, presence of central catheters, ventilators, total parenteral nutrition and delayed initiation of feeds were risk factors for occurrence of nosocomial infections. Most infections, 59.3% occurred at less than 14 days of life. The most common site of infection was blood at 79.7% and the most prevalent organisms were *Pseudomonas aeruginosa* and Methicillin-resistant *Staphylococcus aureus* at 22.5% respectively. Some of the recommendations from the study are that healthcare workers should take extra precautions in collecting blood samples, ensure proper hand hygiene and have external practitioners observe hand hygiene practices in NICU.

KEY TERMS: central line blood stream infections; clinical; healthcare associated infection; neonatal intensive care; neonates; nosocomial infection; retrospective analysis; surgical site infections; total parenteral nutrition; ventilator associated infections.

DEDICATION

This dissertation is dedicated to my sister Nomah who was a pillar of support throughout this journey and a mother to my children, Jabulani and Jade during my absence.

To my partner and my children for their understanding and patience as I was not always available for them when they needed me.

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LIST OF ACRONYMS AND ABBREVIATIONS

APIC	Association for Practitioners in infection control
CAUTI	Catheter associated urinary tract infections
CC	Continuous Care
CDC	Centre for disease control and prevention
CLABSI	Central line associated blood stream infections
CONS	Coagulase-negative staphylococci
COVID-19	Corona virus diseases- 2019
DMAIC	Define, measure, analyse, improve and control
EBM	Expressed breast milk
E-COLI	Escherichia coli
ELBW	Extreme low birth weight
FC	Femoral catheter
HCAI	Healthcare associated infections
HCW	Healthcare worker
HH	Hand hygiene
IC	Intensive care
IM	Intermediate care
JL	Jugular line
LBW	Low birth weight
MDRO	Multidrug resistant organisms
MRSA	Methicillin-resistant staphylococcus aureus
MRSE	Methicillin-resistant staphylococcus epidermidis
NI	Nosocomial infections
NICU	Neonatal intensive care unit

PICC	Peripherally inserted central catheter
PPE	Personal protective equipment
SPRING	Sepsis prevention in NICUs group
SPSS	Statistical package for the social sciences
SSI	Surgical site infections
TPN	Total parenteral nutrition
UAC	Umbilical arterial catheter
UNICEF	United nations children's fund
UNISA	University of south Africa
UVC	Umbilical venous catheter
VAP	Ventilator associated pneumonia
VLBW	Very low birth weight
WHO	World health organisation

CHAPTER 1

ORIENTATION OF THE STUDY

1.1 INTRODUCTION

Nosocomial infections (NIs) also known as healthcare associated infections (HAI) are the leading cause of morbidity and mortality in neonatal intensive care units (NICUs) world-wide (Yong-Chuan, Chen-Fu, Yun-Jiau, Juei- Chao, Po-Yen, Chao-Huei, The-Ming & Fang-Liang 2017:427). This is due to advances in invasive therapeutic and diagnostic procedures and increased survival of preterm babies (Kumar, Shankar, Arya, Deb & Chellani 2018:275). NIs are infections occurring in a patient during the process of care in a hospital or other healthcare facility which was not present or incubating at the time of admission (Hakizimana 2018:1). At any given day, about one in 31 hospital patients world-wide has at least one healthcare associated infection with serious effects on the quality of care as they increase the duration and cost of hospitalization (Centre for disease control 2017:1; Nanou, Paulopoulou, Liosis, Tsoumakas & Saroglou 2015:1). For this reason, continuous interventions on ways to minimise NIs may be mandatory.

Neonatal intensive care units are hospital wards with frequent incidence of NIs because of the demographics of its patients (APIC Text of infection control and epidemiology 2014:41-2). A neonate is a new born from birth to 28 days of age. Lower birth weights, lower gestational age, immunocompromised, inadequate levels of antibodies are factors that increase the frequency of nosocomial infections in NICU (Nanou et al 2015:2). Furthermore, the use of invasive devices, being, mechanical ventilators, chest tubes and central lines, as well as the use of parenteral nutrition and antimicrobial therapy increase the risks of NIs in NICU (UNICEF 2018:10). Other factors that contribute to NIs are contaminated water systems, air-conditioning systems and the physical layout of the facility, being, beds which are close to each other (Mbim, Mbotto & Agbo 2016:5). Nanou et al (2015:2) study on risk factors for nosocomial infections in NICU stated that mortality of infants who developed nosocomial infections exceeds 45% in Greece.

In a study conducted in India on healthcare associated infections in NICU and its correlation with environmental surveillance, 37% of babies developed clinical sepsis, 36% had culture positive sepsis, 12% had pneumonia, 10% meningitis and 2.6% conjunctivitis (Kumar et al 2018:276).

Many of the NIs are preventable and the healthcare environment can be made safer. This means that continuous monitoring and surveillance of infections need to be done as this can help reduce the occurrence of nosocomial infections. Though most infections are associated with inadequate hand hygiene practices, patient-related factors and care related factors also contribute to the occurrence of nosocomial infections (Musu, Lai, Mereu, Galletta, Campagna, Tidore, Piazza, Spada, Massidda, Colombo, Mura & Coppola 2017: E231; Al-Tawfiq & Tambyah 2014:340).

Based on the above discussion, the researcher noted studies regarding neonatal nosocomial infections in other countries, however, no scientific studies were conducted in that regard in Saudi Arabia at the specific healthcare facility. There is a need to investigate specific causes of NIs in NICU in this public healthcare facility in Saudi Arabia in order to make recommendations and create safe healthcare for patients. This study investigated the continuous occurrence of nosocomial infections in the neonatal intensive care unit of a specific Public Healthcare facility in Saudi Arabia. Furthermore, the study identified and described causes and factors contributing to the incidence of NIs in NICU. Recommendations will be presented to management of this healthcare facility on how to mitigate the occurrence of nosocomial infections in NICU.

1.2 BACKGROUND OF THE STUDY

Nosocomial infections are the leading cause of morbidity and mortality world-wide in NICUs (Yong-Chuan et al 2017:427). Every year more than one million neonatal deaths are estimated worldwide, mainly from developing countries due to nosocomial infections. These infections result in prolonged hospital stays, long-term disability, increased resistance of microorganisms to antimicrobials, additional costs for health systems, high costs for patients and their families including unnecessary deaths (Hakizimana 2018:1).

In American hospitals alone, the Centre for Disease Control and Prevention (CDC) estimates that NIs account for an estimated 1.7 million infections and 99 000 associated deaths each year resulting in an estimated \$20 billion in healthcare costs (Patientcare link 2019:2). The European Centre for Disease Prevention and Control estimated that more than 2.6 million new cases of NIs occur every year in Europe (Allegranzi, Kilpatrick, Storr, Kelley, Park & Donaldson 2017: E1178). Among hospital-born babies in developing countries, NIs are responsible for up to 56% of all causes of deaths in the neonatal period, with 75% occurring in South-East Asia and Sub-Saharan Africa. In sub-Saharan Africa, the majority of the reports on infectious diseases and drug resistance are limited to pressing problems associated with Human Immune Virus, Tuberculosis, Malaria and other emerging and re-emerging resistant pathogens. Literature shows that nosocomial infection rates range from 2-49% (Mbim et al 2016:3).

In Saudi Arabia, Al-Khobar region, the rate of nosocomial infections was 2.73 per 1000 admissions after interventions, this was a significant decrease from the previous 3.92 (Kuwaiti & Subbarayalu 2017:265). In Al Qassim region of Saudi Arabia, the hospital-wide rate of NIs ranged from 0.35 to 1.96 per thousand patients per day during the 2012 to 2016 period, with 7.6% of infections from the neonatal intensive care unit (Gupta, Al Khaleefah & Al Harbi 2017:47-48). There are no recently published studies of nosocomial infection rates in the Saudi Arabian region where the specific healthcare facility is located. A study was conducted in Al-Khobar, Saudi Arabia on reducing hospital acquired infection rates using the six sigma DMAIC (Define, Measure, Analyse, Improve and Control) approach (Kuwaiti & Subbarayalu 2017:260-6), but none was specifically conducted in NICU.

Another study was conducted in Saudi Arabia on changes in hand hygiene compliance after a multimodal intervention among healthcare workers (HCWs) from intensive care units (Mahfouz, Al-Zaydani, Abdelaziz, El-Gamal & Assiri 2014:315), but no recent studies were conducted specifically in NICU in Saudi Arabia generally.

Furthermore, continued incidence of NIs in the unit and the paucity of studies on nosocomial infections in NICU in Saudi Arabia has led to this study. This study investigated the continuous occurrence of nosocomial infections, identified and described the causes and factors leading to the occurrence of NIs in NICU in a specific Public Healthcare facility in Saudi Arabia in order to create safe healthcare for patients.

Furthermore, causes and factors contributing to the incidence of nosocomial infections in NICU were identified and described in order to present recommendations to the management of this healthcare facility to help eradicate occurrences of nosocomial infections in NICU.

1.3 STATEMENT OF THE RESEARCH PROBLEM

Nosocomial infections are the leading cause of morbidity and mortality in NICUs worldwide (Yong-Chuan et al 2017:427). These infections continue to be a burden to the health system in NICUs. All infection prevention and control precautionary measures are being taken to minimise the occurrence of nosocomial infections in NICU where the problem was identified. These are; correct isolation procedures, use of standard precautions, correct handling and storage of breast milk and hand hygiene compliance which is above 80% most of the time. It is observed that infections still exist in the unit, thus leading to long periods of hospitalisation, the deterioration in patients' condition, low platelet counts, increased white cell counts, continued re-use of antimicrobials and the increased need for human resources.

The researcher, being a neonatal intensive care nurse and an infection prevention link nurse, noted that there were seven and eight positive cultures, mainly from blood samples in NICU to be studied in the month of April and May 2019 respectively. The cultured organisms were *Serratia Marcescens*, *candida*, *Enterobacter cloacae*, *Enterobacter aeruginosa*, *Acinetobacter Baumannii* and *Pseudomonas aeruginosa*.

If an intervention is not implemented, an outbreak of infections would occur and mortality and morbidity rates will continue to rise. The researcher investigated the continued occurrence of nosocomial infections in NICU at the specific healthcare facility in Saudi Arabia. Furthermore, the study identified and described causes and factors contributing to the incidence of NIs. Recommendations from this study will be communicated to the management of the researched healthcare facility in order to eradicate the continued occurrence of nosocomial infections in NICU. A retrospective analysis of clinical records of neonates was conducted.

1.4 DEFINITION OF KEY CONCEPT

1.4.1 Conceptual definitions

Conceptual definitions present the abstract or theoretical meaning of the concept being studied (Polit & Beck 2017:723):

- 1.4.1.1 Cause** refers to a relationship between variables with the presence or absence of one variable determining the value of the other (Polit & Beck 2017:721).
- 1.4.1.2 Clinical** record refers to the client health record (Stanhope & Lancaster 2016:588).
- 1.4.1.3 Factor** is an agent or element that contributes to the production of a result (Dorland's Medical dictionary 2019:291).
- 1.4.1.4 Incidence** is the number of new nosocomial infections acquired in a period (Rajani & Javeri 2017:2000).
- 1.4.1.5 Intensive care unit** also called critical care units are designed to meet special needs of acutely and critically ill patients (Lewis, Bucher, Hetkemper & Harding 2017:1554).
- 1.4.1.6 Neonatal intensive care unit (NICU)** refers to areas providing intensive care for severely ill new-borns who need continuous nursing, cardiopulmonary care and other supportive services (APIC Text 2014:41-2).
- 1.4.1.7 Nosocomial infection** are infections occurring in a patient during the process of care in a hospital or other healthcare facility which was not present or incubating at the time of admission (Hakizimana 2018:1).

1.4.2 Operational definitions

Operational definitions refer to the definition of concepts or variables in terms of procedures by which it is to be measured (Polit & Beck 2017:727).

- 1.4.2.1 **Cause** refers to refers to elements that causes nosocomial infections.
- 1.4.2.2 **Central line** refers to umbilical venous and arterial catheters, femoral lines and peripherally inserted central lines used for monitoring and/or venous access.
- 1.4.2.3 **Clinical records** refer to medical documents containing patient's information to be used in the study.
- 1.4.2.4 **Extreme low birth weight** is the birth weight below 1000g.
- 1.4.2.5 **Factor** refers to elements that contributes to the occurrence of nosocomial infections.
- 1.4.2.6 **Incidence** refers to the number of identified new cases of nosocomial infections.
- 1.4.2.7 **Intensive care unit** is a part of the hospital where the most critical neonates are admitted and require close monitoring.
- 1.4.2.8 **Neonates** are infants admitted in the NICU.
- 1.4.2.9 **Nosocomial infections**, also called healthcare associated infections are infections occurring in patients receiving care in hospital which was not present or incubating at the time of admission.

1.5 PURPOSE OF THE STUDY

The purpose of this study was to investigate the continued occurrence of NIs in NICU in a specific Public Healthcare facility in Saudi Arabia.

1.5.1 Study objectives

The objectives of this study were:

- to determine the neonatal infection rate in NICU at a specific healthcare facility.
- to identify nosocomial infection sites in NICU.
- to indicate the prevalent organisms leading to NIs in NICU.
- to identify and describe the causes and factors contributing to the incidence of NIs in NICU.
- to present the recommendations to management of the researched specific healthcare facility in eradication of the occurrence of nosocomial infections in NICU.

1.5.2 Research questions

The research questions were:

- What is the neonatal infection rate in NICU?
- What are the identified NIs sites in NICU?
- What are the prevalent organisms leading to NIs in NICU?
- What are the causes and factors contributing to the incidence of NIs in NICU?
- What recommendations should be made in eradication of the occurrence of nosocomial infections in NICU?

1.6 RESEARCH SETTING

A research setting is the physical location and conditions in which data collection takes place in a study (Polit & Beck 2017:744). This study was conducted at a Public Healthcare facility in a specific NICU in Saudi Arabia.

The specific healthcare facility was selected because that is where the researcher observed an increased number of nosocomial infections.

1.7 RESEARCH DESIGN AND METHODS

1.7.1 Research design

A research design is the overall plan for obtaining answers to research questions (Polit & Beck 2017:56). The approach used was a quantitative, descriptive, cross-sectional and retrospective document analysis of clinical records for a period of two years, from 1st October 2017 to 30th September 2019. A self-designed checklist was used.

1.7.1.1 Quantitative design

A quantitative study is defined as a formal, objective, systematic process in which numerical data is used to obtain information about the world (Burns & Grove 2011:43). Numerical values were interpreted by giving meanings that can be generalised to the study population. The study used a quantitative design because the plan was to quantify the results pertaining to the incidence of nosocomial infections at a Public Healthcare facility in a specific NICU in Saudi Arabia.

1.7.1.2 Descriptive design

A descriptive design is one that typically has as its main objective the accurate portrayal of people's characteristics or circumstances and/or the frequency with which certain phenomena occur (Polit & Beck 2017:726). With this approach, clinical records of neonates were reviewed to investigate the status of NIs and to identify and describe causes and factors contributing to the incidence of NIs in NICU at a specific Public Healthcare institution in Saudi Arabia.

1.7.1.3 Cross-sectional design

It is defined as a study in which data are collected at one point in time (Polit & Beck 2017:725). In this study, clinical records of neonates pertaining to the research problem were reviewed at one point in time to provide answers to research questions.

1.7.1.4 *Retrospective document analysis*

Retrospective document analysis is a design in which a phenomenon existing in the present is linked to phenomena that occurred in the past (Polit & Beck 2017:204). The researcher began with the research problem and then examined the correlation to potential causes. Different causes and factors leading to nosocomial infections were identified and described through a review of clinical records over a period of two years from the 1st October 2017 to the 30th September 2019.

1.7.2 *Research methods*

Research methods or research methodology are defined as a particular way of knowing about reality (Brink, Van der Walt & Van Rensburg 2012:24).

This includes the target population, sampling, data collection and specific steps of the research process that ensure objectivity and minimisation of bias.

1.7.2.1 *Population*

A population is the entire group of persons or objects that are of interest to the researcher (Brink et al 2012:131). In this study, the population was one hundred and thirty-eight (138) clinical records of neonates who developed infections during their stay in NICU in a Public Healthcare facility in Saudi Arabia for a period of two years, from the 1st October 2017 to the 30th September 2019.

1.7.2.2 *Sampling technique and sampling*

Sampling refers to the process the researcher uses to select the sample from a population in order to obtain information about a phenomenon in a way that represents the population of interest (Brink et al 2012:132). Sampling also makes it easier for the researcher to conduct a study with limited resources, time and finances. Furthermore, sampling makes it easy to analyse, interpret and generalise the results to the entire population that the sample represents (De Vos, Strydom, Fouche & Delpont 2011:224).

No sampling technique was used. A census was used as the size of the sample was manageable during data collection.

Therefore, one hundred and thirty-eight (138) clinical records of neonates who developed infection during their stay at a NICU of a Public Healthcare facility from the 1st October 2017 to 30th September 2019 was the sample. Information about all infected cases during that period was available in NICU.

1.7.2.3 *Inclusion criteria*

Inclusion criteria refer to those characteristics that the subject or an element possess to be part of the target population (Polit & Beck 2017:250). Inclusion criterion for this study was clinical records of neonates, males and females, admitted in the unit from labour and delivery room and post-natal unit during the period of 1st October 2017 to 30th September 2019 who developed one or more nosocomial infections while receiving care at a NICU of a Public Healthcare facility in Saudi Arabia.

1.7.2.4 *Exclusion criteria*

The study excluded clinical records of neonates that had infections on admission and those that would have been used for instrument testing.

1.7.2.5 *Development and pretesting of the instrument*

A self-developed checklist was used in this study to collect data related to NIs from clinical records of the neonates (refer to Annexure 5). The checklist had six (6) sections. Section A questions included demographic data, being gender and age on admission.

Section B had questions on medical history of the neonate which included weight on admission, resuscitation record, Apgar score, admission diagnosis, vital observations, skin condition and the outcome of admission. Section C included items on causes and factors leading to nosocomial infections in NICU, being the use of central lines, chest tubes, ventilators, total parenteral nutrition and antimicrobials.

Section D consisted of NIs sites; blood, urine, tracheal aspirates, eye, wound swabs and breastmilk. Section E consisted of prevalent organisms leading to NIs in NICU. The last section, which is section F, included items on determining the nosocomial infection rate.

Pre-testing of an instrument was conducted after the instrument was reviewed and accepted by the researcher's supervisor, the NICU director and the statistician. Since pre-testing was conducted during the COVID-19 pandemic, precautionary measures such as wearing masks, gloves and maintaining social distancing were maintained.

The pre-testing of the checklist was done at the same healthcare facility in Saudi Arabia after approvals to conduct the study were granted. A checklist was pre-tested for content validity and its reliability to collect data for the study. Four clinical records were used for pre-testing to test the validity and the reliability of the checklist. The details of pre-testing will be discussed in Chapter 3 in the methodology chapter.

1.7.2.6 Data collection

Data collection is the process of gathering information to address a research problem (Polit & Beck 2017:725). Data was collected after being granted the study approval. Data was collected from the medical records section of the specific healthcare facility.

COVID-19 precautionary measures were maintained on entering the NICU. A surgical mask was worn at all times, hand hygiene performed with 70% alcohol gel, gloves worn on handling clinical documents and social distancing of at least one meter was maintained.

From the register of infected cases obtained from the NICU clerk, the researcher compiled a list of medical record numbers and that list was given to medical records personnel to extract clinical records of neonates for a period of two years, from 1st October 2017 to 30th September 2019.

All records provided by the medical records personnel were recorded and signed by the researcher in a book at the medical records department as evidence that they were received by the researcher. Although clinical records provided were removed from their respective shelves, they were kept in a separate shelf in the doctors' room within the medical records department for easy access by the researcher.

The researcher compiled a list of all clinical records provided for evidence, it was used on returning the clinical records to the medical records personnel for re-filing after data collection. The records used for the study were kept under the supervision of the medical records department personnel to ensure that no records were taken out of the facility during data collection period. The pre-tested checklist was used for data collection (refer Annexure 5).

Furthermore, a similar checklist was used in the data collection to ensure consistency, thus each and every clinical record's information was recorded on its own checklist. The researcher had 138 completed checklists after data collection which were used for data analysis.

Data was collected from Sunday to Thursday (these are weekdays), from 08:00 to 16:00 on a daily basis for a period of two (2) weeks. An informed consent from the research respondents was waived as clinical records which are hospital property were used. Therefore, the permission letter to conduct the study from the selected Public Healthcare facility (refer Annexure 2) and approvals which were granted to conduct the study by the Ethics Research committee of the selected healthcare facility (refer Annexure 2.1), the Director of NICU (refer Annexure 3.1) and the Director of Medical Records (refer Annexure 4.1) were used as informed consent to use clinical records.

Confidentiality of patients' records was maintained throughout the data collection process by avoiding the use of patients' names and their medical record numbers. Unique identification was used by the researcher. The researcher was the only one responsible for data collection to ensure privacy of information. Health professionals' names were not used in the study to ensure anonymity.

After data had been collected, the records extracted were returned to the medical records clerk for re-filing using the compiled list as evidence that the same clinical records that were extracted from the shelves were returned. The checklist was kept under lock and key in the researcher's locker in NICU department for safety and privacy and it was accessible to the researcher only. The information collected was also stored in the researcher's personal computer which is accessed through a password to ensure safe keeping, privacy and confidentiality.

1.7.2.7 *Data analysis*

Polit and Beck (2017:725) describe data management as a systematic organisation and synthesis of research data, in the case of quantitative studies it also involves the testing of hypotheses using the data.

Descriptive statistics was used to provide answers to research questions. Baseline and demographic characteristics were summarised using descriptive measures. A statistician assisted in analysing and summarising data (refer Annexure 6).

IBM Statistical package for the Social Sciences (SPSS) version 26 was used to calculate the statistics. Frequency distribution tables, figures and graphs were used to present and describe the results of the study.

1.8 VALIDITY AND RELIABILITY

1.8.1 Validity

Validity is defined as a determination of how well the instrument reflects the abstract concepts being examined (Burns & Grove 2011:334).

1.8.1.1 Internal validity

It concerns the validity of inferences, given that an empirical relationship exists, it can be assumed it is the independent variable, rather than something else that caused the outcome (Polit & Beck 2017:216). In this study, there are no threats to internal validity as this is a retrospective study where information already exists from the past. The data collection instrument that was used to gather information on the occurrence of nosocomial infections in NICU was pre-tested to avoid threats due to instrumentation.

1.8.1.2 Content validity

Content validity refers to the extent to which an instrument's content adequately captures the construct, whether an instrument has an appropriate sample of items for the construct being measured (Polit & Beck 2017:310). The checklist was submitted to the researcher's supervisor, the NICU director and to the statistician to ascertain whether the information will be relevant and adequately addresses the research questions.

1.8.1.3 Design validity

Design validity is a measure of the truth or accuracy of a claim and it is central in determining whether the study findings are sufficiently valid to add to the evidence base for patient care (Burns & Grove 2011:221). The use of clinical records of neonates with information that was collected routinely and independently for a period of two years (1 October 2017 to 30 September 2019) reduced the opportunity of an observer bias.

1.8.1.4 External validity

It is about the generalisability of causal inferences. It concerns whether inferences about observed relationships will hold over variations in persons, setting, time or measures of the outcomes (Polit & Beck 2017:216). The results of the study will be generalised to other healthcare facilities in Saudi Arabia.

Furthermore, recommendations may benefit NICU in general, healthcare providers in NICU and scholars who aspire to conduct similar studies.

1.8.2 Reliability

The degree to which the instrument can be depended upon to yield consistent results if used repeatedly over time is defined as the reliability (Brink et al 2012:171). The pre-testing of the data collection instrument was done before data collection of the main study to identify weaknesses and correct any ambiguity at the same healthcare facility to ensure reliability. The checklist was pre-tested using four clinical records. Four clinical records that were used to pre-test the instrument, were not used in the main study to avoid duplication of data. To ensure internal consistency, the same kind of information was collected from each clinical record.

An instrument is said to be internally consistent to the extent that its items measure the same trait (Polit & Beck 2017:307). The services of a statistician were incorporated in evaluating internal reliability using Cronbach's Alpha.

1.9 ETHICAL CONSIDERATIONS

1.9.1 Researcher specific considerations

The research proposal was submitted to the Research and Ethics Committee of the University of South Africa's Department of Health Studies for Ethical Clearance (refer Annexure 1). Furthermore, letters requesting permission to conduct the study were written to the Ethics Research Committee at a specific Public Healthcare facility (refer Annexure 2), the Director of NICU (refer Annexure 3) and the Director of Medical Records (refer Annexure 4) at the specific Public Healthcare facility to request permission to conduct the study and to access medical records. Approvals to conduct the study were granted by the Ethics Research committee of the selected healthcare facility (refer Annexure 2.1), the Director of NICU (refer Annexure 3.1) and the Director of Medical Records (refer Annexure 4.1).

1.9.2 Records-specific considerations

1.9.2.1 *Informed consent*

Polit and Beck (2017:143) state that informed consent means that participants have adequate information about the research, comprehend the information and have the ability to consent to or decline participation voluntarily. In this study, informed consent from the research respondents was waived as clinical records which are hospital property were used.

Therefore, the permission letter to conduct the study from the selected Public Healthcare facility (refer Annexure 2) and approvals which were granted to conduct the study by the Ethics Research committee of the selected healthcare facility (refer Annexure 2.1), the Director of NICU (refer Annexure 3.1) and the Director of Medical Records (refer Annexure 4.1) were used as informed consent to use clinical records.

1.9.2.2 *Confidentiality*

Confidentiality is a pledge that any information which participants have provided will not be publicly reported in a manner that identifies the participants and will not be accessible to others (Polit & Beck 2017:147).

Names and medical record numbers of patients and healthcare professionals were not used throughout the study. Patients' clinical records were not removed from the medical records department.

1.9.2.3 *Anonymity*

This is the protection of participants' confidentiality such that even the researcher cannot link individuals with the data they provided (Polit & Beck 2017:719). To ensure anonymity, each and every record was uniquely identified using a system devised by the researcher, using the year and numbers from the medical record number. Furthermore, names of patients and healthcare workers as well as medical record numbers were not used.

1.9.2.4 *Scientific honesty*

The researcher acknowledged authors from all sources referenced in the study. Clinical records were reviewed and data transcribed accurately using the checklist designed by the researcher.

1.10 SIGNIFICANCE OF THE STUDY

This study investigated the continuous occurrence of nosocomial infections, identified and described the causes and factors leading to the occurrence of NIs in NICU of a specific Public Healthcare facility in Saudi Arabia in order to create safe healthcare for patients. Eradicating the occurrence of nosocomial infections in NICU may reduce morbidity and mortality, reduce length of hospital stay and decrease the financial burden on families and healthcare institutions.

Recommendations from this study will be presented to the management of this healthcare facility in order to eradicate the continued occurrence of nosocomial infections in NICU.

1.11 SCOPE AND LIMITATIONS OF THE STUDY

The limitation of the study may be information that would be missing or not documented. The other limitation is that there could be other factors that could have contributed to the incidence of nosocomial infections other than the ones that were identified and described in this study.

1.12 STRUCTURE OF THE DISSERTATION

For the structure of the dissertation see table 1.1 below:

TABLE 1.1: Structure of the dissertation

Chapters	Chapter Name	Description of the Chapters
1	Orientation to the study	Introduction, background to the research problem, problem statement, purpose, objectives and methodology were discussed.
2	Literature Review	Literature related to the study was reviewed.
3	Research design and methods	Research design and methodology, population, sampling, development and pretesting of the data collection instrument, data collection process, design validity and reliability and ethical considerations were discussed.
4	Data analysis, presentation and interpretation.	Data analyses and interpretation of the results were presented in line with set objectives.
5	Discussion, conclusion and recommendations	Discussion, conclusion and recommendations were discussed.

1.13 CONCLUSION

The chapter provided an orientation to the study. The objectives and purpose of the study were discussed. Key terms were defined operationally and conceptually. The research design and the methodology were discussed as well as ethical considerations. The next chapter will address literature review.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

In chapter one, an introduction, background to the study, research purpose, objectives, statement of the problem and research methodology were discussed. In this chapter, a review of the relevant literature will be presented. Literature review is defined as a critical summary of the research on a topic of interest, often prepared to put a research problem in context (Polit & Beck 2017:733). Literature was reviewed with the use of published articles related to the study, study related books, Centre for Disease Control (CDC) website, World Health Organisation (WHO) website and google scholar.

Nosocomial infection is a significant cause of morbidity and mortality in NICUs globally (Wang, Du, Zhao, Yu, Sun & Jiang 2019:8241). The following will be discussed; definition of nosocomial infections, risks of nosocomial infection, transmission of NIs, orientation of the neonatal intensive care unit, prevention of nosocomial infections, perspectives of NIs internationally, in South Africa and in Saudi Arabia.

2.2 DEFINITION OF NOSOCOMIAL INFECTIONS

Wang et al (2019:8241) define NIs as infections acquired during the period of hospitalisation that was absent before or at the time of admission and must occur up to 48 hours after hospital admission.

2.3 RISKS OF NOSOCOMIAL INFECTIONS

The risks of NIs during patient care is related to the mode of transmission of the infectious agent, the type of patient care activity, including medications being received or procedures being performed, the training and experience of the healthcare personnel, staffing ratios and the patient's underlying host defences (APIC Text 2014:21-1).

In neonates, the immunological immaturity, particularly preterm and very low birth weight (VLBW), contribute to their particular vulnerability to nosocomial infections (de Almeida, da Silva, de Oliveira & Areias 2016: para 3). The risks of infection in NICU are divided into new born risk factors and care-related factors (UNICEF 2018:5).

2.3.1 New born risk factors

According to UNICEF (2018:4), lower birth weight, birth weight of less than 2500g is a new born risk factor of nosocomial infections. The incidence of NIs in premature and low birth weight of new born babies is considered as a health threat (Hoseini, Abdinia, Rezaee & Oskouie 2014:25). Extreme low birth weight (ELBW), birth weight below 1000g and very low birth weight (VLBW), birth weight of less 1500g puts neonates at greater risk of NIs due to under-developed skin and greater need for invasive procedures in neonatal intensive care units. Gestational age is described as a key determinant for the increased risk of acquiring NIs. Younger gestational age, being babies delivered before thirty-seven weeks are at great risk of acquiring NIs (Nanou et al 2015:4). The immunology of the neonate, being immunocompromised, immature, ineffective and inadequate levels of antibiotics contributes a lot to the neonate acquiring nosocomial infections. Furthermore, new-borns are devoid of efficient structural barriers, protective endogenous microbial flora and a mature system (Nikkhoo, Lahurpur, Delpisheh, Rasouli & Afkhamzadeh 2015:2).

2.3.2 Care related risk factors

Extremely premature neonates have a high risk of infection due to biological immaturity, frequent invasive procedures and prolonged requirement for respiratory support and parenteral nutrition (Bowen, Callander, Richards & Lindrea 2017: F51). Intensive care stay is linked to the development of nosocomial infections. The NICU environmental surfaces harbour a large number of bacterial and fungal taxa associated with NIs in neonates (Kumar, Shankar, Arya, Deb and Chellani 2018:275), hence it requires constant attention from healthcare workers for the sake of patients' safety.

Standard precautions of infection prevention and control need to be adhered to as hospital wards have highest incidence of NIs (Musu et al 2017: E231).

Healthcare workers are required to observe strict hand hygiene practices before and after handling patients as well as before invasive procedures.

The risks of NIs are further attributed to the presence of invasive medical devices such as use of parenteral nutrition, mechanical ventilation, central venous catheters and antimicrobials (Wang et al 2019:8216). Prolonged use of mechanical ventilation leads to the development of a type of nosocomial infection known as ventilator associated pneumonia (VAP).

Furthermore, the prolonged use of parenteral nutrition and presence of central lines contributes to the development of a central line associated blood stream (CLABSI) type of nosocomial infection. Neonates that had surgeries performed on them are at great risk of acquiring surgical site (SSI) type of infections. Although catheter associated urinary tract infections (CAUTI) are uncommon in NICU, prolonged use of urinary catheters leads to these types of infections.

Antimicrobial therapy is attributed to nosocomial infections as it may lead to multiple drug resistance organism (MDRO) infections. In addition, units that are overcrowded and understaffed may also contribute to the spread of infection as there would be an easy spread of infections from one neonate to another, while understaffing may lead to poor adherence to hand hygiene practices by healthcare workers which could also lead to the spread of infections. Furthermore, the longer the neonate stays in hospital, the higher the risk of developing nosocomial infections (Nair, Steinberg, Habib, Saeed & Raubenheimer 2018:164).

2.4 THE TRANSMISSION OF NOSOCOMIAL INFECTIONS

Chain of infection is a model used in understanding the infectious disease process which is critical in determining the risks of infection and interventions to interrupt the disease process to prevent transmission (APIC Text 2014:21-2). Modes of transfer by which the organism moves or is carried from one place to another comprises of an infectious agent which is an organism that has the ability to cause a disease. They are influenced by virulence, the ability to grow and multiply, infectivity, the ability to enter tissues and duration of exposure which is the length of time the person is exposed to the organism. Reservoirs are places where organisms can exist and reproduce which facilitates their transmission (APIC Text 2014:21-2). These are human, animals, insects, food and environment.

Portal of exit are ways in which an infectious agent leaves its reservoir. These are through sneezing, coughing, biting, faeces, wind, rain, contaminated objects and skin (APIC Text 2014:21-3). Hence the need to isolate patients with suspected or confirmed infections, maintain at least two meters' distance between placements of patients, healthcare workers to practice proper cough etiquette and proper disposal of healthcare waste. Mode of transmission address the specific routes of transmission for different diseases which led to the implementation of transmission-based precautions in healthcare settings.

Portal of entry is any type of opening that allows infections to enter the patient's body and cause an infection, being indwelling catheters, intravascular devices, ventilators, surgical procedures and contaminated blood and food. Immunological deficiencies, poor nutritional status, age, indwelling devices, medications, intensive care stay, invasive procedures and staffing ratios are factors that render patient a susceptible host (APIC Text 2014:21-3).

2.5 ORIENTATION TO A NEONATAL INTENSIVE CARE UNIT OF A SPECIFIC HEALTHCARE FACILITY

The NICU of study admits mainly babies born within the hospital and rarely referrals from nearby hospitals. Prevention of infection in the premature infant who starts life in an intensive care unit with immature immune defences that are further depressed by illness and invasive procedures is an ongoing challenge (APIC Text 2014:41-1). The specific healthcare facility is a Joint Commission International accredited hospital where one of the goals of patient safety is reducing the risk of healthcare associated infections (nosocomial infections). The unit of study is a level 3 structure of neonatal units as it caters for all neonates delivered within the hospital and act as a referral hospital too.

The NICU of study is 51 bedded and a very busy unit hence there is a need for continuous monitoring of nosocomial infections to promote survival of preterm babies. The unit is divided into four sections; intensive care area (IC), negative and positive pressure isolation area (isolation), intermediate care area (IM) and continuous care area (CC).

The intensive care area receives critically ill neonates from labour and delivery room, operating theatre and post - natal or nursery area. Neonates admitted in IC area are term babies, low gestational age, ELBW, VLBW that require invasive and non-invasive

ventilation and central lines. Other indications for admission to the IC area are babies that require surgeries, babies with congenital anomalies and neonates that require complicated procedures including exchange transfusion.

The nurse-patient ratio in IC area is 1:1. IM area receives neonates that are not very critical, usually those that have recovered from an IC area, on oxygen via nasal cannula, delivered with low birth weight requiring monitoring and observation, babies with hypoglycaemia and those with hyperbilirubinemia for high intensity phototherapy treatment that could not be administered in nursery.

The nurse-patient ratio is 1:2 in IM area. Furthermore, the nurse-patient ratio in CC area is 1:3/4 which receives recovered babies from IM area that are breathing well in room air and being prepared for discharge. Neonates with airborne transmitted infections and those received from other hospitals are admitted in negative pressure rooms and the nurse-patient ratio is 1:1.

2.6 PERCEPTIONS OF NOSOCOMIAL INFECTIONS GLOBALLY

Surveillance of NIs is an essential part of quality and safe patient care. Active surveillance systems in NICUs have been developed in the United States of America and Canada by the National Healthcare Safety Network (NHSN), the Vermont Oxford Network and the Canadian Neonatal Network (Crivaro, Bogdanovic, Bagattini, Iula, Catania, Raimondi, Triassi & Zarrilli 2015:1). Furthermore, in Europe, surveillance systems for NIs in NICU are active in Germany and in England. Yong-Chuan et al (2017:428) state that the rates of nosocomial infections in NICUs range from 8.7% to 74.3% with 17.5% reported in a tertiary hospital in Taiwan.

The Institute for Healthcare Improvement developed the concept of "bundles" which are small, straightforward set of evidence-based practices that when performed collectively and reliably, have been proven to improve patient outcomes to help healthcare providers deliver the best possible care for patients undergoing particular treatments with inherent risks (Yong-Chuan et al 2017:428).

Different hospitals in India have a hospital-based infection control policy with the constituting members responsible for surveillance of infections and providing methods of control (Kumar et al 2018:275).

Of the 300 neonates studied by Maqbool, Ashraf, Aslam and Tak (2018:1-3) in Srinagar, India, 112 were identified as having NI which resulted in an infection rate of 37.33%. In Australia, late-onset neonatal infection is a major cause of mortality, prolonged hospitalisation and increased hospital costs for NICU patients and associated with increased risk of neurodevelopmental impairment and cerebral palsy (Bowen et al 2017: F51).

Of the 195 positive blood cultures classified as blood stream infections (BSIs), 66% grew coagulase-negative staphylococcus (CONS), 21% grew Gram-negative organisms and 13% grew other Gram-positive bacteria. However, results improved after the implementation of the Sepsis Prevention in NICUs Group (SPRING) initiative.

While NIs cause an estimated 40% of neonatal deaths in developing countries, in Greece, mortality of infants who developed nosocomial infections exceeds 45% (Nanou et al 2015:2). The incidence of bacteraemia due to central intravascular catheters was the most frequent NI up to 6.4 per 1000 central catheter days followed by pneumonia 8.6% while 15.4% of premature neonates developed other infections such as meningitis, infections of the eyes, mouth or skin (Nanou et al 2015:2).

Despite the use of various infection control strategies which include prophylactic antibiotics, immunoglobulins and physical barriers, the prevalence of nosocomial infections in NICUs still remains high in Taiwan (Yong-Chuan et al 2017:428).

2.7 PERCEPTIONS OF NOSOCOMIAL INFECTIONS IN SOUTH AFRICA

Although prevalence data from African countries is lacking, NIs prevalence rates are estimated to be at least double that of high-income countries (Dramowski, Whitelaw & Cotton 2016:226). Hospitalised children are at risk of NIs due to immunological immaturity and increased handling by healthcare staff at Tygerberg hospital in Cape Town (Dramowski et al 2016:225). Children face additional risk factors in low-resource settings due to malnutrition, human immune virus (HIV), overcrowding, poor infrastructure and lack of provision for infection control (Dramowski et al 2016:225).

The risk of NIs increases as the birth weight of the neonate decreases and the need for invasive procedures increases (Rameshwarnath & Naidoo 2018:93). Klebsiella

pneumoniae with 41.67%, *Staphylococcus aureus* with 20.14% and *Acinetobacter baumannii* with 14.58% were the majority of isolated bacteria at Mahatma Gandhi Memorial hospital (Rameshwarnath & Naidoo 2018:95). Parenteral nutrition, chemotherapy, central intravascular catheter and mechanical ventilation were not noted as risk factors in patients identified with NIs at a hospital in Kimberley, Northern Cape (Nair et al 2018:165).

The risk factors related to the neonate are not discussed. Of the patients identified with NIs, 64% had peripheral vascular catheter inserted, 56% were post-surgery, 24% had immunodeficiency and 20% had a urinary catheter in situ (Nair et al 2018:165). Besides the loss of income and inability to provide for the needs of the family, NIs can lead to legal costs in the present litigation environment when they are due to negligence or substandard healthcare (Nair et al 2018 :162).

2.8 PERCEPTIONS OF NOSOCOMIAL INFECTIONS IN SAUDI ARABIA

Nosocomial infections are considered as a health problem in Saudi Arabia. Although there are limited studies related to NIs, available studies stress on reducing the risks of these infections. Hand hygiene is also regarded as a valuable tool in minimising the transmission of NIs. A study was conducted in Abba, Southern region of Saudi Arabia on hand hygiene compliance among healthcare workers. Hand hygiene compliance among healthcare workers at the beginning of the study was 60.8% and improved to 86.4% after an intervention (Mahfouz, Al Zaydani, Abdelaziz, El-Gamal & Assiri 2014:319). The NI trend was reported high between 2012 and 2015 in a study conducted in Al-Qassim by Gupta et al (2017:47) and a somewhat downward trend was observed in 2016. The most organisms noted were; *Acinetobacter baumannii* (27%), *Pseudomonas aeruginosa* (22%), *E. coli* (11%), *Klebsiella pneumoniae* (10%) and *Candida* (9%) (Gupta et al 2017:47). Intensive care contributes the highest rates of nosocomial infections followed by the medical wards. The common site/type of nosocomial infection were CAUTI with 46%, followed by VAP and CLABSI with 20% and 19% respectively (Gupta et al 2017:47).

In a study conducted in Jeddah, screening and prevention of nosocomial infections in NICU, advances in environmental biology, the rate of infection in intensive care units is identified to be 5-10 higher than general wards while the rate of NIs in NICU is 6-50% per admission (Al-Jabri, Al-Hejin, Gashgari, Bataweel, Abu-Zaid, Mahmoud, Najjar & Ahmed 2019:14-23). The most gram-positive bacteria identified were, Group B Streptococci, Listeria, Staphylococcus aureus, Methicillin-resistant S. Aureus (MRSA) whereas gram-negative bacteria were, Escherichia coli, Enterobacter, Klebsiella, Pseudomonas, Serratia and Salmonella (Al-Jabri et al 2019:17). As NIs are severe for NICU, it is important to know the source and transmission of infections as a significant approach to saving neonates and reducing healthcare infections (Al-Jabri et al 2019:17). There are no recent published studies on NIs in NICU at the specific healthcare facility. Therefore, there is a need for continuous prevention of NIs in NICU and to monitor infection rates.

2.9 PREVENTION OF NOSOCOMIAL INFECTIONS IN NICU

These are measures that a healthcare facility undertakes to prevent any harm caused by infection to patients and healthcare workers (UNICEF 2018:52).

2.9.1 Hand hygiene

Hand hygiene has become a major issue of patient safety while hands of healthcare personnel are the main source of cross transmission of pathogens in healthcare facilities (Hakizimana 2018:2). Hand hygiene (HH) with soap and water or an alcohol-based hand rub is an essential component in the adherence to standard precautions (APIC Text 2014:28-2). Furthermore, HH is an effective tool in the reduction of nosocomial infections in healthcare facilities, especially intensive care units and poor compliance is associated with high rates of NIs (Anwar & Elareed 2019: E3). Bacterial counts on hands of healthcare workers range from 3.9×10^4 to 4.6×10^6 colony forming units/cm² and may include pathogens such as staphylococcus aureus, Klebsiella pneumoniae, Enterobacter, Acinetobacter and candida (Ramasethu 2017:3). Therefore, HH is crucial in the prevention of nosocomial infections. The World Health Organisation has provided guidelines on how HH should be performed (refer Figure 2.1) and the moments of HH which are; before touching a patient, before performing an aseptic procedure, after touching a patient, after touching patient's surroundings and after exposure to body fluids (APIC Text 2014:28-2).

The aim of these guidelines is to improve HH practices worldwide by creating a unified description for hand hygiene methods, right moments and observation process and present multimodal strategies for improvement (Hakizimana 2018:2).



Figure 2.1: How to hand wash and hand rub (WHO 2009:1),

2.9.2 Environmental hygiene

Contaminated surfaces are a reservoir for transmission of pathogens directly through patient contact with the environment or indirectly through contamination of healthcare workers' hands and gloves (Han, Sullivan, Leas, Pegues, Kaczmarek & Umscheid 2015:1). Organisms can survive for a long time on hospital surfaces with contaminated surfaces an important source for potential transmission (Allen, Hall, Halton & Graves 2018:108). Therefore, environmental cleaning is an important component of an infection control strategy to prevent nosocomial infections and for reducing microbial contamination of surfaces and subsequent risk for NIs.

Patient care equipment that is not adequately decontaminated between patients and shared supplies, being topical preparations used on the skin, umbilical cord or eyes can be a source of infection (APIC Text 2014:41-3). Water reservoirs are also potential sources of pseudomonas, stenotrophomonas, Serratia and Flavobacterium and these organisms proliferate in water and in humid environments such as incubators, humidifier reservoirs and respirator nebulizers and tubing (APIC Text 2014:41-4). During delivery of care, healthcare workers should avoid unnecessary touching of surfaces in close proximity to the patient to prevent both contamination of clean hands from environmental surfaces and transmission of pathogens from contaminated hands to surfaces (CDC 2017:1).

2.10 PRECAUTIONARY AND PREVENTATIVE MEASURES

2.10.1 Contact precautions

Contact precautions are used for patients with known or suspected infections that represent an increased risk for contact precaution (CDC 2017). Personal protective equipment (PPE) should be used appropriately. These are gowns and gloves. Gloves and gowns should be worn for all interactions that may involve contact with the patient or the patient's environment. Donning upon room entry and properly discarding before exiting the patient room is done to contain pathogens.

Transport and movement of patients outside of the room is limited to medically-necessary purposes to minimise exposure. When transport or movement is necessary, the infected or colonised area of patient's body should be covered or contained. Furthermore, disposable or dedicated patient-care equipment should be used to prevent cross-infection. However, if common use of equipment for multiple patients is unavoidable, equipment should be cleaned and disinfected before use on another patient.

Cleaning and disinfection of the rooms should be prioritised, ensuring that rooms are frequently cleaned and disinfected focusing on frequently touched surfaces and equipment in the immediate vicinity of the patient.

2.10.2 Droplet precautions

Used for patients known or suspected to be infected with pathogens transmitted by respiratory droplets that are generated by a patient who is coughing, sneezing or talking. Patient should be appropriately placed in a single room to reduce other patients' and staff exposure to pathogens. PPE should be used appropriately and mask worn upon entry into the patient room or patient space. In addition, transport and movement of patients outside of the room should be limited to medically-necessary purposes. If transport or movement outside of the room is necessary, patient to wear a mask.

2.10.3 Airborne precautions

They are used for patients known or suspected to be infected with pathogens transmitted by the airborne route, being tuberculosis, measles, chickenpox and disseminated herpes zoster. Patient is placed in an airborne infection isolation room. In this research setting, they are referred to as negative pressure rooms. The door should be kept closed to prevent the spread of infection. To minimise the risk of healthcare workers getting sick, susceptible individuals are restricted from entering the isolation room if other immune healthcare personnel are available. Furthermore, PPE should be used appropriately. A fit tested N95 mask or higher-level respirator for healthcare personnel and should be removed outside the patient's isolation room.

Transport and movement of patient outside of the room should be limited to medically-necessary purposes. If the movement or transport outside the isolation room is necessary, patient should wear a surgical mask and skin lesions need to be covered. Moreover, susceptible persons should be immunised as soon as possible following unprotected contact with vaccine-preventable infections such as measles, varicella or smallpox.

The most common NIs according to Wasserman and Messina (2018:1) are central line associate blood stream infections (CLABSI), ventilator associated pneumonia (VAP), catheter associated urinary tract infection (CAUTI) and Surgical site infection (SSI). Care bundles have been devised by the (CDC) to guide healthcare workers in the management of devices thus preventing nosocomial infections. These care bundles are simple sets of evidence-based practices that when implemented collectively, improve the reliability of their delivery and improve patient outcomes (Wasserman & Messina 2018:2). Furthermore, care bundles contribute to infection prevention, reduce unnecessary

antibiotic prescribing and may limit the development of antibiotic resistance in healthcare facilities (Wasserman & Messina 2018:2).

2.10.4 Prevention of central line associated blood stream infections (CLABSI)

Blood stream infections are considered CLABSI if they occurred while a central line was in situ or within 48 hours of removal of the central line (Bowen et al 2017: F52).

In a study conducted by Nikkhoo et al (2015:2) in Iran, the prevalence rate of blood stream infection was 6.4%. Blood stream infection was the most prevalent site of nosocomial infection with 45.6% (Basiri, Sabzehei, Shokouhi & Moradi 2015:3). To prevent CLABSI, usage should be monitored and providers educated in appropriate placement techniques- full sterile barrier precautions and appropriate site selection; avoiding use of femoral or other sites likely to be contaminated by bodily fluids (Craven 2016:552).

According to Wasserman and Messina (2018:3), CLABSI prevention bundles refer to insertion and maintenance bundles. Insertion bundles are precautions taken during the insertion of central lines. These are maximum sterile barrier precautions, the use of a surgical mask, sterile gloves, cap, sterile gown, standardised insertion packs and large sterile drape. The skin should be cleaned with alcohol-based chlorhexidine rather than iodine and should be allowed to dry before insertion. Only dedicated staff for central line insertion with competency training should insert these lines. Use of femoral veins for central venous access should be avoided at all times as contamination with bodily fluids is high. Furthermore, insertion guidelines and indications for central use should be available.

Maintenance bundles involve daily review of central line necessity, prompt removal of unnecessary lines, disinfection prior to manipulation of the line, daily chlorhexidine washes in patients who have stayed more than two months, disinfection of catheter hubs, ports and connectors before using the catheter, change of dressing and disinfection of site with alcohol-based chlorhexidine every 5 - 7 days and replacing administration sets within 96 hours and immediately or 24 hours if used for blood/ blood products and lipids respectively (Wasserman & Messina 2018:3).

2.10.5 Prevention of ventilator associated pneumonia (VAP)

Ventilator associated pneumonia is a form of nosocomial pneumonia that occurs in 12-30% of ventilated patients (Khattab 2019:256). Khattab (2019:256) further identifies the risks of VAP as endotracheal tube insertion, micro aspiration of throat secretions between endotracheal tube cuff and the tracheal mucosa, ventilator tubing system and respiratory therapy equipment such as nebuliser and bronchoscope. Elevation of head of bed between 30 and 45 degrees, frequent mouth care (though not applicable in neonates), daily "sedation vacations" and assessment of readiness to extubate, peptic ulcer disease prophylaxis and deep venous thrombosis prophylaxis are measures identified to prevent VAP (Craven 2016:552).

These interventions should be implemented together with standard precautions (hand hygiene and use of gloves when handling respiratory secretions) as well as adequate disinfection and maintenance of equipment and devices (Wasserman & Messina 2018:5). Other components of the VAP bundle are utilisation of endotracheal tubes with subglottic secretion drainage, only for patients ventilated for longer than 24 hours and initiation of safe enteral nutrition within 24-48 hours of intensive care admission.

2.10.6 Prevention of catheter associated urinary tract infection (CAUTI)

Catheter associated urinary tract infection is defined as a urinary tract infection (significant bacteriuria with symptoms and signs attributable to the urinary tract with no other identifiable source) in a patient with current urinary tract catheterisation or who has been catheterised in the past 48 hours (Wasserman & Messina 2018:4). In NICU, urinary catheters are inserted to monitor output in critically ill patients and for urinary retention. It is essential to monitor usage and educate providers on appropriate use of urinary catheters to prevent infections. Healthcare personnel should adhere to aseptic techniques during insertion and thereafter secure devices to prevent trauma (Craven 2016:552). Moreover, backflow of urine into the bladder and stasis should be prevented as this leads to development of infections. Provision of daily care with soap and water and removing the devices as early as possible will also prevent infections.

In addition to the above-mentioned care bundles, to prevent nosocomial infections, hand hygiene is important in handling and care of catheters. Furthermore, urinary catheters can be avoided in NICU by considering alternative methods for urine collection which include intermittent catheterisation and use of nappies (Wasserman & Messina 2018:4).

2.10.7 Prevention of surgical site infections (SSI)

Surgical site infections are infections of the incision or organ or space that occur up to 30 days after surgery (Wasserman & Messina 2018:6). Patients should be washed with soap or an antiseptic agent within a night prior to surgery and administration of parenteral antibiotic prophylaxis within 60 minutes prior to incision and re-dosing is recommended for prolonged procedures and in patients with major blood loss or excessive burns to prevent risks of SSI (Wasserman & Messina 2018:6). Other measures of SSI prevention are avoiding hair removal or use an electric clipper if hair removal is necessary.

Furthermore, alcohol-based disinfectant should be used for skin preparation in the operating room and maintain perioperative normothermia and intraoperative glycaemic control in patients with and without diabetes.

2.10.8 Judicious antibiotic use and prevention of misuse

Antibiotic resistance is a significant risk factor for adverse outcomes in infants with nosocomial infections which can increase mortality risk by 27% for every additional resistance to an antibiotic class (Wang et al 2019:8214). Antimicrobial resistance is generally increasing and has emerged from selective pressure from antibiotic use and transmission via contaminated healthcare workers (Almagor, Temkin, Benenson, Fallach & Carmeli 2018:1). Prevention of nosocomial infections can be achieved through good antimicrobial use and infection control, including hand hygiene. Drug resistant infections such as *Serratia Marcescens* infect blood, urinary tract and may cause pneumonia and meningitis (Wang et al 2019:8214). Furthermore, microbiological cultures are central to a rapid and accurate diagnosis which improves outcomes and reduces resistance (Trubiano & Padiglione 2015:598-602). Gram-negative infections are more resistant than gram-positive organisms (Wang et al 2019:8214).

2.10.9 The use of breast milk and early enteral feeding

The use of maternal breast milk is an inexpensive and simple measure to reduce infection rates. Feeding human milk is associated with lower rates of sepsis and necrotizing enterocolitis in preterm and very low birth weight infants (Ramasethu 2017:3). Early enteral feeding, within two to three days of life is associated with lower rates of nosocomial infections.

Human milk contains secretory antibodies, phagocytes, lactoferrin and prebiotics which improve host defence and gastrointestinal function (Ramasethu 2017:3). However, it is important to note that human milk can be associated with outbreaks of infection in NICUs due to milk sharing, contamination of equipment through milk warmers or collection pumps and poor hygiene practice by healthcare workers during handling of milk (Ramasethu 2017:3).

2.10.10 Reduce the duration of total parenteral nutrition (TPN)

Parenteral nutrition refers to intravenous nutrition with glucose, amino acids, lipids, vitamins and minerals to provide a total nutrition source for an infant (Rudolph 2017:165). Many neonates admitted to NICUs require TPN. Total parenteral nutrition use, especially long-term use in premature and low birth weight infants is considered a risk factor for nosocomial infections (Maqbool et al 2018:1; de Almeida et al 2016:1). Although TPN can be administered through peripheral intravenous lines, it is mainly administered through central lines, peripherally inserted central catheter (PICC) and umbilical venous catheter (UVC) which are a risk of CLABSI. 15.4% cases of bloodstream infection were reported among TPN cases in Australia (Marofi, Bijani, Abdeyazan & Barekatin 2017:488).

2.11 CONCLUSION

This chapter addressed definition of nosocomial infections, the risks of nosocomial infections, transmission of infections, orientation of the neonatal intensive care unit, perspectives of NIs internationally, in South Africa and in Saudi Arabia and prevention of NIs in neonatal intensive care unit. The next chapter, chapter 3, will discuss the research design and methodology.

CHAPTER 3

RESEARCH DESIGN AND METHODS

3.1 INTRODUCTION

An overview of the research design and methodology was provided in chapter 1. This study was aimed at investigating the continued occurrence of nosocomial infections in the neonatal intensive care unit of a specific Public Healthcare facility in Saudi Arabia. This chapter elaborates on the research design and methodology and addresses the following; research setting, research designs, methodology, population, sampling technique and sample, development of an instrument, pre-testing an instrument, data collection, data analysis, validity and reliability and ethical considerations.

3.2 RESEARCH DESIGN

A research design is a plan, structure and strategy of investigation so conceived as to obtain answers to research questions or problems (Kumar 2019:208). The approach used is a quantitative, descriptive, cross-sectional design and retrospective document analysis of clinical records for a period of two years, from the 1st of October 2017 to the 30th of September 2019. A self-designed checklist was used.

3.2.1 Quantitative design

A quantitative study is defined as a formal, objective, systematic process in which numerical data is used to obtain information about the world (Burns & Grove 2011:43). The numerical values were interpreted by giving meanings that can be generalised to the study population. The study used a quantitative design in order to quantify the results pertaining to the incidence of nosocomial infections in NICU at a specific Public Healthcare facility in Saudi Arabia.

3.2.2 Descriptive design

A descriptive design is the design that typically has as its main objective the accurate portrayal of people's characteristics or circumstances and/or the frequency with which certain phenomena occur (Polit & Beck 2017:726). The purpose of using a descriptive approach was to describe the identified causes and factors leading to NIs in NICU. Using this approach, clinical records of neonates were reviewed in order to investigate the status of NIs and to identify and describe causes and factors contributing to the incidence of NIs in NICU at the selected Public Healthcare facility in Saudi Arabia.

3.2.3 Cross-sectional design

Cross-sectional designs also known as one-shot or status studies are some of the most commonly used designs by social science researchers and are best suited to studies aimed at finding out the prevalence of a phenomenon, situation, problem, attitude or issue by taking a cross-section of the population (Kumar 2019:228). They are useful in obtaining an overall picture as it stands at the time of study. In this study, the researcher collected data at one location where clinical records of neonates pertaining to the identified problem were extracted to identify the NI rate, to determine prevalent organisms as well as to identify causes and factors leading to NIs in NICU at the healthcare facility selected for this study. The advantage of using a cross-sectional design is that it is economical although inferring changes over time with such designs is problematic (Polit & Beck 2017:170).

3.2.4 Retrospective document analysis

Retrospective document analysis is where a phenomenon existing in the present is linked to phenomena that occurred in the past (Polit & Beck 2017:204). The researcher began with the research problem and then examined the correlation to potential causes. Retrospective studies are much cheaper and the data used in retrospective analysis was already collected for other purposes other than research. Therefore, bias was minimised because the outcome of this research was not the original reason for the data to be collected (Mann 2003:55). The data on clinical records reviewed by the researcher was collected during patients' admission and hospital stay.

Different causes and factors leading to nosocomial infections were identified and described by reviewing clinical records for a period of two years from the 1st October 2017 to the 30th September 2019.

3.3 RESEARCH METHODOLOGY

Research methods or the research methodology is defined as a particular way of knowing about reality (Brink, Van der Walt & Van Rensburg 2012:24). The target population, sampling, data collection, data analysis and ethical considerations were discussed.

3.3.1 Research setting

A research setting is the physical location and conditions in which data collection takes place in a study (Polit & Beck 2017:744). This study was conducted at a specific Public Healthcare facility in Saudi Arabia. The selected healthcare facility is a public institution that provides tertiary healthcare to military and non-military dependents in the region. The neonatal unit is a 51-bedded unit divided into intensive care area (IC), intermediate area (IM) and continuous care area (CC). Patients in the IC area are the most critical, ventilated and require a one to one nurse-patient ratio. The ones in IM are mostly on nasal cannula oxygen, they require moderate observation and a one to two nurse-patient ratio while the ones in CC are in preparation for discharge with a nurse-patient ratio of one to three.

3.3.2 Research population

A population is the entire group of persons or objects that are of interest to the researcher (Brink et al 2012:131). In this study, the population was one hundred and thirty-eight (138) clinical records of neonates who developed nosocomial infections during their stay in NICU of a Public Healthcare facility in Saudi Arabia for a period of two years, from the 1st October 2017 to the 30th September 2019.

3.3.3 Sampling technique and sampling

Sampling refers to the process the researcher uses to select the sample from a population in order to obtain information about a phenomenon in a way that represents the population of interest (Brink et al 2012:132). Sampling also makes it easier for the researcher to conduct a study with limited resources, time and finances.

Furthermore, sampling makes it easy to analyse, interpret and generalise the results to the entire population that the sample represents (De Vos, Strydom, Fouche & Delpont 2011:224). No sampling technique was used. A census was used as the size was manageable during data collection. Therefore, one hundred and thirty-eight (138) clinical records of neonates who developed nosocomial infections during their stay at a NICU of a Public Healthcare facility from the 1st October 2017 to the 30th September 2019 was the sample. Information about all infected cases during that period was available in NICU.

3.3.3.1 *Inclusion criteria*

Inclusion criteria refer to those characteristics that the subject or an element possess to be part of the target population (Polit & Beck 2017:250). Inclusion criterion for this study was clinical records of neonates, males and females, admitted in the unit from labour to delivery room and post-natal care during the period of 1st October 2017 to 30th September 2019, as well as those who developed one or more nosocomial infections while receiving care at an NICU of a Public Healthcare facility in Saudi Arabia.

3.3.3.2 *Exclusion criteria*

The study excluded clinical records of neonates that had infections on admission and those that would have been used for pre-testing of an instrument.

3.3.4 *Development of the data collection instrument*

An instrument is anything that becomes a means of collecting information for study purposes (Kumar 2019:88). Data collection may be conducted in different ways; through structured interview schedules, observations, checklists, questionnaire, indexes and scales. The researcher used a self-developed checklist to collect data from the clinical records. Checklists, which are also called inventories are catalogues with different attributes, attitudes and perceptions which are used to examine certain characteristics of participants (Younas & Porr 2018:16). The advantages of a checklist are that it is relatively efficient and easy to understand (Polit & Beck 2017:272).

The checklist had six (6) sections (refer Annexure 5).

- Section A: *Demographic data*

Section A had two (2) close-ended questions comprising of items related to gender and age on admission.

- Section B: *Medical history*

Section B had nine (9) close-ended questions on items related to gestational age at birth, weight on admission, resuscitation record, Apgar score, admission diagnosis, vital observations, skin condition and the outcome after nursing care.

- Section C: *Causes and factors contributing to the incidence of NIs in NICU*

Section C included items on causes and factors contributing to the incidence of nosocomial infections in NICU. They are use of central lines, chest tubes, invasive ventilation, total parenteral nutrition, urine catheters, antimicrobials, type of feeding, age at onset of infection, level of care, length of admission and number of external consultations. Twenty-one (21) close-ended questions and one open-ended question on the type of surgery performed were used.

- Section D: *Nosocomial infection sites in NICU*

Section D consisted of one (1) close-ended question on NIs site covering issues such as blood, urine, tracheal aspirates, eye, wound swabs and breastmilk.

- Section E: *Prevalent organism(s) leading to NIs in NICU*

Section E consisted of one (1) open-ended question on the prevalent organisms leading to NIs in NICU.

- Section F: *Nosocomial Infection rate*

The last section, which is section F included items on determining the nosocomial infection rate and there was one (1) close-ended question.

3.3.5 Pre-testing of the instrument

Pre-testing is a procedure for testing and validating an instrument by administering it to a small group of participants from the intended test population and it involves carrying out all aspects of the data collection on a small scale (De Vos et al 2011:267). Pre-testing of the checklist (refer Annexure 5) was conducted after the instrument was reviewed and accepted by the researcher's supervisor, the NICU director and the statistician. The pre-testing of the checklist was necessary in order to help the researcher correct unclear items and identify missing information. A checklist was pre-tested for content validity as well as its reliability in order to collect data for the main study.

The pre-testing of the checklist was conducted at the same healthcare facility in Saudi Arabia after approval to conduct the study was granted by the Research and Ethics Committee of the Department of Health Studies at the University of South Africa (Unisa) (refer Annexure 1) and by the institution's Ethics and Research Committee (refer Annexure 2.1). Four clinical records were pre-tested on the 20th of July 2020 after Saudi Arabia has lifted its nationwide curfew on the 21st June 2020 (Saudi Gazette 20 June 2020).

In order to adhere to the principles of minimising the spread of the COVID-19 virus, a surgical mask was worn on entering the NICU, social distancing of at least one meter was maintained and hand rub with 70% alcohol gel was performed before and after entering the unit. Furthermore, gloves were worn when handling clinical records. Prior to commencement of the pre-testing, the researcher randomly selected five (5) medical record numbers from the NICU census of infected cases to be submitted to the medical records personnel in order to request the clinical records. The required medical record numbers were typed and printed in NICU and submitted on the 16th July 2020 to the medical records personnel together with the approval letters from the university's and the institution's research and ethics committees.

Social distancing of at least one meter was still maintained and a surgical mask worn before entering the medical records department. On the 17th July 2020, the medical records personnel advised that only four (4) clinical records were ready and placed in the doctors' room within the medical records department. The 5th clinical record could not be located, it was missing. The room which was used by the researcher for pre-testing, was for research purposes only and it is called the doctor's room as most researchers are doctors and are within the medical records department. The researcher made an appointment to use the doctors' room to conduct pre-testing of the checklist to avoid having too many people in the room at the same time in order to adhere to social distancing to help minimise the spread of COVID-19 virus.

On the 20th of July 2020, the researcher approached the medical records department for pre-testing of the instrument. A surgical mask was worn. Hand rub with 70% alcohol gel was done at the entrance and gloves worn before entering the medical records department and touching the clinical records.

Clinical records were packed in a compartment with the list that the researcher submitted. Clinical records were double checked with the medical records personnel against the list provided to ascertain that clinical records provided were the correct ones. A surgical mask and gloves were still worn by the researcher and the medical records personnel. Social distancing of at least one meter was still maintained. Pre-testing of one clinical record took forty-eight (48) minutes. It took the researcher three hours and forty-five (45) minutes to complete four clinical records. Informed consent from the research respondents was waived as clinical records which are hospital property were used.

Therefore, the permission letter to conduct the study from the selected Public Healthcare facility (refer Annexure 2) and approvals which were granted to conduct the study by the Ethics Research committee of the selected healthcare facility (refer Annexure 2.1), the Director of NICU (refer Annexure 3.1) and the Director of Medical Records (refer Annexure 4.1) were used as informed consent to use clinical records. Names of patients and healthcare professionals were not used in order to maintain confidentiality. Unique identification known only by the researcher was used to maintain anonymity. Each clinical record had its own checklist.

On completion of the pre-test, requested clinical records were given back to medical records personnel using the list submitted on request so that they can be filed in their respective shelves. This was done so as to ensure that the same clinical records with the same medical record number requested were the same ones being returned.

The results of the pre-test were used to make amendments to the structure of the checklist and add missing information as well as correct unclear items. The researcher noted unclear questions in section A, item 2 and section B, item 1. These questions were subsequently corrected. In section B, question 4, 8 and 9 missing information was identified and added. In section C, question 1.2, 2.2, 4.2 and 8 missing information was added and unclear questions clarified. The supervisor, the statistician and the neonatal intensive care unit director were consulted for approval before the final checklist was corrected in preparation for use in the main study. Clinical records used for pre-testing were not used in the main study to avoid duplication of data. The corrected and approved checklist (refer Annexure 5) was used for data collection of the main study.

3.4 DATA COLLECTION

Data collection is the process of gathering information to address a research problem (Polit & Beck 2017:725). Data was collected from the 27th of September 2020 to the 19th October 2020. Since data collection was conducted during the COVID-19 pandemic, it was imperative for the researcher to adhere to COVID 19 guidelines. Saudi Arabia lifted its nationwide curfew on the 21st June 2020 (Saudi Gazette 20 June 2020).

Data was collected from the medical records section of the selected healthcare facility after ethical clearance was granted by the Department of Health Studies' Research and Ethics Committee of the University of South Africa and the permission was granted by Ethics Research Committee of the selected Public Healthcare facility.

In preparation for data collection, medical record numbers obtained from the census of infected cases at the neonatal intensive care unit were typed by the researcher on a separate document in order to submit the list to the medical records department personnel to request the clinical records. The researcher targeted one hundred and thirty-eight (138) clinical records. On entering the neonatal intensive care unit, the researcher did hand rub with 70% (seventy) alcohol based solution, wore a surgical mask and gloves were also worn on handling clinical documents in adherence to COVID-19 guidelines.

Typed medical record numbers from NICU were printed by the researcher and submitted to the medical records personnel at the medical records department to extract clinical records of neonates for a period of two years, from the 1st October 2017 to the 30th September 2019. In order to adhere to the principles of minimising the spread of COVID-19 virus before entering medical records department, a surgical mask was worn by the researcher and the medical records personnel. Hand rub done with 70% alcohol gel before gloves were worn by the researcher and the medical records personnel on handling clinical records. Social distancing of at least one meter maintained. The clinical records used in pre-testing of the checklist were not included in the main study to avoid duplication of data. The researcher waited for a period of two weeks for the medical records personnel to compile one hundred and eleven (111) clinical records. Twenty-seven (27) deceased patients' clinical records had already been sent to a storage that is away from the institution's premises and were yet to be collected.

The medical records director telephonically notified the researcher of the one hundred and eleven (111) clinical records that were ready. On the 27th September 2020, the researcher approached the medical records department for data collection with the printed pre-tested checklists. COVID-19 protocols were still observed as required. Medical records personnel showed the researcher the area where all the requested clinical records were kept. One hundred and eleven clinical records were packed in a shelf with the list that the researcher submitted for request.

The clinical records were double checked with the medical records personnel against the list to ascertain that clinical records provided were the correct ones. Deceased patients' clinical records were still being searched for. All records provided by medical records personnel were recorded and signed by the researcher in a book at the medical records department as evidence that they were received by the researcher. The researcher compiled a list of all clinical records received for evidence, the list was used for returning clinical records to medical records personnel for re-filing after data collection. One hundred and eleven (111) clinical records which were to be used for data collection were kept under the supervision of the medical records department personnel to ensure that no records were taken out of the facility during data collection period.

Data was collected using the pre-tested checklist from Sunday to Thursday (these are weekdays), from 08:00 to 16:00 on a daily basis for a period of two (2) weeks, from the 27th September 2020 to the 11th October 2020. It was not possible for all clinical records to be found at the same time, therefore the rest (27 records) were collected as they became available. This was on Tuesday the 13th of October, Wednesday the 14th of October and Monday the 19th of October 2020. Data collection was finally completed on the 19th of October 2020, it took seventeen (17) days in total. The researcher had 138 completed checklists and these were used for data analysis.

A similar checklist was used for data collection to ensure consistency, however, each and every clinical record's information was recorded on its own checklist. Unique identification only known to the researcher was used on all records to maintain anonymity. Informed consent from the research respondents was waived as clinical records which are hospital property were used. The permission which was granted by the Ethics Research Committee of the selected public healthcare facility (refer Annexure 2) and approvals which were granted to conduct the study by the Ethics Research committee of the selected healthcare facility (refer Annexure 2.1),

the Director of NICU (refer Annexure 3.1) and the Director of Medical Records (refer Annexure 4.1) were used as informed consent to use clinical records. Names of patients and healthcare professionals were not used to maintain confidentiality. Completed checklists were kept in a researcher's locked cupboard in the neonatal intensive care unit and the key was accessible to the researcher only. Data was also transcribed into the researcher's computer which is password secured in preparation for data analysis.

3.5 DATA ANALYSIS

Data analysis is the process of bringing order, structure and meaning to the mass of collected data and it is an activity of making sense of or interpreting data (De Vos, et al 2011:444). Descriptive statistics was used to provide answers to research questions. Baseline and demographic characteristics were summarised using descriptive measures. A statistician assisted in analysing and summarising data (refer Annexure 6). IBM Statistical package for the Social Sciences (SPSS) version 26 was used to calculate the statistics. Frequency distribution tables, figures and graphs were used to present and describe results of the study. The details of data analysis will be discussed in Chapter 4.

3.6 VALIDITY AND RELIABILITY

3.6.1 Validity

Validity is defined as a determination of how well the instrument reflects the abstract concepts being examined (Burns & Grove 2011:334).

3.6.1.1 *Internal validity*

Internal validity is the degree to which changes in the dependant variable are indeed due to the independent variable rather than to something else (De Vos et al 2011:190).

In this study, there are no threats to internal validity as this is a retrospective study where information already exists from the past. The data collection instrument that was used to gather information on the occurrence of nosocomial infections in NICU was pre-tested to avoid threats due to instrumentation.

3.6.1.2 *Content validity*

Content validity refers to the extent to which an instrument's content adequately captures the construct, whether an instrument has an appropriate sample of items for the construct being measured (Polit & Beck 2017:310). The checklist was submitted to the researcher's supervisor, the NICU director and to the statistician to ascertain whether the information was relevant and adequately addresses the research questions.

3.6.1.3 *Design validity*

Design validity is a measure of the truth or accuracy of a claim and it is central in determining whether research findings are sufficiently valid to add to the evidence base for patient care (Burns & Grove 2011:221).

The use of clinical records of neonates with information that was collected routinely and independently for a period of two years, from the 1st October 2017 to the 30th September 2019 reduced the potential of an observer bias.

3.6.1.4 *External validity*

It is about the generalisability of causal inferences. It concerns whether inferences about observed relationships will hold over variations in persons, setting, time or measures of the outcomes (Polit & Beck 2017:216). The results of the study will be generalised to other healthcare facilities in Saudi Arabia. Furthermore, recommendations may benefit NICU in general, healthcare providers in NICU and scholars who aspire to conduct similar studies.

3.6.2 Reliability

The degree to which the instrument can be depended upon to yield consistent results if used repeatedly over time is defined as the reliability (Brink et al 2012:171). The pre-testing of the data collection instrument was conducted before data collection of the main study to identify weaknesses and correct any ambiguity at the same healthcare facility to ensure reliability. The checklist was pre-tested using four clinical records.

Four clinical records that were used to pre-test the instrument, were not used in the main study to avoid duplication. To ensure internal consistency the same kind of information was collected from each clinical record. An instrument is said to be internally consistent to the extent that its items measure the same trait (Polit & Beck 2017:307).

The services of a statistician were used in evaluating internal reliability through Cronbach's Alpha which measures how closely related a set of items are as a group.

3.7 ETHICAL CONSIDERATIONS

Ethical considerations refer to preferences that influence behaviour in human relations, conforming to a code of principles, the rules of conduct and the responsibility of the researcher (De Vos et al 2011:145).

3.7.1 Researcher specific ethical considerations

The research proposal was submitted to the Research and Ethics Committee of the University of South Africa's Department of Health Studies for Ethical Clearance (refer Annexure 1). Furthermore, letters were written to the Ethics Research Committee (refer Annexure 2) of the specific Public Healthcare facility, the Director of NICU (refer Annexure 3) and the Director of Medical Records (refer Annexure 4) at the specific Public Healthcare facility to request permission to conduct the study and to access clinical records. Approvals to conduct research were granted by the Research and Ethics Committee of the University of South Africa's Department of Health Studies (refer Annexure 1), Ethics Research Committee at the selected healthcare facility (refer Annexure 2.1), the NICU director (refer Annexure 3.1) and the medical records director (refer Annexure 4.1).

3.7.2 Records-specific ethical considerations

3.7.2.1 *Informed consent*

Informed consent implies that respondents are made adequately and accurately aware of the type of information wanted from them, why the information is being sought, what purpose it will be used for, how they are expected to participate in the study and how it will directly or indirectly affect them (Kumar 2019:439). In this study, informed consent from the research respondents was waived as clinical records which are hospital property were used.

Therefore, the permission letter to conduct the study from the selected Public Healthcare facility (refer Annexure 2) and, approvals which were granted to conduct the study by the Ethics Research committee of the selected healthcare facility (refer Annexure 2.1), the Director of NICU (refer Annexure 3.1) and the Director of Medical Records (refer Annexure 4.1) were used as informed consent to use clinical records.

3.7.2.2 Confidentiality

Confidentiality is a pledge that any information which participants have provided will not be publicly reported in a manner that identifies the participants and will not be accessible to others (Polit & Beck 2017:147). Names and medical record numbers of patients and healthcare professionals were not used throughout the study. Patients' clinical records were not removed from the medical records department.

3.7.2.3 Anonymity

This is the protection of participants' confidentiality such that even the researcher cannot link individuals with the data they provided (Polit & Beck 2017:719). To ensure anonymity each and every record was uniquely identified using a system devised by the researcher. Furthermore, names of patients and healthcare workers as well as medical record numbers were not used.

3.7.2.4 Scientific honesty

The researcher acknowledged authors from all sources referenced in the study. Clinical records were reviewed and data transcribed accurately using the checklist designed by the researcher (refer Annexure 5).

3.8 CONCLUSION

This chapter discussed the research design and methodology, including the population, sampling technique, pre-testing of the instrument, the data collection instrument, data analysis, ethical considerations and permission to conduct the study.

The following chapter, chapter 4 will discuss data analysis, presentation and description of the research results.

CHAPTER 4

DATA ANALYSIS, PRESENTATION AND INTERPRETATION

4.1 INTRODUCTION

In chapter 3, the research design and methodology was discussed. This chapter discusses data analysis, presentation and interpretation of the results based on research objectives. The objectives for this study were:

- to determine the neonatal infection rate in NICU at a specific healthcare facility.
- to identify nosocomial infection sites in NICU.
- to indicate the prevalent organisms leading to NIs in NICU.
- to identify and describe the causes and factors contributing to the incidence of NIs in NICU.

4.2 DATA MANAGEMENT AND ANALYSIS

Data analysis is the process of bringing order, structure and meaning to the mass of collected data and the activity of making sense of interpreting and theorising it (De Vos, Strydom, Fouche & Delpont 2011:444). Data was managed and analysed quantitatively and descriptively. The same data extracted from clinical records at the selected healthcare facility were analysed. Frequency distribution tables, figures and graphs were used to present and describe results of the study. Pie charts, bar charts and tables contain variable information in the form of frequencies and percentages. Similar questions were grouped together for analysis. Information was arranged according to the variables on the checklist. An independent statistician was used to help analyse through the use of IBM SPSS version 26.

4.3 RESEARCH RESULTS

Research results are presented based on the following pre-determined variables:

- Demographic data;
- Medical history;
- Causes and factors contributing to the incidence of nosocomial infections in NICU;
- Nosocomial infection sites in NICU;
- Prevalent organism(s) leading to Nis in NICU and
- Nosocomial infection rate.

4.3.1 Sample characteristics

A total of 138 checklists were completed by the researcher during a retrospective document analysis conducted from the 27th of September 2020 to the 19th of October 2020. All checklists had complete information obtained from clinical records.

Table 4.1: Number of clinical records reviewed (N=138)

Gestational Age	Frequency (n)	Valid percent (%)
*<28+6weeks	38	27.5
*29 weeks to 33+6 weeks	38	27.5
*34 weeks to 36+6 weeks	25	18.1
*>37 weeks	37	26.8
Total	138	100

4.4 SECTION A: DEMOGRAPHIC DATA

Section A addressed gender which is male and female and gestational age on admission as risk factors for nosocomial infections.

4.4.1 Gender

The researcher had to indicate on each checklist by encircling the appropriate gender of the neonate.



Figure 4.1 Gender (N=138)

The results as shown in figure 4.1, revealed that out of the one hundred and thirty-eight (138) clinical records reviewed, 50.7% (n=70) were females and 49.3% (n=68) were males. Results of this study show that more females developed nosocomial infections compared to males. The results differ from findings of the study conducted in India on healthcare associated infections in neonatal intensive care unit and its correlation with environmental surveillance by Kumar et al (2018:277) who identified male gender as a significant independent predictor of healthcare associated infections. Samani, Keivanfar, Firouzi, Seyed and Kianifar (2019:4) on their study, bacterial infections and relevant factors in neonates hospitalised at intensive care unit also more males, 57.1%, that developed NIs than females, 42.9%.

4.4.2 Age on admission

Table 4.2: Neonate age on admission (N=138)

Age	Frequency (n)	Valid percent (%)
<28+6weeks	38	27.5
29 weeks to 33+6 weeks	38	27.5
34 weeks to 36+6 weeks	25	18.1
>37 weeks	37	26.8
Total	138	100

Table 4.2 indicated that the researcher classified gestational age on admission into four categories; neonates admitted at equal or less than 28+6 weeks n=38 (27.5%), from 29 weeks to 33+6 weeks n=38 (27.5%), 34 weeks to 36+6 weeks n=25 (18.1%) and those above or equal to 37 weeks n=37 (26.8%). The frequency of neonates admitted at the age of less than 28 weeks and 29 weeks to 33+6weeks and developed NIs was higher n= 38 (27.5%) than other age groups. Results of the study concur with the results of the study on risk factors for nosocomial infections in neonatal intensive care units in Greece conducted by Nanou et al (2015:3) which indicated a significantly lower gestational age in case of nosocomial infection. The results are also similar to the results of a study conducted in China on risk factors of nosocomial infection for infants in neonatal intensive care units: A systematic review and meta-analysis which stated that, gestational age of <37 weeks posed a significantly higher NI risk, RR:3.85, 95%CI (Wang et al 2019:8215). Followed by neonates admitted at the age of more than 37 weeks n=37 (26.8%). The least age group that developed NIs was 34 weeks to 36+6 weeks at n=25 (18.1%).

4.5 SECTION B: MEDICAL HISTORY

Section B addressed the medical history of the neonate in relation to the incidence of NIs in NICU. Pre-determined elements were; gestational age at birth, weight at birth, Apgar

score, admission diagnosis, history of neonatal resuscitation, vital observations, skin condition on admission and outcome of nursing.

4.5.1 Gestational age at birth

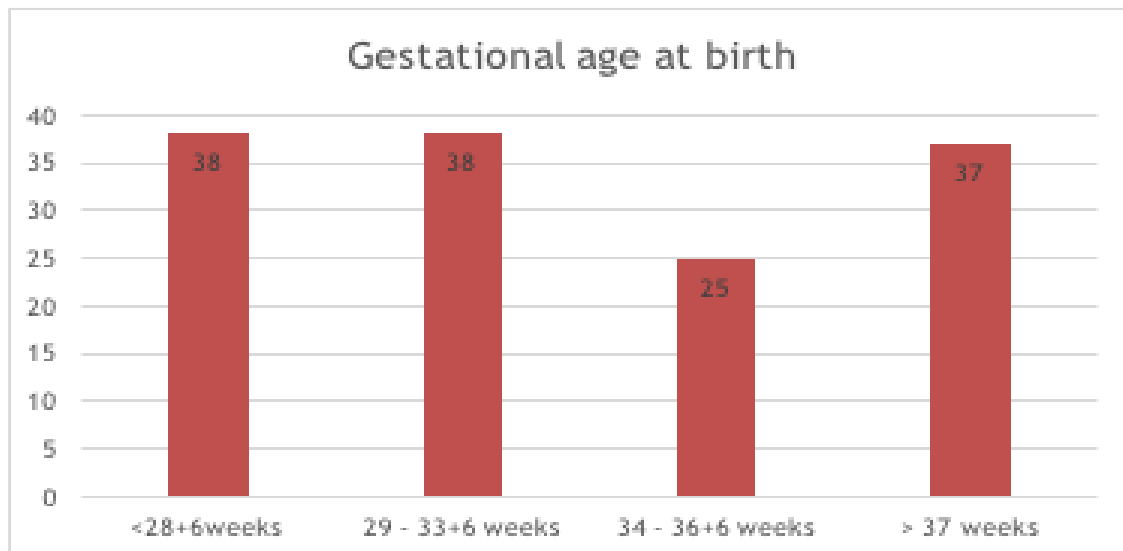


Figure 4.2 Gestational age at birth (N= 138)

The researcher had to select the gestational age at birth from classifications provided. Results revealed that babies born less than 28+6 weeks n=38 (27.5%), from 29 to 33+6 weeks n=38 (27.5%), 34 to 36+6 weeks n=25 (18.1%) and those above or equal to 37 weeks n=37 (26.8%) as shown in figure 4.2. The results of the study indicated that most of the babies (n=38) that developed nosocomial infections were those that were delivered prematurely, at less than 33+6 weeks' gestation which could be a result of under-developed skin. The study results confirm findings by Nanou et al (2015:4) on risk factors for nosocomial infections in neonatal intensive care units which stated that the lower the birth weight, the higher is the risk for nosocomial infection.

4.5.2 Weight at birth

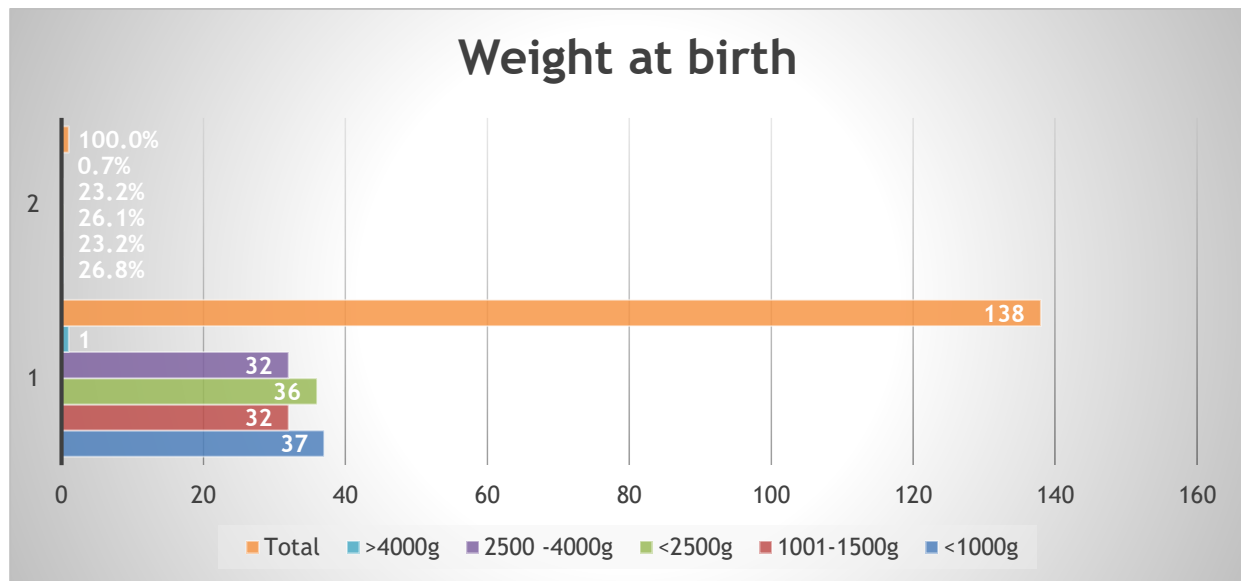


Figure 4.3 Weight at birth (N=138)

The results of the study as shown in figure 4.3 indicated that at birth, most babies are within the weight of less than 1000g n=37 (26.8%). These results could be the reason for the development of nosocomial infections as indicated on the results of the study conducted in China on risk factors of nosocomial infection for infants in neonatal intensive care units: a systematic review and meta-analysis which indicated the incidence of NI was significantly higher in infants with a body weight of <2500g (Wang et al 2019:8215). These were followed by the weight of less than 2500g n=36 (26.1%). These results also correspond with findings on neonatal nosocomial infections by Maqbool et al (2018:2) that identified lower birth weights as one of the factors leading to the incidence of nosocomial infections. The baby weights of 1001 to 1500g and 2500 to 4000g had similar frequency n=32 (23.2%). Furthermore, only one baby n=1 (0.7%) was big for gestation age which indicate that this group of neonates have a lower propensity for developing nosocomial infections.

4.5.3 Apgar score

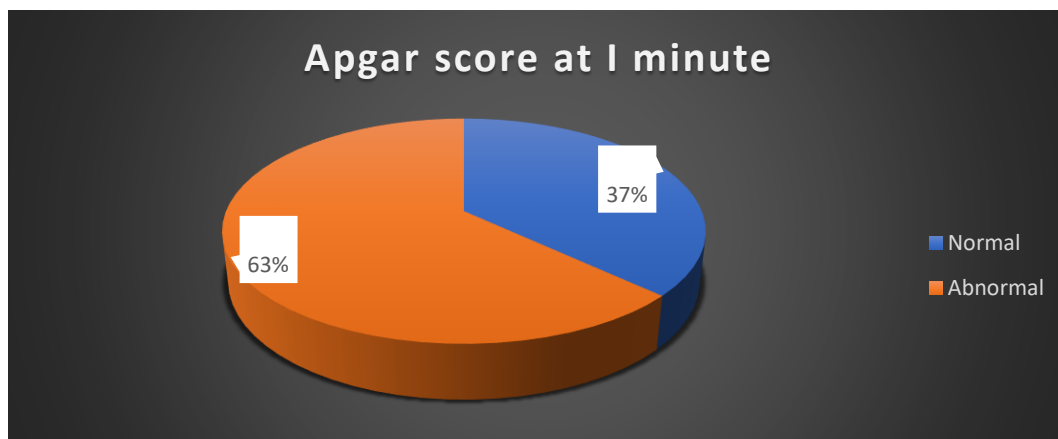


Figure 4.4 Apgar score at 1 minute (N=138)



Figure 4.5 Apgar score at 5 minute (N=138)

As indicated in figures 4.4 and 4.5, babies n=87 (63.0%) had an abnormal Apgar score in the first minute of life and only n=51 (37%) had a normal Apgar score. At 5 minutes n=102 (73.9%) had normal Apgar score, while n=36 (26.1%) of the respondents remained abnormal. The results differ from findings of the study conducted on risk factors associated with nosocomial infections in the neonatal intensive care unit at Mahatma Gandhi Memorial hospital between 2014 and 2015 by Rameshwarnath and Naidoo (2018:97), which stated that neonates with an Apgar score of less than 7 (abnormal) at 5 minutes were at greater risk of acquiring nosocomial infections. In this study, the majority n=102 (73.9%) of the neonates had abnormal Apgar score at 5 minutes and yet still developed NIs.

4.5.4 Diagnosis on admission

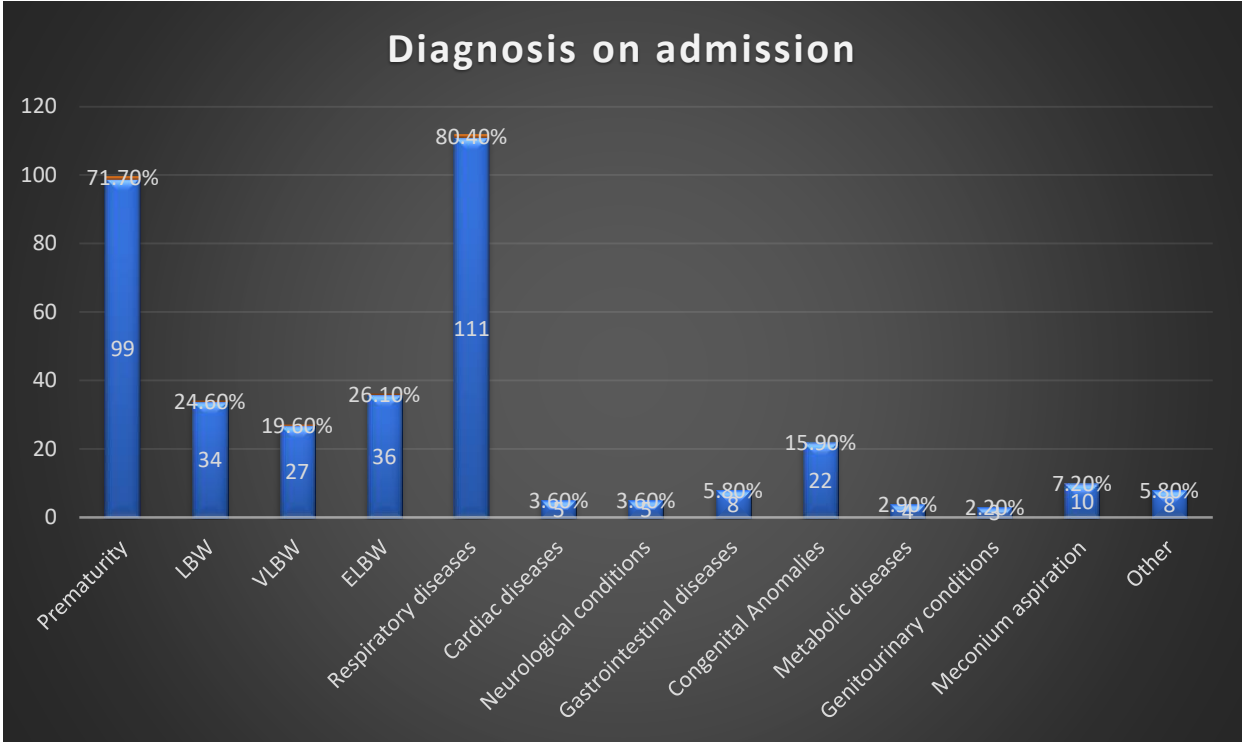


Figure 4.6 Diagnosis on admission (N=138)

Figure 4.6 depicts the diagnosis of the respondents admitted in NICU and developed NIs. Results revealed that respiratory diseases were the leading cause of admission, n=111 (80.4%) followed by prematurity n=99 (71.7%). The study confirms findings on neonatal nosocomial infections by Maqbool et al (2018:2) which identified respiratory distress as the leading cause of admission with 63,0% in the presence of NIs followed by prematurity with 16.67%. Samani et al (2019:3) results on the study conducted in Iran on bacterial infections and relevant factors in neonates hospitalised at intensive care unit differ in that they had prematurity as the most common reason for admission, 46.4%. Neonates admitted with extreme low birth weights (ELBW) were n=36 (26.10%) of respondents, low birth weights (LBW) were n=34 (24.60%), very low birth weights (VLBW) admissions were n=27 (19.60%) and the least admissions were due to genitourinary conditions at n=3 (2.20%). Therefore, results of this study showed that genitourinary conditions have a lower association with nosocomial infections while lower birth weights have a higher association.

4.5.5 History of neonatal resuscitation

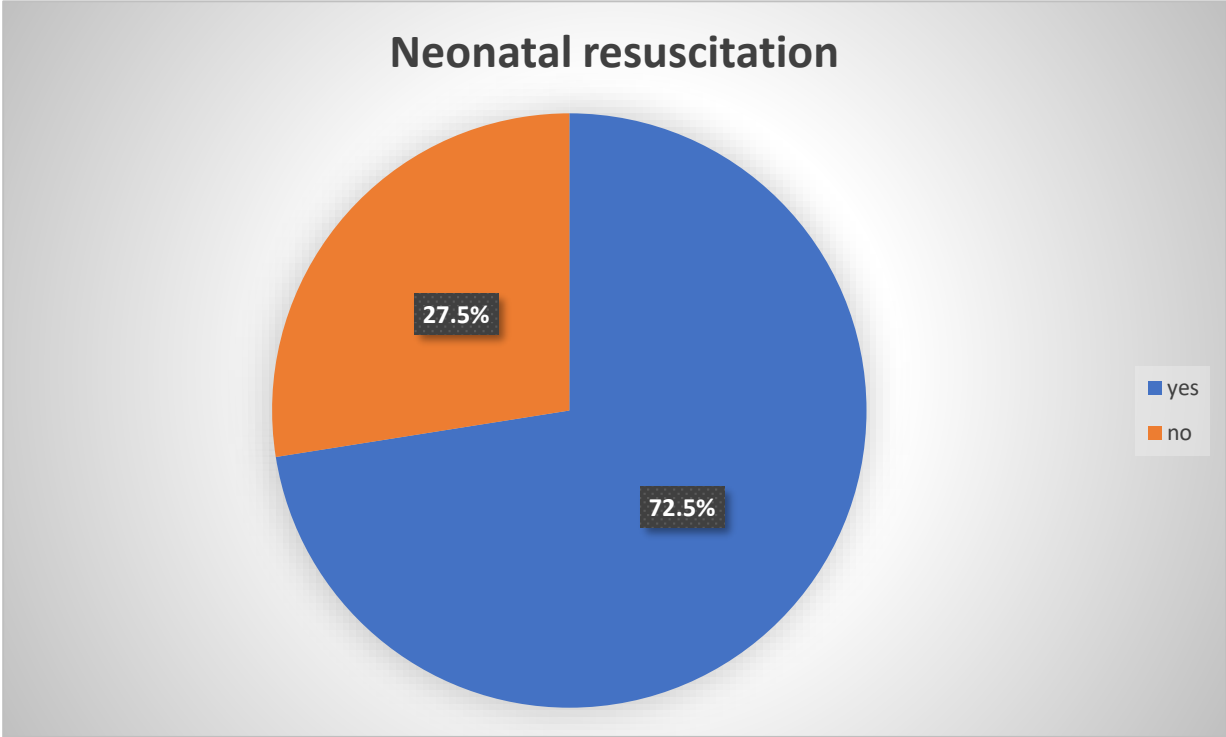


Figure 4.7 History of neonatal resuscitation (N=138)

Neonatal resuscitation is identified as a predisposing factor to development of nosocomial infections. The results in figure 4.7 revealed that n=100 (72.5%) of the respondents had resuscitation done and only n=38 (27.5%) did not receive any resuscitation. Results indicate that neonatal resuscitation is a high-risk factor for developing nosocomial infections. The results of this study differ from findings of the study conducted in India by Kumar et al (2018:277) which claim that resuscitation required as a risk factor for nosocomial infections had the lowest association (OR 0.95; 95% CI 0.65-1.35).

4.5.6 Vital observations

4.5.6.1 Temperature

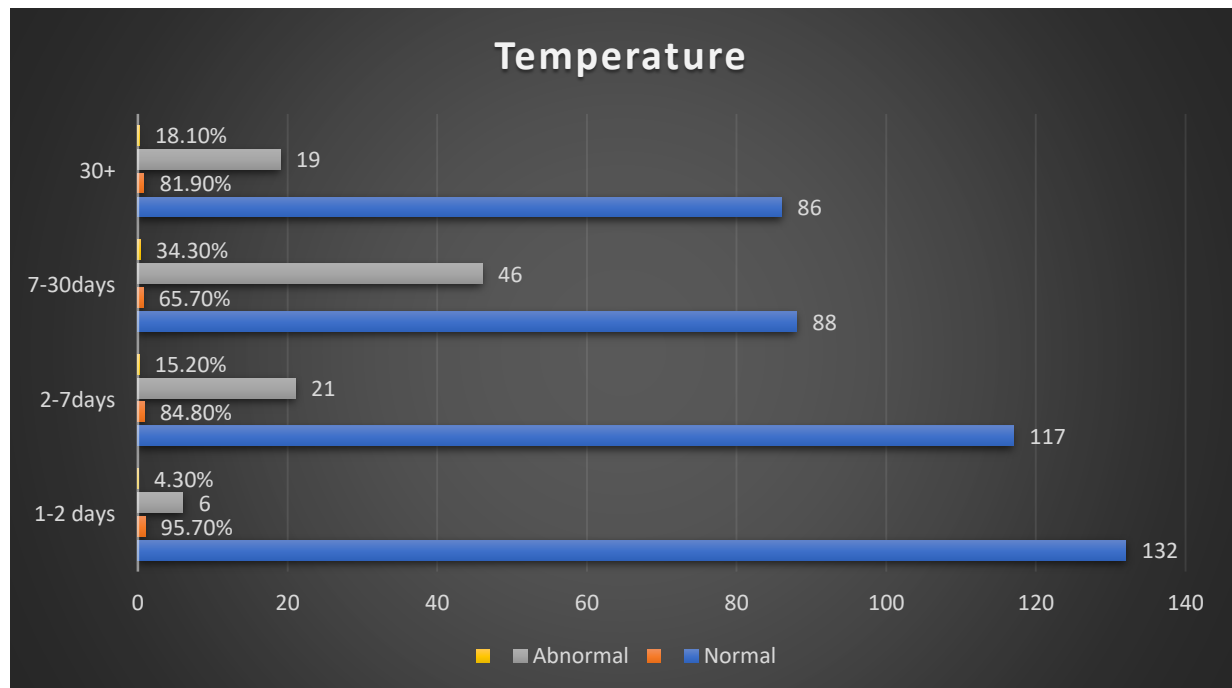


Figure 4.8 Temperature (N=138)

The results in figure 4.8 show that a total of n=132 (95.7%) babies that developed nosocomial infections had normal temperatures at day one to two days of life. A more abnormal temperature n=46 (34.30%) was observed between 7 to 30 days. At 2 to 7 days n=117 (84.8%) of the respondents had normal temperature while n=21 (15.20%) had abnormal body temperatures. This could be attributed to the fact that the longer the baby stays in NICU, the higher the chance of developing NIs which is indicated by a change in temperature. The study supports findings of the study conducted in Spain on five steps to decreasing nosocomial infections in very preterm new-borns: a quasi-experimental study which identified changes in body temperature as clinical criteria in defining late-onset neonatal sepsis (Gonzalez, Castellanos, Gutierrez, Garcia, Fructuoso, Santos, & Gonzalez 2017:29).

4.5.6.2 Pulse

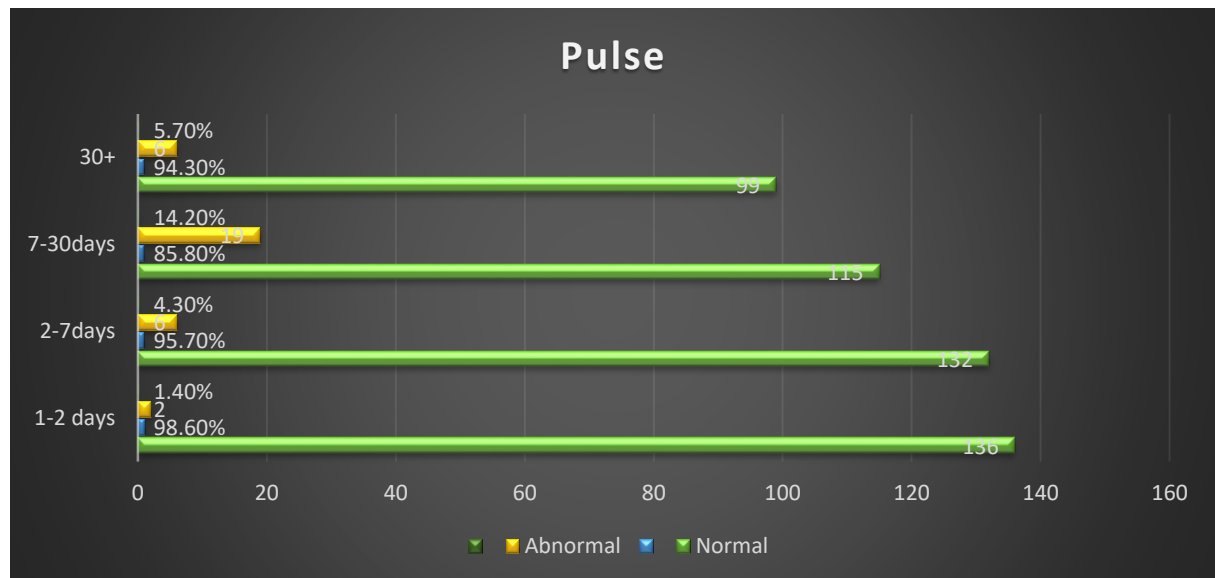


Figure 4.9 Pulse (N=138)

Figure 4.9 revealed that the majority of the respondents $n=136$ (98.6%) had a normal pulse rate on the first and second day of life while only $n=2$ (1.40%) had an abnormal pulse rate. Through-out hospital days, the pulse rate of admitted neonates remained normal for the majority of the respondents. At 7-30 days, the abnormal pulse rate increased $n=19$ (14.20%), which was the highest in this study. The results of the study indicate that pulse rate is not that much affected by the presence of nosocomial infections. The result differs with the study conducted in Spain on five steps to decreasing nosocomial infections in very preterm new-borns which identified cardiovascular instability; bradycardia or tachycardia and rhythm instability as clinical criteria in defining late-onset neonatal sepsis (Gonzalez et al 2017:29).

4.5.6.3 Respirations

Figure 4.10 revealed the results regarding respiration. The majority of the respondents $n=132$ (95.7%) had normal respirations on day 1 to 2 of admission while $n=6$ (4.30%) had abnormal respirations. This indicates that before the presence of NIs, most of the respondents had normal respiratory rates. At 7 to 30 days $n=92$ (68.70%) neonates still had normal respirations while abnormal respirations were higher during this period $n=42$ (31.30%). The results revealed that in the presence of nosocomial infections, some respondents 31.30% responded with abnormal respirations.

This result concurs with the study conducted in Spain on five steps to decreasing nosocomial infections in very preterm new-borns which identified respiratory instability, episodes of apnoea or tachypnoea as clinical criteria in defining late-onset neonatal sepsis (Gonzalez et al 2017:29).

4.5.6.4 Saturation

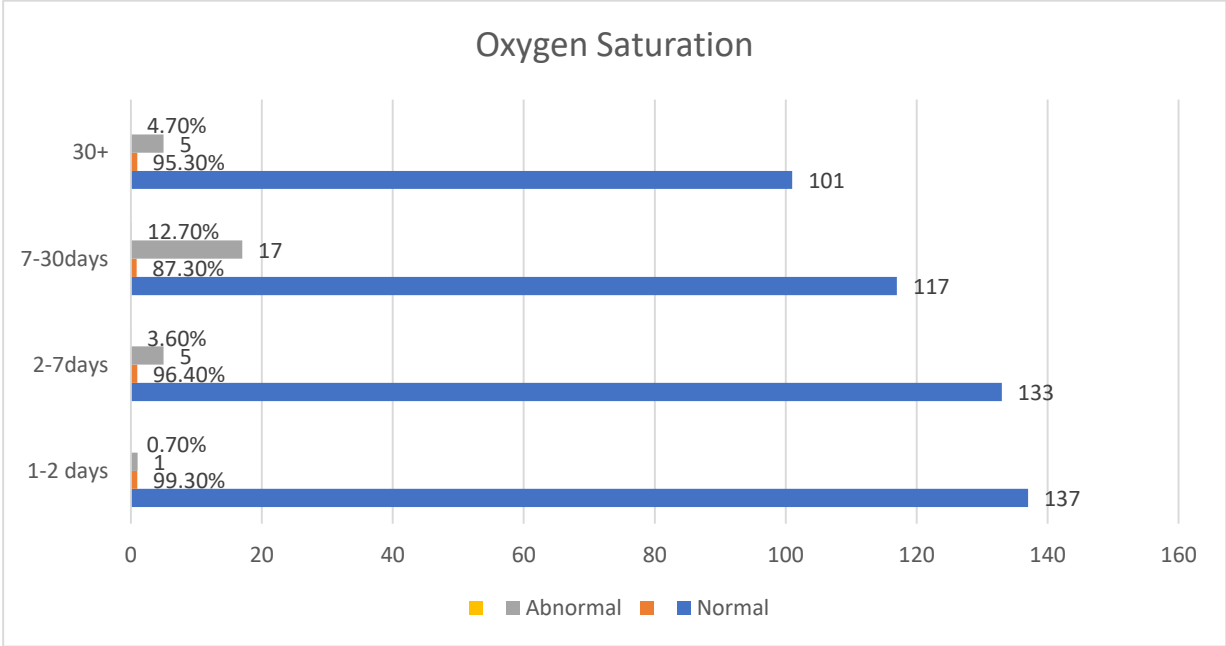


Figure 4.10 Oxygen saturation (N=138)

The results in figure 4.9 indicate that between the first day to second day of life and, second day of life to the seventh day n=137 (99.3%) and n=133 (96.4%) respectively were recorded as normal oxygen saturation values. More abnormal oxygen saturation values n=17 (12.70%) were recorded at 7 to 30 days of life compared to n=1 (0.7%), n=5 (3.60%) and n=6 (4.70%) at 1 to 2 days, 2 to 7 days and more than 30 days respectively. The results of this study showed that NIs did affect the respondents’ oxygen saturation. No previous studies were found that linked oxygen saturation to NIs.

4.5.6.5 Blood pressure

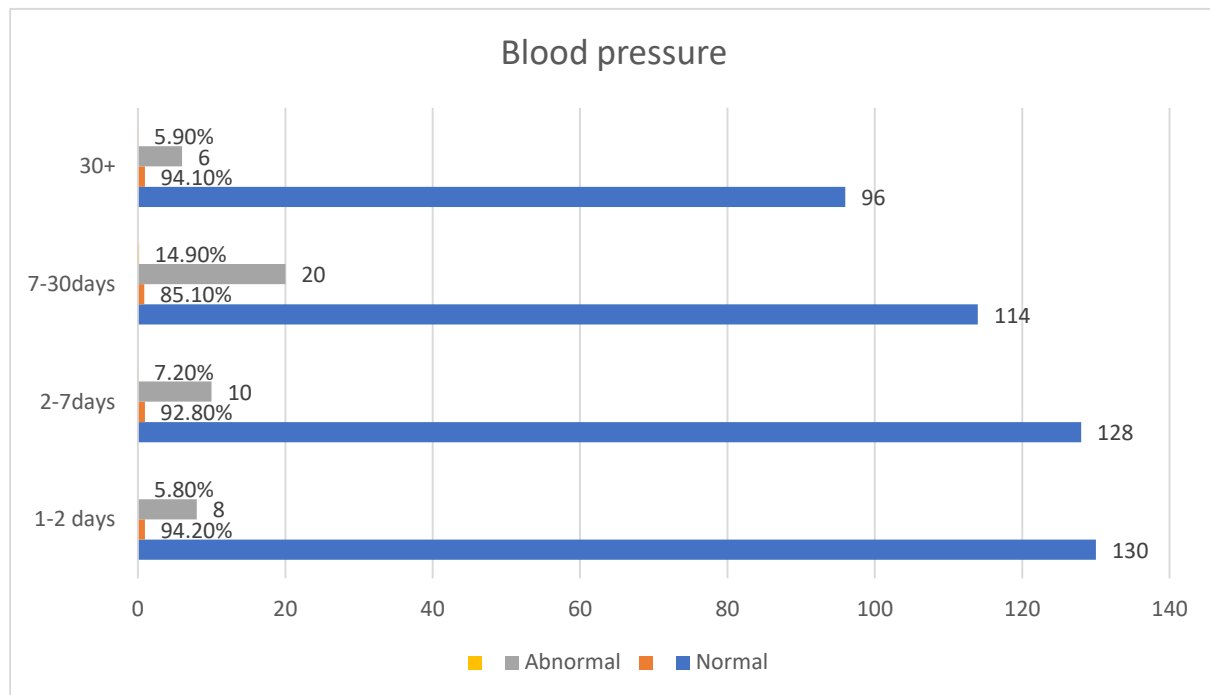


Figure 4.11: Blood pressure (N=138)

According to figure 4.11 results, a total number $n=130$ (94.2%) babies had normal blood pressures between 1 to 2 days of life while a total $n=128$ (92.8%) were recorded with normal blood pressure at 2 to 7 days of life. The majority of neonates had normal blood pressure recordings ranging at 94.20%, 92.80%, 85.10% and 94.10% respectively, while abnormal blood pressure readings were found in $n=8$ (5.80%), $n=10$ (7.20%), $n=20$ (14.90%) and $n=6$ (5.90%) respectively. The results of this study suggest that blood pressure has no significant relationship with nosocomial infections. The result differs with the study conducted on five steps to decreasing nosocomial infections in very preterm new-borns which identified cardiovascular instability and hypotension as clinical criteria in defining late-onset neonatal sepsis (Gonzalez et al 2017:29).

4.5.7 Condition of skin on admission

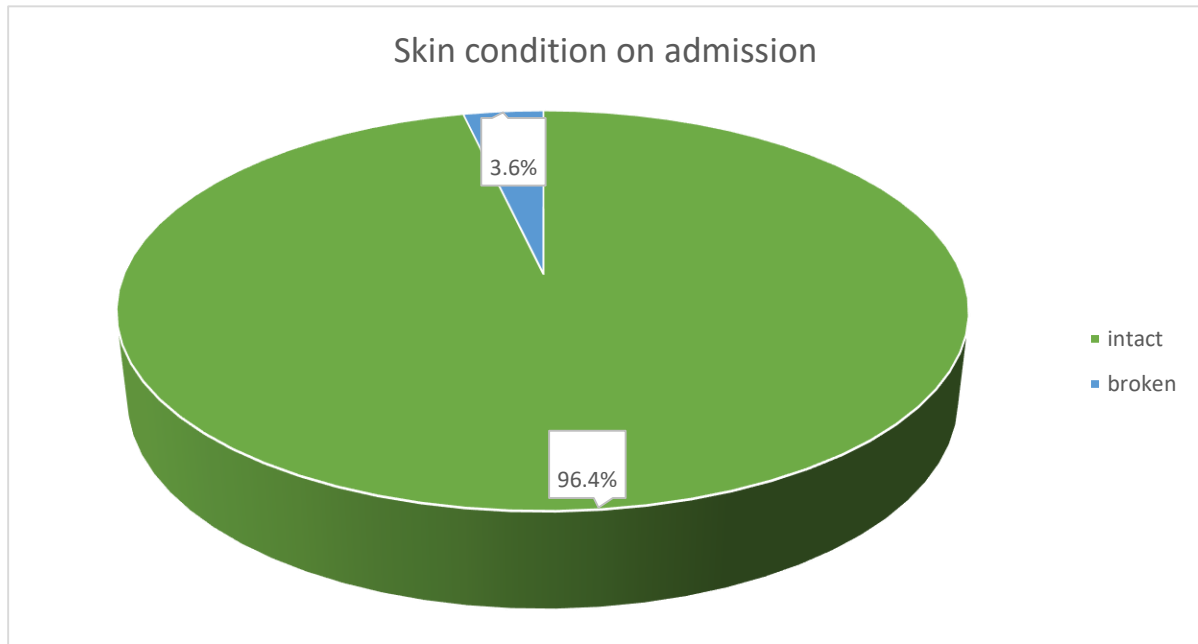


Figure 4.12 Skin condition on admission (N=138)

The results in figure 4.12 indicated the skin condition of the respondents who developed nosocomial infections during the care in NICU. The majority of the respondents $n=133$ (96.4%) had an intact skin while $n=5$ (3.6%) had a break in the skin. The skin condition was not associated with the risk of nosocomial infection. It should be noted that a break in the skin could be a site of entry for pathogens leading to NIs and yet neonates with an intact skin still developed NIs. This could be attributed to under developed skin of premature infants. This finding supports the results of the study conducted in China on risk factors of nosocomial infection for infants in neonatal intensive care units, a systematic review and meta-analysis which stated that body mass is the most important independent risk factor for NIs in premature ill infants (Wang et al 2019:8218).

4.5.8 Final diagnosis during the neonatal stay in NICU

Table 4.3: Final diagnosis after stay in NICU (N=138)

Final diagnosis	Frequency (n)	Percentage (%)
Prematurity	94	68.1
Low birth weight (LBW)	32	23.2
Very low birth weight (VLBW)	27	19.6
Extremely low birth weight (ELBW)	34	24.6
Respiratory diseases	106	76.8
Congenital cardiac diseases	19	13.8
Neurological diseases	13	9.4
Congenital anomalies	28	20.3
Metabolic disorders	5	3.6
Genitourinary conditions	6	4.3
Meconium Aspiration	6	4.3
Other	62	44.9

Table 4.3 indicates the final diagnosis of neonates that were admitted in NICU during a two-year period from the 1 October 2017 to the 30 September 2019. Respiratory diseases, n=106 (76.8%) were the majority of admissions followed by prematurity n=94 (68.1%), LBW n=32 (23.2%), VLBW were n=27 (19.6%), ELBW were n=34 (24.6%), congenital cardiac diseases were n=19 (13.8%), neurological diseases were n=13 (9.4%), congenital anomalies were n=28 (20.3%), genitourinary conditions were n=6 (4.3%), Meconium aspiration were n=6 (4.3%) and the least were metabolic disorders n=5 (3.6%). The results show that respiratory diseases and prematurity were the leading diagnosis in the incidence of NIs. These results are in accordance with findings on neonatal nosocomial infections in Srinagar by Maqbool et al (2018:2), which showed respiratory distress syndrome and prematurity n=190 (63.0%) and n=50 (16.67%) respectively.

4.5.9 Outcome after nursing care

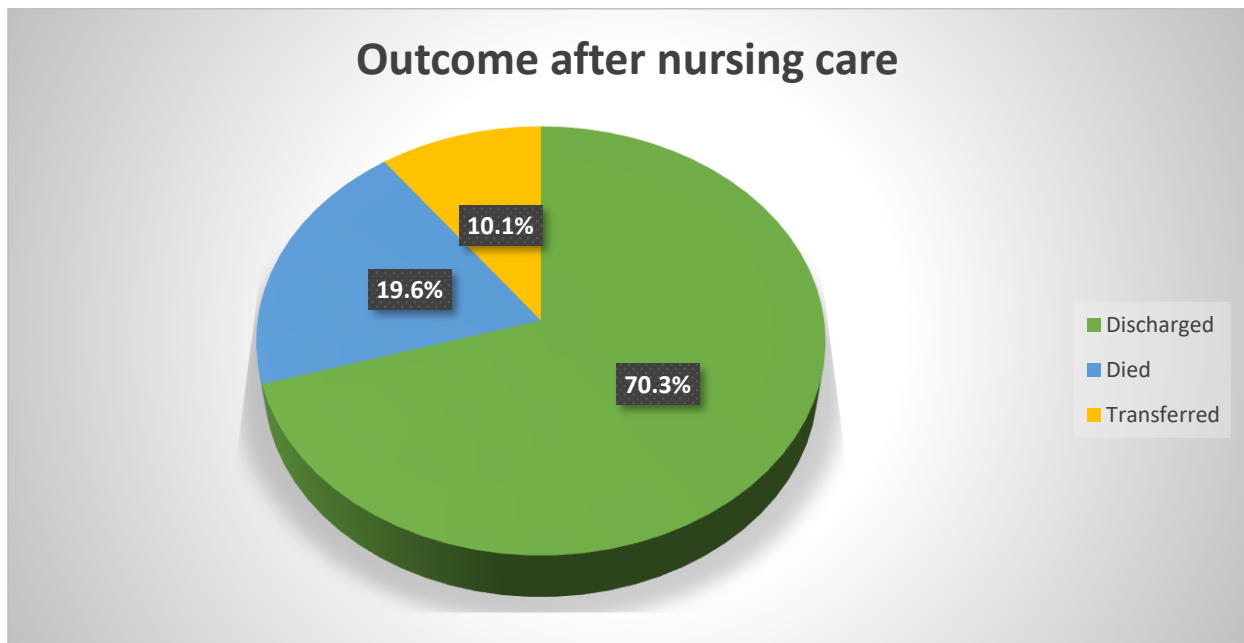


Figure 4.13 Outcome of nursing care (N=138)

The results in figure 4.13 indicate the outcome of all the babies admitted in NICU who developed NIs. Ninety-seven n=97 (70.3%) of the respondents were discharged, n=27 (19.6%) died and only n=14 (10.1%) were transferred out of NICU to other units within the healthcare facility or to other hospitals. Results of the study indicate that neonatal mortality rate due to nosocomial infections was high. These results are almost similar to results of the study on evaluating the incidence and risk factors of nosocomial infection in neonates hospitalised in the neonatal intensive care unit of Fatemieh hospital in Hamadan, Iran 2012-2013 by Basiri et al (2015:2) which had overall mortality rate of 7.6%.

4.6 SECTION C: CAUSES AND FACTORS CONTRIBUTING TO THE INCIDENCE OF NIS IN NICU

Causes and factors contributing to the incidence of NIs in NICU were reviewed as follows:

4.6.1 Use of central lines

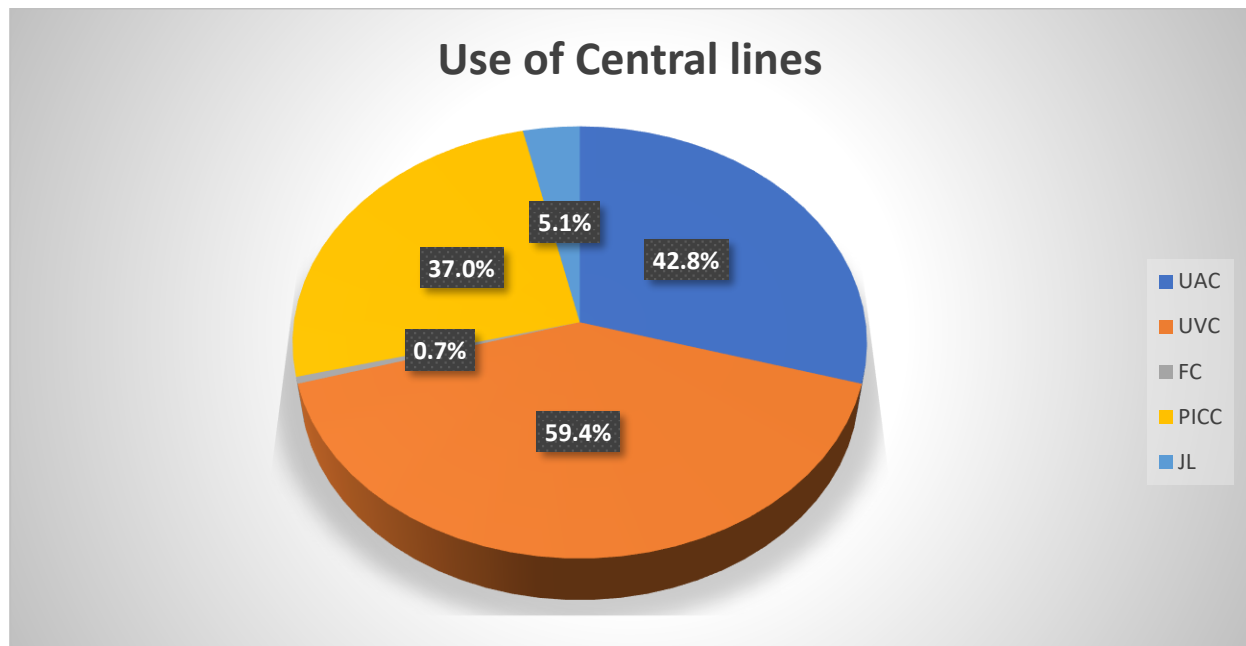


Figure 4.14 Use of central lines (N=138)

The use of central lines which are part of therapeutic interventions in NICU are a contributing factor to the incidence of nosocomial infections. The results in figure 4.14 revealed that the majority of causes and factors contributing to the incidence of NIs in NICU are related to umbilical venous catheterisation (UVC) which were the majority n=82 (59.4%), followed by umbilical arterial catheters (UAC) n=59 (42.8%), followed by peripherally inserted central catheters n=51 (37.0%), jugular central lines were n=7 (5.1%) and only n=1 (0.7%) femoral catheter.

This finding confirms the results of the study on risk factors associated with nosocomial infections in the NICU at Mahatma Gandhi Memorial hospital between 2014 and 2015 by Rameshwarnath and Naidoo (2018:95) which indicated that 67.36% of central venous catheter use on the cases. Femoral catheters are not widely used in NICU due to the close proximity to body excretions leading to high risk of blood stream infections.

4.6.1.1 Duration of central lines

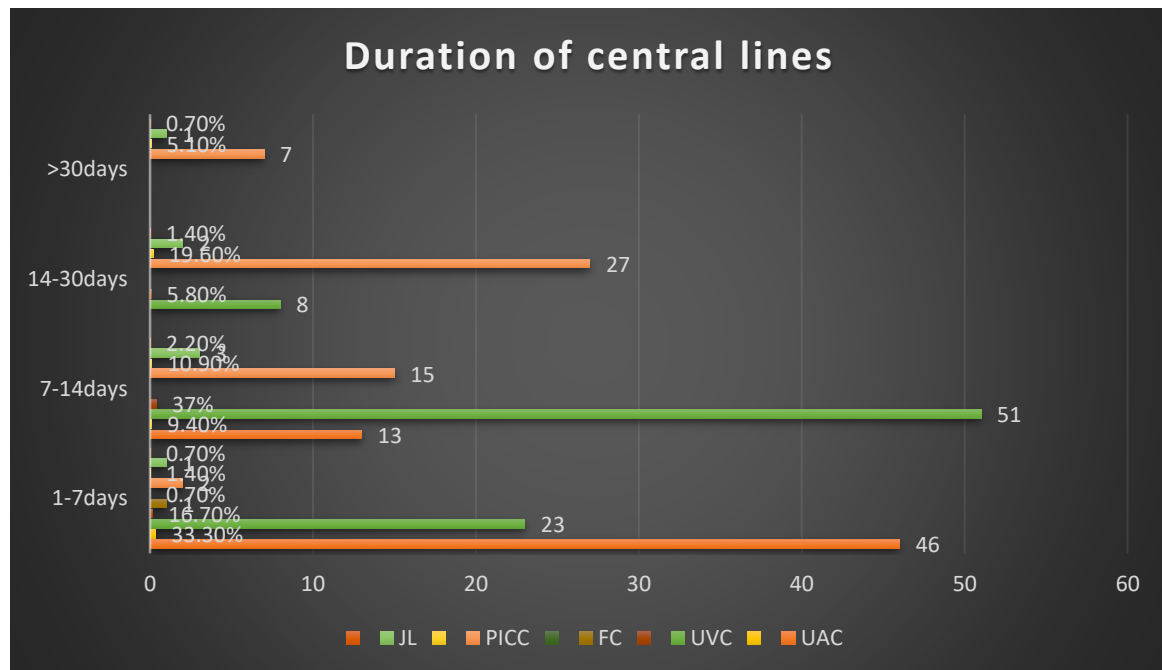


Figure 4.15 Duration of central line (N=138)

The figure 4.15 showed how long the central lines were kept in situ. It is imperative to remove the central lines as soon as possible to minimise the risk of nosocomial infections. In this study setting, it is acceptable to keep umbilical venous catheter (UVC) in situ for up to 14 days and umbilical arterial catheter (UAC) for only 5 days. The majority of UVC n=51 (37.0%) were kept in situ for a period of between 7 to 14 days, n=8 (5.8%) UVC were kept for 14 to 30 days, n=23 (16.7%) were kept for 1 to 7 days and none were in situ for more than 30 days. For UAC n=46 (33.3%) were kept for 1 to 7 days, n=13 (9.4%) were in situ for 7 to 14 days and none were kept in situ for more than 14 days or more than 30 days. Only n=1 (0.7%) femoral catheter (FC) was kept in between 1 to 7 days while peripherally inserted central catheter (PICC) n=2 (1.4%) was kept in for 1 to 2 days, n=15 (10.9%) was kept in situ for 7 to 14 days, n=27 (19.6%) was the majority duration of PICC at 14 to 30 days and n=7 (5.1%) were kept for more than 30 days. Jugular lines (JL) n=1 (0.7%) were kept in for 1 to 7 days, n=3 (2.2%) were kept for 7 to 14 days, n=2 (1.4%) were kept in between 14 to 30 days and only n=1 (0.7%) was kept in situ for more than 30 days.

The results show an acceptable (14days) duration on the majority of UVC as per the study conducted in Korea on central line-associated bloodstream infections in neonates which stated that the maximum duration of UVC should not exceed 14 days (Cho & Cho 2019:82). The duration of UAC also supports findings of the study conducted in Korea on central line-associated bloodstream infections in neonates which stated a duration of not more than 5 days (Cho & Cho 2019:82).

4.6.1.2 Care of central lines

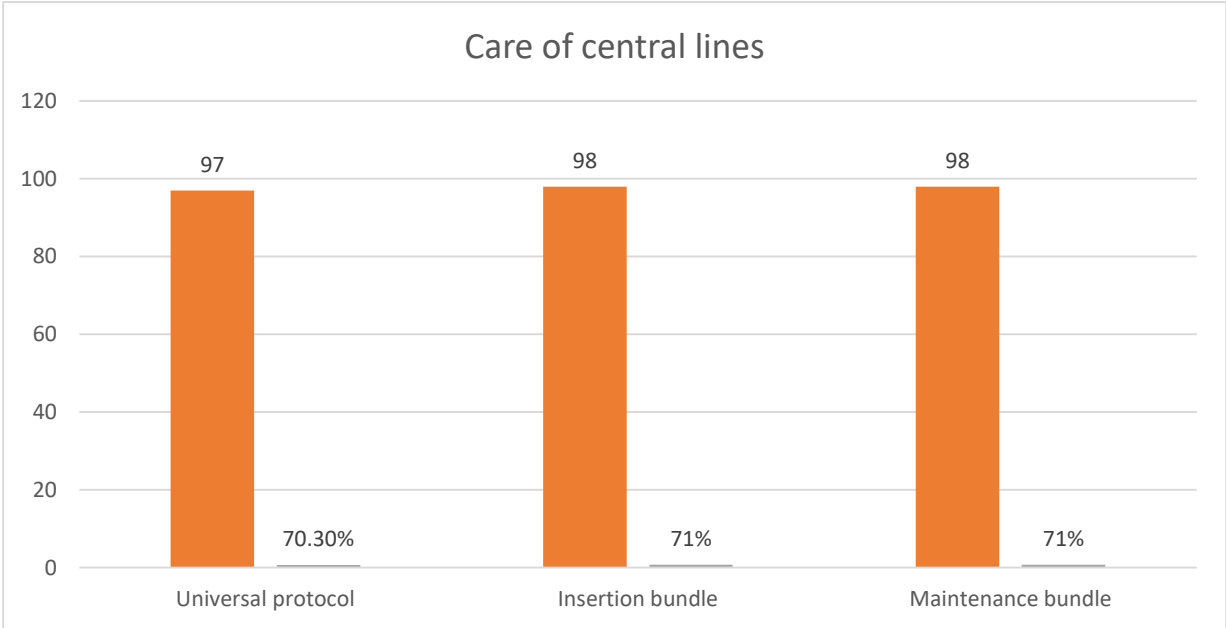


Figure 4.16 Care of central lines (N=138)

Figure 4.16 depicts the care provided for the central lines. According to Wasserman and Messina (2018:3), central line blood stream infection (CLABSI) prevention bundle are the insertion and maintenance bundles. Insertion bundles are precautions taken during the insertion of central lines and maintenance bundles are precautions taken during the care, handling or manipulation of central lines. Results from the study show that the majority n=98 (71%) of the respondents had insertion and maintenance bundles adhered to. Universal protocol was followed in n=97 (70.3%) of the respondents. Despite that, the respondents still developed nosocomial infections. These results indicate that there could be other factors which could have led to the development of nosocomial infections other than the care of central lines.

4.6.1.3 Use of invasive ventilation

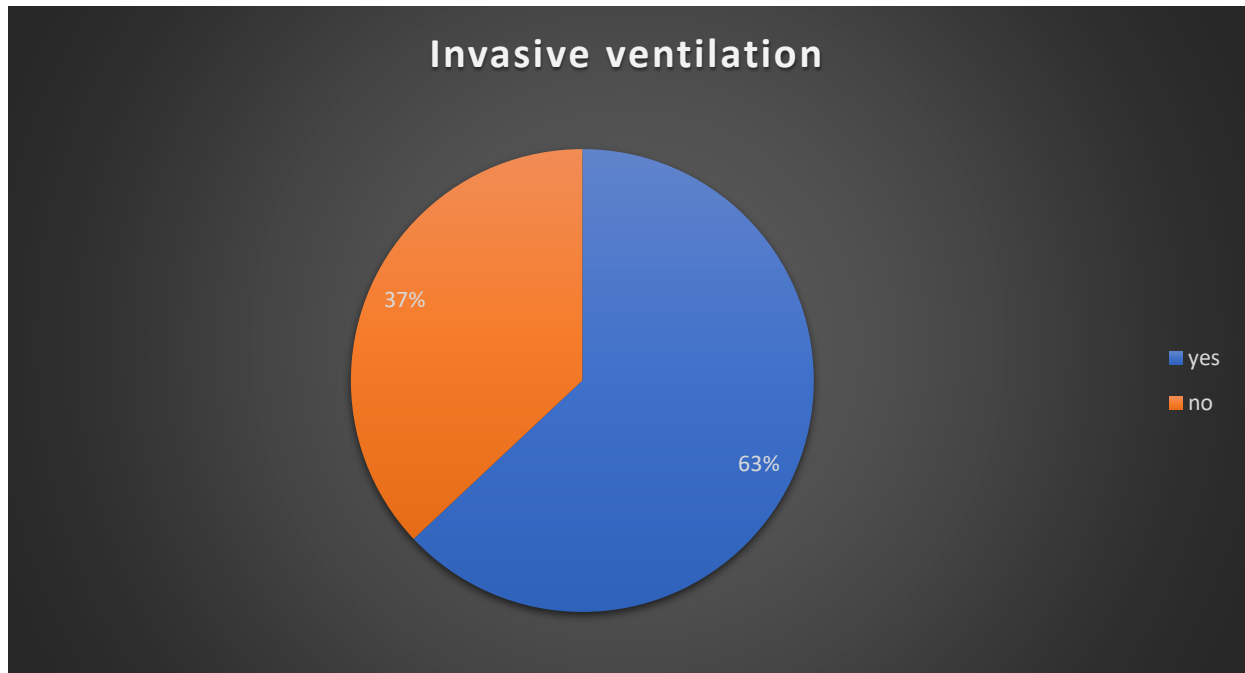


Figure 4.17 Use of invasive ventilation (N=138)

The use of invasive ventilation is a therapeutic intervention in premature neonates which contributes to a type of nosocomial infection called ventilator associated pneumonia (VAP) (Lee, Lee & Chen 2017:17). Figure 4.17 shows the results of the respondents who developed NI with invasive ventilation and those who did not. The majority of the respondents n=87 (63%) of the respondents were on invasive ventilation while n=51 (37%) were not. The results reveal ventilators as causes and factors leading to nosocomial infections.

This finding corresponds with the results of the study conducted on risk factors of nosocomial infection for infants in neonatal intensive care unit by Wang et al (2019:8215) which states that infants who underwent mechanical ventilation had a higher incidence (RR:3.16, 95% CI: 2.21 -4.50) of NI than those who did not. The results are also similar to the results of the study conducted in South Africa on risk factors associated with nosocomial infections in the neonatal intensive care at Mahatma Gandhi Memorial hospital between 2014 and 2015 which had ventilation, 33.33% associated with NIs (Rameshwarnath & Naidoo 2018:95).

4.6.2 Ventilator duration

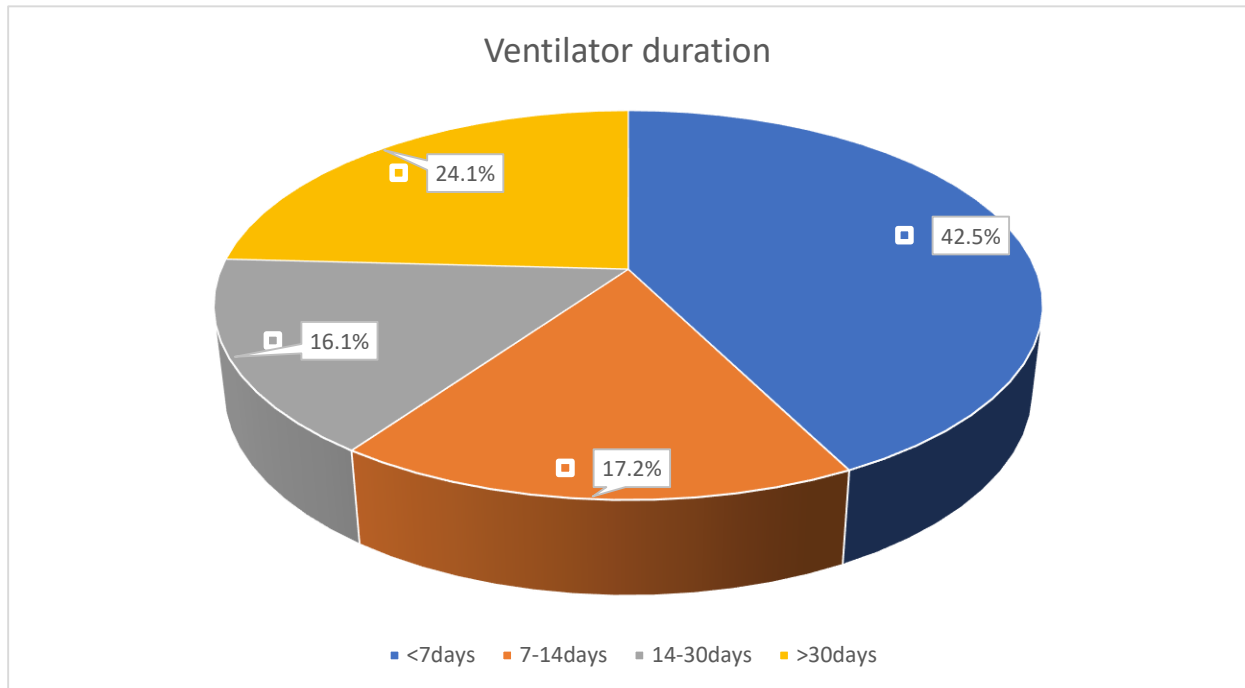


Figure 4.18 Ventilator duration (N=138)

Figure 4.18 showed the duration of invasive ventilation. The majority n=37 (42.5%) of respondents with NI had ventilation for less than 7 days, followed by n=21 (24.1%) who had ventilation for more than 30 days while n=15 (17.2%) had ventilation for 7 to 14 days. The lower duration of ventilation was n=14 (16.1%) for 14 to 30 days' duration. The results do not show the relationship of ventilator duration to the incidence of nosocomial infection. The results of this study are different from the results of the study conducted in the neonatal intensive care unit of Fatemeh hospital in Hamadan, Iran 2012-2013 by Basiri et al (2015:2) who identified long-term mechanical ventilation among others as an independent factor related to NIs.

4.6.3 Presence of chest tubes

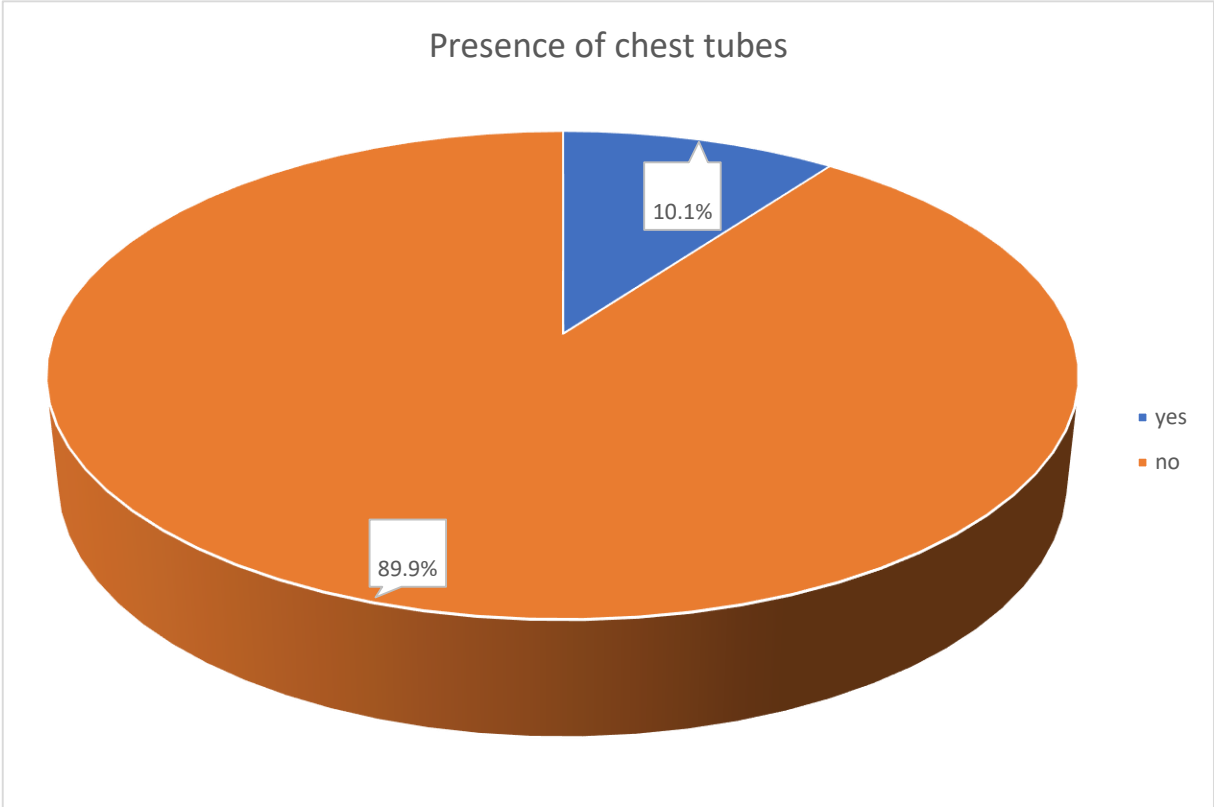


Figure 4.19 Presence of chest tubes (N=138)

Though chest tubes are one of the invasive procedures performed in NICU that may cause the incidence of NI, only n=14 (10.1%) of the respondents had chest tubes and the majority n=124 (89.9%) had no chest tubes as shown in the figure 4.19. This study concluded that presence of chest tubes was not an independent factor in causing NIs.

4.6.3.1 Duration of chest tubes

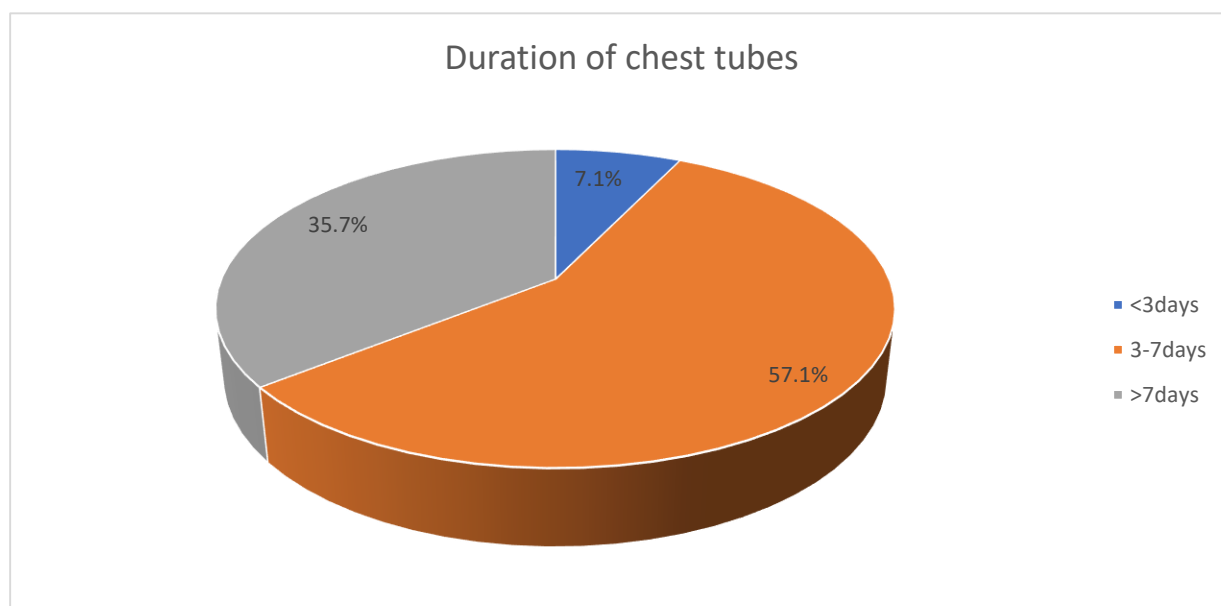


Figure 4.20 Duration of chest tubes(N=138)

Figure 4.20 showed the duration of chest tubes. The majority n=8 (57.1%) of the respondents who had chest tubes in situ had them for 3-7 days, n=5 (35.7%) had the chest tubes in for more than 7 days and only n=1 (1.7%) had a chest tube in for less than three days. In this research setting, contribution of chest tubes to nosocomial infection is minimal due to less use of chest tubes and the fact that the durations are kept to a minimum of 3 to 7 days, n=8 (57.1%).

4.6.4 Use of urine catheter

Table 4.4: Use of urine catheter (N=138)

Action	Response	Frequency (n)	Percentage
Presence of urine catheter	Yes	19	13.8%
	No	119	86.2%
Total		138	100%
Duration	<1day	15	78.9%
	>1day	4	21.1%
Care: Insertion	Yes	19	13.8%
Maintenance	Yes	5	3.6%

Table 4.4 showed how urine catheters were used in this research setting. Though a minority n=19 (13.8%) of the respondents had urine catheters, urine catheters are still considered a risk factor for NIs in neonates. The use of urine catheters in this study is minimal, n=119 (86.2%) of the respondents did not have urine catheters inserted yet they developed infections. These results differ from the results of the study conducted in Italy on surveillance of healthcare-associated infections in a neonatal intensive care unit during 2006-2010 which had urinary tract infections as the most frequent device-unrelated nosocomial infections (Crivaro et al 2015:4). All the respondents that had urine catheter inserted n=19 (13.8%) had insertion and maintenance bundles to prevent the introduction of infections. Most urine catheters n=15 (78.9%) were used for collection of urine samples for culture and thus kept for less than one day.

4.6.5 History of surgery

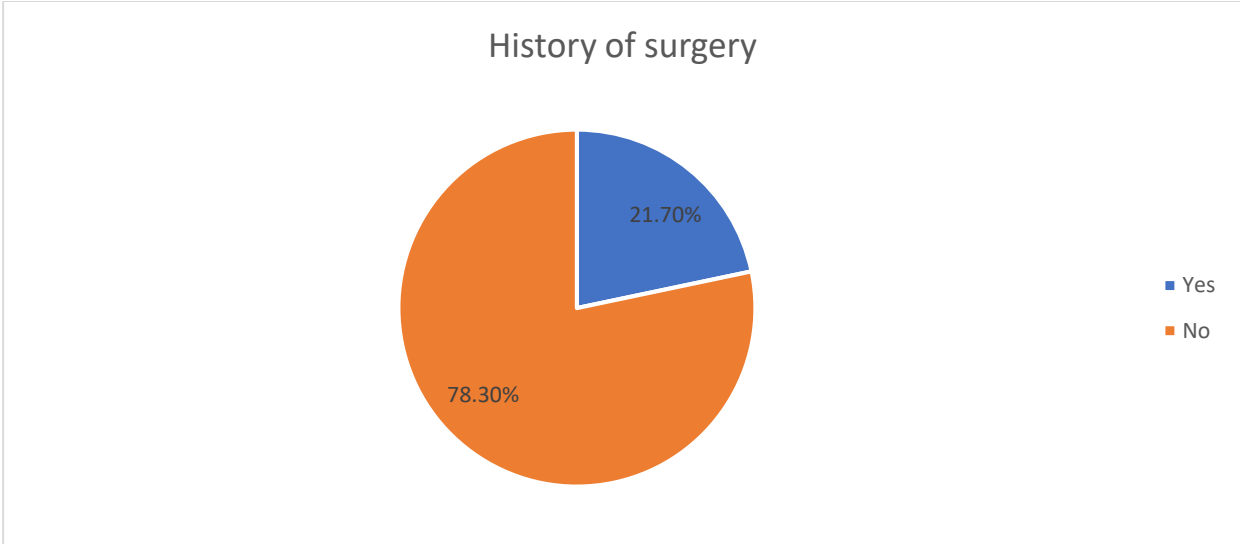


Figure 4.21 History of surgery (N=138)

Figure 4.21 showed the results of the respondents that developed NIs with or without a history of surgery. The majority n=108 (78.30%) of the respondents had no history of surgery while n=30 (21.70%) had a history of surgery. Surgery is a risk factor for a type of nosocomial infections called surgical site infections (SSI). The results of this study show that not all infections were related to surgical intervention.

4.6.6 Antimicrobial use

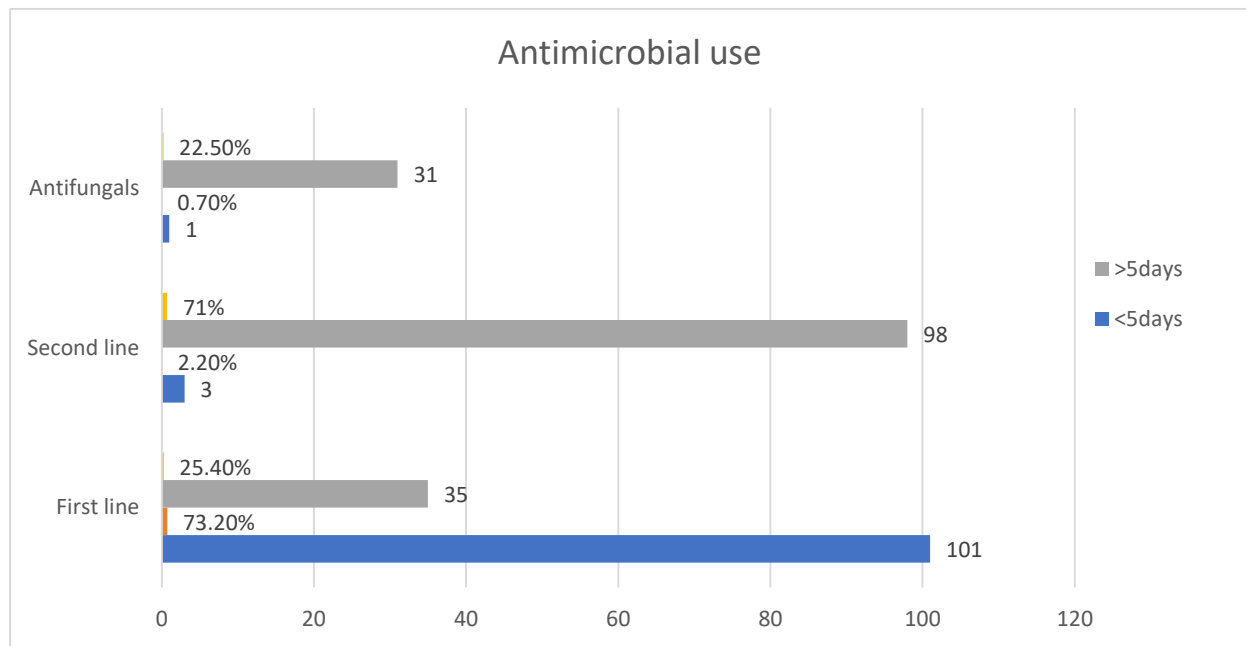


Figure 4.22 Antimicrobial use (N=138)

Figure 4.22 illustrates the use of antimicrobials in NICU. The majority of the respondents n=101 (73.20%) had first line antibiotics administered on them for a total of 5 days or less while minority n=35 (25.4%) received antibiotics for more than 5 days. The use of second line antibiotics for more than 5 days was n=98 (71%) while only n=3 (2.20%) received them for less than 5 days. Furthermore, n=1 (0.7%) received antifungals for less than 5 days while n=31 (22.5%) received an antifungal for more than 5 days. This finding concurs with the results of the study conducted in Iran on neonatal blood stream infections in tertiary referral hospitals in Kurdistan which identified previous antibiotic consumption as a variable associated with blood stream infection (Nikkhoo et al 2015:2). The results differ from the results of the study conducted in South Africa on risk factors associated with nosocomial infections in the neonatal intensive care unit at Mahatma Gandhi Memorial hospital that had case neonates receiving less antibiotics on admission 97.20% than controls, 100% (Rameshwarnath & Naidoo 2018:95).

It should be noted that prolonged use of antimicrobials leads to antibiotic resistant bacteria. Antibiotic resistance poses a major threat to public health since for many infections antibiotic treatment is no longer effective (Almagor et al 2018:2).

4.6.7 Total parenteral nutrition (TPN)

Table 4.5: Use of TPN (N=138)

Activity	Response	Frequency (n=138)	Percentage
Use of TPN	Yes	106	76.8%
	No	32	23.2%
Total		138	100
Duration	<7days	17	12.3%
	>7days	89	64.5%

The use of TPN is an independent factor related to NIs (Basiri et al 2015:2). Table 4.5 depicts that from the respondents, n=106 (76.8%) had TPN and only n=32 (23.2%) did not have it. The results show that the presence of TPN is a risk factor for NIs. The results correspond with the results of the study conducted in Australia where 15.4% cases of bloodstream infection were reported among TPN cases (Marofi et al 2017:488). The duration of TPN is also an important factor in reducing infections. As illustrated in table 4.5, n=89 (64.5%) of respondents had TPN for over seven days while n=17 (12.3%) had it for less than seven days.

4.6.8 Feeding

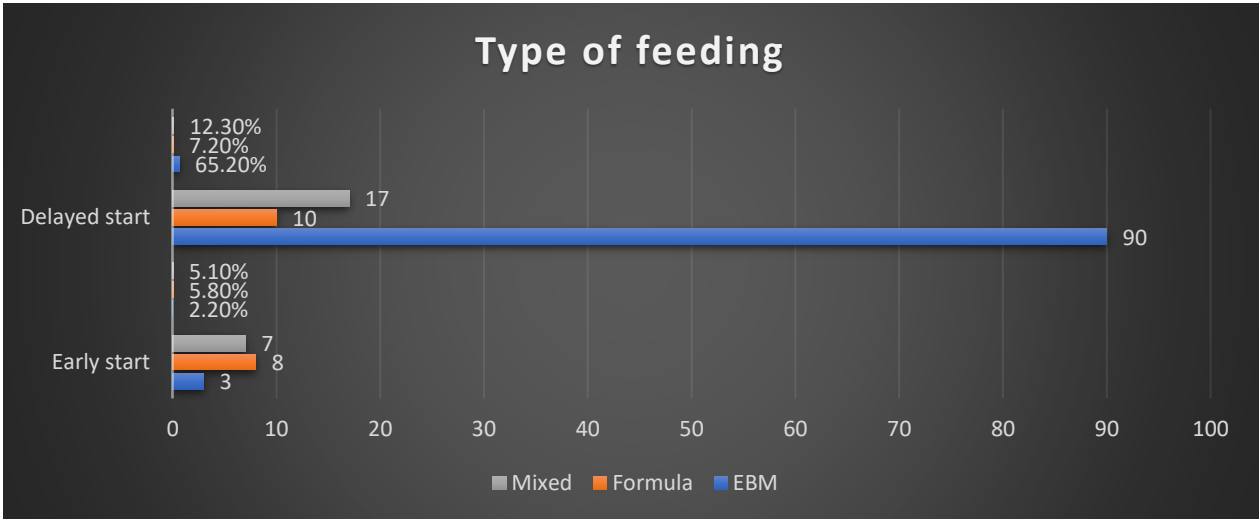


Figure 4.23 Type of feeding (N=138)

Figure 4.23 shows how feeds were initiated on the respondents. The results of this study indicate that the majority of the respondents n=90 (65.20%) had delayed start of feeds with expressed breast milk (EBM) while only n=3 (2.20%) had an early start which could have led to the presence of NIs. Only n=3 (2.20%) had an early start on feeds with EBM, while n=8 (5.80%) had an early start of feeds with formula milk and n=7 had an early feed initiation with mixed feeds. Delaying the initiation of feeds with human milk is a contributing factor to the development of NIs. The study results are supported by findings of the study in India conducted on prevention and treatment of neonatal nosocomial infections by Ramasethu (2017:3) which states that early enteral feeding with human milk is associated with lower rates of sepsis.

4.6.9 Age at onset of infection

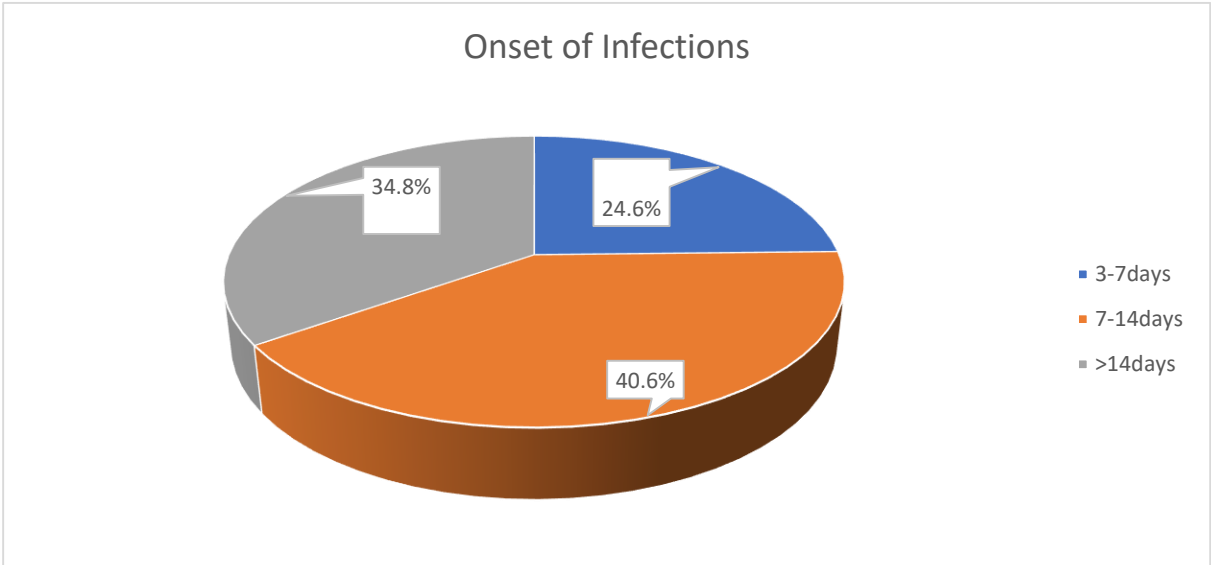


Figure 4.24 Onset of infections (N=138)

The results of figure 4.24 show that most infections n=56 (40.6%) occurred at the age of 7-14 days, followed by the age of more than 14 days old n=48 (34.8%) and the least infections occurred at 3-7 days n=34 (24.6%). This could be related to the presence of indwelling catheters, the number of consultations the respondents are exposed to at that time and the NICU environment being a high risk for NIs. This result differs from the results of the study conducted in Iran on neonatal blood stream infections in tertiary referral hospital in Kurdistan which had most infections developing at less than seven days (Nikkhoo et al 2015:2).

4.6.10 Level of care

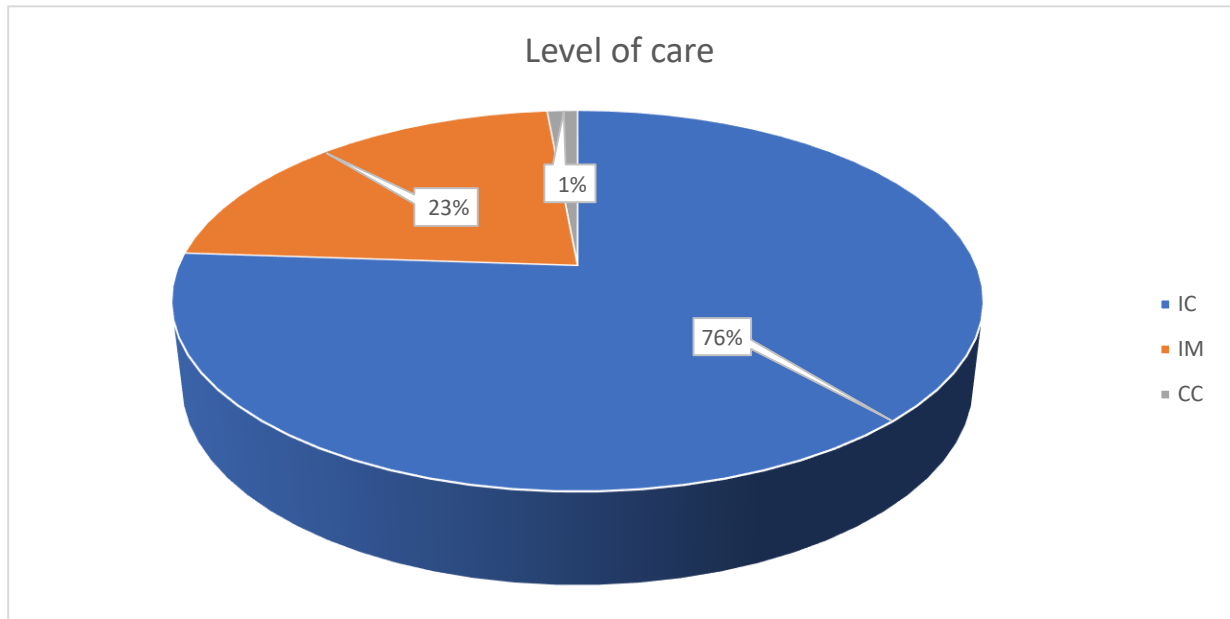


Figure 4.25 Level of care (N=138)

Figure 4.25 revealed that most infections $n=105$ (76%) occur in the intensive care (IC) area. This result could be due to the fact that patients in this area are in their first few days of life and are critically ill with attachments such as ventilators, chest tubes and central lines and also have many external consultations due to the nature of their illness. Only $n=31$ (23%) of the respondents acquired infection while in intermediate care (IM) area and $n=2$ (1%) acquired infection during care in continuous care (CC). Special attention needs to be paid to the IC care area to reduce the spread of nosocomial infection. The results of the study support findings of the study conducted in China on risk factors of nosocomial infection for infants in neonatal intensive care units which suggested NICU environment during early life as significant in incidence of nosocomial infection (Wang et al 2019:8218).

4.6.11 Length of admission

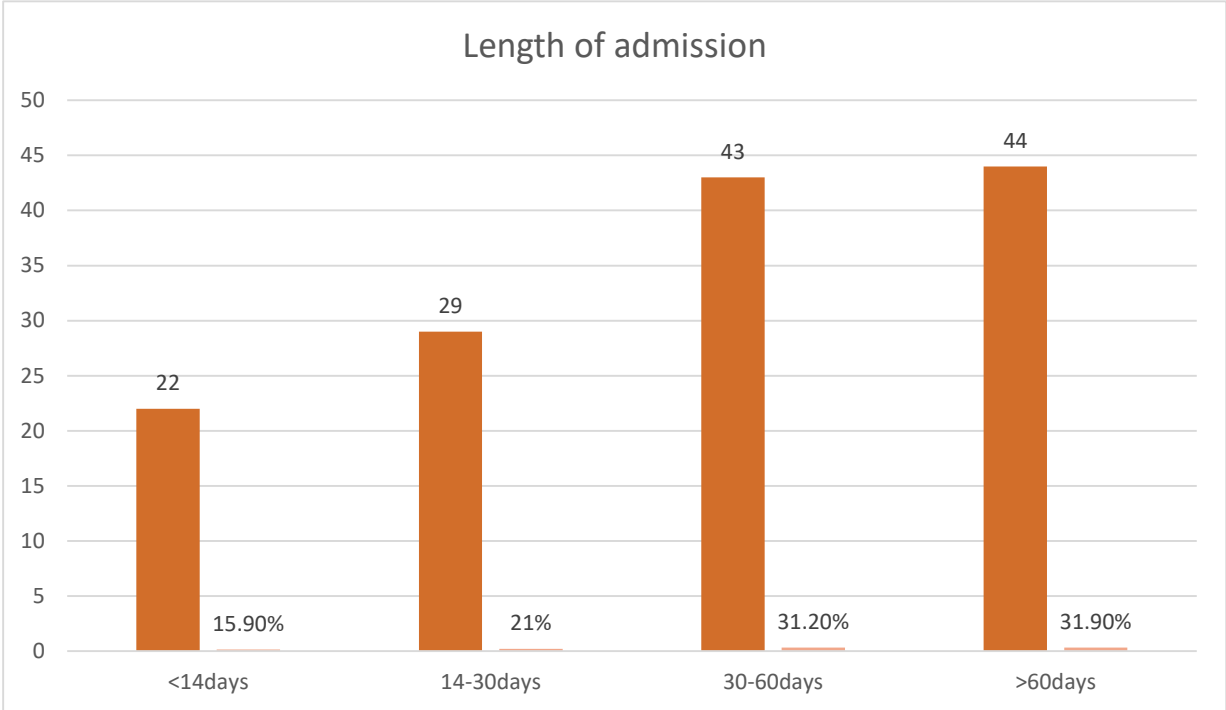


Figure 4.26 Length of admission (N=138)

Figure 4.26 illustrates the length of admission of the respondents. The results of this study show that nosocomial infections do contribute to long periods of hospitalisation as evidenced by n=44 (31.9%) of the respondents staying in the neonatal unit over 60 days. A number of neonates n=43 (31.2%) still remained hospitalised for 30 to 60 days while n=22 (15.9%) were admitted for less than 14 days. These results are the same with the study conducted in Italy on *Serratia Marcescens* infections in neonatal intensive care units which identified length of stay more of than 30 days in new born services as an independent risk factor for nosocomial infections- *Serratia Marcescens* (Cristina, Sartini, & Spagnolo 2019:4). These results further concur with the results of the study, Surveillance of nosocomial infections in a Bulgarian neonatal intensive care unit conducted in Bulgaria by Rangelova, Raycheva, Kevorkyan, Krasteva and Dermendzhiev (2020:755) which stated that infected patients had a significantly longer median hospital stay than non-infected ones.

4.6.12 Number of external consultations

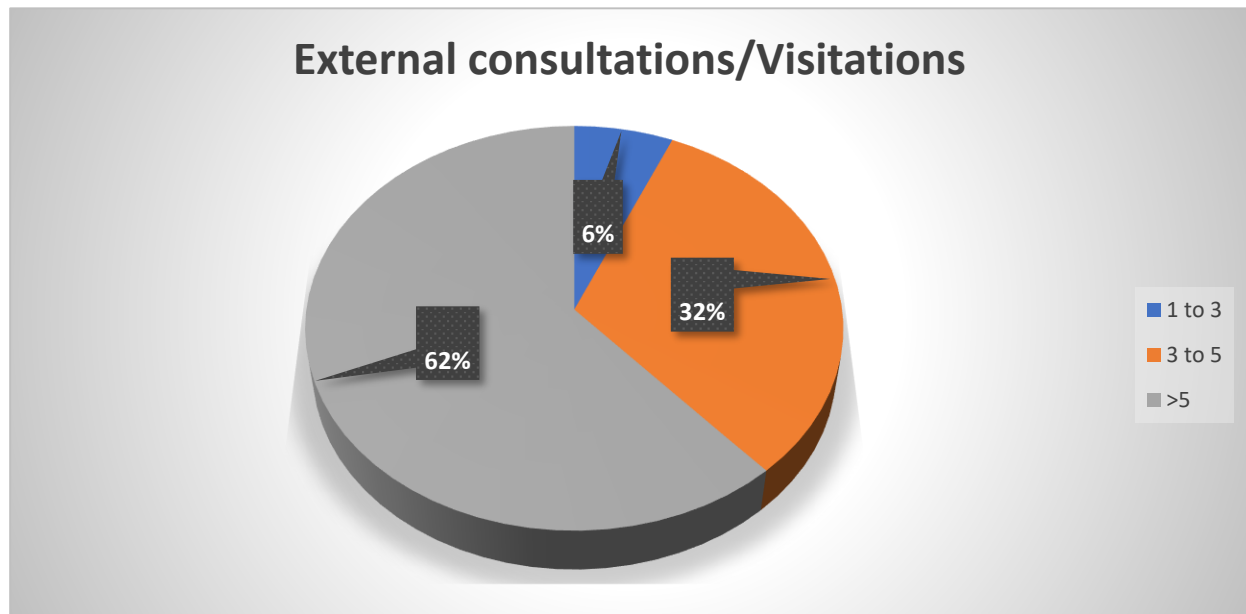


Figure 4.27 Number of external consultations/ visitations (N=138)

In NICU, it is very important to minimise visitors so as to reduce the spread of infections but it can be unavoidable in situations where neonates need to be referred for external consultations such as X-rays, ultrasound scans, echocardiography, pulmonary specialists, cardiac specialists, respiratory therapy and dieticians which all contribute to the recovery of the neonate. Figure 4.27 showed that from the respondents, n=85 (62%) had more than five consultations which could have led to the development of infections. This could be minimised by observing strict hand hygiene before touching patients and before sterile procedures. Those who had 3 to 5 consultations had frequency of n=44 (32%) and babies who had less visitations constituted only n=9 (6%) of all the infections. It is therefore noted in this study that the less the visitations or consultations the less the rate of infection.

4.7 SECTION D: NOSOCOMIAL INFECTION SITES IN NICU

Table 4.6: Nosocomial infection sites in NICU (N=138)

Site	Frequency (n)	Percentage
Blood	110	79.7%
Tracheal Aspirates	2	1.4%
Eye and wound swab	30	21.7%
Urine	3	2.2%
Breastmilk	2	1.4%
Other	5	3.6%

Table 4.6 showed that blood infection sites had the most frequency n=110 (79.7%) followed by eye and wound swabs n=30 (21.7%). There was n=5 (3.6%) of other sites of nosocomial infections and n=3 (2.2%) urine cultures. Finally, tracheal aspirates and breastmilk had the least frequencies n=2 (1.4%).

The results of frequent blood stream infections in this study corresponds with findings of the study conducted in Hamadan, Iran which had blood stream infections as the most prevalent site with 45.6% (Basiri et al 2015:2). The study evaluated the incidence and risk factors of nosocomial infection in neonates hospitalised in the neonatal intensive care unit of Fatemieh hospital. Special attention need to be paid by healthcare workers to hand hygiene and aseptic techniques during blood specimen collections. Eye and wound swabs were the second leading n=30 (21.7%) sites of NIs. The results are the same as the findings of Basiri et al (2015:2) who had 40.3% of conjunctivitis as the second leading after blood stream 45.6% in the neonatal intensive care unit of Fatemieh hospital in Hamadan, Iran, 2012-2013. The results of the study also concur with the results of the study conducted in Iran on bacterial infections and relevant factors in neonates hospitalised at intensive care unit that had blood and eye as the most frequent sampling sites, 25% & 23.2% respectively (Samani et al 2019:3).

4.8 SECTION E: PREVALENT ORGANISMS LEADING TO NIS IN NICU

Table 4.7: Prevalent organisms in NICU (N=138)

Organism	Frequency (n)	Percentage (%)
Acinetobacter baumannii complex	1	0.7
Candida famata	1	0.7
Candida parapsilosis	2	1.4
Citrobacter Freundii	1	0.7
Citrobacter koseri	1	0.7
Citrobacter sedlakii	1	0.7
CONS	3	2.2
E-Coli	18	13
Elizabethkingia meningoseptica	1	0.7
Enterobacter aeruginosa	1	0.7
Enterobacter Cloacae	4	2.9
Enterococcus Faecalis	1	0.7
Klebsiella Oxytoca	2	1.4
Klebsiella Pneumoniae	15	10.9
MRSA	11	8.0
MRSE	31	22.5
Pantoea spp	1	0.7
Pseudomonas aeruginosa	31	22.5
Raoultella ornithinolytica	1	0.7
Serratia Marcescens	14	10.1
Staphylococcus aureus	9	6.5
Staphylococcus capitis	12	8.7
Staphylococcus epidermidis	5	3.6
Staphylococcus haemolyticus	2	1.4

Staphylococcus Hominis ssp	2	1.4
Staphylococcus lugdunensis	2	1.4
Staphylococcus simulans	1	0.7
Staphylococcus warneri	1	0.7
Stenotrophomonas maltophilia	2	1.4
Streptococcus agalactiae	2	1.4

Table 4.7 showed a number of organisms identified during the two-year period in NICU at a specific healthcare facility. The results of this study revealed that MRSE and *Pseudomonas aeruginosa* were the leading organisms with both n=31 (22.5%) respectively. This result confirms results of the study conducted in Italy on surveillance of healthcare-associated infections in a neonatal intensive care unit during 2006-2010 where *Pseudomonas aeruginosa* was the most frequent (17%) organism (Crivaro et al 2015:3). *Pseudomonas aeruginosa* was also one of the leading organisms identified in the study Surveillance of nosocomial infections in a Bulgarian neonatal intensive care unit by Rangelova et al (2020:755), conducted in Bulgaria. These results differ from the results of the study conducted at Mahatma Gandhi Memorial hospital between 2014 and 2015 that had *Klebsiella Pneumoniae* as the most frequent, 41.67% (Rameshwarnath & Naidoo 2018:95). MRSE could be associated with poor techniques of collecting blood specimens leading to contamination.

E-Coli is the second leading with n=18 (13%), *Klebsiella Pneumoniae* were n=15 (10.9%), *Serratia Marcescens* were n=14 (10.1%), *Staphylococcus capitis* were n=12 (8.7%), MRSA were n=11 (8%), *Staphylococcus aureus* were n=9 (6.5%), *Staphylococcus epidermidis* were n=5 (3.6%), *Enterobacter Cloacae* were n=4 (2.9%), CONS were n=3 (2.2%) while *Candida parapsilosis*, *Klebsiella Oxytoca*, *Staphylococcus haemolyticus*, *Staphylococcus Hominis ssp*, *Staphylococcus lugdunensis*, *Stenotrophomonas Maltophilia* and *Streptococcus agalactiae* were all n=2 (1.4%) respectively. Furthermore, *Acinetobacter baumannii* complex, *candida famata*, *Citrobacter Freundii*, *Citrobacter sedlakii*, *Elizabethkingia meningoseptica*, *Enterobacter aeruginosa*, *Enterococcus Faecalis*, *Pantoea spp* and *Raoultella ornithinolytica* had the least frequencies of n=1 (0.7%) each. In terms of *Acinetobacter* species, the results of this study differ from the results of the study conducted in India on epidemiology of blood stream infections in

neonatal intensive care unit at a tertiary care centre by Rajani and Javeri (2017:2003) which had Acinetobacter species as the second leading organism with 24%.

4.9 SECTION F: NOSOCOMIAL INFECTION RATE

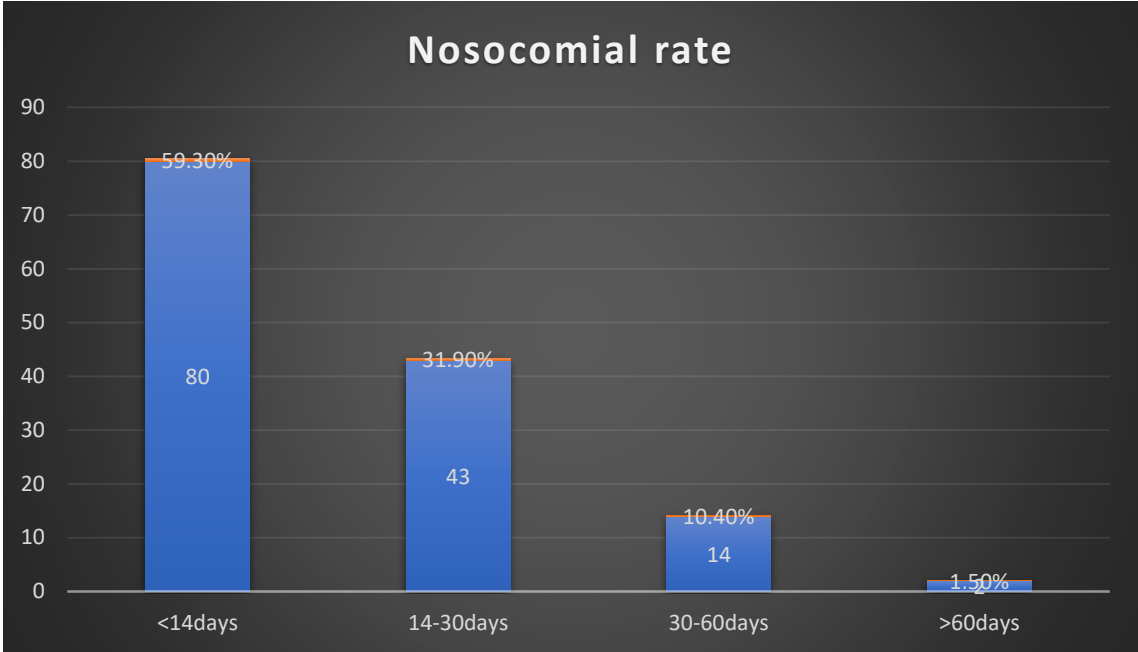


Figure 4.28 Nosocomial infection rate (N=138)

Figure 4.28 indicated that the majority of infections n=80 (59.3%) occurred at less than 14 days of life which could be attributed to the poor developed skin of the neonate at that time. It is also noted that n=43 (31.9%) of the respondents developed infections in the period of 14 to 30 days of life. As the baby develops and the skin matures, the rate of infection becomes lower as observed at 30 to 60 days of life with only n=14 (10.4%) and only n=2 (1.5%) at over 60 days of life. The result of the study confirms findings of the study conducted in China on risk factors of nosocomial infection for infants in neonatal intensive care units which suggested NICU environment during early life as significant in incidence of nosocomial infection (Wang et al 2019:8218).

4.10 CONCLUSION

This chapter presented the analysed data in frequency tables and graphs. The results of the study were interpreted and discussed supported by literature. Findings from the research were interpreted in line with results from similar studies. Chapter 5 will discuss the summary and recommendations from the study.

CHAPTER 5

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 INTRODUCTION

In chapter 4, the results of the study were discussed. Data was analysed, presented and interpreted. In this chapter, the results will be discussed and summarised. Summary findings from the research will be used to make recommendation in relation to the problem statement and objectives of the study.

5.2 SUMMARY OF THE RESEARCH RESULTS

The purpose of this study was to investigate the continued occurrence of NIs in NICU of a specific Public Healthcare facility in Saudi Arabia. The study's objectives were:

- to determine the neonatal infection rate in NICU at a specific healthcare facility.
- to identify nosocomial infection sites in NICU.
- to indicate the prevalent organisms leading to NIs in NICU.
- to identify and describe the causes and factors contributing to the incidence of NIs in NICU.
- to present the recommendations to management of this specific healthcare facility in eradication of the occurrence of nosocomial infections in NICU.

5.2.1 The neonatal infection rate in NICU

This study determined that the highest rate of infections n=80 (59.3%) occurred at less than 14 days of life and the lowest at over 60 days of life. This could be due to the fact that at that time respondents were in intensive care area and the skin was underdeveloped, delicate with lots of invasive and non-invasive procedures. The results differ from the results of the study by Nanou et al (2015:3) on risk factors for nosocomial infections in neonatal intensive care units which stated that neonates hospitalised in open NICU were more likely to develop NIs compared to those who were hospitalised in closed NICU. The findings of the current study are supported by the results of the study

conducted in China on risk factors of nosocomial infection for infants in neonatal intensive care units, a systematic review and meta-analysis which suggested NICU environment during early life as significant in incidence of nosocomial infection (Wang et al 2019:8218). Wang et al (2019:8214) cited approximately 30% of the incidence of NIs in NICU leading to up to 40% of reported neonatal deaths in developing countries.

5.2.2 Nosocomial infection sites in NICU

The results showed blood as the most common site of infection, n=110 (79.7%) and eye and wound sites as the second leading n=30 (21.7%). The most common blood sites could be associated with the use of central lines. Special attention needs to be paid to the collection of blood specimens and aseptic techniques by healthcare workers to minimise contamination. The result of frequent blood stream infections in this study corresponds with the results of the study conducted in Hamadan, Iran on the incidence and risk factors of nosocomial infection in neonates hospitalised in the neonatal intensive care unit of Fatemeh hospital, which had blood stream infections as the most prevalent site with 45.6% (Basiri et al 2015:2). These results are also the same as the results of the study, bacterial infections and relevant factors in neonates hospitalised at intensive care unit, conducted in Iran, where blood and eye were the leading sites at 25% and 23.2% respectively (Samani et al 2019:3).

5.2.3 Prevalent organisms leading to nosocomial infections in NICU

Many organisms were identified during the study period and these were; *Acinetobacter baumannii* complex, *Candida famata*, *Candida parapsilosis*, *Citrobacter Freundii*, *Citrobacter sedlakii*, *Citrobacter koseri*, CONS, *E-coli*, *Elizabethkingia meningoseptica*, *Enterobacter aeruginosa*, *Enterobacter cloacae*, *Enterococcus Faecalis*, *Klebsiella pneumoniae*, *Klebsiella Oxytoca*, MRSA, MRSE, *Pantoea* spp, *Pseudomonas aeruginosa*, *Raoultella ornithinolytica*, *Serratia Marcescens*, *Staphylococcus aureus*, *Staphylococcus capitis*, *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Staphylococcus Hominis* ssp, *Staphylococcus lugdunensis*, *Staphylococcus simulans*, *Staphylococcus warneri*, *Stenotrophomonas maltophilia* and *Streptococcus agalactiae*. Prevalent organisms were *Pseudomonas aeruginosa* and MRSE at n=31 (22.5%) respectively. These results confirm findings of the study conducted in Italy on surveillance of healthcare-associated infections in a neonatal intensive care unit during 2006-2010 where *Pseudomonas aeruginosa* was the most frequent (17%) organism (Crivaro et al 2015:3). These results differ from the study conducted in Iran on bacterial infections and

relevant factors in neonates hospitalised at intensive care unit which had staphylococcus epidermidis, Enterococcus, Klebsiella as the most isolated organisms (Samani et al 2019:3). CONS, Candida and Klebsiella were the most isolated microbes in a study conducted in Greece (Nanou et al 2015:3). These results differ from the results of the current study.

5.2.4 Causes and factors leading to the incidence of NIs in NICU

The results of this study revealed the use of central lines, history of resuscitation, presence of invasive ventilation, use of total parenteral nutrition, use of antimicrobials and initiation of feeds as factors leading to the incidence of NIs in NICU. These are all risk factors for NIs in infants in NICU (Wang et al 2019:8215). The use of central lines, being the umbilical venous catheter (UVC), umbilical arterial catheter (UAC) and peripherally inserted central catheter (PICC) was high, n=82 (59.4%), n=59 (42.8%) and n=51 (37.0%), respectively. This could have led to NIs in the respondents.

The results of the study correlate with the results of the study on risk factors associated with nosocomial infections in the NICU at Mahatma Gandhi Memorial hospital between 2014 and 2015 by Rameshwarnath and Naidoo (2018:95) which indicated 67.36% of central venous catheter use on the cases. Although time out, insertion and maintenance bundles were used in this study, there is need for strict adherence to these to reduce the risks of nosocomial infections. Furthermore, duration of central catheters should be minimised as follows, UVC to a maximum of 14 days, UAC to a maximum of 5 days (Cho & Cho 2019:82). It is advisable to remove central catheters as soon as they are not needed. The selected public healthcare facility should offer guaranteed continued attention and support through provision of adequate patient to-staff ratios to minimise the risks of NIs (Lee 2019:382).

Most of the respondents n=100 (72.5%) had a history of resuscitation thus resuscitation was identified as a risk factor of NIs. The results of this study differ from the results of the study conducted in India by Kumar et al (2018:277) who had resuscitation required as a risk factor for nosocomial infections at lowest association (OR 0.95; 95% CI 0.65-1.35). There is a need for healthcare workers to take extra precautions during resuscitations as infection prevention and control measures can be breeched in these instances. Although duration of ventilation had no direct association to the occurrence of NIs, presence of invasive ventilation, n=87 (63%) was a significant cause and factor leading to the incidence of NIs in this study. The results correspond with the results of the study

conducted on risk factors of nosocomial infection for infants in neonatal intensive care unit conducted in China by Wang et al (2019:8215) which states that infants who underwent mechanical ventilation had a higher incidence of NI than those who did not.

The study also revealed that the use of TPN, n=106 (76.8%) was a significant cause of nosocomial infections. These results confirm findings of the study conducted in Australia where 15.4% cases of bloodstream infection were reported among TPN cases (Marofi et al 2017:488). It will be ideal for physicians to reduce the use and duration of TPN to minimise the incidence of NIs in NICU.

The study results also revealed that the use of antimicrobials was one of the risk factors for the occurrence of NIs in NICU. From the respondents, n=101 (73.20%) were on antimicrobials. This result supports findings of the study conducted in Iran on neonatal blood stream infections in tertiary referral hospitals in Kurdistan which identified previous antibiotic consumption as a variable associated with blood stream infection (Nikkhoo et al 2015:2).

Furthermore, results revealed that feeding was initiated late, after the second day for most of the respondents, n=90 (65.2%). Early initiation of feeds is associated with reduced nosocomial infections. Therefore, there is a need for healthcare workers in this specific healthcare facility to improve in this practice. The study results are supported by the findings of the study in India on prevention and treatment of neonatal nosocomial infections by Ramasethu (2017:3) which states that early enteral feeding with human milk is associated with lower rates of sepsis.

Lastly, the study results showed that most of the infections, n=105 (76%) occurred in the IC area. There is a need for healthcare workers to pay special attention to patients in this area. The study results show no specific association of NIs in this specific healthcare facility to the history of surgery, presence and duration of urine catheters, presence and duration of chest tubes and duration of invasive ventilation.

5.3 RECOMMENDATIONS

Based on the results of the study the researcher proposes the following recommendations:

5.3.1 Health care workers (Doctors and nurses)

- Exercise extra caution (strict aseptic techniques) on collection of blood specimens to avoid contaminations;
- Ensure proper hand hygiene with alcohol-based hand rub and/or with soap and water according to the WHO 5 moments of hand hygiene, mainly in the intensive care (IC) area;
- Adhere to infection prevention strategies during neonatal resuscitation to minimise the risk of infections and,
- Make use of the bundles for central lines, urine catheters and ventilators to minimise nosocomial infections.

5.3.2 Health care workers (Physicians)

- Minimise the use of umbilical central lines where possible and when central lines are needed, to make use of peripherally inserted central catheters. central lines should be removed as soon as not required;
- Minimise use of invasive ventilators and limit duration where possible. Encourage the use of non-invasive ventilation methods to prevent the risk of ventilator associated infections;
- Encourage proper antenatal care to minimise premature deliveries;
- Initiate feeds as early as possible and encourage use of human milk to avoid feeding intolerance which leads to development of NIs;
- Limit the use of total parenteral nutrition and,
- Where possible, to limit the use of antimicrobials.

5.3.3 Future research

- Evaluate the knowledge and attitudes of healthcare workers on infection prevention and control in NICU;
- Determine the causes of premature deliveries and how they can be prevented;
- Hand hygiene compliance among healthcare workers in intensive care area;
- Barriers to initiation of feeds and use of human milk in Saudi Arabia.

5.3.4 Public healthcare facility

- Ensure availability of personal protective equipment including stock items that assist in minimising nosocomial infections;
- Ensuring good air circulation within the NICU;
- Provision of adequate nurses especial in IC area where 1:1 nurse patient ratio is required, and,
- Have external practitioners conduct random hand hygiene observations in NICU. It is important to have hand hygiene compliance monitored and maintained at highest level.

5.4 CONTRIBUTION OF THE STUDY

The following are expected contributions of the study:

- From the results of the study, the management of the institution can know where most infections take place and find ways to manage them;
- With possible causes identified, physicians can work on minimising those possible causes of NIs and,
- Healthcare workers will improve the infection prevention standards in NICU.

5.5 LIMITATIONS OF THE STUDY

The study was conducted in one public hospital in Saudi Arabia and the result cannot be generalised to all public hospitals in Saudi Arabia. Some information could not be found and there could be other causes of nosocomial infections in neonatal intensive care unit other than ones identified in this study.

5.6 CONCLUDING REMARKS

This chapter presented conclusions, recommendations and limitations and discussed them in relation to the study objectives. Data was collected retrospectively from the 138 clinical records of neonates who developed NIs during their stay in NICU at a selected public healthcare facility in Saudi Arabia. A self-designed checklist was used for data collection. The study results revealed gestational age of less than 33+6 weeks, neonatal

resuscitation and lower birth weight less than 1000g as risk factors for the development of nosocomial infections. The most common reasons for admissions of respondents was prematurity and respiratory conditions.

Although most of the respondents were discharged, mortality rate is still considered high and NIs led to prolonged hospitalisation. Possible causes and factors leading to development of NIs at the selected public healthcare facility were; use of central lines, being umbilical venous catheters and umbilical arterial catheters, use of mechanical ventilators, use of antimicrobials, use of total parenteral nutrition and delay in initiation of feeds, human milk. Most NIs occurred at 7 to 14 days of life and in intensive care area of NICU. Furthermore, the most common site of infections was blood followed by eye and wound sites while the common organisms identified were *Pseudomonas aeruginosa* and MRSE

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ANNEXURE 1: ETHICAL CLEARANCE LETTER



**RESEARCH ETHICS COMMITTEE: DEPARTMENT OF HEALTH STUDIES
REC-012714-039 (NHERC)**

12 February 2020
Dear Beauty Ndlovu

Decision: Approval

HSHDC/953/2020

Student: Beauty Ndlovu

Student No: 42/51225

Supervisor: Prof KA Mahoe

Qualification: PhD

Joint Supervisor:

Name: Beauty Ndlovu

Proposal: Nosocomial Infections In neonatal intensive care unit of a Public Healthcare facility in Saudi Arabia

Qualification: MA

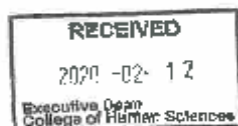
Risk Level: Negligible

Thank you for the application for research ethics approval from the Research Ethics Committee: Department of Health Studies, for the above mentioned research. Final approval is granted from 12 February 2020 to 12 February 2023.

The application was reviewed in compliance with the Unisa Policy on Research Ethics by the Research Ethics Committee: Department of Health Studies on 11/02/2020.

The proposed research may now commence with the proviso that:

- 1) The researcher/s will ensure that the research project adheres to the values and principles expressed in the UNISA Policy on Research Ethics.*



UNISA
University of South Africa
P.O. Box 17003, Rosebank, Johannesburg 2018
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Fax: +27 (0)11 705 1214
www.unisa.ac.za

Open Rubric

2) Any adverse circumstance arising in the undertaking of the research project that is relevant to the ethicality of the study, as well as changes in the methodology, should be communicated in writing to the Research Ethics Review Committee, Department of Health Studies. An amended application could be requested if there are substantial changes from the existing proposal, especially if those changes affect any of the study-related risks for the research participants.

3) The researcher will ensure that the research project adheres to any applicable national legislation, professional codes of conduct, institutional guidelines and scientific standards relevant to the specific field of study.

4) You are required to submit an annual report by 30 January of each year that indicates that the study is active. Reports should be submitted to the administrator: _____ Should the reports not be forthcoming the ethical permission might be revoked until such time as the reports are presented.

Note:

The reference numbers (top middle and right corner of this communiqué) should be clearly indicated on all forms of communication (e.g. Webmail, E-mail messages, letters) with the intended research participants, as well as with the Research Ethics Committee: Department of Health Studies.

Kind regards,


Prof JM Malhbe-Nekke
CHAIRPERSON
mathijm@unisa.ac.za


Prof KM Masemola
DEAN OF COLLEGE OF HUMAN SCIENCES

ANNEXURE 2: REQUEST PERMISSION TO CONDUCT RESEARCH AT KING SALMAM ARMED FORCES HOSPITAL, TABUK, SAUDI ARABIA

22 APRIL 2020

Dear Sir/Madame

I, **Beauty Ndlovu**, am doing research with the University of South Africa, in the Department of Health towards Master of Public Health at the University of South Africa. The title of this study is **Nosocomial Infections in neonatal intensive care unit**.

The purpose of this study is to investigate the current status of nosocomial infections by conducting a retrospective analysis of clinical records of neonates in neonatal intensive care unit of a public healthcare facility. The findings will be presented as recommendations to the management of the specific healthcare facility in eradication of the occurrence of nosocomial infections in neonatal intensive care unit. Should you have concerns about the way in which the research has been conducted, you may contact:

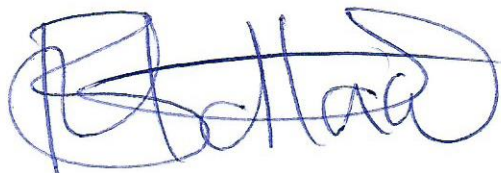
Supervisor: Tel: +2712 429 2393, email, maboeka@unisa.ac.za.

Chair of the University of South Africa, Department of Health Studies, Research Ethics Committee: Prof J E Maritz, Tel: +2712 429 6534, Email: maritje@unisa.ac.za.

Thank you for taking time to read this information sheet and for participating in this study.





Thank you.

Yours sincerely



Beauty Ndlovu

ANNEXURE 2.1: APPROVAL LETTER FROM RESEARCH COMMITTEE OF THE SELECTED HEALTH CARE FACILITY

<p>ARMED FORCES HOSPITALS ADMINISTRATION NORTHWESTERN REGION, KSA</p>		<p>إدارة مستشفيات القوات المسلحة بالمطقة الشمالية الغربية المملكة العربية السعودية</p>
<p>ACADEMIC AFFAIRS RESEARCH ETHICS COMMITTEE APPROVAL FORM</p>		
<p>NAME OF PRINCIPAL INVESTIGATOR: BEAUTY NDLOVU ETHICS ID NUMBER: KSAFH-REC-2020-326 TITLE: Nosocomial infections in neonatal intensive care unit at King Salman Armed Forces Hospital in Saudi Arabia. Causes and Risk Factors. CO-INVESTIGATORS: Attallah Al Howaiti</p>		
<p>The above-noted proposal has been submitted for expedited ethics review and found to be ethically acceptable. The proposal includes:</p>		
<p>1. The Ethics Approval Form 2. Research Protocol 3. Data sheet collection.</p>		
<p>Please note that this approval is subject to the following conditions:</p>		
<p>1. Consent for participant agreement to be enrolled in the trial and access to personal information in chart review is required. Participation in the questionnaire is considered as approval of the participant.</p>		
<p>2. A Progress Report must be submitted by the year end, containing the following information:</p>		
<p>i.) The number of subjects recruited;</p>		
<p>ii.) A description of any protocol modification;</p>		
<p>iii.) Any unanticipated problems involving risks to subject or to others, withdrawal of subjects from the research, or complaints about the research.</p>		
<p>iv.) A summary of any recent literature, findings, or other relevant information, especially information about risks associated with the research.</p>		
<p>v.) The expected date of termination of this project.</p>		
<p>3. A final report must be submitted to the research office at the completion of the project.</p>		
<p>4. The research project must be published under the name of our hospital with the name of the investigators and also need to mention had approval from the Research & Research Ethics Committee.</p>		
<p>Please note that you have been named as the principal collaborator on this study because students are not permitted to serve as principal investigators. Please accept the Board's best wishes for success in your research.</p>		
 <p>DR. KHALID AL QUAER Chairman Research Ethics Committee</p>	<p>07 JUL 2020</p>  <p>BRIG. GEN. DR. BANDAR AL AL-QAHTANI Asst. Hosp. Dir. for Academic Affairs</p>	
Form No. 1032-1030	KACST Reg. No: HO-07-TU-002 Date: 16/12/1434 Issued: 02 November 2014	Page 1 of 1

ANNEXURE 3: PERMISSION LETTER FROM THE NEONATAL INTENSIVE CARE UNIT DIRECTOR AT THE SPECIFIC HEALTHCARE FACILITY

25 MARCH 2020

I, **Beauty Ndlovu**, am doing research with the University of South Africa, in the Department of Health towards Master of Public Health at the University of South Africa. **The title of this study is Nosocomial Infections in neonatal intensive care unit.**

The purpose of this study is to investigate the current status of nosocomial infections by conducting a retrospective analysis of clinical records of neonates in neonatal intensive care unit of a public healthcare facility. The findings will be presented as recommendations to the management of the specific healthcare facility in eradication of the occurrence of nosocomial infections in neonatal intensive care unit.

Should you have concerns about the way in which the research has been conducted, you may contact:

Supervisor: Tel: +2712 429 2393, **email**, maboeka@unisa.ac.za.

Chair of the University of South Africa, Department of Health Studies, Research Ethics Committee: Prof J E Maritz, Tel: +2712 429 6534, Email: maritje@unisa.ac.za.

Thank you for taking time to read this information sheet and for participating in this study.

Thank you.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Beauty Ndlovu', written in a cursive style.

Beauty Ndlovu

ANNEXURE 3.1: APPROVAL LETTER FROM THE DIRECTOR OF NICU

 موافقة القسم على إجراء دراسة بحثية (إجراءات العمل الموحدة رقم 30) Departmental Approval for Undertaking a Research Study (SOP 30)	
Title of the Proposal: <u>Nosocomial Infections</u> <u>in neonatal intensive care unit of</u> <u>a Public healthcare facility in Saudi</u> <u>Arabia</u> Investigator's Name: <u>BEAUTY NDLOYU</u> Date: <u>16 APRIL 2020</u>	عنوان المقترح البحث: اسم الباحث: التاريخ:
To The Chairman of Research Ethics Committee Greetings, We consent for the above mentioned research study to be conducted in our section/department. Please be advised that Dr/ <u>Mr Atallah Alhaweiti</u> will be the administrative supervisor of the above investigator. Best regards, The abovementioned research study is not feasible to be conducted in our section/department due to the following reasons:	إلى: رئيس لجنة أخلاقيات البحث السلام عليكم ورحمة الله وبركاته: نود إفادتكم بموافقتنا على إجراء الدراسة البحثية المذكورة أعلاه في القسم / الإدارة التابعة لنا. يرجى الافادة بان الدكتور / السيد تم تعيينه مشرفا إداريا على الباحث المذكور أعلاه . وتقبلوا تحياتنا يرجى الافادة بعدم جدوى إجراء الدراسة البحثية المذكورة أعلاه في القسم / الإدارة التابعة لنا وذلك للأسباب التالية:
Name of Director/Head: <u>Dr. Atallah Alhaweiti</u> Signature: Department/Section: <u>NICU</u>	اسم مدير الإدارة / رئيس القسم: التوقيع: الإدارة / القسم:

ANNEXURE 4: PERMISSION LETTER FROM THE MEDICAL RECORDS DIRECTOR TO ACCESS MEDICAL RECORDS AT KING SALMAM ARMED FORCES HOSPITAL, TABUK, SAUDI ARABIA

4 MAY 2020

I, Beauty Ndlovu, am doing research with the University of South Africa, in the Department of Health towards Master of Public Health at the University of South Africa. The title of this study is **Nosocomial Infections in neonatal intensive care unit**. The purpose of this study is to investigate the current status of nosocomial infections by conducting a retrospective analysis of clinical records of neonates in neonatal intensive care unit of a public healthcare facility. The findings will be presented as recommendations to the management of the specific healthcare facility in eradication of the occurrence of nosocomial infections in neonatal intensive care unit.

Should you have concerns about the way in which the research has been conducted, you may contact:

Supervisor: Tel: +2712 429 2393, email, maboeka@unisa.ac.za.

Chair of the University of South Africa, Department of Health Studies, Research Ethics Committee: Prof J E Maritz, Tel: +2712 429 6534, Email: maritje@unisa.ac.za.

Thank you for taking time to read this information sheet and for participating in this study.

Thank you.

Yours sincerely



Beauty Ndlovu

ANNEXURE 4.1: APPROVAL LETTER FROM THE DIRECTOR OF MEDICAL RECORDS



**Medical Services Department for Armed Forces
Scientific Research Center
Research Ethics Committee**

SECTION B – DEPARTMENT APPROVALS

Please Obtain Your Department Head's Signature and Signatures of All Departments/Divisions/Services Whose Operations Will Be Affected by Your Protocol. This Is To Ensure That Prior To Commencement Of The Investigation; These Individuals Have Had An Opportunity To Assess The Impact Of The Proposal On Their Area. This Will Include Reviewing The Proposed Budget So They Can Accommodate Any Additional Requirements Arising From The Protocol.

TITLE OF PROPOSED RESEARCH: Nosocomial infections in neonatal intensive care unit at King Salman Armed Forces Hospital in Saudi Arabia.

	DEPARTMENT	PRINT NAME	SIGNATURE	DATE
<input type="checkbox"/> Yes <input type="checkbox"/> No	ANESTHESIOLOGY			
<input type="checkbox"/> Yes <input type="checkbox"/> No	CARDIOLOGY			
<input type="checkbox"/> Yes <input type="checkbox"/> No	DENTAL SERVICE			
<input type="checkbox"/> Yes <input type="checkbox"/> No	EMERGENCY DEPT.			
<input type="checkbox"/> Yes <input type="checkbox"/> No	FMC			
<input type="checkbox"/> Yes <input type="checkbox"/> No	INTERNAL MEDICINE			
<input type="checkbox"/> Yes <input type="checkbox"/> No	MED LAB/PATHOLOGY/ HEMATOLOGY			
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	MEDICAL RECORDS	Nahla Al-Hadi		27.10.2022
<input type="checkbox"/> Yes <input type="checkbox"/> No	MIS			
<input type="checkbox"/> Yes <input type="checkbox"/> No	NURSING UNIT			
<input type="checkbox"/> Yes <input type="checkbox"/> No	OBSTETRICS & GYNECOLOGY			
<input type="checkbox"/> Yes <input type="checkbox"/> No	ONCOLOGY			
<input type="checkbox"/> Yes <input type="checkbox"/> No	PEADIATRIC			
<input type="checkbox"/> Yes <input type="checkbox"/> No	PHARMACY			
<input type="checkbox"/> Yes <input type="checkbox"/> No	PREVENTIVE MEDICINE			
<input type="checkbox"/> Yes <input type="checkbox"/> No	PRINCE SULTAN KIDNEY CENTER			
<input type="checkbox"/> Yes <input type="checkbox"/> No	QI&PS			
<input type="checkbox"/> Yes <input type="checkbox"/> No	RADIOLOGY			
<input type="checkbox"/> Yes <input type="checkbox"/> No	SURGERY			
<input type="checkbox"/> Yes <input type="checkbox"/> No	OTHERS:			

NAME AND SIGNATURE OF THE PRINCIPAL INVESTIGATOR Beauty Ndlovu (BN)

ANNEXURE 5: CHECKLIST

Nosocomial Infections in neonatal intensive care unit-checklist

Case Number:

Circle the appropriate response

SECTION A- DEMOGRAPHIC DATA

1. Gender

Male	1
Female	2

2. What was the age on admission?

<28+6 weeks	1
29 weeks to 33+6 weeks	2
34 weeks to 36+6 weeks	3
>37 weeks	4

SECTION B –MEDICAL HISTORY

3. What was the gestational age at birth?

<28+6 weeks	1
29 weeks to 33+6 weeks	2
34 weeks to 36+6 weeks	3
>37 weeks	4

4. What was the weight at birth?

ELBW <1000g	1
VLBW 1001g to 1500g	2
LBW <2500g	3
2500g to 4000g	4
LGA >4000g	5

*ELBW-extreme low birth weight, VLBW-very low birth weight, LBW-low birth weight &LGA-Large for gestational age.

5. What was the Apgar score?

1 minute	5 minutes
1	2

6. What was the diagnosis on admission?

Prematurity	1
Low birth weight LBW	2
VLBW	3
ELBW	4
Respiratory diseases	5
Congenital cardiac diseases	6
Neurological Conditions	7
Gastrointestinal diseases	8
Ear, nose and throat	9
Congenital anomalies	10
Metabolic disorders	11
Genitourinary conditions	12
Meconium Aspiration	13
Other (specify)	14

7. Is there a history of neonatal resuscitation?

Yes	1
No	2

8. How was the vital observations?

Time frame	Normal (1)				Abnormal (2)			
	1-2 days	2-7 days	7-30 days	>30 days	1-2 days	2-7 days	7-30 days	>30 days
Temperature	1	1	1	1	2	2	2	2
Pulse	1	1	1	1	2	2	2	2
Respirations	1	1	1	1	2	2	2	2
Oxygen saturation	1	1	1	1	2	2	2	2
Blood pressure	1	1	1	1	2	2	2	2

9. What was the condition of skin on admission?

Intact	1
Broken	2

10. What was the final diagnosis during the neonates stay in NICU?

Prematurity	1
Low birth weight LBW	2
VLBW	3
ELBW	4
Respiratory diseases	5
Congenital cardiac diseases	6
Neurological Conditions	7
Gastrointestinal diseases	8
Ear, nose and throat	9
Congenital anomalies	10
Metabolic disorders	11
Genitourinary conditions	12
Meconium aspiration	13
Specify other	14

11. What was the outcome after nursing care?

Discharged	1
Died	2
Transferred	3

Section C- Causes and factors contributing to the incidence of NIs in NICU

12. Where were the central lines inserted?

Central lines	Yes	No
Umbilical arterial catheter (UAC)	1	2
Umbilical venous catheter (UVC)	1	2
Femoral catheter	1	2
Peripherally inserted central catheter (PICC)	1	2
Jugular Line	1	2

12.1 What was the duration of central lines?

	1-7 days	7-14 days	14 - 30days	>30 days	N/A
Umbilical arterial catheter (UAC)	1	2	3	4	0
Umbilical venous catheter (UVC)	1	2	3	4	0
Femoral catheter	1	2	3	4	0
Peripherally inserted central catheter (PICC)	1	2	3	4	0
Jugular line	1	2	3	4	0

12.2 How was the care of central lines?

Care	YES	NO	N/A
Universal protocol	1	2	0
Insertion bundle	1	2	0
Maintenance bundle	1	2	0

13. Was the patient on invasive ventilation?

Yes	1
No	2

13.1 If yes what was the duration?

	<7 days	7-14 days	14-30 days	>30 days
Ventilation duration	1	2	3	4

13.2 Ventilator bundle

Yes	1
No	2
N/A	0

14. Presence of chest tubes:

Yes	1
No	2

14.1 If yes what was the duration?

	<3days	3-7 days	>7 days
Chest tube duration	1	2	3

15. Was there a urinary catheter?

Yes	1
No	2

16.1 If yes, what was the duration?

	< 1day	>1 day
Urinary catheter	1	2

16.2 How was the care of urinary catheter?

	Yes	No	N/A
Insertion bundle	1	2	0
Maintenance bundle	1	2	0

17. Is there a history of surgery?

Yes	1
No	2

17.1 Specify type of surgery

18. What was the duration of antimicrobials used?

	<5 days	>5 days
First line drugs	1	2
Second line drugs	1	2
Antifungals	1	2

19. Was there use of total parenteral nutrition (TPN)?

Yes	1
No	2

19.1 If yes, what was the duration?

	<7days	>7days
Duration of TPN	1	2

20. What was the type of feeding?

	Early start (first day of life)	Delayed start (after 2 days of life)
Exclusive breastmilk	1	2
Formula feeds	1	2
Mixed feeds	1	2

21. What was the age at onset of infection?

3-7 days	1
7- 14 days	2
>14 days	3

22. Indicate the level of care

Intensive care area (IC)	1
Intermediate care area (IM)	2
Continuous Care area (CC)	3

23. What was the length of admission?

<14 days	1
14- 30 days	2
30- 60 days	3
>60 days	4

24. Number of external consultations/visitations.

1	1
1 to 3	2
3 to 5	3
>5	4

Section D- Nosocomial infection sites in NICU.**25. Types of culture samples**

Blood	1
Tracheal aspirates	2
Eye and wound swabs	3
Urine	4
Breastmilk	5
Other	6

Section E- Prevalent organism(s) leading to NIs in NICU.**26. Write the name and site of the cultured organism(s) in the following table:**

Name	Site

Section F- Nosocomial infection rate

27. When was nosocomial rate determined?

<14 days	1
14- 30 days	2
30- 60 days	3
>60 days	4

ANNEXURE 6: STATISTICIAN REPORT

Acknowledgement of statistical analysis support provided

This is to certify that I, Dr Dion van Zyl, provided statistical analysis support for the research project **Nosocomial infections in neonatal intensive care unit of a public healthcare facility in Saudi Arabia.**

The research project was conducted by **Beauty Ndlovu (42751225)** of the Department of Health Studies, College of Human Sciences, Unisa in fulfilment for the completion of the following qualification: **Master of Public Health.**

The following analysis was conducted based on the data analysis plan provided by the researcher:

- Database design in IBM SPSS and data importing
- Calculation of univariate frequency and descriptive statistics



Dion van Zyl

Date: 2021/04/12

Personal Information

Surname : Van Zyl
Full name : Hendrik Jacobus Dion
ID number : 731222 5064 080
Contact number : 082 329 7570

Tertiary Education (Completed)

Institution : University of Pretoria
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Institution : University of Pretoria
Year : 1997
Qualification : **B. Com. Hon. Econometrics**

Institution : Damelin Management School
Year : 1997
Qualification : **Diploma in Small Business Management**

Institution : Oxford Brookes University (UK)
Year : 2002
Qualification : **Master of Business Administration (MBA)**

Institution : University of Pretoria
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Qualification : **PhD Marketing Management**

Professional Membership:

Association : **Southern African Association of Institutional Researchers (SAAIR)**

ANNEXURE 7: EDITING CERTIFICATE

23 APRIL 2021



EDITING CERTIFICATE

I hereby confirm that I have proof-read, formatted and edited the style, layout, references and language of the

Master of Public Health dissertation

to be submitted to

UNISA

by

Beauty Ndlovu

Entitled

Nosocomial infections in neonatal intensive care unit of a public healthcare facility in Saudi Arabia.

Student number : 42751225

(123 pages, 25 940 words)

Note: The edited work described here may not be identical to that submitted. The author, at its sole discretion has the prerogative to accept, delete or change amendments made by the editor before submission.



Margaret-Ann Limakatso Dingalo
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Membership year: March 2021 to February 2022

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Technical guideline used: MNUALL/301/0/2020

Page layout

- Margin: Left 2.5 cm and the rest 2 cm
- Line spacing: 1.5
- Letter size: 12 and 14 For Chapter headings as per recommendation
- Letter type: Arial
- Justification: Full justification
- Page numbering: Bottom middle of the page

Paragraph numbering

- **CHAPTER HEADINGS: FONT SIZE 14 BOLD AND CAPS**
- **1st headings: BOLD + CAPTIAL LETTERS [1.1]**
- **2nd headings: Bold + Lowercasing [1.1.1]**
- **3rd headings: *Bold+ Lower casing + italic [1.1.1.1]***

Language

- English UK spelling

Tables

- Numbered consecutively according to the chapters
- Label at the top
- A reference to the table at the bottom in size 10 lettering aligned to the right
- Line spacing 1
- Table contents Arial font size 12

Figures

- Numbered consecutively according to the chapters
- Label at the bottom, Arial font size 12 aligned to the left
- Reference for a figure in size 10 lettering aligned to the right
- Each figure centered on a page

References

- In-text references and list of sources checked in line with the abbreviated Harvard system of referencing and listing of sources

PERSONAL DETAILS

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- Editing certificate: UCT, Cape Town
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