VACCINATION COVERAGE IN CHILDREN AGED 12-23 MONTHS OLD IN REFILWE TOWNSHIP, GAUTENG PROVINCE

MASTER OF PUBLIC HEALTH (MPH)
BONTELE ROSA MOTLOUNG
2016
VACCINATION COVERAGE IN CHILDREN AGED 12-23 MONTHS OLD IN REFILWE TOWNSHIP, GAUTENG PROVINCE

BY

BONTLE ROSA MOTLOOUNG

A Research Dissertation submitted in partial fulfilment of the requirements for the Degree Master of Public Health, in the School of Health Care Sciences, Faculty of Health Science, at the Sefako Makgatho Health Sciences University

Supervisor: Mrs L Fernandes
Co Supervisor: Prof RJ Burnett

2016
DECLARATION

I, Bontle Motloung (student number: 200700830) hereby declare that this research report is my own work. This dissertation is being submitted to the Sefako Makgatho Health Sciences University for the degree Master of Public Health. It has not been submitted before for any degree or examination at this or any other University. This is my work in execution, and all materials used have been properly acknowledged.

Signature: ........................................... Date: ...........................................

Full name: Bontle Rosa Motloung
ACKNOWLEDGEMENTS

First, I would like to give thanks to Almighty God for giving me strength to complete this study. Secondly I would like to thank my parents Mr Lebuhang Motloung and Mrs Lindi Motloung for all their support and encouragement to continue with my studies.

I would also like to thank the following people:

- My supervisors Mrs Lucy Fernandes and Prof Rosemary Burnett for their invaluable support, advice and guidance throughout the study, it wouldn't be possible without your support.
- Ms Charlotte van den Broek (Masters Student from the University of Antwerp in Belgium), Ms Anna Msiza and Ms Maria Skosana who helped me with data collection by assisting me with the interviews in Refilwe Township.
- Prof Jeffrey Mphahlele and Mr Mabina Mogale from the South African vaccination and Immunisation centre (SAVIC) who encouraged me to enrol into this programme.
- The Tshwane Municipality for their permission, cooperation and for providing me with the necessary information to conduct my study; and the residents and study participants of Refilwe Township for graciously cooperating during the study.
ABSTRACT

**Background:** Childhood vaccination has proven to be an important and cost-effective public health intervention tool in the prevention, elimination and eradication of vaccine preventable diseases. Although EPI-SA has seen many successes since it was introduced in 1995, several studies have shown that it is faced with numerous challenges such as pockets of low vaccination coverage, frequent measles outbreaks, low community knowledge on immunisation and discrepancies between the official country vaccination coverage data and estimates by WHO and UNICEF.

**Objectives:** The objectives of this study were to (i) to determine the EPI-SA coverage for children aged 12-23 months old and (ii) for those children who are not fully vaccinated, to determine the reasons why they not vaccinated in Refilwe Township, Gauteng Province, South Africa.

**Method:** A descriptive survey was conducted applying guidelines from the WHO EPI coverage survey manual strategy for (i) assessing vaccination coverage according to the Road to Health Card; and (ii) reasons given by care-givers for non-vaccination in children aged 12-23 months in Refilwe Township, Gauteng Province. A complete census of the Refilwe Township was conducted.

**Results:** A total of 173 children were surveyed of which 89% (154/173) of children aged between 12-23 months were fully vaccinated, and 11% (19/173) of children were partially vaccinated. The most common reason for non-vaccination of children was vaccines not available at clinics 26.3% (5/19); other reasons varied from caregivers being too busy to take their children for vaccinations 15.8% (3/19), and lack of motivation 15.8% (3/19) from the side of the caregiver.

**Conclusion:** The high fully immunised coverage rate of 89% is just a percent below the 90% national level target set by the EPI-SA. However there is a need to improve on vaccine availability at clinics and to educate the community on the importance of completing the recommended EPI schedule in order to protect children from vaccine-preventable diseases.
## CONTENTS

DECLARATION .................................................................................................................. iii

ACKNOWLEDGEMENTS ............................................................................................... iv

ABSTRACT ....................................................................................................................... v

LIST OF TABLES ............................................................................................................ ix

LIST OF FIGURES .......................................................................................................... ix

LIST OF APPENDICES ................................................................................................... ix

LIST OF ABBREVIATIONS ............................................................................................. x

Chapter 1 Introduction ..................................................................................................... 1

1.1 Introduction and background .................................................................................... 1

1.2 Study problem ............................................................................................................ 2

1.3 Purpose of the study ................................................................................................. 3

1.3.1 Aim ......................................................................................................................... 3

1.3.2 Specific objectives ............................................................................................... 3

1.4 Significance of the study .......................................................................................... 3

Chapter 2 Literature review ............................................................................................. 4

2.1 Immunity ..................................................................................................................... 4

2.1.1 Innate immunity ................................................................................................... 4

2.1.2 Adaptive immunity ............................................................................................. 4

2.2 Vaccines ..................................................................................................................... 6

2.3 Vaccine types ............................................................................................................ 6

2.3.1 Live, attenuated vaccines .................................................................................... 6

2.3.2 Inactivated vaccines ......................................................................................... 7

2.3.3 Subunit vaccines ............................................................................................... 7

2.3.4 Toxoid vaccines ............................................................................................... 8

2.3.5 Conjugate vaccines ........................................................................................... 8

2.4 Immunisation ............................................................................................................ 8

2.5 The South African Expanded Programme on Immunisation (EPI-SA) .................... 9
2.6 Diseases targeted by the EPI-SA ................................................................. 11
  2.6.1 Tuberculosis .......................................................................................... 11
  2.6.2 Polio ........................................................................................................ 12
  2.6.3 Hepatitis B ............................................................................................. 13
  2.6.4 Rotavirus disease .................................................................................. 14
  2.6.5 Tetanus .................................................................................................. 15
  2.6.6 Pneumococcal disease ......................................................................... 16
  2.6.7 Measles .................................................................................................. 17
  2.6.8 Pertussis ................................................................................................ 18
  2.6.9 Haemophilus influenzae type b infection .............................................. 19
  2.6.10 Diphtheria ............................................................................................ 20

2.7 The Road to Health Card ......................................................................... 21

2.8 Immunisation coverage ............................................................................ 21
  2.8.1 Immunisation or vaccination coverage surveys .................................... 22
  2.8.2 Reasons for non-vaccinations .............................................................. 22

Chapter 3 Research methods ....................................................................... 24
  3.1 Study design .............................................................................................. 24
  3.2 Study setting .............................................................................................. 24
  3.3 Study population ....................................................................................... 25
    3.3.1 Inclusion criteria ................................................................................ 25
    3.3.2 Exclusion criteria ............................................................................... 25
  3.4 Sampling procedure .................................................................................. 25
  3.5 Data collection ........................................................................................... 26
  3.6 Data collection tools ................................................................................ 26
  3.7 Data analysis ............................................................................................... 27
  3.8 Reliability and validity ............................................................................. 27
  3.9 Ethical considerations .............................................................................. 27
Chapter 4 Results ........................................................................................................... 29

4.1 Deviation from initial protocol sampling procedure ........................................... 29

4.2 Demographic data .................................................................................................. 29

4.3 Vaccination status ................................................................................................. 30

4.3.1 Objective 1 ........................................................................................................ 30

4.3.2 Objective 2 ........................................................................................................ 33

Chapter 5 Discussion, conclusions and recommendations ........................................... 37

5.1 Vaccination coverage ............................................................................................ 37

5.1.1 Under 1 year vaccination coverage ................................................................. 37

5.1.2 Vaccination coverage of individual vaccines .................................................... 37

5.1.3 Drop-out rates ................................................................................................... 38

5.1.4 Missed vaccination opportunities .................................................................... 39

5.2 Reasons for non-vaccinations and missed vaccination opportunities ............... 39

5.3 Limitations of the study ....................................................................................... 41

5.3.1 Selection bias because of low response rate .................................................... 41

5.3.2 Information bias ............................................................................................... 42

5.4 Conclusions ........................................................................................................... 42

5.5 Recommendations ............................................................................................... 43

Chapter 6 References ................................................................................................. 51
LIST OF TABLES

Table 4.1 Age distribution of the children in months .................................................. 30
Table 4.2 Vaccination coverage for different vaccine combinations ......................... 32
Table 4.3 Reasons for non-vaccination ....................................................................... 34

LIST OF FIGURES

Figure 2.1 Flow chart of the immune system ............................................................... 5
Figure 2.2 EPI-SA childhood immunisation schedule 2009 .................................... 10
Figure 3.1 Position of Refilwe Township in the City of Tshwane Municipality ...... 24
Figure 4.1 Sex distribution of the children (n=173) ..................................................... 30
Figure 4.2 Vaccination status of the children (n=173) .................................................. 31
Figure 4.3 Vaccination coverage for individual vaccines ........................................... 31
Figure 4.4 Receipt of 2nd vaccine dose vs 1st and 2nd vaccine doses combined ......... 33
Figure 4.5 Old EPI-SA RTHC which does not include vaccines introduced in 2009 ................................................................................................................. 35
Figure 4.6 Private sector RTHC which does not include OPV(1) .............................. 36

LIST OF APPENDICES

Appendix A The infant immunization cluster form ...................................................... 45
Appendix B The reasons for immunisation failure cluster form ................................. 46
Appendix C Medunsa Research and Ethics Committee clearance certificate ......... 47
Appendix D Tshwane Metropolitan Municipality clearance certificate .................. 48
Appendix E Sepedi participant consent form .............................................................. 49
Appendix F English participant consent form ......................................................... 50
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AEFV</td>
<td>Adverse Events Following Vaccination</td>
</tr>
<tr>
<td>AFP</td>
<td>Acute Flaccid Paralysis</td>
</tr>
<tr>
<td>aP</td>
<td>Acellular pertussis</td>
</tr>
<tr>
<td>BCG</td>
<td>Bacillus Calmette-Guérin</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>DNA</td>
<td>Deoxyribonucleic Acid</td>
</tr>
<tr>
<td>DT</td>
<td>Diphtheria, tetanus vaccine</td>
</tr>
<tr>
<td>DTaP</td>
<td>Diphtheria, tetanus, acellular pertussis vaccine</td>
</tr>
<tr>
<td>DTaP-IPV/Hib</td>
<td>Diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis vaccine and <em>Haemophilus influenzae</em> type b vaccine</td>
</tr>
<tr>
<td>DTP</td>
<td>Diphtheria, tetanus, pertussis vaccine</td>
</tr>
<tr>
<td>DTwP</td>
<td>Diphtheria, tetanus, whole-cellular pertussis vaccine</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Programme on Immunisation</td>
</tr>
<tr>
<td>EPI SA</td>
<td>Expanded Programme on Immunisation South Africa</td>
</tr>
<tr>
<td>GAPPD</td>
<td>Global Action Plan for the Prevention and control of Pneumonia and Diarrhea</td>
</tr>
<tr>
<td>Gavi</td>
<td>Global Alliance for Vaccines and Immunization</td>
</tr>
<tr>
<td>GIVS</td>
<td>Global Immunization Vision and Strategy</td>
</tr>
<tr>
<td>GVAP</td>
<td>Global Vaccine Action Plan</td>
</tr>
<tr>
<td>HBsAg</td>
<td>Hepatitis B virus surface antigen</td>
</tr>
<tr>
<td>HBV</td>
<td>Hepatitis B virus</td>
</tr>
<tr>
<td>Hep B</td>
<td>Hepatitis B vaccine</td>
</tr>
<tr>
<td>Hib</td>
<td><em>Haemophilus influenzae</em> type b</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>HST</td>
<td>Health System Trust</td>
</tr>
<tr>
<td>IPV</td>
<td>Inactivated Polio Vaccine</td>
</tr>
<tr>
<td>Acronym</td>
<td>Full Form</td>
</tr>
<tr>
<td>---------</td>
<td>-----------</td>
</tr>
<tr>
<td>MCV</td>
<td>Measles containing vaccine</td>
</tr>
<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
</tr>
<tr>
<td>MREC</td>
<td>MEDUNSA Research Ethics Committee</td>
</tr>
<tr>
<td>NIAID</td>
<td>National Institute of Allergy and Infectious Diseases</td>
</tr>
<tr>
<td>NHLS</td>
<td>National Health Laboratory Service</td>
</tr>
<tr>
<td>NICD</td>
<td>National Institute for Communicable Diseases</td>
</tr>
<tr>
<td>NNT</td>
<td>Neonatal tetanus</td>
</tr>
<tr>
<td>OPV</td>
<td>Oral Polio Vaccine</td>
</tr>
<tr>
<td>PGEI</td>
<td>Polio Global Eradication Initiative</td>
</tr>
<tr>
<td>PCV</td>
<td>Pneumococcal conjugate vaccine</td>
</tr>
<tr>
<td>RDP</td>
<td>Reconstruction and Development Programme</td>
</tr>
<tr>
<td>RNA</td>
<td>Ribonucleic acid</td>
</tr>
<tr>
<td>RTHC</td>
<td>Road to Health Card</td>
</tr>
<tr>
<td>RV</td>
<td>Rotavirus vaccine</td>
</tr>
<tr>
<td>SADoH</td>
<td>South African Department of Health</td>
</tr>
<tr>
<td>SAVIC</td>
<td>South African Vaccination and Immunisation Centre</td>
</tr>
<tr>
<td>SIAs</td>
<td>Supplementary Immunisation Activities</td>
</tr>
<tr>
<td>SMU</td>
<td>Sefako Makgatho Health Sciences University</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>Td</td>
<td>Tetanus, diphtheria vaccine</td>
</tr>
<tr>
<td>TT</td>
<td>Tetanus Toxoid</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>VAPP</td>
<td>Vaccine-associated Paralytic Poliomyelitis</td>
</tr>
<tr>
<td>VDPV</td>
<td>Vaccine-derived Polio Virus</td>
</tr>
<tr>
<td>VPD</td>
<td>Vaccine Preventable Disease</td>
</tr>
<tr>
<td>WHA</td>
<td>World Health Assembly</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>wP</td>
<td>whole-cellular pertussis</td>
</tr>
</tbody>
</table>
Chapter 1 Introduction

1.1 Introduction and Background

Childhood immunisation as prescribed by the World Health Organization (WHO) Expanded Programme on Immunization (EPI) is one the most cost-effective public health tools for the prevention and control of childhood diseases; the programme prevents over 2.5 million child deaths each year globally (WHO, 2010a). During the programme’s introduction stage in 1974, it was designed to reduce morbidity and mortality against the six traditional childhood diseases, diphtheria, pertussis, tetanus, measles, polio and tuberculosis; however since then vaccines against more diseases have been included into the programme (Chauke-Moagi and Mumba, 2012). Furthermore reducing child mortality and increasing the proportion of children immunised against measles was one of the Millennium Development Goals (MDG) indicators (MDG4) of health (WHO/ The United Nations Children’s Fund [UNICEF], 2004). The South African Expanded Programme on Immunisation (EPI-SA) has achieved several milestones since its inception in 1995 that will be discussed further in Chapter 2.

In an effort to reach the MDG4, and at the same time also respond to challenges in global immunisation, the WHO and UNICEF developed the Global Immunisation Vision and Strategy (GIVS) in 2006. GIVS composed a number of immunisation goals and strategies to aid countries in improving and sustaining immunisation coverage (WHO, 2011). In 2009 EPI-SA introduced two new vaccines into the programme, the pneumococcal conjugate vaccine-13 (PCV) and the rotavirus vaccine in keeping in line with the GIVS set goals and strategies (National Department of Health-SA Vaccinator’s Manual [SADoH], 2012).

In May 2012, the World Health Assembly (WHA) endorsed the Global Vaccine Action Plan (GVAP) 2011-2020 which builds on the success of the GIVS, and further aims to “improve health by extending from 2020 and beyond the full benefits of immunisation to all people, regardless of where they are born, who they are, or where they live” (WHO, 2013a). More recently, the WHO and UNICEF published the Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea.
(GAPPD) with the aim to end preventable childhood deaths due to pneumonia and diarrhoea by 2025 (WHO/UNICEF, 2013).

These global action plans on immunisations are good guidelines that countries including South Africa can use in order to improve immunisation coverage. In 2011 the South African National Department of Health’s (SADoH) EPI (EPI-SA) in an effort to reach MDG4 aimed to increase immunisation coverage for under one year-olds to at least 90% at national level and 80% in all districts by 2015 (SADoH, 2012).

1.2 Study Problem

Despite all the successes of the EPI-SA, several studies have shown that it is faced with numerous challenges such as pockets of low vaccination coverage, frequent measles outbreaks and low community knowledge on immunisation (McMorrow et al, 2009; Ndirangu et al, 2009; Schoub, 2011; Wiysonge et al, 2012; Ntshoe et al, 2013).

There are also discrepancies between the official vaccination coverage data issued by the EPI-SA and estimates by WHO and UNICEF. The EPI-SA reported that 94% of South African children were reached by benchmark triple vaccinations against diphtheria, whooping cough and tetanus (DTP3) in 2012 but the international organisations (WHO/UNICEF) reported a rate of 72% (Health Systems Trust [HST], 2013; WHO/UNICEF, 2014). Valid immunisation coverage data is therefore important in identifying groups at risk of vaccine preventable diseases as well as to identify gaps within the EPI-SA. Thus the collection of valid immunisation coverage data is needed in order to strengthen EPI-SA.

Immunisation coverage surveys are used for this purpose, and several surveys have been conducted in various districts of South Africa (van Turennout et al, 2003; Corrigall et al, 2008; Fadnes et al, 2011). However, no immunisation coverage survey has been conducted in Refilwe Township, thus there is a need for this study. An important justification for conducting this study in the Refilwe Township is that the 2009 measles epidemic in South Africa started in Gauteng Province (where Refilwe Township is situated) and spread to the rest of the country. The principal researcher is of the opinion that an investigation into reasons why caregivers fail to comply with
the EPI is important and may reveal information that could help in strengthening the EPI-SA.

1.3 Purpose of the Study

1.3.1 Aim

To investigate vaccination coverage of children aged 12-23 months in Refilwe Township, Gauteng Province.

1.3.2 Specific Objectives

- To determine the EPI-SA coverage for children aged 12-23 months old in Refilwe Township, Gauteng Province.
- For those children who are not fully vaccinated, to determine the reasons why children aged 12-23 months old in Refilwe Township are not vaccinated.

1.4 Significance of the Study

This household immunisation coverage survey is important and can be used to validate immunisation administrative data collected at healthcare facilities in the Refilwe Township. Also in the absence of national immunisation surveys, small scale immunisation surveys such as this one are important in providing the data that are lacking.

It is expected that results obtained from this study will provide insight into the vaccination coverage of children between the ages of 12-23 months from the Refilwe Township in Gauteng Province. Results obtained from this study will also identify ways to improve the immunisation services in Refilwe Township, that can also be used at all levels of the health system to evaluate its performance and find ways to improve immunisation activities and thereby reduce morbidity and mortality from vaccine preventable diseases.
Chapter 2 Literature Review

2.1 Immunity

Immunity can be described as the ability of the human body to tolerate or eliminate biological materials indigenous or foreign to the body. The state of immunity is conferred either through an immune response generated by immunisation or previous infection. Immunity is indicated by the production of antibodies by an organism in response to the presence of a specific foreign organism or group of closely related organisms (Baxter, 2007; SADoH, 2012; Centers for Disease Control and Prevention [CDC], 2015a). Immunity can either be described as innate or acquired immunity, see figure 2.1.

2.1.1 Innate immunity

Innate or natural immunity is obtained at birth and is the first line of defence against any foreign invaders. An innate immune response is non-specific to any pathogen, and thus depends on physical, physiological and chemical barriers in response to injury or invasion by a pathogen. The main cells of the innate immunity are white blood cells which are monocytes, neutrophils, eosinophils, basophils, and natural killer cells (Alberts et al, 2002; Cruvinel et al, 2010; Greenwood et al, 2012). Cells of the innate immune system are not memory cells, therefore they do not offer any long term protection against any foreign entity, however they play an important role in the initiation of an efficient and effective acquired immune response (Cruvinel et al, 2010; Delves, 2015).

2.1.2 Adaptive immunity

Adaptive or acquired immunity differs from innate immunity in that it is specific when responding to a foreign pathogen. The effector cells of the adaptive immune system have surface receptors that respond specifically to a particular epitope present on the surface of the foreign antigen. An initial response by the adaptive immune system takes time to develop, however subsequent exposure to the same antigen will be much quicker and more effective (Nauta, 2011; Greenwood et al, 2012; CDC, 2015a). An adaptive immune response is either humoral, cellular mediated or both.

Humoral immunity is also known as antibody mediated response because once it is activated it stimulates specific B cells to develop into plasma cells which are then
triggered into secreting antibodies (immunoglobulins) into the lymph and blood stream. The released antibodies then attack the foreign pathogen (Nauta, 2011; Greenwood et al, 2012).

Cellular mediated immune response is dependent on the development of thymus-derived small lymphocytes also known as T-cells that are specific to the foreign pathogen. T-cells are generally active against intracellular organisms (Greenwood et al, 2012; Delves, 2015).

There are two basic mechanisms for acquiring specific immunity, either through natural infection with a pathogen or through artificial immunisation. This mechanism is known as active acquired immunity which confers long-lasting immunity against the specific inducing pathogen. This is in contrast to passive immunity which is obtained through the transfer of antibodies for example from mother to child during pregnancy and lactation. Passive immunity often provides effective protection, but this protection wanes (disappears) with time, usually within a few weeks or months (Nauta, 2011; SADoH, 2012; Delves, 2015).

Figure 2.1 Flow chart of the immune system (Source: Virtual Medical Centre available at http://www.myvmc.com/anatomy/human-immune-system).
2.2 Vaccines

The WHO defines a vaccine as a biological preparation that improves immunity to a particular disease. A vaccine either contains a harmless version of a disease-causing microbe that has been weakened or killed, or a part of the disease-causing microbe, such as its toxin or one of its surface proteins. Following vaccination, the immune system is stimulated and recognises the microbe as foreign. The immune system is thus tricked into releasing T-lymphocytes and antibodies that will be able to recognise the same disease causing microbe in later infections (SADoH, 2012; CDC, 2013; WHO, 2015b).

Vaccines may also contain additional substances that aid to improve the immune response (adjuvants) and substances that help stabilise the vaccine (preservatives and stabilisers) (Baxter, 2007).

2.3 Vaccine Types

Vaccines are classified into two major types, the live attenuated vaccines and the inactivated vaccines. The inactivated vaccines can be further divided into four groups depending on the nature of the vaccine antigens.

2.3.1. Live, attenuated vaccines

These live vaccines are derived from “wild” microbes, and contain a version of the disease-causing microbe that has been weakened, or attenuated in a laboratory so that it cannot cause disease. The attenuation process of the microbes present in the vaccine is usually attained through repeated culturing (CDC, 2015a; National Institute of Allergy and Infectious Diseases [NIAID], 2008). Live vaccines are ideal for viral diseases, because they are able to replicate within a cell and produce a cell-mediated immune response (WHO, 2016a). In order for the live vaccines to elicit an immune response in the vaccinated person, they need to be able to replicate. Because vaccination with a live vaccine is the closest thing to natural infection, the immune system will not be able to differentiate between an infection from the live vaccine and natural infection (CDC, 2013). Thus these vaccines elicit strong cellular and humoral responses. Live vaccines may confer lifelong immunity following vaccination with just one or two doses. Live vaccines are fragile and easily damaged by heat and light, therefore they need to be stored under low temperatures in order
to remain potent. Examples of live attenuated vaccines that are currently available include measles, rotavirus, polio (oral polio vaccine) and the bacterial Bacillus Calmette-Guérin (BCG) (NIAID, 2008; CDC, 2013; CDC, 2015a).

2.3.2 Inactivated vaccines
An inactivated or killed vaccine is produced by growing disease-causing microbes in culture media, then inactivating it with chemicals, heat or radiation. Although the vaccine is inactivated, the microbe’s antigens, are still present in the vaccine, and are able to elicit an immune response following vaccination (Baxter, 2007; NIAID, 2008; CDC, 2015a). Inactivated vaccines cannot replicate, and will not revert back to the disease causing microbe. Inactivated vaccines stimulate a weaker immune response when compared to live vaccines (CDC, 2013). The first dose of the inactivated vaccine does not elicit any protective immunity, but instead primes the immune system, while vaccination with an inactivated vaccine is mostly vaccine induced humoral with very little vaccine induced cellular immune response. Antibody titres against the inactivated antigen may thus wane with time. Thus to elicit a protective response will require several additional doses or booster doses. Inactivated vaccines are easier to store than live vaccines and can be transported in a free-dried form. They are also much safer to use in vulnerable individuals such as those with a compromised immune system or who are pregnant. Examples of inactivated vaccines that are currently available include among others; polio and pertussis (NIAID, 2008; CDC, 2015a; WHO, 2016a).

2.3.3 Subunit vaccines
Subunit vaccines do not contain any live components of the microbe; they contain only the antigenic parts of the microbe that best stimulate the immune system. Subunit vaccines can be produced by growing the microbe in culture in the laboratory, and then chemically isolating the antigenic parts to be used in the vaccine; or through the use of recombinant DNA technology, by extracting genes that code for antigen from the microbe and inserting them into either a virus or yeast cells; the resulting recombinant vector will express the antigen (NIAID, 2008; CDC, 2013). Because subunit vaccines contain parts of the microbe, they are safer and more stable than live vaccines. Examples of subunit vaccines that are currently available include the acellular pertussis vaccine and the recombinant Hepatitis B (hep B) vaccine (NIAID, 2008; WHO, 2013b).
2.3.4 Toxoid vaccines
Toxoid vaccines contain a bacterial toxin which is the main cause of the symptoms associated with the disease. The bacterial toxin is rendered harmless by isolating it from the bacterium and inactivating it by treating with formalin (a solution of formaldehyde and sterilised water). Following this detoxification process the toxins are now called toxoids and are safe to use in vaccines. Toxoid vaccines elicit a weak immune response when compared to other types of vaccines. To increase the immunogenicity, the toxoid is adsorbed to aluminium or calcium salts (adjuvants), and multiple doses are used. Toxoid vaccines are safer than most live vaccines as they do not contain any live components of the microbe and thus cannot multiply or revert back to “wild” type. They are also very stable and have a long life, as they are not readily affected by temperature and light. Examples of toxoid vaccines that are currently available include tetanus toxoid and diphtheria toxoid (Baxter, 2007; NIAID, 2008; WHO, 2013b).

2.3.5 Conjugate vaccines
Conjugate vaccines are inactivated subunit vaccines that possess an outer coating of certain bacteria that is composed of long chains of sugar molecules called polysaccharides. The polysaccharides are then chemically combined with a protein molecule in the process known as conjugation. The process of conjugation changes the immune response from T-cell independent immune response, to a T-cell dependent immune response. The T-cell dependent immune response is immunogenic in the immature immune systems of infants and younger children following multiple administrations of the vaccine. An example of a conjugate vaccine that is currently available is the conjugate vaccine for pneumococcal disease (Baxter, 2007; NIAID, 2008; CDC, 2015a).

2.4 Immunisation
The WHO defines immunisation as the process in which an individual is made immune or resistant to an infectious disease, typically through vaccination (WHO, 2015b). The immunisation process has played a huge role in the control, elimination and eradication of vaccine preventable diseases, therefore resulting in improved health and survival among children globally (Madhi et al, 2014).
2.5 The South African Expanded Programme on Immunisation (EPI-SA)

In South Africa the EPI was introduced in 1974, however back then the programme was fragmented because of the system of apartheid. In 1995, a new EPI-SA was formed through the unification of all immunisation services in the country, with the purpose to prevent morbidity and mortality rates of vaccine preventable diseases that burden children and pregnant women (SADoH, 2012; Wiysonge et al, 2012). In its initial stages, the EPI-SA offered vaccines against six childhood diseases (tuberculosis, polio, tetanus, diphtheria, pertussis and measles). However since then, the EPI-SA has been in the fortunate position to keep pace with WHO recommendations (Ngobo and Cameron, 2012), having added the Hep B vaccine in 1995, *Haemophilus influenzae* type b (Hib) vaccine in 1999, pneumococcal conjugate vaccine (PCV), rotavirus vaccine (RV) in 2009 and *Human papillomavirus* (HPV) in 2014 (Chauke-Moagi and Mumba, 2012; Machingaidze et al, 2013; Botha and Richter, 2015), and now offers protection against 11 vaccine preventable diseases. Figure 2.2 shows the old EPI-SA immunisation schedule which does not include Hexavalent, HPV and the new measles vaccine schedule.

The EPI-SA programme has claimed its position as the leader in the African region by being the first to introduce several vaccines (rotavirus vaccine and pneumococcal conjugate vaccine) and new combination vaccines (DTaP-IPV//Hib) (Baker, 2010; SADoH, 2012). The EPI-SA is designed to mainly target children (13 years and younger) and pregnant women, with a policy put in place that states that immunisation services in South Africa should be available at all public healthcare facilities for free for this two vulnerable groups (SADoH, 2012).
Figure 2.2 EPI-SA childhood immunisation schedule 2009 (Source Western Cape Department of Health (2015), available at https://www.westerncape.gov.za/image/2011/7/vaccination.jpg)
2.6 Diseases targeted by the EPI-SA

2.6.1 Tuberculosis

Tuberculosis (TB) is an infectious bacterial disease caused by the bacillus *Mycobacterium tuberculosis* (WHO, 2004; SADoH, 2014). TB commonly affects the lungs (pulmonary TB), but it can affect various other parts of the body (extrapulmonary TB) including the brain and kidneys. TB transmission occurs from person to person through air droplet nuclei (<5 microns), for example when an infected person (active respiratory disease) coughs, sneezes or talks the bacilli are released into the air and can be inhaled leading to latent infection. TB can remain in the air for long periods of time depending on the environment. The risk of infection following exposure to the organism increases with prolonged exposure and close contact. Progression from infection to active TB disease will depend on the immune status of the individual, with the most risk in the elderly, children <5 years of age and individuals with suppressed immunity (e.g. HIV positive individuals) (WHO, 2004; SADoH, 2014).

The general symptoms of active pulmonary TB include coughing sometimes with sputum or blood, chest pains, weight loss, fever, and night sweats. People with latent infection often show no symptoms and cannot transmit the organism. Extrapulmonary TB infections are almost never infectious, except in cases where there is a co-infection with pulmonary TB. TB is treatable with a six months course of antibiotics; however in the absence of treatment, the death rate is very high. Immunisation against TB provides protection against the progression of TB from infection to active disease, and also offers protection to children against other known serious forms of TB including, TB meningitis and disseminated TB (WHO, 2004; SADoH, 2012; SADoH, 2014).

The WHO estimates that about one-third of the world’s population is infected with latent TB, with 5-10% at risk of developing active TB (WHO, 2004; SADoH, 2014). Despite the availability of effective anti-TB treatment and a vaccine, TB remains a major global health problem with over 1.5 million deaths and 9.4 million new cases in 2014 (WHO, 2015c). The 2015 Global Tuberculosis Report reported South Africa as one of the top 10 countries of 2014 with the highest number of incident cases; it was
also reported as having the largest number of HIV associated TB cases (WHO, 2015c).

Vaccination strategy

The Bacille Calmette-Guérin (BCG) vaccine developed in 1921 remains the only vaccine against TB meningitis and miliary disease; however it does not confer any protection against active pulmonary TB infection (WHO, 2004). The BCG vaccine contains a live attenuated strain of the *Mycobacterium bovis*. The WHO (2004) recommends that a single dose of BCG be given to all infants as soon as possible after birth, in all countries with a high burden of TB. Immunisation with BCG vaccine reaches over 80% of neonates and infants in most developing countries, and is the most widely used vaccine compared to all current vaccines that are part of national EPI programmes (WHO, 2004; SADoH, 2012).

2.6.2 Polio

Poliomyelitis (polio) is a highly infectious viral disease that can result in irreversible paralysis or death cause by the poliovirus. Polio can affect any age group, but it most commonly occurs in young children under five years of age (SADoH, 2012; WHO, 2014). The poliovirus is a ribonucleic acid (RNA) virus of the enterovirus subgroup which are transient inhabitants of the gastrointestinal tract (GIT). There are three serotypes of the wild poliovirus, type 1, type 2 and type 3. Unfortunately having immunity to one type does not confer immunity to the other types (CDC, 2015d; SADoH, 2012).

Wild poliovirus is commonly transmitted from person to person through the faecal-oral route in environments of poor sanitation; however it can also be transmitted through the oral-oral (mouth-fingers-mouth) route in environments with good sanitation. Mixed patterns of transmission of the poliovirus occur in most environments (Robertson, 1993; WHO, 2014; CDC, 2015d). Following entry through the mouth, the poliovirus replicates in the pharynx and GI tract and then spreads to other areas in the body, including the anterior horn cells of the spinal cord resulting in acute flaccid paralysis (AFP). The majority of wild poliovirus infections show no symptoms, however 25% of infections may develop minor symptoms such as fever, headaches and sore throat. The incubation period for non-paralytic poliomyelitis is usually 3 to 6 days and for paralytic poliomyelitis is usually 7 to 21 days (CDC, 2012;
WHO, 2014). People infected with non-paralytic or paralytic poliomyelitis can excrete the virus in stools, thus areas of low immunisation coverage are at a higher risk of polio transmissions (WHO, 2014; SADoH, 2012).

Globally the continued use of polio vaccines have resulted in a significant decrease of more than 99% in wild poliomyelitis cases from an estimated 350 000 cases in 1988 to 407 cases in 2013 (Polio Global Eradication Initiative [PGEI], 2015). In 2014 only three countries namely Afghanistan, Nigeria and Pakistan remained with endemic polio (WHO, 2014; CDC, 2014). Recently (2015), only 60 cases of wild poliomyelitis have been reported in Afghanistan and Pakistan (PGEI, 2015).

Vaccination strategy

There are two types of polio vaccines available worldwide; the inactivated polio vaccine (IPV) and the live attenuated oral poliovirus vaccine (OPV) (WHO, 2014). Because OPV contains live attenuated polioviruses, it can under very rare circumstances result in vaccine-associated paralytic polio (VAPP) or vaccine-derived polio virus (VDPV). Over 90% of circulating VDPV and approximately 40% of all VAPP cases are caused by the type 2 component of trivalent polio vaccine (tOPV). And for this reason the WHA has called for a global switch from tOPV to bivalent OPV (bOPV), which only contains type 1 and 3 polio serotypes. The switch is scheduled to take place in April 2016 (PGEI, 2015; Diop et al, 2015). Currently the EPI-SA offers both these vaccines; a trivalent OPV containing the 3 three polio serotypes is given at birth and IPV which is offered as part of the DTaP-IPV//Hib combination vaccine, is given at 6, 10 and 14 weeks (SADoH, 2012).

2.6.3 Hepatitis B

Hepatitis B (HB) is a highly infectious viral disease cause by the hepatitis B virus (HBV), a partially double-stranded deoxyribonucleic acid (DNA) virus, and a member of the Hepadnaviridae family (Previsani and Lavanchy, 2002; WHO, 2009a). HBV is most commonly transmitted from person to person through the exchange of bodily fluids during sexual intercourse, unscreened blood transfusions, the use of needles contaminated with HBV infected blood and from mother to child during pregnancy (WHO, 2009a; Block et al, 2007). In the sub-Saharan region the most common route of transmission is horizontal transmission between young children (Tabor et al, 1985; Karim et al, 1988). HB is a liver disease, the virus attaches and replicates in the
hepatocytes of infected individuals. The first six months following infection with HBV, an individual may develop acute HBV infection which may vary in severity from non-symptomatic infection to mild ailment. Should the acute infection not be cleared, an infected individual is at risk of developing chronic HBV infection which may lead to serious health problems such as liver cirrhosis, Hepatocellular carcinoma or death (Carey, 2009; Liang, 2009; WHO, 2009a). Individuals who are infected with HBV perinatally are at a higher risk of developing chronic HBV infection (80%-90%), followed by children infected before the age of 6 years (30%) (Previsani and Lavanchy, 2002; WHO, 2009a).

The WHO estimates that globally more than 2 billion people have been infected with HBV and that approximately 360 million people are living with chronic HBV infection (WHO, 2009a). The prevalence of mono-infection with HB in South Africa has been estimated at approximately 10% for the rural population and 1% in urban areas (Firnhaber and Ive, 2009).

Vaccination strategy

The recombinant HB vaccine manufactured from the production of HB surface antigen (HBsAg) in yeast, Saccharomyces cerevisiae has been available since 1986. This yeast-derived vaccine is highly effective for both pre-exposure and post-exposure prophylaxis (Ott and Aruda, 1999; WHO, 2009a; Burnett et al, 2012). The EPI-SA introduced the monovalent HB vaccine in 1995, which was administered to young children intramuscularly at 6, 10 and 14 weeks (Burnett et al, 2012; SADoH, 2012). In an effort to reduce the number of injections administered to children during the EPI programme, the EPI-SA is in the process of switching from the monovalent HB vaccine to a combination hexavalent vaccine Hexaxim® (DTaP-IPV-Hib-Hep B) (Amayeza Info Centre, 2015).

2.6.4 Rotavirus disease

Rotavirus is a highly infectious virus that causes gastroenteritis or the inflammation of the stomach and intestines. The rotavirus is a double stranded RNA virus from the Reoviridae virus family. Rotavirus infection is the leading cause of severe diarrhoea among children under the age of 5 years worldwide (WHO, 2013e). The rotavirus is easily transmitted through the faecal-oral-route, when infected individuals shed the virus in their stool into the environment. Once in the environment, it can be spread
through contaminated hands, objects, food and water (SADoH, 2012; WHO, 2013e; PATH, 2014).

Although rotavirus infections mostly occur in children under the age of 5 years, infants and children between the ages of 3 months and 2 years are at a higher risk of experiencing severe rotavirus disease. Symptoms of a rotavirus infection include vomiting, very watery diarrhoea, fever, abdominal pain and dehydration. Rotavirus infections are most common during the winter months. Following infection with the virus, symptoms can occur anywhere from 2 to 3 days, and may last up to 3 to 8 days. Symptoms can be managed through proper replacement of body fluids by oral rehydration. Severe rotavirus infection can be prevented through immunisation (SADoH, 2012; WHO, 2013e; PATH, 2014).

The WHO estimated that, worldwide more than 4 million rotavirus gastroenteritis associated deaths were reported in 2008. Rotavirus infection was also responsible for millions of hospitalisations and clinic visits (WHO, 2013e; Tate et al, 2012). In South Africa death due to diarrheal causing disease is ranked third in children under the age of 5 years (Bradshaw et al, 2003).

Vaccination strategy

Worldwide there are two rotavirus vaccines (RV) licensed for use routinely in immunisation programmes, the Rotarix® and the Rotateq™ vaccines. The EPI-SA uses the Rotarix® vaccine; it is given orally in two doses at 6 and 14 weeks of age (SADoH, 2012; WHO, 2013a; PATH, 2014).

2.6.5 Tetanus

Tetanus (lockjaw) is a non-communicable bacterial disease caused by toxins produced by *Clostridium tetani*. *C. tetani* is a gram positive, spore forming bacteria (WHO, 2006b; CDC, 2012). Transmission of tetanus occurs when the spores from the *C. tetani* which are commonly found in soil are introduced into acute wounds, and release a toxin which blocks inhibitory neurotransmitters in the central nervous system (WHO, 2010a; WHO, 2006b). This results in the typical muscle rigidity and spasms of a general tetanus infection. Tetanus can affect children and adults, either following birth in an unsanitised environment (neonatal tetanus or NNT) or through an exposed wound (WHO, 2010a; WHO, 2006b; SADoH, 2012).
In 1989 the WHA announced plans to eliminate NNT globally. Since the call for global elimination of NNT, the condition has decreased from more than 400 000 deaths in 1994 to 49000 deaths in 2013 (WHO, 2006a; UNICEF, 2010; Khan et al, 2015). In South Africa NNT cases dropped from 177 in 1988 to a range of 6-10 cases in 1998 to 2006 (Ngcobo, 2008). In 2002 South Africa met the goal set by the WHA to eliminate maternal and NNT as a public health problem (Ngcobo, 2008; SADoH, 2012).

Vaccination strategy

The tetanus vaccine is a toxoid vaccine that contains a modified neurotoxin which induces protective antitoxin. The vaccine is available as a single tetanus toxoid (TT) or as TT-containing combination vaccines with diphtheria (Td) and pertussis (DTaP or DTwP) (WHO, 2006a). In most countries including South Africa DTaP, is given in combination with IPV, *Haemophilus influenzae* type b (Hib), hepatitis B as DTaP-IPV-HepB/Hib or hexavalent vaccine. In the EPI-SA schedule hexavalent vaccine is given at 6, 10 and 14 weeks, with a booster dose at 18 months. Two additional doses of tetanus vaccine are given at 6 and 12 years of age as Td vaccine (SADoH, 2012).

2.6.6 Pneumococcal disease

Pneumococcal disease is caused by multiple serotypes of the *Streptococcus pneumoniae* bacteria (pneumococcus). Pneumococcus is commonly found in the respiratory tract of healthy individuals. Infection with pneumococcus is acquired through inhalation of contaminated respiratory tract droplets when an infected individual coughs, talks or sneezes. The population that is at risk of invasive infection by pneumococcus includes the elderly, children under 2 years of age and children in group childcare settings (SADoH, 2012; WHO, 2012).

Infection with pneumococcus may lead to invasive pneumococcal infections such as severe pneumonia and meningitis. It also causes non-invasive or less-invasive pneumococcal infections such as the common ear and sinus infections (WHO, 2012).

Morbidity and mortality caused by pneumococcal disease is a major cause for concern worldwide. In 2005 the WHO estimated that globally more than 1 million deaths are caused by pneumococcal disease annually, with about 700000 deaths occurring in children under the age of 5 years (WHO, 2005). In South Africa a study
conducted by von Gottenberg et al (2013) showed a significant decline in the incidence of invasive pneumococcal disease from 54.8% during the pre-vaccine era to 17.0% following introduction of PCV into the EPI-SA.

Vaccination strategy

There are several PCVs that are licensed for use against pneumococcal infections that may contain up to 23 serotypes of the pneumococcal bacteria. The EPI-SA currently offers PCV-13 in its schedule at 6 and 10 weeks, with a booster dose at 9 months of age (Madhi et al, 2012; SADoH, 2012).

2.6.7 Measles

Measles is a highly contagious disease caused by the measles virus which is a single stranded RNA virus from the Paramyxoviridae family. Measles is spread easily through the inhalation of infected respiratory air droplets from coughing, sneezing or breathing. The measles virus can also be spread through direct contact of infected upper respiratory tract secretions (WHO, 2009b; CDC, 2015c).

Some common symptoms following infection with measles include fever, red eyes, coughing and runny nose, followed by the appearance of a rash 3 to 5 days later. Mortality from measles usually arises from complications such as encephalitis, severe diarrhoea and pneumonia. Measles related complications are most common in children under the age of 5 years, especially those who are malnourished and have a vitamin A deficiency (WHO, 2009b; CDC, 2015c).

Worldwide before the introduction of the measles vaccine, the disease was responsible for an estimated 2.6 million deaths annually. Worldwide death due to measles has decreased from 197 000 in 2007 to approximately 114 900 in 2014 (WHO, 2009a; WHO, 2015a). In South Africa there has been multiple measles outbreaks in the recent past due to failure to reach optimal vaccine coverage (McMorrow et al, 2009). The first outbreak occurred between 2003 and 2005 involving 1676 lab confirmed cases, the second very large outbreak occurred between 2009 and 2011 and involved 18431 laboratory confirmed cases (McMorrow et al, 2009; Ntshoe et al, 2013). This is evidence that there is a need to strengthen immunisation programmes in South Africa.
Vaccination strategy

There are several live, attenuated measles vaccines licensed for use worldwide. The measles vaccine may be offered either as a monovalent vaccine or measles containing vaccine (MCV) with rubella, mumps or varicella (WHO, 2009b; CDC, 2015c). The EPI-SA offers the monovalent measles vaccine at 9 months and second dose at 18 months of age (SADoH, 2012). Currently, a new measles monovalent vaccine has replaced the old one and it is given at a different schedule of 6 months and 12 months. Measles vaccination is also commonly offered during mass immunisation campaigns or supplementary immunisation activities annually of following an outbreak to all children between the ages of 6 months and 15 years (WHO, 2009b; Bernhardt et al, 2013).

2.6.8 Pertussis

Pertussis or whooping cough is a highly infectious respiratory bacterial disease caused by *Bordetella pertussis*. *B. pertussis* is a gram negative bacterium of the Alcaligeriaceae family that colonises the human respiratory tract. Pertussis spreads easily through infected air droplets from person to person during coughing or sneezing. It can also be spread through direct contact with infected secretions from the nose and mouth. Parents are a common source of pertussis infections for infants, while other adult household dwellers also provide another potential source of infection for infants. Pertussis infections commonly occur among children aged between 1-5 years; however the disease is particularly severe and even fatal in infants. In adolescents and adults, it is often unrecognized because its course is frequently asymptomatic (USAID, 2003; Cherry, 2005; SADoH, 2012).

Symptoms following infection with pertussis are usually mild at first and may resemble those of a common cold. After 1 to 2 weeks symptoms may become severe, due to thick mucus accumulation inside the lung airways causing uncontrollable coughing (SADoH, 2012; WHO, 2010c).

WHO estimates that in 2008, about 16 million cases of pertussis occurred globally, 95% of which were in developing countries, and that about 195000 children died from the disease (WHO, 2010a). In 2011 more than 160000 cases of pertussis were reported worldwide, with about 5800 cases reported in the African region (WHO, 2010a; WHO, 2013d). Between April 2008 and June 2011, 311 laboratory confirmed
cases of pertussis were reported in South Africa (National Health Laboratory Services [NHLS], 2011).

Vaccination strategy

There are two types of pertussis vaccines available, the whole-cell pertussis vaccine (wP) which contains killed *B. pertussis* organisms and the acellular pertussis vaccine (aP) which contains highly purified individual pertussis antigens. The vaccine in the EPI-SA is available as the acellular pertussis in a combination form with tetanus, diphtheria, IPV, hep B and (Hib) as hexavalent vaccine. In the EPI-SA schedule hexavalent vaccine is given at 6, 10 and 14 weeks, with a booster dose at 18 months (USAID, 2003; SADoH, 2012; WHO, 2010c).

2.6.9 *Haemophilus influenzae* type b infection

Hib is a bacterium which is a major cause of severe meningitis, pneumonia, and other invasive diseases especially in children under the age of 5 years (Obonyo and Lau, 2006; WHO, 2013e). Hib disease is spread from person to person through the transmission of respiratory air droplets to susceptible individuals. Infection with *Hib* can lead to either a local disease from direct spread; or it can lead to invasive disease by invading the blood stream and spreading to other sites in the body (WHO, 2013b).

The major burden of *Hib* disease is among children under the age of 5 years, especially within the age range 4-18 months old. More than 90% of invasive Hib disease occurs in this age group. In developed countries there is low *Hib* mortality (46%), whereas in developing countries especially in the African and Asia regions there is high mortality at 80% among children less than 12 months of age (SADoH, 2012; WHO, 2013b).

Vaccination strategy

A Hib conjugate vaccine is available for use in immunisation programmes. The Hib conjugate vaccine is usually given as part of a combination vaccine together with other vaccines. The vaccine in the EPI-SA is also available as in a combination form with tetanus, diphtheria, hep B, IPV, and pertussis as hexavalent vaccine. In the EPI-SA schedule hexavalent vaccine is given at 6, 10 and 14 weeks, with a booster dose at 18 months (SADoH, 2012; WHO, 2013b).
2.6.10 Diphtheria

Diphtheria is an acute disease caused by the toxin released by the bacterium *Corynebacterium diphtheriae*. There are four strains of *C. diphtheriae* that produce toxin which can cause severe disease in humans (SADoH, 2012; CDC, 2015d). Diphtheria is spread through the inhalation of infected air droplets and close physical contact (WHO, 2006a; CDC, 2015b). Following infection by *C. diphtheriae* the bacteria is present in the nasopharyngeal tract where a toxin is released and causes local tissue damage and pseudo-membrane formation (SADoH, 2012; CDC, 2015b). Diphtheria may lead to mild or severe illness, or it may be without symptoms. Depending on the anatomical site of disease, diphtheria can develop into a local infection which is classified as non-invasive diphtheria and symptoms may include sore throat, barking cough and enlarged lymph nodes in the neck. Diphtheria can also develop into a more serious systemic infection in which the diphtheria bacteria invade organs such as the kidneys, heart and nervous system; this form of *C. diphtheriae* infection may be fatal (WHO, 2006a; CDC, 2015d).

There has been a drop in the incidence of diphtheria cases in developed countries compared to developing countries in which diphtheria remains endemic (WHO, 2006a; Johnston, 2011). In South Africa the number of reported diphtheria cases declined from 29 cases in the 1990s to less than 5 in the 2000s (Liebenberg et al, 2009). Most recently in 2015, there were several cases of confirmed and suspected diphtheria cases in KwaZulu Natal, which resulted in one fatality (National Institute for Communicable Diseases [NICD], 2015).

**Vaccination strategy**

The vaccine that is available for prevention of diphtheria is a conjugate vaccine that contains formalin detoxified diphtheria toxin. The diphtheria vaccine is available only as part of a combination vaccine with other vaccines such as tetanus, pertussis, IPV and Hib (WHO, 2006a). The EPI-SA schedule offers 6 doses of diphtheria vaccine as part of the DTaP-IPV//Hib combination vaccine at 6, 10 and 14 weeks, with a booster dose at 18 months. Two additional doses are given at 6 and 12 years old in the form of the Td vaccine (WHO, 2006a; SADoH, 2012).
2.7 The Road to Health Card

The road to health card (RTHC) or booklet is a tool that is used to monitor the overall health and the development of the child. It is given for free in both private and public healthcare facilities to mothers after the birth of the child (Tarwa and de Villiers, 2007). The RTHC contains important health information about the child such as, the mother’s antenatal care history, family history, details about the labour and birth of the child, guidelines for infant feeding, history of illness, the child’s growth development and immunisation history (WHO, 1991; Tarwa and de Villiers, 2007; SADoH, 2012).

With regards to immunisation history, the RTHC provides information such as vaccine doses received by the child, the vaccine batch number, the date of vaccination and next appointment date (WHO, 1991; SADoH, 2012). RTHCs also contain helpful information for the mother or caregiver about the vaccines given and the diseases they protect against; also information about what to do in the case of adverse events following vaccination (AEFV) (Tarwa and de Villiers, 2007; SADoH, 2012).

During vaccine coverage studies RTHCs can be used as a tool to verify whether a child has received a vaccine and if they were at the appropriate age when vaccinated (WHO, 1991). Healthcare workers can also use the RTHC to screen for missed vaccination opportunities, and where indicated, to vaccinate the child. Several studies have shown that in settings where healthcare workers check the RTHC at clinic visits (Tarwa and de Villiers, 2007), and where caregivers understand the importance of the RTHC, the children are more likely to have good immunisation statuses (Asuzu, 1991; Schoub et al, 1991).

2.8 Immunisation Coverage

WHO defines immunisation coverage as the proportion of individuals in the target population who have been immunised (WHO, 1991). Routine immunisation coverage is the most basic indicator of performance of an immunisation programme and is widely used as a basic health indicator (Ngcobo, 2008). The goals of the EPI-SA for immunisation coverage are to achieve fully immunised coverage for children under the age of 1 year of at least 90% at national level and 80% in all districts by the year
2015 (SADoH, 2012). There are two ways to measure immunisation coverage through (i) administrative data on doses administered then recorded at healthcare facilities or through (ii) immunisation coverage survey methods (WHO, 2016b).

2.8.1 Immunisation or vaccination coverage surveys

Vaccination coverage surveys study a fraction of a population in a systemic way in order to determine the immunisation status of the overall population (WHO, 1991; WHO, 2005). Results obtained following a vaccination coverage survey provide information about childhood immunisation, and if the immunisation targets set at district and national level are being achieved. Vaccination coverage surveys also provide a platform for those working in the healthcare sector to come into direct contact with individuals in the population who are not receiving vaccines and the reasons behind these non-vaccinations. There are several similar studies that have been conducted locally in different parts of South Africa including, a study conducted by Corrigall et al (2008) in the Western Cape Province which aimed to determine the immunisation coverage of children aged 12-23 months old. The study population included 3705 caregivers who were interviewed and data collected through the observation of the RTHC. Results showed 76.8% immunisation coverage for vaccines due by 9 months and 53.2% for those vaccines due by 18 months. Another similar study was conducted in 3 different geographical areas in South Africa, Paarl (Western Cape), Umlazi (KZN) and Rietvlei (North West). A total of 1137 children between birth and up to 2 years of age were surveyed over a period of 3 years (2006-2008) through 5 interviews with their caregivers. Results from the study were 94% of children from Paarl were fully vaccinated, 88% from Umlazi and only 62% from Rietvlei were fully vaccinated (Fadnes et al, 2011). Results obtained from vaccination coverage surveys may also be used to supplement or validate official administrative coverage reports (WHO, 1991; WHO, 2005). In 2012 the EPI-SA reported that 94% of children in South Africa received DTP3, whereas WHO/UNICEF reported a rate of 72% (HST, 2013; WHO/UNICEF, 2014).

2.8.2 Reasons for non-vaccinations

These are reasons provided by caregivers explaining why they do not take their children for immunisations or why they did not return for more immunisations (WHO, 2005). Corrigall et al (2008), found that major reasons given for non-vaccination by caregivers of children aged 12-23 months old in the Western Cape were clinic-
related factors (47%), with the two commonest reasons being missed opportunities (34%) and being told by clinic staff to return another time (20%). Results obtained here can help in taking the necessary steps to improve immunisation services.
3.1 Study Design
A quantitative descriptive survey was conducted by adapting the WHO Immunization Coverage Cluster Survey protocol (WHO, 2005) for the South African setting.

3.2 Study Setting
The study was conducted in the Refilwe Township situated near the mining town of Cullinan, east of Pretoria in the Gauteng Province. The township was established in 1991 for employees of the Cullinan Diamond mine. However it has since grown into a township divided into old mine employee’s government-provided four roomed houses, new government-provided Reconstruction and Development Programme houses and informal settlements. According to the 2011 Census the Refilwe Township population stands at 19757 (7654.18 per Km$^2$), with the majority being black (98.65%) and Sepedi speaking (51.61%). The majority of the residents in Refilwe Township are of low socioeconomic class (Frith, 2011).

![Figure 3.1 Position of Refilwe Township in the City of Tshwane Municipality](Source: Local Government Handbook, 2015)
3.3 Study Population

The study population included all caregivers of children between the ages of 12-23 months who had been residents for at least 6 months in the Refilwe Township. The 12-23 months age range was selected because these children should have completed their less than 1 year immunisations as per EPI-SA schedule (WHO, 2005).

3.3.1 Inclusion criteria- All caregivers of children aged between 12-23 months during the study period residing in the Refilwe Township who gave consent to participate in the study and who were in possession of the RTHC were included.

3.3.2 Exclusion criteria- If any of the inclusion criteria was not applicable, the child was excluded from the study.

3.4 Sampling Procedure

Initially the WHO ‘30 by 7’ EPI cluster sampling procedure, specifically developed to test for vaccination coverage, was used (WHO, 2005). An aerial map depicting all the households of the township was obtained from the Tshwane City Planning and Development Department. Based on the map and the number of households the township was then divided into 30 clusters. Thereafter 7 units (households) per cluster were visited using the WHO Immunization Coverage Cluster Survey Reference manual (WHO, 2005). First, the map of each selected cluster was used to randomly select the first household in each cluster. Thereafter the researchers moved from house to house in a predetermined manner, visiting every nth house (i.e. the number of houses in the cluster divided by 7) until 7 children of appropriate age with RTHCs and a consenting caregiver were surveyed. However due to the low number of eligible participants being identified on the first day of the survey, this sampling method was abandoned and replaced by a complete census of the township. In cases where there was more than one eligible child in the same household, data on only the youngest child was collected as recommended by the WHO (WHO, 2005).
3.5 Data Collection
Data collection was conducted by one researcher and three research assistants who were trained for two days in accordance with the WHO Immunization Coverage Cluster Survey Reference manual (WHO, 2005). The research assistants were also given training on the EPI-SA and the importance of vaccination and risks associated with low vaccine coverage.

3.6 Data Collection Tools
Data collection was conducted through the use of two researcher-assisted structured questionnaires. The two standardised and validated questionnaires are known as:
(1) The infant immunisation cluster form (immunisation coverage) (Appendix A) and
(2) The reasons for immunisation failure cluster form (Appendix B); both were adapted from the WHO Immunization Coverage Cluster Survey Reference manual (WHO, 2005).

The infant immunisation cluster form (immunisation coverage) consisted of closed-ended questions related to general identification data, such as cluster number, vaccination history, gender, age, date of data collection and identification of interviewer.

For children who were found to be partially vaccinated, the caregivers were also asked questions by the interviewer about the reasons why they were not vaccinated using the second questionnaire, ‘The reasons for immunisation failure cluster form’. This second questionnaire also consisted of closed-ended questions with three sections namely: Section 1: with general identification data such as participant number. Section 2: asks questions grouped under broad categories of lack of information, lack of motivation and obstacle why children are not vaccinated and Section 3: identification of the interviewer.

Whenever lack of motivation or no faith in immunisation or “other” was given as a reason for no vaccination of a child, the caregiver was asked to provide more details which were then captured on a third separate sheet by the researcher.

In addition to the interviews, cell phone cameras were used to capture pictures of all the RTHCs that were presented by the caregivers.
3.7 Data Analysis

Raw data from the cluster forms were captured on Microsoft Excel (Microsoft Office 2013). The data were then compared with the photos of the RTHCs captured in the field. After validating the data with the photos, they were cleaned, coded and then imported to Epi Info™ 7 for further analysis. Descriptive statistical analyses were conducted. These included determinations of the mean age, median age and age range; the proportion of boys and girls included in the study; the vaccination coverage of the different vaccines and vaccine series, and drop-out rates; and frequencies of reasons why children are not vaccinated. The results will be presented in frequency tables, charts and graphs in Chapter 4.

Immunisation coverage was estimated as the proportion of children who have been fully vaccinated against the 10 diseases of the EPI, which for under-one year of age coverage includes a birth dose of BCG vaccine; 2 doses of OPV at 0 and 6 weeks; 3 doses of DTaP-IPV/Hib at 6, 10 and 14 weeks; 3 doses of Hep B vaccine also given at 6, 10 and 14 weeks; 2 doses of Rotavirus vaccine at 6 and 14 weeks; 3 doses of PCV at 6, 14 weeks and a booster dose at 9 months; and 1 dose of measles vaccine at 9 months.

3.8 Reliability and Validity

The two questionnaires used in this study for data collection were adapted from the WHO Immunization Coverage Cluster Survey Reference manual. These standardised questionnaires have been validated and are commonly used in both developed and developing countries globally as data collection instruments used to determine vaccine coverage and reasons for non-vaccination. Only children whose caregivers were able to produce their RTHC were included in the study. Photos of the RTHC captured in the field were used to double check and correct any errors that may have been present on the cluster forms.

3.9 Ethical Considerations

Ethical clearance was obtained from the Medunsa Research Ethics Committee (Appendix C). Permission to conduct the study was obtained from the Tshwane Metropolitan Municipality, Department of Health (Appendix D). All participants were given full information about the aim of the study and were required to sign a consent form, printed in Sepedi (Appendix E) and English (Appendix F). The consent forms
were read and explained to those participants who could not read. Only demographic data of importance for analysis was recorded and child, mother or caregiver information was kept strictly confidential.
Chapter 4 Results

4.1 Deviation from initial protocol sampling procedure

As previously stated in Chapter 3, the initial plan was to collect data using the WHO ‘30 by 7’ cluster sampling method. However, following the first day of data collection it was clear that the ‘30 by 7’ method would not be an efficient method to continue with in order to reach the targeted sample size of 210 eligible children. Below is a list of main reasons why the ‘30 by 7’ method was inefficient in reaching the targeted sample size, in order of most commonly observed to least commonly observed during the survey:

1) There was no one in the household
2) There was no child of the eligible age in the household
3) The mother or caregiver of the child was not at the household
4) The RTHC of the child was unavailable
5) The mother or caregiver refused to consent to participate

Because of these reasons, a decision was taken to conduct a full census of the Refilwe Township. All the households were visited starting from the 16th of February 2015 until the 27th of March 2015.

The total number of the households in the township according to the map obtained from the Tshwane City Planning and Development Department is 6111. Out of the 6111 houses visited there was someone at home to be informed about the project in 2041 households. From these 2041 households only 8.5% (173/2041) had a child who was eligible (correct age; consenting care giver in possession of a RTHC for the child) for this project. Therefore the final sample size and denominator for the level of coverage was 173 RTHC observed and analysed at the end of the study.

4.2 Demographic Data

Figure 4.1 illustrates the proportion of boys (n=74) and girls (n=99) in the study population. Ages ranged from 12.0 to 23.4 months. The mean age was 17.4 months (standard deviation: 3.4), the median age was 17.5 months and mode age was 14.2 months. The age distribution of the children whose caregivers took part in the study is presented in Table 4.1.
Figure 4.1 Sex distribution of the children (n=173).

Table 4.1 Age distribution of the children in months (n=173).

<table>
<thead>
<tr>
<th>AGE IN MONTHS</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.0 – 12.9</td>
<td>22</td>
<td>12.7%</td>
</tr>
<tr>
<td>13.0 – 13.9</td>
<td>11</td>
<td>6.4%</td>
</tr>
<tr>
<td>14.0 – 14.9</td>
<td>22</td>
<td>12.7%</td>
</tr>
<tr>
<td>15.0 – 15.9</td>
<td>18</td>
<td>10.4%</td>
</tr>
<tr>
<td>16.0 – 16.9</td>
<td>8</td>
<td>4.6%</td>
</tr>
<tr>
<td>17.0 – 17.9</td>
<td>11</td>
<td>6.4%</td>
</tr>
<tr>
<td>18.0 – 18.9</td>
<td>14</td>
<td>8.1%</td>
</tr>
<tr>
<td>19.0 – 19.9</td>
<td>18</td>
<td>10.4%</td>
</tr>
<tr>
<td>20.0 – 20.9</td>
<td>18</td>
<td>10.4%</td>
</tr>
<tr>
<td>21.0 – 21.9</td>
<td>15</td>
<td>8.7%</td>
</tr>
<tr>
<td>22.0 – 22.9</td>
<td>10</td>
<td>5.8%</td>
</tr>
<tr>
<td>23.0 – 23.9</td>
<td>6</td>
<td>3.5%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>173</strong></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>

4.3 Vaccination Status

4.3.1 Objective 1: Immunisation coverage of children aged 12-23 months old in Refilwe Township.

All the 173 (100%) children who were surveyed in the Refilwe Township had received one or more of the vaccines that are recommended by the EPI-SA schedule up to 9 months of age. Figure 4.2 illustrates the proportions of children who were fully immunised (154/173) versus those who were partially immunised (19/173).
Figure 4.2: Vaccination status of the children (n=173).

The vaccination coverage for the specific vaccines recommended by the EPI-SA from birth to 9 months is presented in Figure 4.3.

Figure 4.3 Vaccination coverage for individual vaccines.

The vaccination coverage for the different vaccine combinations and drop-out rates between the scheduled vaccinations are presented in Table 4.2. The highest drop-
out rate was observed between children who were fully immunised at 14 weeks second dose of RV2 and those who were fully immunised at 9 months.

Table 4.2 Vaccination coverage for different vaccine combinations.

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>Frequency</th>
<th>Percentage (%)</th>
<th>Drop-out Rate (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG+OPV0</td>
<td>172</td>
<td>99.4</td>
<td>0.6</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1</td>
<td>167</td>
<td>96.5</td>
<td>2.9</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1</td>
<td>165</td>
<td>95.4</td>
<td>1.2</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1+Penta1</td>
<td>165</td>
<td>95.4</td>
<td>0.0</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1+Penta1+HepB1</td>
<td>165</td>
<td>95.4</td>
<td>0.0</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1</td>
<td>165</td>
<td>95.4</td>
<td>0.0</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2</td>
<td>163</td>
<td>94.2</td>
<td>1.2</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2</td>
<td>163</td>
<td>94.2</td>
<td>0.0</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2+RV2</td>
<td>161</td>
<td>93.1</td>
<td>1.2</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2+RV2+Penta3</td>
<td>160</td>
<td>92.5</td>
<td>0.0</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2+RV2+Penta3+HepB3</td>
<td>160</td>
<td>92.5</td>
<td>0.0</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2+RV2+Penta3+HepB3+PCV2</td>
<td>160</td>
<td>92.5</td>
<td>0.0</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2+RV2+Penta3+HepB3+PCV2+Measles</td>
<td>154</td>
<td>89.0</td>
<td>3.5</td>
</tr>
<tr>
<td>BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2+RV2+Penta3+HepB3+PCV2+Measles+PCV3</td>
<td>154</td>
<td>89.0</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Fully Immunised</strong></td>
<td><strong>154</strong></td>
<td><strong>89.0</strong></td>
<td></td>
</tr>
</tbody>
</table>

* vaccine drop-out rate has been calculated using the number of children who received the previous vaccine in the schedule as the denominator.

Figure 4.4 illustrates how for some vaccines, the frequency of the second dose is higher than the combined frequency of the first + second doses. That is, in the RTHC the vaccine is recorded as being given as a second or third dose, without the first
dose ever being received. This discrepancy between individual vaccines has a negative effect on the overall vaccine coverage of the population.

**Figure 4.4 Receipt of 2\textsuperscript{nd} vaccine dose vs 1\textsuperscript{st} and 2\textsuperscript{nd} vaccine doses combined.**

4.3.2 Objective 2: Reasons for non-vaccinations

From the 173 children who were surveyed in the study, only 19 (11.0\%) were found to be partially immunised i.e. missing one or more vaccinations as observed on their RTHC. The second questionnaire grouped the reasons for non-vaccination into 3 categories as presented in Table 4.3.
Table 4.3 Reasons for non-vaccination (n=19)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Reason</th>
<th>Frequency</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lack of Information</strong></td>
<td>Unaware of the need to vaccinate</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Unaware of the need to return for 2nd or 3rd dose</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Fear of side-effects</td>
<td>1</td>
<td>5.3</td>
</tr>
<tr>
<td></td>
<td>Wrong ideas about contraindications</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Place and/or time of immunisation unknown</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Lack of Motivation</strong></td>
<td>Postponed until another time</td>
<td>1</td>
<td>5.3</td>
</tr>
<tr>
<td></td>
<td>Cultural/religious reasons</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Rumours about vaccination</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>No faith in vaccinations</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>*Other</td>
<td>3</td>
<td>15.8</td>
</tr>
<tr>
<td><strong>Obstacles</strong></td>
<td>Time of immunisation inconvenient</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Vaccine not available</td>
<td>5</td>
<td>26.3</td>
</tr>
<tr>
<td></td>
<td>Mother too busy</td>
<td>3</td>
<td>15.8</td>
</tr>
<tr>
<td></td>
<td>Family problem including illness of mother</td>
<td>1</td>
<td>5.3</td>
</tr>
<tr>
<td></td>
<td>Child ill - brought but not given immunisation</td>
<td>2</td>
<td>10.5</td>
</tr>
<tr>
<td></td>
<td>Long waiting time at health facility</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>**Other</td>
<td>3</td>
<td>15.8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>19</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>1. Mother reported to have taken child for all vaccinations, but the RTHC shows that some were missed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Mother reported that she takes the child to the clinic only when sick</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Mother skipped some of the early vaccines due to lack of motivation, and will not go for catch-up because she is afraid of the nurses.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>**<strong>Other</strong></td>
<td>1. Mother in possession of the old EPI-SA RTHC which does not list the vaccines introduced into the EPI-SA from 2009, thus it is unclear whether or not the child received the vaccines (see Figure 4.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Mother also in possession of the old EPI-SA RTHC, however, although the new vaccines were hand written onto the old RTHC, the mother reports that to her knowledge the child received all the required vaccines and she was not informed by the nurses that there was a missed vaccine.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Mother in possession of the private sector RTHC, which differs from the government provided RTHC and does not offer OPV (1) at 6 weeks. Thus it is unclear whether or not the child received the vaccine (see Figure 4.6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 4.5 Old EPI-SA RTHC which does not include vaccines introduced in 2009.
Figure 4.6 Private sector RTHC which does not include OPV(1).
CHAPTER 5 Discussion, Conclusions and Recommendations

5.1 Vaccination Coverage

5.1.1 Under 1 year vaccination coverage

The under-one year of age vaccination coverage in Refilwe Township was determined only through the examination of RTHCs of children aged between 12 and 23 months. The study results show that the vaccination coverage in Refilwe Township is 89%, which is higher than the set minimum target of 80% at district level and below the set national target of 90% for fully immunised children at 12 months of age (SADoH, 2012; HST, 2014). According to the District Health Barometer (2013/14), the national vaccine coverage for 2013/14 was below the target goal at 84.4%; and 109% for Gauteng Province. A similar study conducted by Corrigall et al (2008) in the Western Cape Province, found the vaccination coverage to be lower than that of the current study at 76.8%. However this study by Corrigall et al (2008) excluded vaccinations with Hib and Hep B; and was conducted prior to the national introduction of PCV and RV. Another study which was also conducted prior to the national introduction of PCV and RV between 2006 and 2008 in three sites in South Africa, (Fadnes et al, 2011) found the vaccination coverages to range from 94% for Paarl (Western Cape Province), 88% in Umlazi (KwaZulu Natal Province) to 62% in Rietvlei (also KwaZulu Natal Province).

5.1.2 Vaccination coverage of individual vaccines

Vaccine coverage for individual vaccines was found to be greater than 90% for all vaccines which exceeds the target goals set at both district and national level. BCG and OPV0, which are the vaccines given at birth had 100% and 99% coverage respectively. The Measles1 and PCV3 vaccines are both given at 9 months and had the lowest individual vaccine coverage at 94.8% and 94.2% respectively. Similarly, in other studies that were conducted in South Africa, BCG had the highest individual vaccine coverage (Corrigall et al, 2008; Fadnes et al, 2011; Wright et al, 2011), and Measles1 had the lowest individual vaccine coverage (Wright et al, 2011).

This low vaccine coverage for Measles 1 and PCV 3 vaccines may be explained by three possible reasons:
• Mothers are no longer on maternity leave and are back at work, and thus may be too busy to take the child to the clinic for vaccinations.

• Because of the large gap in time between the last vaccines at 14 weeks and the 9 months vaccines, mothers may have forgotten about vaccinations.

• Mothers may have thought that vaccinations are no longer necessary as the child was growing well without any illnesses.

These presumptions are supported by a study that was conducted in the Garankuwa Township (Wright et al, 2011), which found that an astounding 89.6% of mothers reported that their children’s RTHCs were not up-to-date because their children were growing well, while 17% reported that they were not reminded of the next vaccination appointment. Therefore this shows that there is a need for ways in which caregivers should be educated about the importance of completing the schedule and be reminded regularly about their next vaccination appointment through the local healthcare facility. This can be done through mini vaccination lessons while the parents queue at the clinic or by mobile phone reminders (Hofstetter et al, 2015; Rand et al, 2015).

5.1.3 Drop-out rates

According to WHO, an immunisation drop-out rate that is greater than 10% is unacceptable, and is an indication of problems in the immunisation programme’s service delivery (WHO, 2005). For this study, the drop-out rates between all the vaccine series (Table 4.3) were below 10%, which indicates that the quality of the immunisation programme in the Refilwe Township meets the WHO requirements. Ideally there should not be drop-outs between individual vaccines in the same series since they are given at the same time. However, there were a number of drop-outs between vaccines given at the same time, for example there was a drop-out rate of 0.6% between BCG and OPV0, i.e. there was one child who received BCG but did not receive OPV0. Also, although 100% of the children received both Penta 1 and HepB1 at 6 weeks, there were children who did not receive the rest of the 6 weeks vaccines. This trend was also observed at 10 and 14 weeks, as well as at 9 months. This could be due to poor data capturing on the RTHC by the nurses, or it could also be due to vaccine stock-outs at the clinic, which was reported by 26% of caregivers of children who were not fully immunised in this study. Vaccine stock-outs were
reported as the major challenge for vaccination programmes by the Health-e News investigation services (Health e-News, 2014). They conducted weekly vaccination monitoring at five clinics in Gauteng, Eastern Cape and Limpopo, and they found that during that time there were stock-outs of polio, rotavirus, hepatitis B and Penta vaccines that lasted from 1 to 4 weeks. The actual reasons that were given by mothers explaining these drop-out rates in the current study are discussed in the following sections.

5.1.4 Missed vaccination opportunities
The WHO (2015b) defines missed vaccination opportunities as any contact with a health service that did not result in an eligible child or woman receiving the needed vaccines. The WHO (2013d) reports that the most common reason for missed vaccinations especially in developing countries is due to poor healthcare worker practices. According to the SADoH (2012), in order to minimise these missed vaccination opportunities, healthcare workers need to check the RTHC at every healthcare facility visit, and if it is not up-to-date, the child should be vaccinated with all missed doses appropriate for age. For example, when a child is brought in for their 9 months measles 1 and PCV3 vaccines, they can also be given any of the vaccines missed at 6, 10 or 14 weeks. In the current study however, this was not always the case because the results showed that 94.2% of children received their Measles1 and PCV3, but the overall coverage was at 89.0%. This may be an indication that nurses don’t always check the RTHC.

5.2 Reasons for Non-vaccinations and Missed Vaccination Opportunities
Of the 173 children whose caregivers participated in this study, 11% were found to be partially immunised. Their caregivers were asked to give reasons why their children have not completed the vaccination schedule

The most common reason given in this study for failure to complete the vaccination schedule for children aged between 12-23 months in the Refilwe Township was obstacles experienced by caregivers in their personal lives and at the healthcare facilities. Just over 26% of the caregivers of partially vaccinated children reported that the unavailability of vaccines at the healthcare facility was their biggest obstacle. This finding is similar to the results of the study conducted in the Western Cape (Corrigall et al, 2008), which also found that 47.1% of their participants whose
children were partially vaccinated, reported clinical factors as the biggest reason for failure to complete the child’s vaccination schedule, with 8% of this group reporting vaccine unavailability as their reason. Another similar study conducted in the Garankuwa Township (Wright et al, 2011), also reported that 16.2% of children in their study were partially vaccinated due to service related problems, which included being turned away from the healthcare facility due to unavailability of vaccines. This is also in line with the results of the investigation conducted by Health-e News, which revealed that vaccine stock-outs are common in South African clinics. Vaccine stock-outs occur when the demand for the vaccines by the community, cannot be met by the healthcare facility’s inventory (Unite for Sight, 2010). Therefore healthcare workers at the healthcare facilities need to improve on vaccine management which involves proper estimation of vaccines needed for a particular population over a stated supply period (Tarwa and de Villiers, 2007; Unite for Sight, 2010). Another common reason for incomplete vaccination given by caregivers in the Refilwe Township was that caregivers are working and thus are too busy to take the child to the local Refilwe clinic on vaccination days (Mondays to Wednesdays), as reported by several mothers. However the South African Department of Health maintains that every day should be a vaccination day at all healthcare facilities that offer immunisation services (SADoH, 2012).

Other reasons for non-vaccinations and missed vaccination opportunities that were commonly reported in the study included: lack of information regarding vaccine side-effects (5.3%), and vaccine contraindications that resulted in sick children being turned away from the clinic and not being given a return date for once the child is well (10.5%). This is in agreement with the Corrigall et al (2008) study, which reported that 24.5% of participants, whose children were partially vaccinated, cited incorrect ideas about vaccination contraindications in relation to sick children. Healthcare workers need to be well informed about vaccine safety with regards to side-effects and contraindications in order to avoid future non-vaccinations and missed vaccination opportunities. One participant reported that she was not motivated to take the child for immunisations because she was afraid that the nurses would be rude to her since she had missed more than one vaccine. Parents’ bad experiences at immunisation visits due to lack of support and bad attitude has been
shown to play a role in low childhood immunisation (Helman and Yogeswaran, 2004; Schwarz et al, 2009).

5.3 Limitations of the Study

5.3.1 Selection bias because of low response rate

The initial recommended WHO ‘30 by 7’ cluster sampling method was changed due to reasons given in the previous chapter. Therefore a complete census of the township was attempted; however the targeted sample size of 210 was not reached and only 173 respondents were surveyed. Possible explanations for the reasons detailed in the previous chapter, based on the researcher’s experiences during data collection, are discussed below:

- There was no one in the household

The survey was conducted in working hours during the day when it was the safest for the researchers. However, because Refilwe Township is situated in the mining and tourist town of Cullinan, a majority of the residents are employed by the mine and guesthouses, and by homeowners in the suburbs (as domestic workers and gardeners) around the mine. This may have resulted in an underrepresentation of caregivers who are employed, and an overrepresentation of those who are not employed, in the final sample.

- There was no child of the eligible age in the household

In some households where there was someone home, there was no child of the eligible age. Possible explanation could be, since Cullinan is a mining and tourist town with job opportunities, most people move there seeking employment and thus once employed, they may leave their children behind with grandparents in the rural areas where there are few job opportunities. They chose to leave the children behind because most of the jobs are for low salary and thus they cannot afford to pay for childcare. This is a very common trend in South Africa where children are raised by grandparents in the rural areas due to parents’ labour migrations (Statistics South Africa, 2010).

- The mother of the child was not at the household
In some households although there was a child of the eligible age, the mother was not around to give consent. The child was left with either a nanny or grandparent who did not know where the child’s RTHC is placed or did not feel comfortable participating in the survey without the mother’s consent. In some cases the child was being watched at the non-parent caregiver’s household without their RTHC. The SADoH states that the RTHC should be kept safe and available where ever the child is in case of an emergency.

- The mother or caregiver refused to consent to participate

In a few cases, the mother of the child refused to give consent to participate in the survey. In some of these cases, the caregivers seemed untrusting and fearful of the researchers, despite the researchers reassuring them that they are not nurses or department of health officials, but merely students conducting research for degree purposes. It is possible that because the child’s HIV status is disclosed on the RTHC, this may also have made mothers reluctant to participate.

5.3.2 Information bias

- There may be recall bias in this study, since caregivers needed to recall the reasons why their child missed a specific vaccination. The researcher could not verify some specific reasons given by caregivers e.g. if it was true that the local clinic experienced specific vaccine shortages at the time when children were taken for vaccination.

5.4 Conclusions

The vaccination coverage in the Refilwe Township is high at 89%, which is above the 80% target goal set at district level and nearly reaches the 90% goal that is set at national level by EPI-SA. The remaining 11% were all found to be partially vaccinated, with 0% having received no vaccinations, therefore this indicates that there is good access to immunisation services in the Refilwe Township.

Reasons given for partial immunisation included obstacles (73.7%), lack of motivation (21.1%) and lack of information (5.3%). Unavailability of vaccines at healthcare facilities proved to be the main reason why most of the children were
partially immunised (26.3%). Vaccine stock-outs remain a big problem in healthcare facilities and have an impact on the overall vaccine coverage of South Africa.

Based on the findings of the study, there clearly is a need for interventions that will strive to improve the level of vaccination coverage in communities.

5.5 Recommendations
The following recommendations are given for health policy makers, healthcare workers, and the community to take into consideration:

- There needs to be an improvement in vaccine procurement at healthcare facility level. This can be achieved through continuous training of healthcare workers on how to manage vaccine logistics and maintain an efficient vaccine cold-chain that will prevent vaccine stock-outs and wastage.
- The National and District health offices need to ensure that their facilities are offering immunisation services every day beyond closing hours so that employed parents can also have the opportunity to vaccinate their children.
- The National Department of Health should consider implementing an electronic immunisation data capturing system that is also able to send out SMS reminders to caregivers to bring their children for their scheduled immunisation visit.
- Through social mobilisation campaigns, the Refilwe Township community can be reached and educated on the importance of immunisation services and how community leaders and fathers can also play a role in ensuring that children are taken for vaccinations.
- Because healthcare workers especially nurses are the first and sometimes the only contact that caregivers have with the health system, there is a need for their healthcare practices to be improved.
  - Healthcare workers should be up-to-date on immunisation issues, and be able to educate caregivers on the importance of immunisation and completion of the recommended immunisation schedule.
  - Caregivers should be educated on why it is important to keep the RTHC safe and in the same household where the baby is residing.
o Nurses should also be reminded to always check a child’s RTHC on every visit, and to appropriately offer catch-up vaccines where necessary. This could be done through training or the display of posters at strategic points around the healthcare facility.

o Nurses should also inform mothers on their upcoming immunisation dates.

o Nurses also need to be educated on the importance of practicing friendliness and patience with their patients even under stressful and resource limited environments.
Appendix A The infant immunization cluster form.

<table>
<thead>
<tr>
<th>CLUSTER FORM 1: Infant Immunisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cluster Number:</td>
</tr>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>Road To Health Card:</td>
</tr>
<tr>
<td>Gender:</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Date Of Birth:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participant Number:</th>
<th>Caregiver</th>
<th>Road To Health Card</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>IMMUNISATION COVERAGE</th>
<th>Received</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine</td>
<td>Age Of Child</td>
</tr>
<tr>
<td>BCG</td>
<td>At birth</td>
</tr>
<tr>
<td>OPV (0)</td>
<td>At birth</td>
</tr>
<tr>
<td>OPV (1)</td>
<td>6 weeks</td>
</tr>
<tr>
<td>RV (1)</td>
<td>6 weeks</td>
</tr>
<tr>
<td>DTaP-IPV/Hib (1)</td>
<td>6 weeks</td>
</tr>
<tr>
<td>Hep B (1)</td>
<td>6 weeks</td>
</tr>
<tr>
<td>PCV (1)</td>
<td>6 weeks</td>
</tr>
<tr>
<td>DTaP-IPV/Hib (2)</td>
<td>10 weeks</td>
</tr>
<tr>
<td>Hep B (2)</td>
<td>10 weeks</td>
</tr>
<tr>
<td>RV (2)</td>
<td>14 weeks</td>
</tr>
<tr>
<td>DTaP-IPV/Hib (3)</td>
<td>14 weeks</td>
</tr>
<tr>
<td>Hep B (3)</td>
<td>14 weeks</td>
</tr>
<tr>
<td>PCV (2)</td>
<td>14 weeks</td>
</tr>
<tr>
<td>Measles vaccine (1)</td>
<td>8 months</td>
</tr>
<tr>
<td>PCV (3)</td>
<td>9 months</td>
</tr>
</tbody>
</table>

Name Of Interviewer: | Date:
Appendix B The reasons for immunisation failure cluster form.

<table>
<thead>
<tr>
<th>Participant number:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mark (x) corresponding to the single most important reason given by mother</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunisation Status</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Immunized</td>
<td></td>
</tr>
<tr>
<td>Partially Immunized</td>
<td></td>
</tr>
<tr>
<td>Fully Immunized</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lack Of Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Unaware of the need to vaccinate</td>
<td></td>
</tr>
<tr>
<td>Unaware of the need to return for 2nd or 3rd dose</td>
<td></td>
</tr>
<tr>
<td>Fear of side-effects</td>
<td></td>
</tr>
<tr>
<td>Wrong ideas about contraindications</td>
<td></td>
</tr>
<tr>
<td>Place and/or time of immunisation unknown</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lack Of Motivation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Postponed until another time</td>
<td></td>
</tr>
<tr>
<td>Cultural/religious reasons</td>
<td></td>
</tr>
<tr>
<td>Rumours about vaccination</td>
<td></td>
</tr>
<tr>
<td>No faith in vaccinations</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Obstacles</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of immunisation inconvenient</td>
<td></td>
</tr>
<tr>
<td>Vaccine not available</td>
<td></td>
</tr>
<tr>
<td>Mother too busy</td>
<td></td>
</tr>
<tr>
<td>Family problem including illness of mother</td>
<td></td>
</tr>
<tr>
<td>Child ill – brought but not given immunisation</td>
<td></td>
</tr>
<tr>
<td>Long waiting time at health facility</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature of interviewer:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix C  Medunsa Research and Ethics Committee Clearance Certificate

UNIVERSITY OF LIMPOPO
Medunsa Campus

MEDUNSA RESEARCH & ETHICS COMMITTEE

CLEARANCE CERTIFICATE

MEETING: 08/2014
PROJECT NUMBER: MREC/H/310/2014: PG

PROJECT:
Title: Vaccination coverage in children aged 12 – 23 months old in Refilwe Township, Gauteng Province

Researcher: Ms B Motloung
Supervisor: Ms I Fernandes
Co-supervisor: Prof RJ Burnett
Department: Public Health
School: Health Care Sciences
Degree: MPH

DECISION OF THE COMMITTEE:
MREC approved the project.

DATE: 02 October 2014

DR C BAKER
DEPUTY CHAIRPERSON MREC

The Medunsa Research Ethics Committee (MREC) for Health Research is registered with the US Department of Health and Human Services as an International Organisation (COR0004319), as an Institutional Review Board (IRB00038123), and functions under a Federal Wide Assurance (FWA00003419)

Endorsed: 11 October 2015

Note:
(i) Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee.
(ii) The budget for the research will be considered separately from the protocol. PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.

Finding Solutions for Africa
Appendix D Tshwane Metropolitan Municipality, Department of Health clearance certificate

TSHWANE RESEARCH COMMITTEE CLEARANCE CERTIFICATE

Meeting: N/A

PROJECT NUMBER: 06/2015

Title: Vaccination coverage in children aged 12-23 months old in Refilwe township, Gauteng Province
Researcher: Bontle Motioung
Co-Researcher:
Supervisor: Ms I Fernandes
Department: Public Health

DECISION OF THE COMMITTEE

Approved

NB: THIS OFFICE REQUESTED A FULL REPORT ON THE OUTCOME OF THE RESEARCH DONE

Date: 08/02/15

Mr. Peter Siwimba
Chairperson Tshwane Research Committee
Tshwane District

Mr. Pitzi Mokhopone
Chief Director, Tshwane District Health
Tshwane District
2015: 02. 16

NOTE: Resubmission of the protocol by researcher(s) is required if there is departure from the protocol procedures as approved by the committee.
# Appendix E Sepedi participant consent form

**Participant Consent Form (Sepedi)**

<table>
<thead>
<tr>
<th>TIALELETSO 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNIVERSITY OF LIMPOPO (Medunsa Campus). SEPEDI CONSENT FORM</td>
</tr>
</tbody>
</table>

Setatamente mabapi le go tšea karolo ka go Teko le Dinyakidišo tša Teko.

Lemla la Teko:

**VACCINATION COVERAGE IN CHILDREN AGED 12-23 MONTHS OLD IN SEFILWE TOWNSHIP, GAUTENG PROVINCE.**

Ke badišika kwele ka ga tshedinodo mabapi le "tšakemišešo le morena wa" dinyakidišo tšo di šokotšwe tšererego gomme ke le ka fiwa monyella wa go bošifhi dipotšotši gomme ka fiwa nako yeo e lekamego gore ka nqanitšile ka ga tata ye. Ke lóga ke kwediši ka tšakemišešo le morena wa dinyakidišo tšo gabotše. Go se ka gongeleši go kgasha tema ka tshelo efe gova efe.

Ka a kwediši gore go kgasha tema Teko/Protekšo/Dinyakidišo tša Teko ya Khinšela a ke ga bošišo gore noko nqoši go kgasha tsho nako nqoši gova efe nito le gore ka fe mabaka. Se ka se ka se le khusele efe gova efe go kalaho ya ka mabaka ya nako a ka gope e ka se le kgasha le go e ka le tshokomelo yeo ka e humanego go gongela yake ya ka mabaka.

Ke a tshelo gore Teko/Protekšo/Dinyakidišo tša Teko ya Khinšela a di dumeletšwe ka Medunsa Campus Research and Ethics (MOREC). Yambeshi ya Limpopo (Khomphase ya Medunsa) / Dr George Mukhoti Hospital ka tshelo gabotše gore dipolo tša Teko/Dinyakidišo/ Protekšo tša * di dumeletšwe merego ya saenso gomme di ka phitšatšwa. Ke dumeletšwe le sa, go fea gofešošo tši ka bo ka tšokomelo.

Mo ka fe tshokomelo ya go kgasha tema Teko/Dinyakidišo/ Protekšo *.

<table>
<thead>
<tr>
<th>Leina la matšotšo</th>
<th>Motešo</th>
<th>Mosea o wa matšotšo gova moshicomedi.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lefelo.</td>
<td>Thotsi</td>
<td>Lešašišišiši shedi</td>
</tr>
</tbody>
</table>

Setatamente ka Monyakidiši

Ke temo ka tshedinodo ka ishina košošo yeo e ngwadišwe * mabapi le Teko/Dinyakidišo/ Protekšo ye. * Ke dumela go amešiši diqošišo dife gova dife tšo ka mosa mabapi le Teko/Dinyakidišo/ Protekšo ka boqoni ka moo nka igonego ka gona. Ke ta tata la lela yeo e dumelošwe.

<table>
<thead>
<tr>
<th>Leina la Monyakidiši</th>
<th>Mosea o</th>
<th>Lešašišišiši shedi</th>
<th>Lefelo</th>
</tr>
</thead>
</table>
*Phumula tšeo di sego malebe.*
Appendix F English participant consent form

Participant Consent Form (English)

UNIVERSITY OF LIMPOPO (Medunsa Campus) ENGLISH CONSENT FORM

VACCINATION COVERAGE IN CHILDREN AGED 12-23 MONTHS OLD IN REFILWE TOWNSHIP, GAUTENG PROVINCE.

I have heard the aims and objectives of the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.

I understand that participation in this Project is completely voluntary and that I may withdraw from it at any time and without supplying reasons.

I know that this Project has been approved by the Medunsa Research Ethics Committee (MREC), University of Limpopo (Medunsa Campus). I am fully aware that the results of this Project will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this Project.

............................................................

Signature of Parent/Care Giver.

............................................................  ............................................................  ............................................................

Place. Date Witness

Statement by the Researcher

I provided verbal information regarding this Project.
I agree to answer any future questions concerning the Project as best as I am able.
I will adhere to the approved protocol.

............................................................

Name of Researcher Signature

............................................................

Date Place
Chapter 6 References


Local Government Handbook (2015). Position of Refilwe Township in the City of Tshwane Municipality. Available at:


